Straight Talk on FSMA Inspections:
How They Work and What to Expect

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MAINE DEPARTMENT OF AGRICULTURE, CONSERVATION & FORESTRY
Quality Assurance & Regulations

What is FSMA?

The Food Safety Modernization Act is:

- Mandatory food safety law passed in 2011.
- First major update to the federal food code since 1938.
- Establishes science-based minimum standards for produce handling on farms.
- Applies a preventive approach to ensuring food safety.
- Uses systems-based thinking to provide adaptability of Rules to a wide range of businesses.
- Implemented in 7 different parts.

Funding for this presentation was made possible, in part, by the Food and Drug Administration through grant PAR-16-137.

What is FSMA?

The Food Safety Modernization Act's 7 parts:

1. **Produce Safety Rule**
2. Preventive Controls for Human Food
3. Preventive Controls for Animal Food
4. Foreign Supplier Verification Programs
5. Accreditation of 3rd Party Auditors/Certification Bodies
6. Sanitary Transport of Human & Animal Food
7. Prevention of Intentional Contamination/Adulteration

What Are the Underlying Ideas?

The **Produce Safety** Rule is based on consumer health and produce safety fundamentals:

- Microbiological pathogens can make people sick.
- Pathogens are more likely to make vulnerable people sick, including the **young**, the **elderly**, the **pregnant**, and the **immunocompromised**.
- Pathogens are commonly found in animal and human feces.
- Pathogens most commonly contaminate food via:
  - People
  - Water
  - Food contact surfaces, including equipment
  - Biological soil amendments

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What's Special About the Produce Safety Rule?

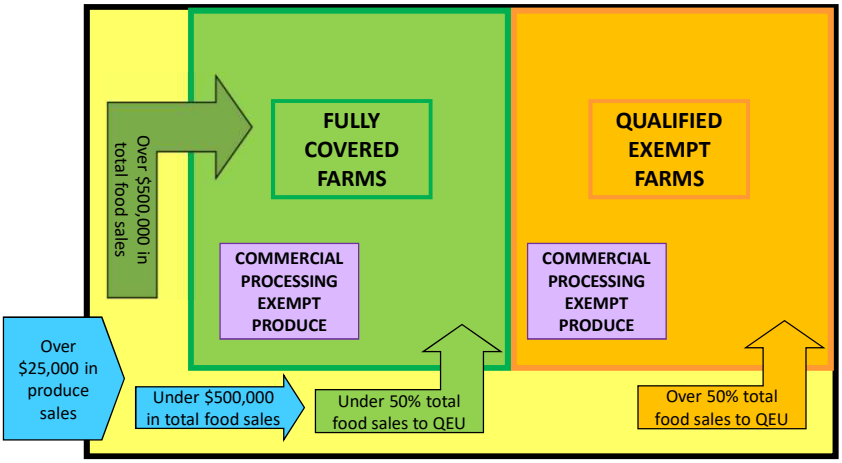
In many parts of the US, there **has never been jurisdiction for food safety on produce farms**.

As a result, these are brand new regulations for farms in many states.

The FDA has structured the implementation of the Produce Safety Rule to build in time to learn by:

- **Funding states** to provide education & outreach.
- **Partnering with states** to do the boots-on-the-ground inspections.
- **Staggering compliance dates** by farm size to give time to get ready.
- Making **initial inspections** educational in nature, with only egregious conditions triggering official compliance action.
- **Developing collaborative partnerships** to provide resources and technical advice to farmers.

Who Is Covered by the Produce Safety Rule?



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What Is Covered by the Rule?

- COVERED PRODUCE =
  - **All produce generally consumed raw**.
- COVERED ACTIVITIES =
  - **All growing, harvesting, packing, and holding activities.**
  - Certain narrowly defined processing activities on-farm.
- COVERED FARMS =
  - **Farms doing <u>covered activities</u>, with <u>covered produce</u>.**

What Is <u>NOT</u> Covered by the Rule?

- PRODUCE THAT IS RARELY CONSUMED RAW =
  - **Produce not generally consumed raw**, as substantiated by consumer data.
  - **All 'rarely consumed raw' produce is listed in the 'exhaustive' list in the PSR**.
- CROPS GROWN FOR ON-FARM OR PERSONAL USE.
- SEEDS AND FOOD GRAINS =
  - **Small, hard fruits or seeds of arable crops** that are primarily grown and processed for use as meal, flour, baked goods, cereals or oils.
- CROPS GROWN FOR ANIMAL FEED =
  - Covered under the Preventive Controls for Animal Food.

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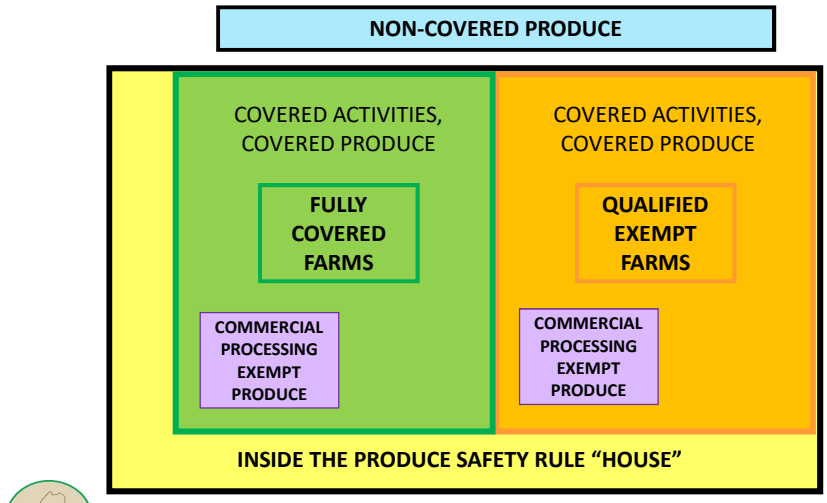
What Is Covered by the Rule?



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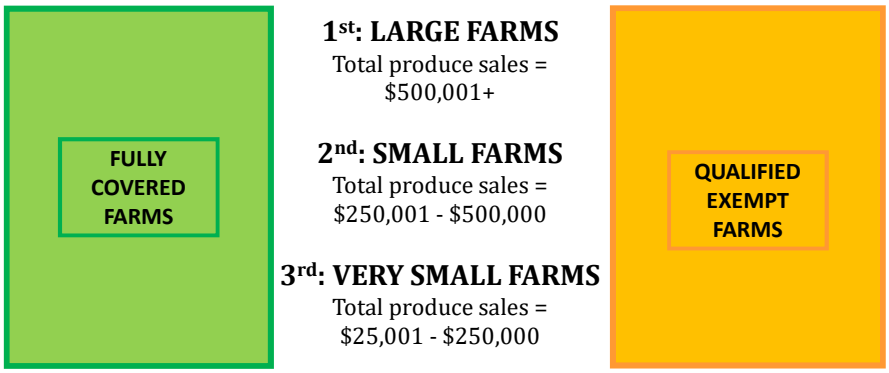
Who Gets Inspected?



INSPECTIONAL PRIORITY IS FULLY COVERED FARMS

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Who Does the Inspections?

In Maine, Produce Safety Rule inspections are done by the **Federal/State Inspection Service**, based in Presque Isle, operating **under FDA authority**.

We're a small team within the **Department of Agriculture, Conservation & Forestry** that does:

- GAP audits.
- Commodity crop inspections for potatoes, broccoli, apples, etc.
- FSMA Produce Safety Rule education & outreach.
- FSMA Produce Safety Rule inspections.

Our team is credentialed by the FDA to authorize us to do these inspections.

When Are Compliance & Inspection Dates?

COVERED FARM SIZE:	PRODUCE SAFETY RULE COMPLIANCE	COMPLIANCE INSPECTIONS	WATER SUBPART COMPLIANCE
LARGE FARMS Produce Sales = $500,001+	January 26, **2018**	Spring **2019**	January 26, **2022**
SMALL FARMS Produce Sales = $250,001 - $500,000	January 28, **2019**	Spring **2020**	January 26, **2023**
VERY SMALL Produce Sales = $25,000-$250,000	January 27, **2020**	Spring **2021**	January 26, **2024**

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How Do Inspections Work?

PREPARATION

- Connect with DACF.
- Attend a training.
- Ask for On-Farm Readiness Review.
- Work on any problem areas.

INSPECTION

- DACF schedules with you.
- Opening interview.
- Field & facility visit.
- Discuss any issues.
- Inspection forms issued during inspection.

FOLLOW THROUGH

- Inspection reports written & mailed to you.
- Make plan to address issues.
- May be follow up inspections.

How Do Inspections Work?

STEP 1: PREPARATION

Connect with DACF—*we'll help you determine your coverage status and where to start.*

Attend a PSA Grower Training—*required for fully covered farms.*

Ask for On-Farm Readiness Review—*these FREE farm walk-arounds are friendly and non-regulatory, and are a great time to ask questions and troubleshoot issues.*

Work on any problem areas—*take what you've learned and begin making any changes you need.*

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How Do Inspections Work?

STEP 2: INSPECTION

Scheduling the inspection—*DACF will call to schedule your initial inspection for when you're in peak production.*

Opening interview—*we sit down and go over basics, show you our FDA credentials, issue the Notice of Inspection, and discuss the inspection plan.*

Visiting fields & facilities—*we'll observe your covered activities, ask questions about your operation, and may interview your workers.*

Records review—*we'll look at the records you're required to keep for Produce Safety Rule compliance.*

How Do Inspections Work?

STEP 2: INSPECTION

Discuss any issues as we go along—*we'll take the time to discuss things along the way so we can learn from each other and understand where concerns may be coming from.*

Corrective actions—*you can take corrective actions for any issues while we're there and we'll make sure to document that in our reports.*

Close out meeting—*we'll discuss any observations and issue the Inspection Form 4056 at the end of the inspection.*

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How Do Inspections Work?

STEP 3: FOLLOW THROUGH

Inspection reports from the DACF—*after the inspection we write a more descriptive report and mail it to you.*

Request for a response—*we may ask for your written response to issues of concern.*

Make plans to address issues—*think about how you propose to address any food safety issues and implement those plans.*

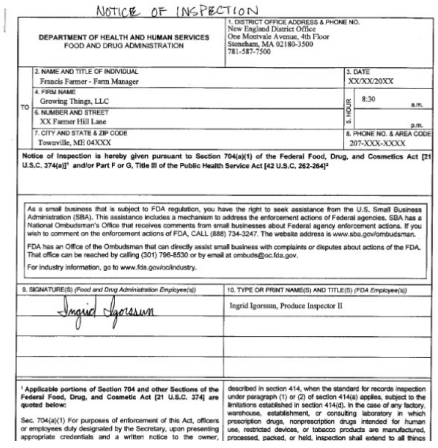
Possible follow up visits—*when observed issues are concerning enough, DACF may come do a follow up inspection to ensure public health is being protected.*

Next routine inspection—*at your next routine inspection we'll check in on the progress you're making.*

What Are All These Forms?

FDA Form 482: NOTICE OF INSPECTION

- Official FDA form issued at the **beginning** of every inspection.
- Serves as Notice of Inspection.
- States authorization under Federal Food, Drug, & Cosmetic Act (FD&C Act) to inspect premises and access necessary documents.
- Issued to most responsible party present for the farm.
- Always includes inspector's name, position, & signature.



NOTICE OF INSPECTION

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

1. DISTRICT OFFICE ADDRESS & PHONE NO.
New England District Office
One Montvale Avenue, 4th Floor
Stoneham, MA 02180-3500
781-587-7500

2. NAME AND TITLE OF INDIVIDUAL
Francis Farmer - Farm Manager

3. DATE
XX/XX/20XX

TO

4. FIRM NAME
Growing Things, LLC

5. NUMBER AND STREET
XX Farmer Hill Lane

5. HOUR
8:30 a.m.
p.m.

7. CITY AND STATE & ZIP CODE
Townville, ME 04XXX

8. PHONE NO. & AREA CODE
207-XXX-XXXX

Notice of Inspection is hereby given pursuant to Section 704(a)(1) of the Federal Food, Drug, and Cosmetics Act [21 U.S.C. 374(a)][1] and/or Part F or G, Title III of the Public Health Service Act [42 U.S.C. 262-264][1]

As a small business that is subject to FDA regulation, you have the right to seek assistance from the U.S. Small Business Administration (SBA). This assistance includes a mechanism to address the enforcement actions of Federal agencies. SBA has a National Ombudsman's Office that receives comments from small businesses about Federal agency enforcement actions. If you wish to comment on the enforcement actions of FDA, CALL (888) 734-3247. The website address is www.sba.gov/ombudsman.

FDA has an Office of the Ombudsman that can directly assist small business with complaints or disputes about actions of the FDA. That office can be reached by calling (301) 796-8530 or by email at ombude@oc.fda.gov.

For industry information, go to www.fda.gov/oc/industry.

9. SIGNATURE(S) (Food and Drug Administration Employee(s))
Ingrid Igorsson

10. TYPE OR PRINT NAME(S) AND TITLE(S) (FDA Employee(s))
Ingrid Igorsson, Produce Inspector II

[1] Applicable portions of Section 704 and other Sections of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374] are quoted below:

Sec. 704(a)(1) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, ... described in section 414, when the standard for records inspection under paragraph (1) or (2) of section 414(a) applies, subject to the limitations established in section 414(d). In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products are manufactured, processed, packed, or held, inspection shall extend to all things

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What Are All These Forms?

FDA Form 4056: PRODUCE FARM INSPECTION OBSERVATIONS

- Official FDA form issued at the **end** of every inspection.
- Records basic inspection information, including observations.
- Issued to most responsible party present for the farm.
- Includes Maine DACF office contact information.
- Always includes inspector's name, position, & signature.
- 9 pages long.

INITIAL INSPECTION w/NO EGREGIOUS CONDITIONS

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

FDA

PRODUCE FARM INSPECTION OBSERVATIONS

Name of State and Department *(if acting under commission with FDA)*
Maine Department of Agriculture, Conservation & Forestry

DISTRICT OFFICE ADDRESS
744 Main Street, Suite 5
Presque Isle, ME 04769

DISTRICT OFFICE PHONE NUMBER
207-764-2100

DATE(S) OF INSPECTION
XX/XX/20XX

FEI NUMBER
XXX

LAST NAME, FIRST NAME, MIDDLE INITIAL AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED *(Most responsible individual present)* TO:
Farmer, Francis F. - Farm Manager

FARM NAME *(include business name, if different)*
Growing Things, LLC

OWNER/OPERATOR
Francis Farmer

FARM MAILING ADDRESS
POB XXX
Townville, ME 04XXX

FARM PHYSICAL LOCATION, IF DIFFERENT FROM MAILING ADDRESS *(e.g., location identifiers such as GPS coordinates)*
XX Farmer Hill Lane
Townville, ME 04XXX

TYPE OF INSPECTION:
☒ Initial ☐ Routine ☐ Follow-up ☐ For-cause
☐ Other *(please specify)*

CROPS OBSERVED DURING INSPECTION
Leafy greens, cucumbers, tomatoes, turnips, carrots, mixed herbs, peas, string beans.

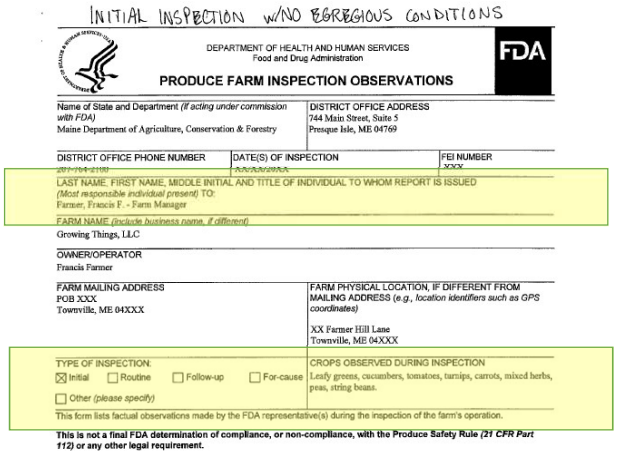
This form lists factual observations made by the FDA representative(s) during the inspection of the farm's operation.

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.

Representatives of the regulatory agency should record their observations on this form as clearly and specifically as possible and should order their observations by significance within each area (most important first). In some cases, an observation may relate to more than one topic area. Representatives of the regulatory agency should record observations in the topic area listed below that, in the representatives' judgment, is the most appropriate topic. Not all topic areas may be applicable in every situation. In addition, representatives of the regulatory agency may not examine every aspect of the farm's operation during an inspection, so a topic area left blank should not be interpreted to mean the farm is in compliance, or not in compliance, with requirements related to that topic area.

What Are All These Forms?

FDA Form 4056: PRODUCE FARM INSPECTION OBSERVATIONS



INITIAL INSPECTION w/NO EGREGIOUS CONDITIONS

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

FDA

PRODUCE FARM INSPECTION OBSERVATIONS

Name of State and Department *(if acting under commission with FDA)*
Maine Department of Agriculture, Conservation & Forestry

DISTRICT OFFICE ADDRESS
744 Main Street, Suite 5
Presque Isle, ME 04769

DISTRICT OFFICE PHONE NUMBER

DATE(S) OF INSPECTION

FEI NUMBER
XXX

LAST NAME, FIRST NAME, MIDDLE INITIAL AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED *(Most responsible individual present)* TO:
Farmer, Francis F. - Farm Manager

FARM NAME *(include business name, if different)*
Growing Things, LLC

OWNER/OPERATOR
Francis Farmer

FARM MAILING ADDRESS
POB XXX
Townville, ME 04XXX

FARM PHYSICAL LOCATION, IF DIFFERENT FROM MAILING ADDRESS *(e.g., location identifiers such as GPS coordinates)*
XX Farmer Hill Lane
Townville, ME 04XXX

TYPE OF INSPECTION:
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☐ Other *(please specify)*

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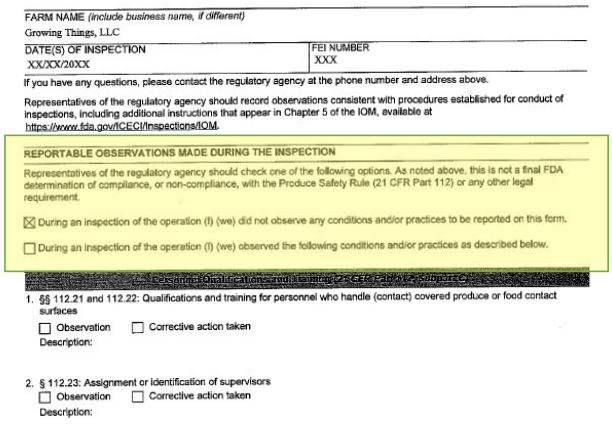
What Are All These Forms?

FDA Form 4056: PRODUCE FARM INSPECTION OBSERVATIONS



FARM NAME *(include business name, if different)*
Growing Things, LLC

DATE(S) OF INSPECTION	FEI NUMBER
XX/XX/20XX	XXX

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.

[redacted]

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:

What Are All These Forms?

FDA Form 4056: PRODUCE FARM INSPECTION OBSERVATIONS

43. §§ 112.144(b) and (c), 112.147 and 112.148: Testing spent irrigation water or in-process sprouts for pathogens *(written sampling plan, collection and testing, corrective actions)*
   ☐ Observation ☐ Corrective action taken
   Description:

44. § 112.160: Record-keeping
   ☐ Observation ☐ Corrective action taken
   Description:

[redacted]

45. § 112.161 - 112.167:General record-keeping
   ☐ Observation ☐ Corrective action taken
   Description:

[redacted]

46. Other
   ☐ Observation ☐ Corrective action taken
   Description:

FDA REPRESENTATIVE SIGNATURE	FDA REPRESENTATIVE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
Ingrid Igerssun	Ingrid Igerssun, Produce Inspector II	XX/XX/20XX

FORM FDA 4056 (01/19) Page 7 of 9

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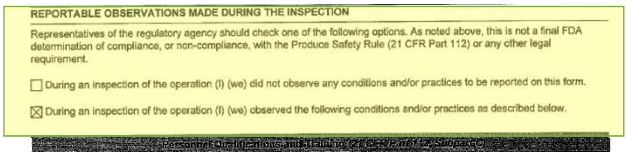
Egregious Conditions on the Form 4056

FDA Form 4056: PRODUCE FARM INSPECTION OBSERVATIONS

When there are egregious conditions, they must be:

- Recorded on the Form 4056
- Reported to the FDA's Office of Compliance for further direction.
- Must be addressed.



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.

Because Maine is acting under FDA authority for the Produce Safety Rule regulatory inspections, compliance and enforcement actions are guided and directed by the FDA's Office of Compliance.

Egregious Conditions on the Form 4056

FDA Form 4056: PRODUCE FARM INSPECTION OBSERVATIONS

4. § 112.31: Measures to prevent ill or infected persons from contaminating covered produce with microorganisms of public health significance

☒ Observation ☐ Corrective action taken

Description:
Visibly ill workers were handling produce and food contact surfaces. One harvest worker tried to cover their mouth to prevent vomit from contacting covered produce and tools, but was unable to prevent contamination of both. Another worker was observed rushing to the bathroom numerous times within a 40 minute span. Both continued handling covered produce and harvest tools after episodes. Management did not take action to prevent visibly ill workers from handling covered produce or food contact surfaces.

34. § 112.131: Control and disposal of sewage

☒ Observation ☐ Corrective action taken

Description:
Toilet facilities were not properly draining and effluent was overflowing on to the washing room floor where covered produce was sitting on the floor in wax boxes. Wax boxes of product contaminated with toilet effluent were then stacked up for shipping.

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What Are All These Forms?

FDA Produce Farm Inspection Report Summary

- Official FDA form completed **after** every Produce Safety Rule Inspection done by States.
- More descriptive report of inspection information, observations, and discussions with management.
- Includes corrective actions taken during inspections, and timelines for corrective actions proposed by farms afterwards.
- Mailed to farms once completed by DACF.

Examples of Written Observations on the Inspection Report Summary:

Example for a Non-Egregious Condition:

Observation:

Hoses in the wash/pack house did not have backflow prevention devices. Several were submerged in wash sinks or lying on the ground in pooled water.

Discussion with Management:

We discussed the potential risks of hoses lying on the ground and later being submerged in wash water used for covered produce. We also discussed the potential for contamination of the water distribution systems from backflow from hoses lying in water.

We discussed the protection offered by backflow prevention devices and the requirement of §112.133(d) not to allow backflow from, or cross connection between, piping systems that discharge waste water and those used to carry water for a covered activity, for sanitary operations, or for use in hand-washing facilities.

Documentation (photographs, records) collected/attached: N

Corrective Action Taken by Management During Inspection:

Anticipated Date of Corrective Action (if not during inspection):

What Are All These Forms?

FDA Produce Farm Inspection Report Summary

Examples of Written Observations on the Inspection Report Summary:

Example for an Egregious Condition:

Observation: ****Egregious Condition as noted on Form 4056****

Toilet facilities were not properly draining and effluent was overflowing onto the washing room floor where covered produce was sitting on the floor in wax boxes. Wax boxes of product contaminated with toilet effluent were then stacked up for shipping.

This did not meet the conditions of §112.131 to control, manage, and dispose of sewage in a manner that prevents contamination of covered produce, food contact surfaces, areas used for covered activities, agricultural water sources, and agricultural water distribution systems with known or reasonably foreseeable hazards.

Discussion with Management:

We discussed the immediate risks of toilet effluent flowing into the production area where covered produce is being washed, packed, and stored. We discussed the adulteration of the covered produce in contact with the effluent, and the cross-contamination of other boxes when stacked on top of each other.

Management reported that it was only water running from the tank, not sewage backing up. Their sanitation records last record cleaning the packing room floor 3 days prior to our inspection.

Documentation (photographs, records) collected/attached: Y

1A. Toilet overflowing in bathroom by wash/pack room.
1B. Toilet effluent flowing into wash/pack room.
1C. Wax boxes of cucumbers sitting on the floor in toilet effluent.
1D. Wax boxes contaminated with effluent stacked and dripping onto other product.

Corrective Action Taken by Management During Inspection:

Anticipated Date of Corrective Action (if not during inspection):

Management has committed to suspending use of their wash/pack room until the toilet effluent problem is fixed. Their plumber is scheduled to arrive tomorrow and the they anticipate completing the repairs by XX/XX/20XX. All affected product will be destroyed by XX/XX/20XX.

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What Happens If There's A Problem?

Real talk? Something always goes wrong when the inspector is there. Don't sweat that. We know how to separate that out on inspection day. **But the stakes do get higher if there's an issue that could imminently make people sick.**

In that case we'll be assessing whether there's:

1. A **SOURCE** of contamination.
2. A **ROUTE** of contamination.
3. **CONTAMINATED PRODUCT** that *is* or *is about to be* circulated into commerce.
4. Conditions that will **CONTINUE TO CONTAMINATE PRODUCT** if left unaddressed.
5. A **SYSTEMIC** cause of the problem.

What Happens If There's A Problem?

IF THERE IS A PUBLIC HEALTH CONCERN:

1. We ask lots of questions to determine the facts and the scope of what is affected by the problem.
2. You can, and may have to take corrective action to address the immediate public health risk.
3. We consult with the FDA's Office of Compliance. (We are required to do this in the case of Egregious Conditions.)
4. DACF & the FDA determine the best course of action to resolve the public health risk.
5. The FDA's Office of Compliance ultimately directs any compliance or enforcement actions.
6. If there is still work to do after the inspection to correct the problem, we may set up a follow up inspection.

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What Happens If There's A Problem?

WHAT CAN COMPLIANCE ACTIONS LOOK LIKE?

Regulators have no desire to shut down any businesses, but there are several options if there is a public health concern. The FDA may choose any of the following as appropriate to the severity of the issue:

- Warning Letters.
- Structured Corrective Action Plans.
- Educational sessions.
- Notice of potential compliance or enforcement actions.
- Stop sales.
- Seizure/embargo of product.
- Ordered destruction of product.

What Happens If There's A Problem?

WHAT HAPPENS MOST OFTEN IN MAINE?

The roll out of initial inspections for the Produce Safety Rule is intentionally educational.

Most of the time we're:

- Discussing any causes for concerns.
- Making sure any immediate concerns are dealt with before we leave.
- Asking for your voluntary plan to address the top food safety issues.
- Discussing the more minor things so you're aware of them.
- Giving you time to make changes and adapt.

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Frequently Asked Questions

WHAT DO YOU NEED TO SEE FOR MY INSPECTION?

- Your covered activities—growing, harvesting, packing, and holding.

DO YOU NEED TO SEE ALL OF THOSE ACTIVITIES?

- Not necessarily. But we try to see as many as we can so we can get a good picture of food safety on your farm.

DO YOU NEED TO SEE EVERY FIELD AND FACILITY I HAVE?

- Not necessarily. If you have more acreage than we can get to, we'll choose a representative selection of fields so we get a good feel for how you're handling food safety risks.
- We will go through the appropriate storages for product, food packaging, tools and equipment pretty thoroughly.

Frequently Asked Questions

WHAT DOES AN INSPECTION COST ME?

- Nothing! The Produce Safety Rule is a mandatory federal regulation, so you are <u>not</u> charged for an inspections.

DO I NEED TO BE WITH THE INSPECTORS THE WHOLE TIME?

- Someone responsible for food safety on your farm will need to spend a good portion of the inspection with us. You're welcome to trade off if you need to, but it helps your team if you can be with us throughout.

CAN I JUST TAKE YOU TO MY BEST CREW IN MY CLOSEST FIELD?

- We'll need to observe your workers harvesting, packing, and doing regular handling chores. We're not expecting perfection, we just want to see what a normal day looks like. If we feel like we're not getting a good representation, we will ask to see other crews in further fields.

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Frequently Asked Questions

HOW LONG DOES AN INSPECTION TAKE?

- It varies depending upon the scope of your operation in both scale and complexity. Our inspections in 2019 have ranged from **2 hrs** to **2½ days**. Most have averaged between **4-6 hrs**.

ARE THERE BREAKS?!

- Yes, definitely! We work with you to break so you can redirect crews and we can clarify our notes or questions. If the inspection is going to take us into the afternoon, we'll plan on a lunch break so we all get a break.

CAN I HAVE OTHER PEOPLE WITH ME FOR MORAL SUPPORT?

- Absolutely. On your own inspection you can invite anyone you like. We will just have to be careful about our confidential handling of your information in front of your guests.

Frequently Asked Questions

WHO KNOWS ABOUT WHAT HAPPENS ON MY INSPECTION?

- We are bound by federal and state confidentiality policies. We do not share your information with anyone who is not credentialed to do this work by the FDA. We do consult with the FDA for technical and compliance direction.
- We <u>are</u> government workers though, so if someone files a Freedom of Information Act (FOIA) request, our notes and reports can be made public. Confidential or proprietary information is redacted before any documents are provided to answer FOIA requests.

GO BACK TO THE FDA PART—WHEN WOULD THEY KNOW MY NAME?

- The FDA is being careful not to get into identifying farm information. Unless there's an egregious condition requiring compliance action, we discuss the situations, not the names or locations. They <u>are</u> authorized to access our information, but so far are being careful partners.

Funding for this presentation was made possible, in part, by the Food and Drug Administration through grant PAR-16-137.

Frequently Asked Questions

WILL I GET A CERTIFICATE THAT I PASSED MY INSPECTION?

- No. You will get the inspection forms and reports we discussed above. Certificates are issued for voluntary 3rd party audits and certifications, not for inspections.

SO ARE MY INSPECTION REPORTS PUBLIC?

- We don't publish any of our reports. If the FDA were to issue you a Warning Letter, that would be published publicly. Barring that or a FOIA request, the only people seeing your reports are you and us.

OKAY. AND I CAN ASK YOU GUYS QUESTIONS WITHOUT GETTING IN TROUBLE?

- Definitely. We know asking questions helps all of us, so don't worry about us showing up the next day if you're working on figuring something out. Give us a call and we'll help you out however we can.

Frequently Asked Questions

WILL I BE INSPECTED IF I'M A QUALIFIED EXEMPT FARM?

- You definitely can be. Fully covered farms are the inspectional priority, but you're responsible for being ready for inspection by the compliance dates based on farm size.

SO YOU JUST CHECK MY PAPERWORK IF I'M QUALIFIED EXEMPT?

- Not quite. We will review the modified requirements for Qualified Exempt farms (labeling with farm name and address, maintaining sales records, & annual written verification of QE status).
- We **also** are responsible for looking around Qualified Exempt farms to ensure there are no practices or conditions that might result in adulteration or public health risks.

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FAQ: What Are The Most Common Issues?

MAINE DEPARTMENT OF AGRICULTURE, CONSERVATION & FORESTRY www.maine.gov/dacf/qar/

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IN SUMMARY

1. **START AT THE BEGINNING—**
   1. Make contact with the DACF.
   2. Confirm your coverage status.
2. **PREPARE—**
   1. Attend a PSA Grower Training.
   2. Request an On-Farm Readiness Review.
   3. Know your requirements and ask your questions.
3. **KNOW WE'RE ROLLING THINGS OUT SLOW AND STEADY—**
   1. We'll schedule the inspections ahead of time.
   2. We'll ask lots of questions and consider everything before acting.
4. **WE'RE HERE TO EDUCATE AND LEARN TOGETHER.**
   1. We will share what we know.
   2. We're here to learn from you about your farm too.

THANK YOU!

maine DEPARTMENT OF Agriculture Conservation & Forestry
QUALITY ASSURANCE & REGULATIONS

QUESTIONS?

Call us at: 207-764-2100
Email us at: leah.cook@maine.gov

www.maine.gov/dacf/qar/
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