



On-Farm Readiness Review



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Objectives

- Provide talking points around OFRR for audiences.
- Discuss opportunities for outreach.
- Results of what we've done so far.



Differences of Audits and Inspections

Audit

- Usually points based.
- Annual
- Crop Specific
- Consequences of failure are loss of sales

PSR Inspection

- NOT points based.
- May or may not be annual
- Covers whole farm
- Consequences of failure may be a fine, recall or closure.



On-Farm Readiness Review

- **Not points based**
- **Voluntary**
- **Confidential**
- **Happens once (in most cases)**
- **Covers whole farm**
- **Covers critical areas of the farm**



Why Might a Farmer Want an OFRR?

- It is voluntary, confidential and free.
- It helps align what they're doing to what's required in the rule.
- It helps them figure out what they're missing.
- It provides personalized discussion on their farm food safety activities.
- Notes taken remain the property of the farmer (no FOIA-able records)
- It will improve the farmer's readiness for a PSR inspection.



On-Farm Readiness Review Partners

- FDA
 - Produce Safety, Office of Regulatory Affairs, inspector
- USDA
 - FDA liaison, GAP auditor
- Extension
 - Michigan, New Jersey, Florida, North Carolina
 - Produce Safety Alliance





On-Farm Readiness Review DRAFT: WATER

Regulation	Recommendation	Evaluation
Text of the Regulation	Possible activities that may lead to compliance with the regulation.	
<p>§ 112.12(a) You may establish alternatives to certain specific requirements of subpart E of this part, as specified in § 112.49, provided that you satisfy the requirements of paragraphs (b) and (c) of this section.</p>	<p>Any alternative used must be specified in § 112.49. The list of alternatives includes:</p> <ul style="list-style-type: none"> a) microbial quality criterion using an appropriate indicator of fecal contamination b) pre-harvest microbial die-off rate and accompanying maximum time interval c) minimum number of samples used in the initial survey of an untreated surface water source d) minimum number of samples used in the annual survey of an untreated surface water source 	<p>If an alternative is used, documentation is available in farm records, in the scientific literature, or through a third party. The documentation is in compliance with Subpart O</p>
<p>§ 112.12(b) You may establish and use an alternative to any of the requirements specified in paragraph (a) of this section, provided you have adequate scientific data or information to support a conclusion that the alternative would provide the same level of public health protection as the applicable requirement established in this part, and would not increase the likelihood that your covered produce will be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act, in light of your covered produce, practices, and conditions.</p>	<p>Support the alternative (see § 112.12(a) and § 112.49) with scientific data or other information.</p> <p>The support must include evidence that</p> <ul style="list-style-type: none"> • the alternative provides the same level of public health protection as use of the relevant value in the codified Rule. • the alternative does not increase the likelihood of adulteration compared to the relevant value in the codified Rule in light of practices and conditions on the farm. 	<p>If an alternative is used, documentation is available in farm records, in the scientific literature, or through a third party. The documentation is in compliance with Subpart O</p>
<p>§ 112.12(c) Scientific data and information used to support an alternative to a requirement specified in paragraph (a) of this section may be developed by you, available in the scientific literature, or available to you through a third party. You must establish and maintain documentation of the scientific data and information on which you rely in accordance with the requirements of subpart O of this part. You are not required to notify or seek prior approval from FDA regarding your decision to establish or use an alternative under this section.</p>	<p>Keep documents or other records to support the validity of the alternative and appropriate use of the alternative.</p> <p>Keep the supporting documentation for the alternative in the farm records, or ensure that it is available in the scientific literature or available via a third party. Documentation should be kept along with other farm records as required in § 112.50(b)(8) (see § 112.50 for general requirements for records, detailed in subpart O)</p>	<p>If an alternative is used, documentation is available in farm records, in the scientific literature, or through a third party. The documentation is in compliance with Subpart O</p>

Additional Tool Components

- Each module of the OFRR corresponds to a resource document module in the tool

Regulation	Recommendation	Evaluation
Text of the Regulation	Activities leading to compliance with the regulation	

The first column includes the section and the text of the regulation that apply to this module

Additional Tool Components

- Each module of the OFRR corresponds to a resource document module in the tool

Regulation	Recommendation	Evaluation
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The second column addresses activities that may lead to compliance with the regulation. “Must” and “Should” are used

Additional Tool Components

- Each module of the OFRR corresponds to a resource document module in the tool

Regulation	Recommendation	Evaluation
Text of the Regulation	Activities leading to compliance with the regulation	

This column includes how compliance with the regulation may be evaluated by the reviewers, it includes records, when the records are mandatory

When can I get an OFRR?

- OFRRs can be scheduled right now.
- USUALLY they happen during harvest, so they'll take place in the season.



How many people will conduct an OFRR?

- We expect most OFRR teams to include 2-3 people.
- Unless you're part of one of the trainings, those classes are currently at about 25 people!



How do I sign up for an OFRR?

- Send a request to Heather Borden at MSU Extension.

ofrr@msu.edu

- Use the subject “OFRR Request”.
- Reference your farm address and contact info.



Will someone just show up for an OFRR?

- NO – this is a voluntary program you register for.
- It's not only voluntary, its also free!



Will signing up put me on some sort of a list for an inspection?

- Not intended to!
- And it may even drop you lower on the list of farms needing an inspection



Will they review my records during an OFRR?

- NO – the OFRR will ask if you are keeping the records required by the PSR, but will not perform a records review.



What if they find something wrong during an OFRR?

- Egregious Conditions
 - A practice condition, or situation on an farm or in a packinghouse that is reasonably likely to lead to:
 - Serious adverse health consequences or death from the consumption of or exposure to covered produce
 - An imminent public health hazard is posed if corrective action is not taken immediately
- If an “Egregious Condition” is found reviewers have been trained in a course of actions to follow with the grower
 - If product has not entered commerce, and the issue can be immediately addressed, FDA will **not** be notified



Is anyone else offering this service?

- OFRR's will be run by State Departments of Agriculture
- Eventually, the OFRR materials will be available online, and other consultants or growers can use as they wish



Results so far...

- 75 OFRRs Reported in NCR for 2018
- 28 Confirmed Covered Farms.
- All but 8 farms either meet minimum standards, or need minor improvements.



Most Used WAQs

- Health and Hygiene
- Wild and Domestic Animals
- Preharvest Sanitation
- Harvest Sanitation



Most In Need of Improvement

- Worker Training
- Harvest Sanitation
- Health and Hygiene



Areas of Concern

- **Worker Training**
 - Inadequate records.
- **Harvest Sanitation**
 - Inadequate cleaning and sanitizing of contact surfaces.
 - Inadequate cleaning of reusable containers.
- **Health and Hygiene**
 - Inadequate worker training.
 - Inadequate sick leave policy.
 - Inadequate visitor notification.



What type of assistance do farms need to meet compliance?

- Time (37 Responses)
- Technical assistance (39 Responses)
- Significant monetary investment (3 Responses)





Fall 2018 Training Dates

November 7 – Dundee, MI

December 6 – Grand Rapids, MI



Enroll online at

<https://events.anr.msu.edu/2018FallPSA/>

On-Farm Readiness Review Summary

- Final tool will be used by extension and others as educational tool for growers and packers under the Produce Safety Rule to use for self-assessment.
- Utility of the tool will improve after FDA releases guidance



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