

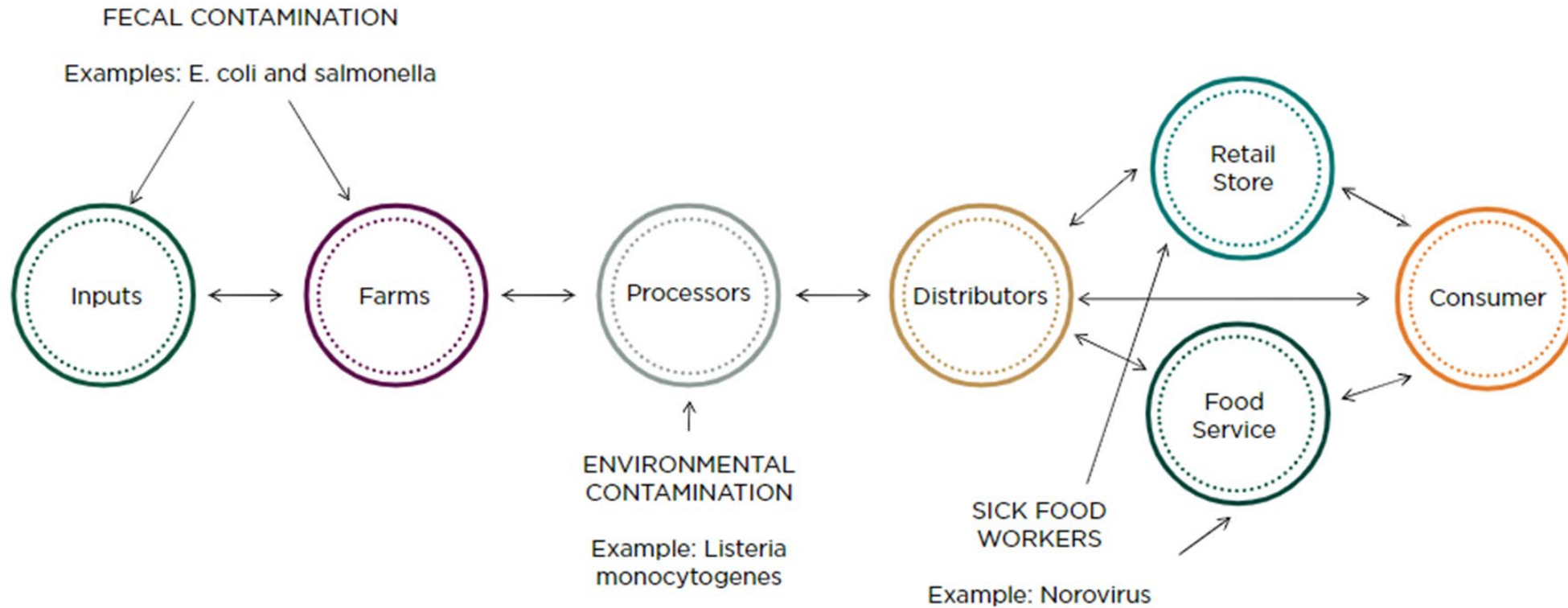
# Evaluating FSMA readiness through voluntary programs



Jordan DeVries, Produce Safety Technician at Newaygo Conservation District; covering Kent, Lake, Mason, Muskegon, Newaygo, Oceana and Ottawa Counties



# Supply Chain Strategies for Produce Safety



# Is FSMA for ME?...!!!

[www.producesafetyalliance.org](http://www.producesafetyalliance.org)  
[www.canr.msu.edu/agrifood\\_safety](http://www.canr.msu.edu/agrifood_safety)  
[www.miffs.org](http://www.miffs.org) [www.fda.gov](http://www.fda.gov)



Do you report  $\geq$ \$1,000 in farm based annual sales on line 8 of IRS schedule F?

A) Do you sell  $\geq$ \$25,000 produce? (both fresh and going to processing) 

B) Do you conduct covered activities? (grow, harvest, pack, hold?)

C) Do you sell FSMA covered produce? (not on exhaustive list of R.C.R.)

1) if so, are you ineligible for a processing exemption? 

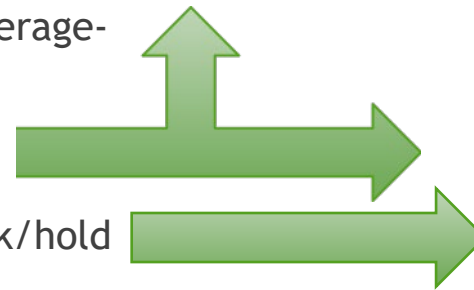
2) if so, are you ineligible for qualified (direct sales) exemption? 

-note: total farm sales cannot exceed \$500,000 over pre. 3 yr. average-

2) If you answered YES to all, You are a FSMA-PSR covered farm

a) primary production farm? Grows, and can harvest/pack/hold

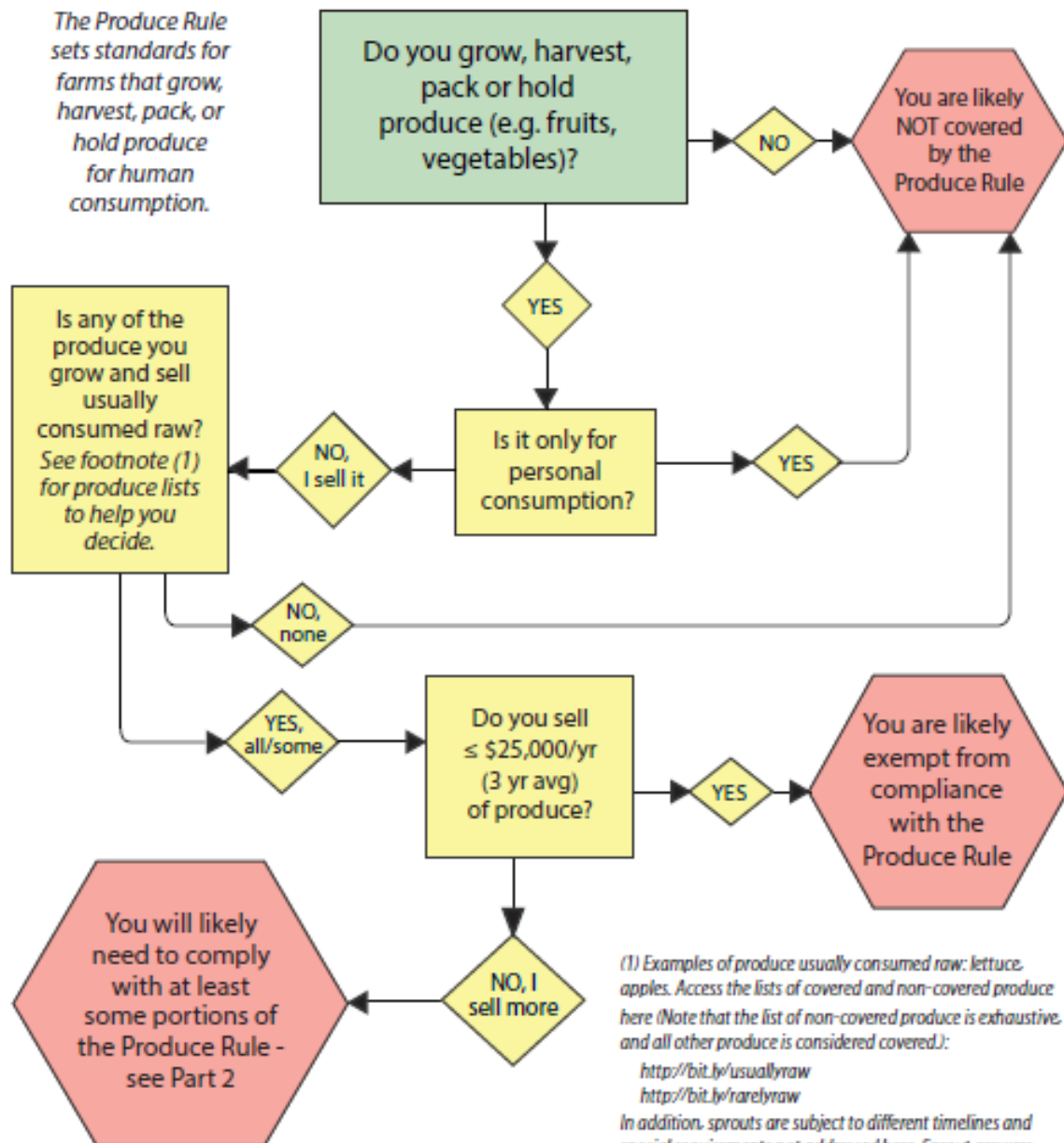
b) secondary activities farm? Does not grow, but can harvest/pack/hold



# Am I Affected by the FSMA Produce Rule?

## Produce Rule?

The Produce Rule sets standards for farms that grow, harvest, pack, or hold produce for human consumption.



(1) Examples of produce usually consumed raw: lettuce, apples. Access the lists of covered and non-covered produce here (Note that the list of non-covered produce is exhaustive, and all other produce is considered covered): <http://bit.ly/usuallyraw> <http://bit.ly/rarelyraw>  
 In addition, sprouts are subject to different timelines and special requirements not addressed here. Sprout growers

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

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.

- 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.

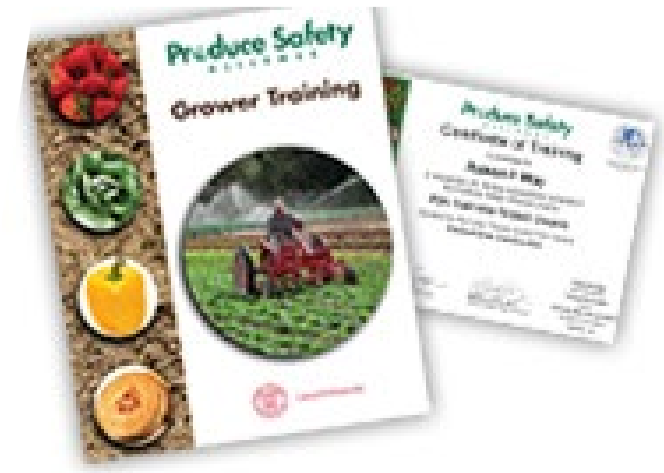
**YES**

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.



## Produce Safety Alliance grower training \*\*\*meets training requirement for PSR\*\*\*

- ▶ Day-long Course Schedule
- ▶ Introduction to Produce Safety
- ▶ Worker Health and Hygiene Training
- ▶ Soil Amendments
- ▶ Wildlife, Domestic Animals & Land Use
- ▶ Production Water
- ▶ Postharvest Water
- ▶ Postharvest Handling and Sanitation
- ▶ How to Develop a Farm Food Safety Plan
- ▶ Evaluation and final questions

# Upcoming Training Opportunities

- ▶ Mar. 28<sup>th</sup> South Haven
  - ▶ Interest for Bear Lake/Scottville early April?
- ▶ Spanish Language Trainings
  - ▶ May 30 South Haven
  - ▶ May 31 Hart



## CURSO DE CAPACITACIÓN PARA PRODUCTORES DE LA ALIANZA PARA LA INOCUIDAD DE LOS PRODUCTOS AGRÍCOLAS FRESCOS (PRODUCE SAFETY ALLIANCE)-EN ESPAÑOL

JUEVES 21 DE FEBRERO DE 2019 - SOUTH HAVEN, MI

9:00 AM - 5:00 PM

Lake Michigan College - South Haven Campus, Room 221  
125 Veterans Blvd, South Haven, MI 49090

Para registrarse, Contacto a: Filiberto Villa Gomez 269-830-2309 [filibertovilla@sbcglobal.net](mailto:filibertovilla@sbcglobal.net)

VIERNES 22 DE FEBRERO DE 2019 - GRAND RAPIDS MI

9:00 AM - 5:00 PM

Kent County MSU Extension Office  
775 Ball Ave NE, Grand Rapids, MI 49503

Para registrarse, Contacto a : Filiberto Villa Gomez 269-830-2309 [filibertovilla@sbcglobal.net](mailto:filibertovilla@sbcglobal.net)

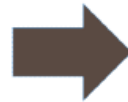
ALOJADO POR AGRICULTORES LATINOS UNIDOS DE MIFFS & MSU EXTENSION



Formación Gratuita Para Agricultores



# Potential Steps to Compliance



Extension Bulletin E-3153 • December 2017

## Michigan's Produce Safety Risk Assessment

For direct market fruit and vegetable producers

A voluntary and confidential produce safety program that provides confidence that inspected practices are consistent with the current U.S. Food and Drug Administration Produce Safety Rule as well as provides recognition with a certificate of completion of the program



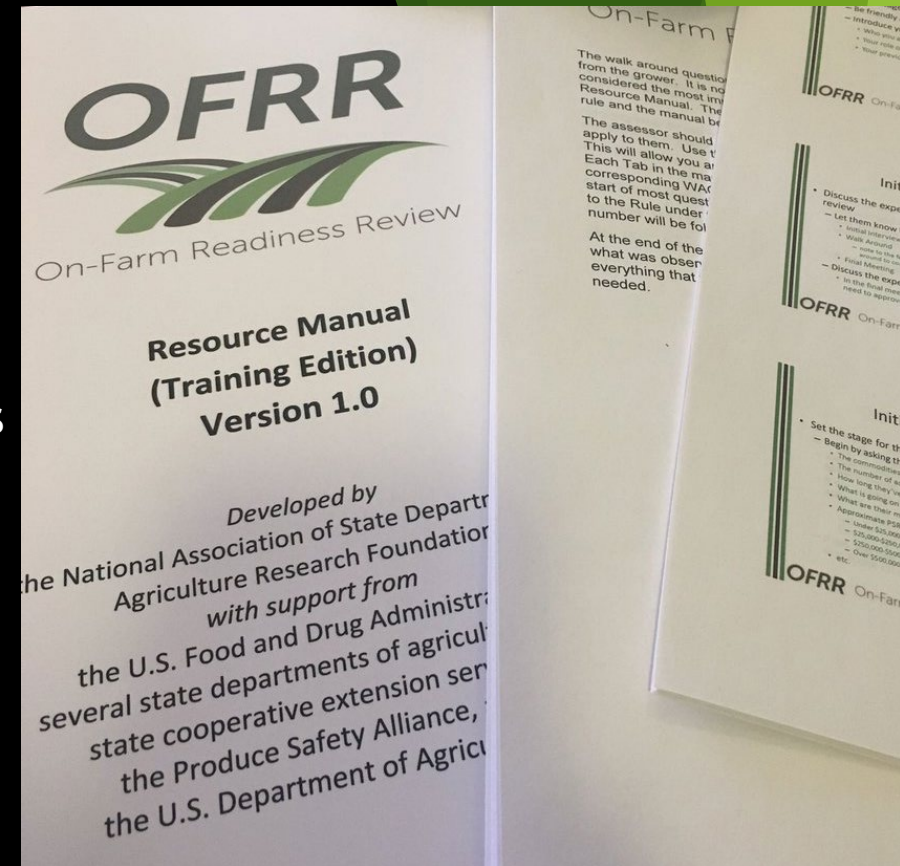
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MICHIGAN CONSERVATION DISTRICTS

Michigan Department of AGRICULTURE & Rural Development

# On Farm Readiness Review

- ▶ Not points based
- ▶ Happens once
- ▶ Covers whole farm
- ▶ Covers critical areas
- ▶ Voluntary
- ▶ Confidential



- ▶ Grower should attend Produce Safety Alliance Grower Training
- ▶ Email [ofrr@MSU.edu](mailto:ofrr@MSU.edu) to schedule review team visit (during harvest)
- ▶ Video: [www.canr.msu.edu/agrifood\\_safety/on-farm-readiness-reviews](http://www.canr.msu.edu/agrifood_safety/on-farm-readiness-reviews)
- ▶ Introduction, walk-around questions and discussion takes 2-3 hours
- ▶ resource manual is left with grower to guide compliance strategies



# Produce Safety Risk Assessment

- ▶ Developed from 2010-2016 Safe Food Risk Assessment.
- ▶ Review of Food Safety Practices by Produce Safety Technician
- ▶ Voluntary
- ▶ Confidential
- ▶ Meets PSR risk assessment requirements, good 'onboarding' exercise

Extension Bulletin E-3153 • December 2017

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fruit and vegetable  
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A voluntary and confidential produce safety program that provides confidence that inspected practices are consistent with the current U.S. Food and Drug Administration Produce Safety Rule as well as provides recognition with a certificate of completion of the program.

MICHIGAN STATE UNIVERSITY | Extension



- ▶ Farm food safety plan required for certificate of completion
- ▶ Certificate from MDARD can be requested to display to customers
- ▶ Email [Jordan.devries@macd.org](mailto:Jordan.devries@macd.org) to plan an appointment,
  - ▶ unlike OFRR, does not need to be conducted during harvest
- ▶ Ideal for growers <\$25k, process/direct sales exemption

# What to Expect of a Regulatory Inspection

- ▶ the inspector will call the farm owner, manager, or person in charge, to schedule the inspection.
- ▶ During the pre-inspection call, the inspector will make a preliminary determination about whether the PSR applies to your farm.
- ▶ If your farm is covered by the rule, the inspector or investigator will schedule an inspection date that works for both the inspector and the person in charge. In most cases, the inspection will be scheduled within five (5) business days.
- ▶ **Can have unannounced inspection:**
  - ▶ 1. If your farm has had produce safety issues in the past that have not been corrected;
  - ▶ 2. If a follow-up inspection is needed, an unannounced inspection may be needed to observe the necessary changes;
  - ▶ 3. If your farm is unresponsive or is unwilling to set a date for the inspection; or
  - ▶ 4. In response to a complaint, recall, or foodborne outbreak investigation.



# What to Expect of a Regulatory Inspection

- ▶ The first inspection for every farm, regardless of compliance year, will be an initial inspection that will be verbal in nature with no inspection record. Exception: egregious cond.
- ▶ The inspector will introduce himself or herself (name, title, agency), provide the reason for the inspection, and show identification.
- ▶ The inspector will provide you with a brief description of the reason for the inspection and activities to be conducted during the inspection.
- ▶ The inspector or investigator will ask you about the activities performed the day(s) of the inspection, such as whether the farm is planting, harvesting, packing or holding, and about the farm's organization.

# What to Expect of a Regulatory Inspection

- ▶ During the inspection, the inspector will observe your farm operation. This may take several hours and the farm representative may or may not be asked to join them. At the farm owner's request, their lawyer, crop consultant, Food Safety Plan consultant, or Farm Bureau Representative may join them on the inspection. The inspector will not bring anyone else onto the farm except for another trained inspector.
- ▶ He or she may ask questions about farming practices and operations that cannot be observed during the inspection. It is very important that the farm representative is able to clearly communicate their food safety management practices, and the farm's food safety culture.
- ▶ In course of the the second inspection, he or she will take notes, may take pictures, may collect samples, and will review and may copy records, such as worker training, water system inspection and sanitation agent use records.
- ▶ Throughout the inspection, the inspector or investigator will explain what is being looked at and why. If there are any regulatory concerns, the inspector or investigator will discuss them with you and explain the reason(s) for each regulatory concern and the public health significance.

# Regulatory inspection exit interview

- ▶ The inspector or investigator will go over any regulatory concerns and findings and provide you with information on resources and technical assistance.
  - ▶ If you are able to make corrections during the inspection, the inspector or investigator will document them.
  - ▶ If the deficiency cannot be corrected during the inspection, the inspector or investigator will work with you to determine a reasonable time frame to implement preventive measures and corrective actions.
  - ▶ If an egregious condition is encountered, the inspector will be forced to take further action, including reporting to the Food and Drug Administration's Office of Regulatory Affairs.
- ▶ During the exit interview, the inspector or investigator will also identify preventive produce safety practices and conditions on your farm based on the requirements of the PSR. The inspector or investigator will also answer any questions you may have regarding the inspection.
  - ▶ He or she will also provide you with an inspection sheet with agency contact information that will document the inspection.

# Regulatory inspection sheet, form 4056

FARM NAME (include business name, if different)

DATE(S) OF INSPECTION

FEI NUMBER

If you have any questions, please contact the regulatory agency at the phone number and address above.

Representatives of the regulatory agency should record observations consistent with procedures established for conduct of inspections, including additional instructions that appear in Chapter 5 of the IOM, available at

<https://www.fda.gov/ICECI/inspections/IOM>.

## REPORTABLE OBSERVATIONS MADE DURING THE INSPECTION

Representatives of the regulatory agency should check one of the following options. As noted above, this is not a final FDA determination of compliance, or non-compliance, with the Produce Safety Rule (21 CFR Part 112) or any other legal requirement.

- During an inspection of the operation (I) (we) did not observe any conditions and/or practices to be reported on this form.
- During an inspection of the operation (I) (we) observed the following conditions and/or practices as described below.

### Personnel Qualifications and Training (21 CFR Part 112, Subpart C)

1. § 112.21 and 112.22: Qualifications and training for personnel who handle (contact) covered produce or food contact surfaces

- Observation     Corrective action taken

Description:

2. § 112.23: Assignment or identification of supervisors

- Observation     Corrective action taken

Description:

# Sanitation of tools and equipment

- ▶ FSMA Records required for sanitation activities (use of sanitizing agent)
- ▶ Sanitation not required, but PSR has a “catch-all” phrase § 112.112 that says you must provide reasonable assurances that produce is not contaminated with microorganisms of public health significance”
- ▶ Good idea to assess workers use of knives, aprons, gloves, pick bags.
  - ▶ Can grower ensure that they stay clean or are sanitized adequately?
- ▶ New Produce Safety Alliance factsheet: Introduction to Selecting an EPA-Labeled Sanitizer

Chemical Sanitizer Monitoring Form

Date	Initials	Test Strip Results	Use



## SaniDate® 5.0

(Alternate Brand Names: StorOx 5.0 Post Harvest Treatment, GreenClean Max Algaecide, SaniDate WTO, GreenClean WTO, GreenClean Liquid 5.0)

FOR COMMERCIAL USE

MASTER LABEL

**Sublabel A: General Uses**  
**Sublabel B: Agricultural Uses**  
**Sublabel C: Aquatic uses**



**ACTIVE INGREDIENTS:**  
 Hydrogen Peroxide..... 23.0%  
 Peroxyacetic Acid..... 5.9%  
**INERT INGREDIENTS:**..... 71.7%  
**TOTAL:**..... 100.0%

Sold by:  
 BioSafe Systems, LLC  
 22 Meadow Street  
 East Hartford, CT 06108  
 Tel.: (888) 273-3088

**70299: Manufacturer (Biosafe Systems, LLC)**  
**19: Product (Sanidate 5.0)**

EPA Registration No.: 70299 - 19  
 EPA Establishment No.: EPA Est. No.87441-IL-001, 080548-NV-001, 082521-GA-001  
 Net Contents: 2.5, 5, 30, 55, 275 gallons

**Figure 1:** Sanidate 5.0 is a commonly used sanitizer with the EPA registration number 70299-19. The first field, 70299, is specific to the manufacturer (Biosafe Systems, LLC), and the second field, 19, identifies the Sanidate 5.0 product itself. In this example, there is no third number because the company does not have a private label.

# Disposal of used wash line graywater

- ▶ In Michigan, produce wash water is considered wastewater subject to DEQ Part 451, you must apply for discharge permit to dispose of it, no matter how clean it is.
  - ▶ Permit cost is \$200, can land-apply at agronomic rate, or dispose of in DEQ approved wastewater treatment structure.
  - ▶ Must take samples of each solution to be discharged and apply for separate permit for each solution
  - ▶ MDARD currently working with MDEQ to allow for produce farm exemption, similar to livestock exemption for manure lagoon waste land application

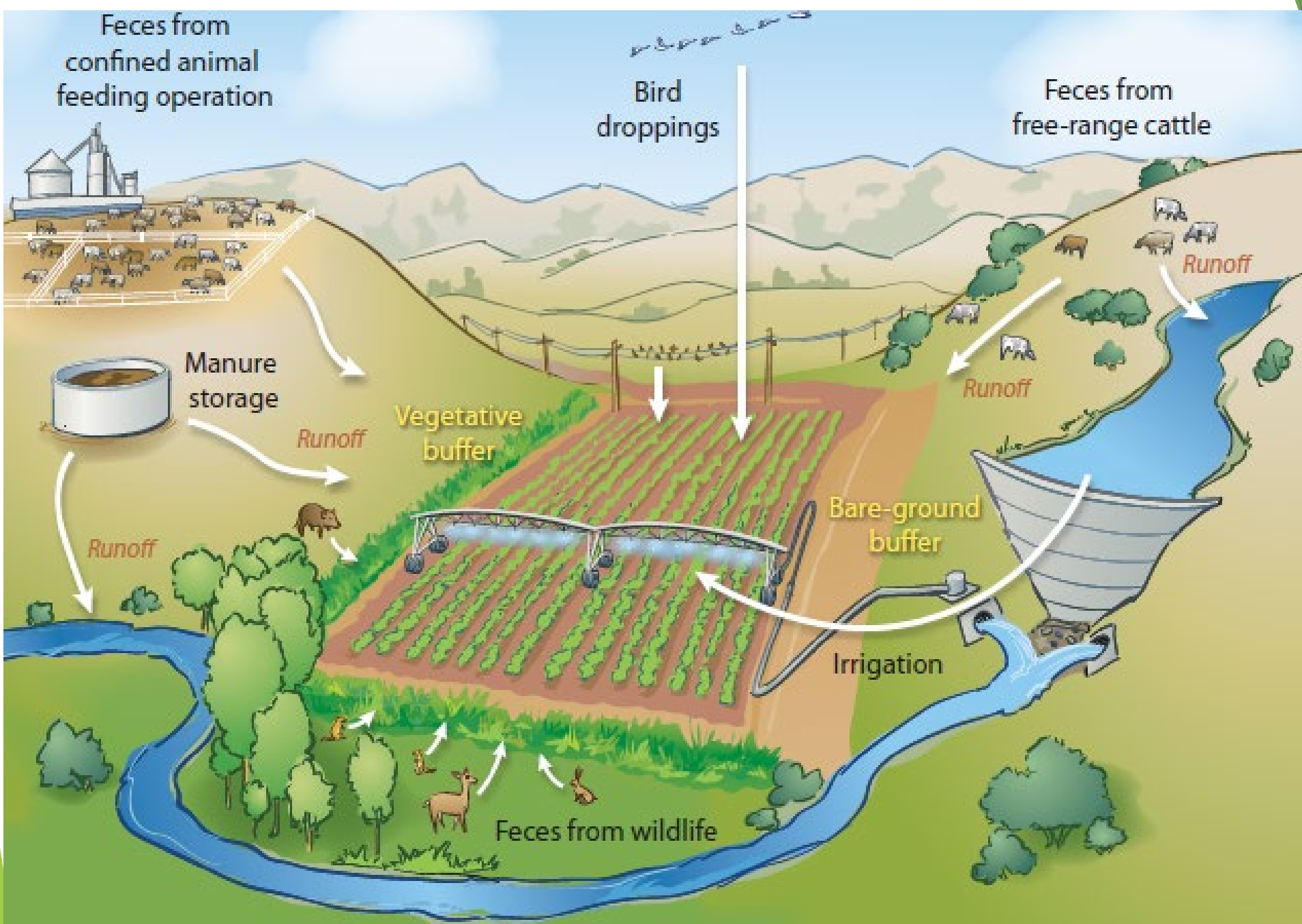




# Water system inspection

- ▶ Grower will be expected to be able to articulate ability to anticipate produces safety risks through ag. production water.
  - ▶ Risk assessment
  - ▶ Corrective action
  - ▶ Documentation & recordkeeping
- ▶ Production/postharvest water testing requirements still being determined by FDA, but likely to remain intact.
- ▶ Approved irrigation water labs:
  - ▶ [www.canr.msu.edu/news/find\\_the\\_right\\_water\\_testing\\_lab\\_for\\_food\\_safety\\_modernization\\_act\\_produce](http://www.canr.msu.edu/news/find_the_right_water_testing_lab_for_food_safety_modernization_act_produce)





# Qualified (direct sales) exemption eligible?

▶ During the previous 3-year period, more than half of the average annual monetary value of the food the farm sold was directly to qualified end-users:

- ▶ The consumer of the food (consumer does not include a business); or
- ▶ A restaurant or retail food establishment that is located:
  - ▶ In the same State or the same Indian reservation as the farm that produced the food; or
  - ▶ Not more than 275 miles from such farm
- ▶ The average annual value of all food the farm sold during the 3-year period preceding the applicable inspection compliance year was less than \$500,000



# If your farm is eligible for the qualified exemption, you must follow modified requirements by 1/1/2020:

1. When a food packaging label is required, you must prominently and conspicuously display on the food packaging label the name and the complete business address of the farm where the produce was grown; or
2. When a food packaging label is not required on food you must prominently and conspicuously display, *at the point of purchase*, the name and complete business address of the farm where the produce was grown, on a label, poster, sign, placard (internet sales: e-notice)



# If your farm is eligible for the qualified exemption, you must follow modified requirements by 1/1/2020:

3. A qualified exempt farm must keep adequate records necessary to demonstrate that the farm satisfies the criteria for the qualified exemption including:
  1. Records that show the farm is below the \$500,000 sales threshold.
  2. Selling more to qualified end users than non-qualified end users (50% +1 rule). -Using line 8 on schedule F tax filing (3 yr inflation adjusted avg.)
  3. That the purchaser is a qualified end user (retail consumers, direct sales to restaurants, grocery stores)
4. The farm must also keep a written record that reflects an annual review and verification of the farm's continued eligibility for the qualified exemption. (signed review by responsible party)





## Michigan On-Farm Produce Safety

- ▶ **Landen Tetil** Produce Safety Technician Marquette Conservation District P: 906-226-8871 x105  
E: [Landen.Mqtcondist@gmail.com](mailto:Landen.Mqtcondist@gmail.com)
- ▶ **Jordan DeVries** Produce Safety Technician Newaygo Conservation District P: 231-225-3072  
E: [Jordan.Devries@macd.org](mailto:Jordan.Devries@macd.org)
- ▶ **Michelle Jacokes** Produce Safety Technician Manistee Conservation District P: 231-889-9666  
E: [Michelle.Jacokes@macd.org](mailto:Michelle.Jacokes@macd.org)
- ▶ **Emily Hale** Produce Safety Technician Blue Water Conservation District P: 810-404-5083  
E: [Emily.Hale@macd.org](mailto:Emily.Hale@macd.org)
- ▶ **Micah Hutchison** Produce Safety Technician Genesee Conservation District P: 810-820-2681  
E: [Micah.Hutchison@macd.org](mailto:Micah.Hutchison@macd.org)
- ▶ **Victoria Toney** Produce Safety Technician Berrien Conservation District P: 269-471-9111 x3  
E: [Victoria.Toney@macd.org](mailto:Victoria.Toney@macd.org)
- ▶ MSU Extension Agrifood Safety: Heather Borden FSMA Produce Safety Logistics Coordinator P: 517.768.2038  
E: [bordenhe@msu.edu](mailto:bordenhe@msu.edu)

