FSMA-What to Expect

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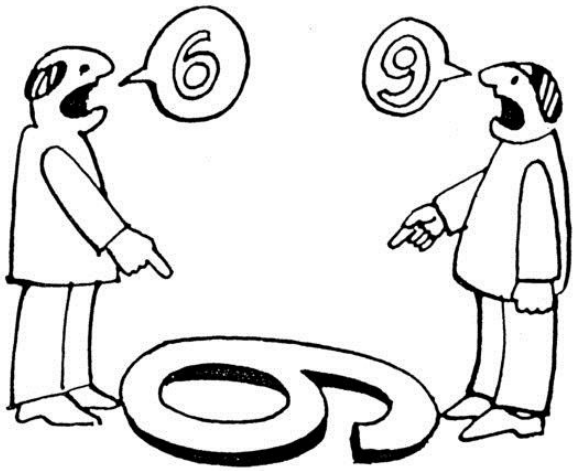
NDA

Nevada Department of Agriculture

FSMA-What to Expect

- **What are everyone's current perceptions of FSMA-PSR?**



Background-why FSMA

- **Signed into law in 2011**
- **Due to food borne illness outbreaks related to produce**
- **Goal to establish more secure domestic and imported food sources-preventative vs reactive**
- **Regulations for law released January 2016**

Is food secure in US?

Table 1. Deadly Multistate Outbreaks of Foodborne Illness in the U.S., 2006-2011

Year	Pathogen	Food Source	Cases of Illness	Number of Deaths	Number of States
2011	*Listeria monocytogenes*	Cantaloupes (Jensen Farms)	145	30[a]	28
2011	*Salmonella heidelberg*	Ground turkey (Cargill)	136	1	34
2009	*Escherichia coli* 0157:H7	Ground beef (Fairbank Farms)	26	2	8
2009	*Salmonella typhimurium*	Peanut butter (King Nut)	714	9	46
2008	*Salmonella saintpaul*	Jalapeño peppers (Mexico)	1,442	2	43
2006	*Escherichia coli* 0157:H7	Baby spinach (Dole)	199	3	26

[a] *One miscarriage was reported in a pregnant woman.*
Source: Reference 3.

- **2011 CDC estimated 47.8 million Americans contracted food-borne illness**
- **55,961 hospitalized**
- **1,351 deaths**

Chart provided by: US Pharmacist Publisher

Food Safety Outbreaks

2006 Spinach E-coli O157

- 205 illness
- 3 deaths

Gardenknowhow.com

2011 Cantaloupe Listeria

- 147 illness across 28 states
- 30 deaths

Drax.com

What's the Consensus

- **You're doing great!**
  - First and foremost, thank you!
  - Growers work incredibly hard, and the law is to protect those growers from financial loss from food borne illness.

What's the Consensus?

- **Through outbreaks we've learned valuable lessons:**
  - Contamination sources on the farm & handling facilities
  - Practices for avoiding these contamination points
  - Let's work together!

What is FSMA-PSR?

- **Food Safety Modernization Act, Produce Safety Rule-**Regulations for ensuring growers of a designated size and scope are employing practices to minimize food safety risks

Who Influenced the Rules?

- Industry, FDA, USDA, and public comment have all played a role in developing standards

Standards are Based on:

- **Science based standards**
- **Previous issues encountered**
- **What we've learned from previous outbreaks**
- **Prevention vs reaction**

How Does this Impact You?

- **Farm scopes include products commonly consumed raw. <u>Exempt</u> crops include:** asparagus, beans; collards; sweet corn; cranberries; dates; dill (seeds and weed); eggplants; figs; horseradish; hazelnuts; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; winter squash; sweet potatoes; and water chestasparagus; black beans, great Northern beans, kidney beans, lima beans, navy beans, and pinto beans; garden beets (roots and tops) and sugar beets; cashews; sour cherries; chickpeas; cocoa beans; coffee nuts
- Food grains, including 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)

Exemptions Continued

- Produce that is used for personal or on-farm consumption
- Farms that have an average annual value of produce sold during the previous three-year period of $25,000 or less (gross income)
- This includes all produce, not just produce on the commonly consumed raw list

Exemptions Continued

- The rule provides an exemption for produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance, under certain conditions

Exemption example

- **Tomato grower that is sending all crops to be processed into tomato sauce**
- **Still must maintain records that verify tomatoes are be sent for this processing**

Indystar.com

Qualified Exemption

- The farm must have food sales averaging less than $500,000 per year during the previous three years; and
- The farm's sales to qualified end-users must exceed sales to all others combined during the previous three years. A qualified end-user is either (a) the consumer of the food or (b) a restaurant or retail food establishment that is located in the same state or the same Indian reservation as the farm or not more than 275 miles away

However……

- **Farm must still meet modified requirements even if exempt:**

  -Business name and production address on the product label or at point of sale (compliance by Jan 1, 2020)

  -Maintain records that verify eligibility for exemption or qualified exemption (compliance by Jan 1, 2016)

Qualified Exemption Ex.

- **Farm sells an annual average (over a three year period) of $200,000 in livestock sales, $50,000 of leafy greens via farmers markets, $100,000 in jams and salsas, and $150,000 in alfalfa hay.**

When do I need to Comply?

PSR were finalized January 2016. Inspections will begin 1 year past each deadline

Business Size	Compliance Dates for Sprouts	Compliance Dates For Most Produce	Water Related Compliance Dates[1]	Compliance Date for Qualified Exemption Labeling Requirement [2]	Compliance Date for Retention of Records Supporting a Qualified Exemption
All other businesses (>$500K)	1/26/17	1/26/18	1/26/22	1/1/2020	1/26/16
Small businesses (>$250K-500K)[3]	1/26/18	1/28/19	1/26/23		
Very small businesses (>$25K-250K)[4]	1/28/19	1/27/20	1/26/24		

Compliance Dates Defined

- Very small: >$25,000 but <$250,000 average annual gross produce sales over 3 years (January 2020 effective date)
- Small:>$250,000 but <$500,000 average annual gross produce sales over 3 years (January 2019)
- All other farms (January 2018)

Water Quality Dates

- Compliance for certain aspects of water quality will allow for an additional 2 years beyond overall compliance to fulfill testing and record keeping provisions

Primolo.de

Modified Exemptions Dates

- Labeling requirements January 2020
- Retention records supporting eligibility for modified exemption, effective date of the rule (January 2016)

Overview of the PSR

- **PSR prioritizes on frequent biological risks associated with produce:**
  - **-water quality**
  - **-animal waste use**
  - **-animal intrusion**
  - **-health and hygiene practices**

PSA-Agriculture Water Use

- Irrigation
- Fertigation
- Crop sprays
- Cooling

- Frost protection
- Dust abatement
- Other uses where water directly contacts produce

PSA-Evaluating Risks of Ag Water

Three main impact points for produce safety risks related to production water are:

1. Production water source and quality
   - Public water supply, ground water, surface water
   - Testing frequency and sampling location
2. Application method
   - Water that does not contact the harvestable portion
   - Water that contacts the harvestable portion of the crop
3. Timing of application
   - At planting or close to harvest

PSA-Probability of Contamination

Public Water Supply

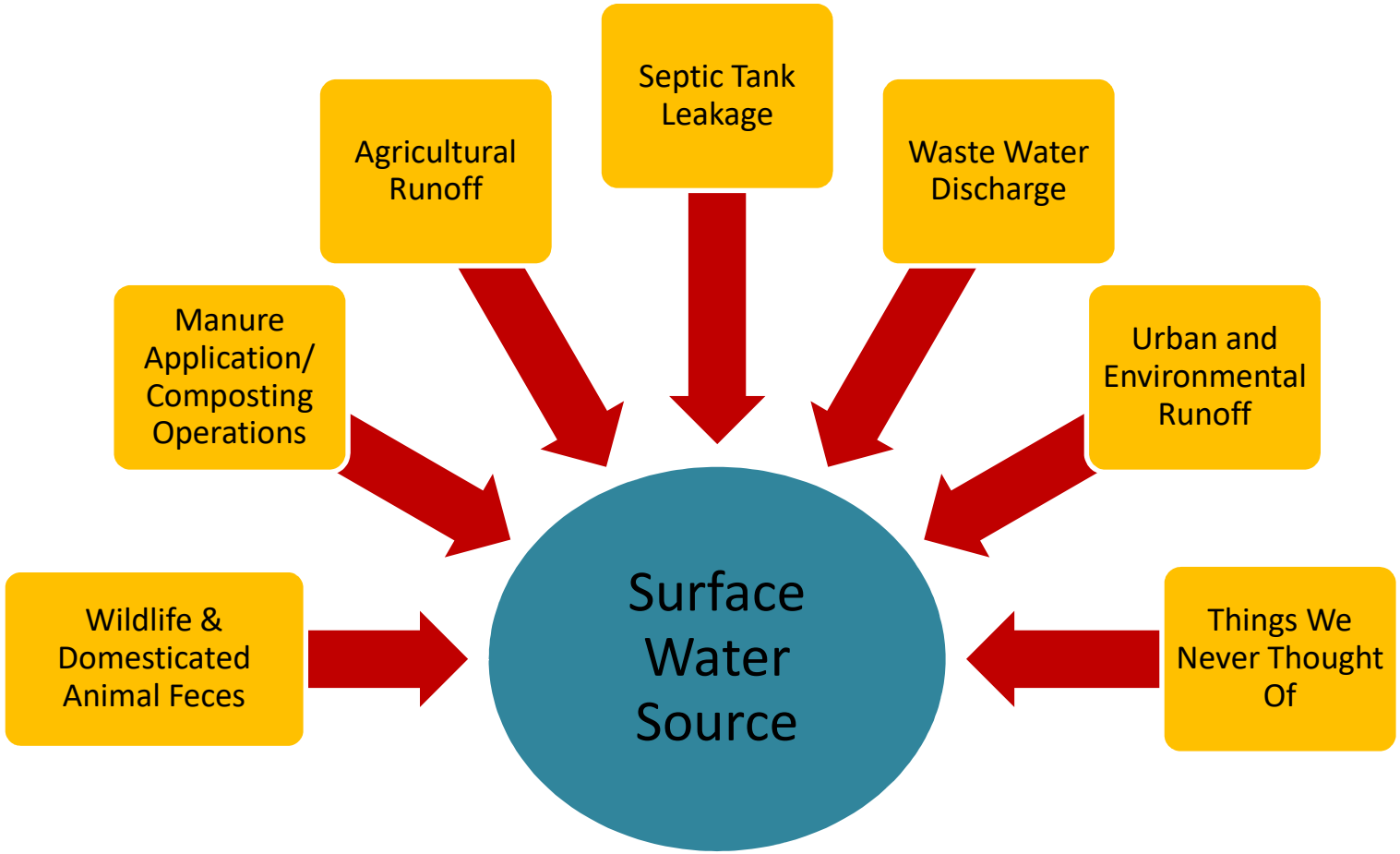
Treated

Ground Water

Surface Water

Open to Environment

PSR-Potential Sources of Surface Water Contamination



PSR-Preventing Contamination of Surface Water Sources

- **Assess nearby land use and upstream water activities to identify risks**
  - Work with neighbors and local watershed groups to understand and minimize identified risks
- **Assess and address runoff risks**
  - Develop diversion ditches, berms or containments to minimize environmental runoff, runoff from manure and compost piles, or runoff from livestock feeding areas
- **Monitor and control animal access to irrigation water sources where practical (e.g., irrigation reservoirs)**

PSR-Methods of Irrigation

- **Overhead (sprinkler)**
  - Higher risk: A direct water application method resulting in contact with produce
- **Flood (surface, furrow)**
  - May avoid direct contact with produce
  - Consider risk of contact with contaminated soil during harvest or from splash
- **Drip (trickle, subsurface, micro, under canopy)**
  - Lower risk: Produce generally not in direct contact (except root crops), reduces foliar diseases, improves water use efficiency

Local Challenges

Irrigation sources may vary annually

- How does a grower determine which sources to develop a water profile?
- This concern has been expressed to FDA

Discussion on what concerns growers

What resources can NDA and UNR provide? (highlight survey)

PSR-Less Contact with Water = Lower Risk

A key question for evaluation of risk is:

"Is the water applied using a direct water application method?"

- If the answer is "never", the risk from water is very low
- If the answer is "yes", the type of commodity, quality of the water and the timing of the application should be reviewed to assess risks

PSR-Pathogens on Produce May Die Off Over Time

- Environmental conditions can influence die-off rates including
  - Desiccation (drying out)
  - Sunlight (ultraviolet irradiation)
  - Temperature and humidity
  - Starvation and competition

- Some pathogens may be ‘protected’ on the plant and survive for extended periods of time
- Under some conditions, pathogens can even regrow on a plant so avoiding contamination is best

PSR-Inspect Agricultural Water Sources and Water Distribution Systems

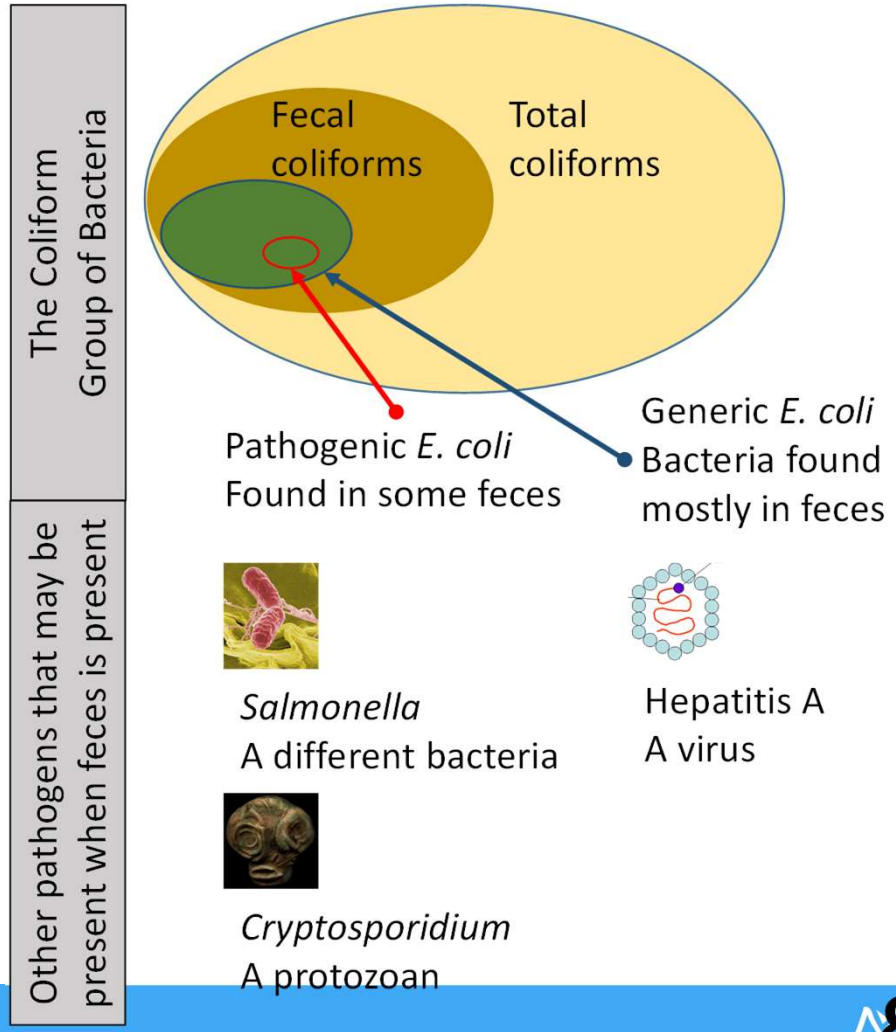
- Water can be contaminated at the source, or at the distribution system
- Mapping all water distribution systems is recommended
- Water sources and distribution systems must be inspected at least annually
- Must keep water sources free of debris, trash, domesticated animals, and other hazards

PSR-Evaluating Water Quality: Use of Microbial Water Quality Profiles

- **Testing is the only way to quantitatively evaluate the microbial quality of the water**
- **The water quality profile can help:**
  - Understand the long-term quality of source water
  - Understand appropriate uses for each source
  - Determine if corrective measures are needed if the microbial water quality profile exceeds numerical GM and STV criteria in the FSMA Produce Safety Rule

SR-Generic *E. coli* is an Established Indicator

- **Generic *Escherichia coli* *(E. coli)* is an indicator of fecal contamination**
- ***E. coli* is not a direct measure of the presence of human pathogens**
- ***E. coli* is the indicator used to measure water quality in the FSMA Produce Safety Rule**



PSR-Water Quality Criteria for Water Used During Growing Activities

- Apply to water used with a direct water application method to covered produce
- Each source of production water must be tested to evaluate whether its water quality profile meets the following criteria (*which is under review*):
  - **126 or less** colony forming units (CFU) generic *E. coli* per 100 mL water geometric mean (GM)

    AND
  - **410 or less** CFU generic *E. coli* per 100 mL water statistical threshold value (STV)

PSR-Microbial Water Quality Profile: Survey of Ground Water Sources

Source	Initial and Annual Testing Requirement
Ground	4 or more times during the growing season or over the period of a year 1 or more samples rolled into profile every year after initial year

- Profile samples must be representative of use and must be collected as close in time as practicable to, but before, harvest

PSR-Microbial Water Quality Profile: Survey of Surface Water Sources

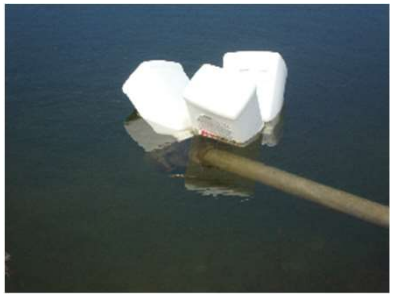
Source	Initial and Annual Testing Requirement
Surface	20 or more times over a period of 2 to 4 years 5 or more samples rolled into profile every year after initial survey

- Profile samples must be representative of use and must be collected as close in time as practicable to, but before, harvest

PSR-Where Do I Collect Samples?

- **Surface water and ground water:**
  - Take a representative sample appropriate for the water source

- **Municipal/public water supply:**
  - No sample required if testing reports obtained from the water utility, treatment plant, or lab
  - Optional sampling at different points in the distribution system can be useful



PSR-Corrective Measures

- **Three types of corrective measures are allowed if the microbial water quality profile does not meet water quality criteria:**
  1. Apply a time interval for microbial die off
     i. Between last application and harvest
     ii. Between harvest and the end of storage and/or removal during activities such as commercial washing
  2. Re-inspect the water system, identify problems, and make necessary changes and confirm effectiveness
  3. Treat the water

FDA Update on Water Quality Standards 02/01/17

- The 2017 Winter Policy Meeting for the National Association of State Departments of Agriculture provided an update from FDA on water quality standards testing
- FDA visited numerous farms and your message has been heard
- FDA has indicated that they intend to simplify the water testing standards
- No specifics on what this will entail was released

Soil Amendments

PSA-Soil Amendments & Food Safety Risks

- Biological soil amendments, especially those that include untreated (raw) manure, pose significant microbial risks
- Synthetic (chemical) soil amendments can also impact food safety, if not prepared and applied properly
- Risks should be assessed when selecting and applying all soil amendments on produce fields

PSA-Assessing Your Risks

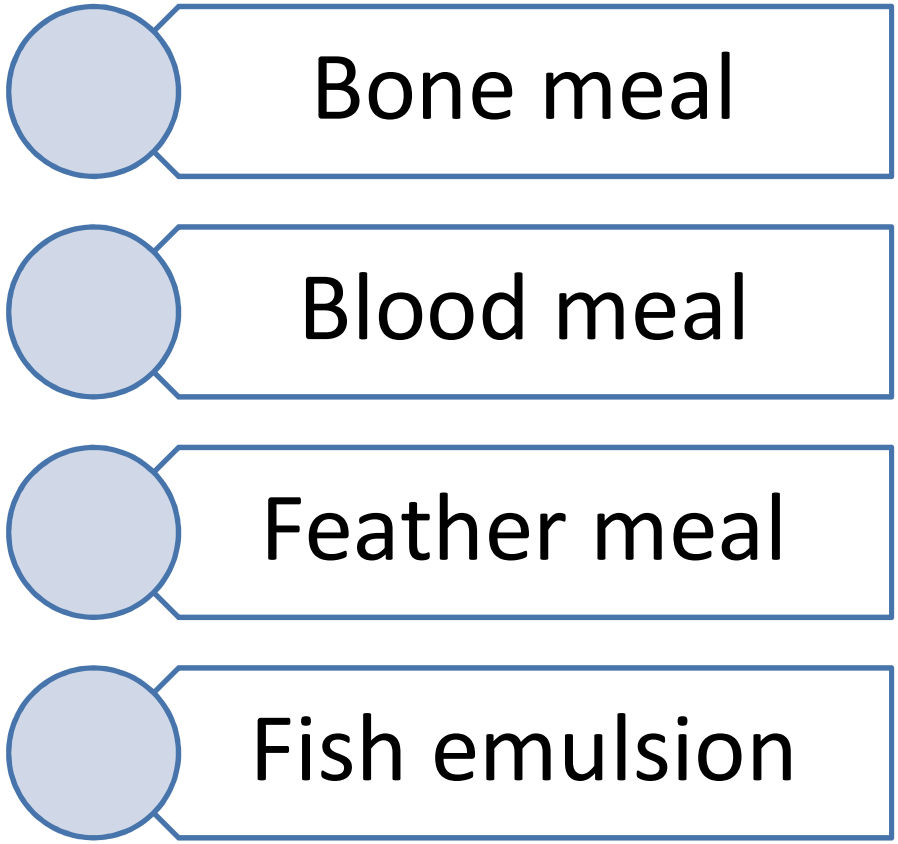
- **What type of soil amendments do you use?**
  - Raw manure, composted manure, chemical, etc.
- **What crops receive soil amendments?**
  - Fresh produce or agronomic crops
- **When do you apply them?**
  - Days to harvest, time of year
- **How do you apply them?**
  - Incorporated, injected, surface applied
- **How much and how often do you apply them?**
  - Excessive application can lead to environmental impacts

PSA-Human Waste & Biosolids

- Human waste is prohibited for use on produce crops, unless it meets the EPA regulation for biosolids (40 CFR part 503)
- Untreated human waste may contain pathogens, heavy metals, or other contaminants
- May not be accepted by produce buyers
- Management of biosolids not discussed because use is infrequent in fresh produce production

PSA-Non-Manure Based Soil Amendments of Animal Origin

- **Should be processed to eliminate pathogens or must be considered untreated biological soil amendments of animal origin**



Verification from Suppliers

Soil Amendments of Animal Origen

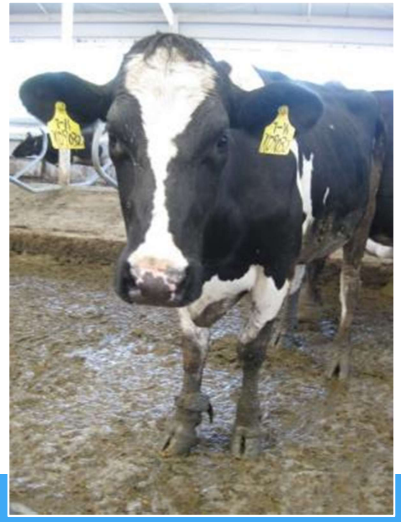
- Suppliers should be providing treatment verification
- Have a repour with your supplier-they should have treatment records
- If applying raw manure-maintain a record of when applied and when crops began to be harvested.
- Do not apply directly to produce when plant has budded (side-dress or apply prior to budding)
- *Once plant buds it is considered whole fruit (study on salmonella)

PSA-The Value of Manure

- Increases soil tilth, fertility, and water holding capacity
- Sound nutrient management and waste utilization for those with animal production or partnering with other farms who have animals
- Widely available and cost effective

PSA-Pathogens in Animal Manure

- All manures can carry human pathogens
- Some animals tend to be reservoirs for certain pathogens
- Many things can affect animals shedding pathogens in their manure
  - Age
  - Rearing practices
  - Diet
  - Season
  - Environmental conditions



PSA-Untreated Soil Amendments

- **Untreated biological soil amendments of animal origin-high risk since no treatment to reduce pathogens**
- **All of the following soil amendments would be considered untreated:**
  - Raw manure
  - 'Aged' or 'stacked' manure
  - Untreated manure slurries
  - Untreated manure teas
  - Agricultural teas with supplemental microbial nutrients
  - Any soil amendment mixed with raw manure

- Aqueous Solution: Applying a compost mixed with microbially safe water prior to applying (must be applied within 60 min)
- Compost Tea: Brewing this mixture longer than 60 minutes.

- **Cannot apply compost tea foliarly, but must be applied to minimize bud contact**
- **If adding mollasses to fully composted manure it reverts to untreated soil amendment.**

PSA-Reducing Soil Amendment Risks

- **Selection**
- **Treatment**
- **Application Timing**
- **Application Methods**
- **Handling and Storage**
- **Recordkeeping**

PSA-Composting Options

Must use a scientifically valid process:

1. **Aerated static composting: aerobic, minimum 131°F (55°C) for 3 days, followed by curing with proper management to ensure elevated temperatures throughout all materials**
2. **Turned composting: aerobic, minimum of 131°F (55°C) for 15 days, minimum 5 turnings, followed by curing**
3. **Other scientifically valid, control composting processes**

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PSA-Reducing Risks During Application

Steps you should take to reduce risks:

- Maximize the time between application and harvest
- Do not contact the edible (bud) portion of the crop during application.
- Minimize risks to adjacent produce crops if you are field spreading manure

Recordkeeping: Soil Amendments

Soil amendments can introduce microbial risks, so you should document:

- Type and source of soil amendment
- Rates and dates of application
- Handling and sanitation practices used that reduce risks

There are a few records required for treated biological soil amendments of animal origin within the Produce Safety Rule

- Some details are outlined on the next few slides

PSA-Recordkeeping: On-Farm Composting

Key factors in the composting process must be documented. These may include the following steps depending on the process used:

- Time
- Temperatures
- Turnings
- Other processing steps

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PSA-Recordkeeping: Soil Amendments Supplied by a Third Party

Documentation should be kept of:

- The name and address of the supplier
- What soil amendments were purchased
- The date and amount purchased
- Lot information, if available

Documentation must be collected from the supplier:

- To ensure the supplier has used scientifically validated treatment processes and monitoring during the production of the treated amendment (including compost)
- To ensure proper handling requirements have been met

PSA-Manure Summary

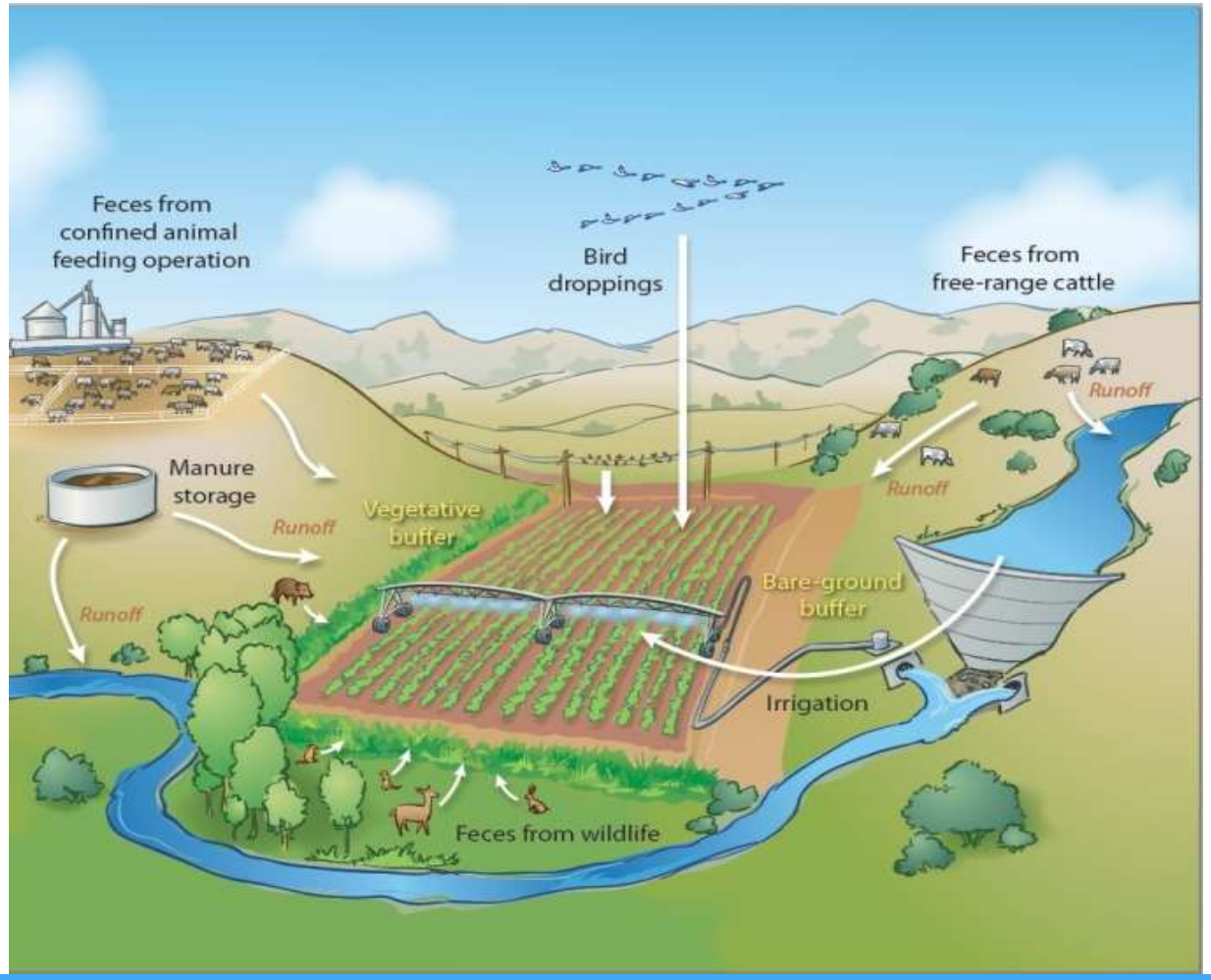
- **Soil amendments can introduce produce safety risks, especially those that contain raw manure**
- **To reduce risks associated with soil amendments:**
  1. Apply untreated manure to non-produce fields
  2. Treat raw manure using a scientifically validated, controlled process
  3. Extend the time between application of raw manure and harvest
- **Make sure storage areas do not contaminate fields, water sources, or packing areas**
- **Train workers who handle and apply soil amendments**
- **Develop sanitation steps for tools and equipment**
- **Keep records of soil amendment applications and treatments**

Wildlife, Domesticated animal, land use

Animals Are A Produce Safety Concern Because They:

- **Can carry human pathogens**
  - e.g., *E. coli* O157:H7, *Salmonella, Listeria monocytogenes*
- **Can spread human pathogens**
  - By depositing feces in fields
  - By spreading fecal contamination as they move
- **Are very difficult to control**
  - Birds and small animals travel unnoticed
  - If fencing is used, even the best fence can be breached
  - Complete exclusion is not possible

Managing Food Safety on the Farm Can Be a Complex Issue!



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PSA-Wildlife on the Farm

- Can be a natural and valuable part of the landscape and farm environment
- Depending on species, management options may be limited by county, state, or federal law
- May be resident or transient (e.g., migrating species)
- Wildlife with close association to human activities may pose greater risks
  - e.g., seagulls feeding at dumps, starlings feeding in cattle feedlots

PSA-Co-Management: Striking a Balance

- Farmers must address food safety requirements, but should keep the conservation of natural resources in mind
- Farmers also have stewardship, aesthetic, and business objectives of their own
- Co-management considers both food safety and conservation of natural resources

PSA-Monitoring Wildlife Activity

- **During the growing season:**
  - Monitor for feces and evidence of intrusion
  - Evaluate the risk of fecal contamination on produce (e.g., tree vs. root crop)
  - Consider past observations and wildlife attractants

- **Immediately prior to harvest**
  - Monitor for fecal contamination, signs of animal activity (e.g., trampling, rooting, feeding, tracks)
  - Assess risks and decide if the crop or a portion of the crop can be safely harvested

PSA-Deterring Wildlife

Decoys

Fencing & Netting

PSA-Deterring Wildlife

Visual Deterrents

Noise Deterrents

Tactile Repellent

Relocation

PSA-Domesticated Animals on the Farm

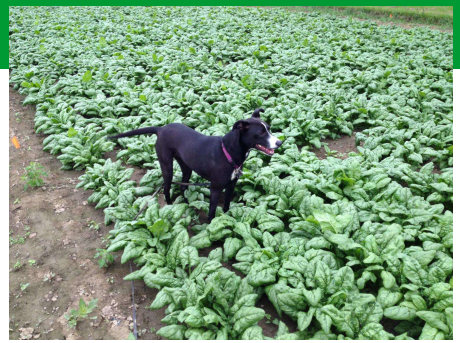
- Domesticated animals, such as livestock and pets, may harbor human pathogens
- Domesticated animals are sometimes used in fields
  - As draft animals
  - As wildlife management (i.e., dog
  - To graze crop residues/culls
- **Assess the risk if animals are allowed or are likely to enter your production fields**

PSA-Assessing Risks: Domesticated Animals

- **Are domesticated animals allowed in the field while the crop is present as part of the production process?**
  - Are they working animals?
- **Are workers aware of cross-contamination risks from fecal contamination of hands, clothing, shoes, and equipment after handling animals or fecal material?**
- **Are production fields rotated into grazing land?**
  - If manure is present on the ground, one recommendation is to extend the period of time between when animals were grazed and when produce can be planted

Pets

- Should be excluded from produce fields
- Visitors to the farm should be instructed to leave their pets at home
- Farms with petting zoos should have handwashing sinks available and signage instructing visitors of the food safety policies



PSA-Pre-Harvest Assessment

A process to assess fields before harvest to help determine if:

- Fecal contamination is present, or signs indicate a risk (e.g., tracks, trampling, rooting, feeding)
- Fresh produce has been contaminated and cannot be harvested
- Corrective actions, such as no-harvest buffer zones, are necessary
- Harvest can safely proceed

PSA-Recordkeeping

Records must be kept for:

- Worker training

Records should be kept for:

- Pre-plant land assessments
- Monitoring for animal activity
- Actions taken to reduce the risks related to animal intrusion into crop (domesticated animals and wildlife)
- Pre-harvest risk assessments
- Intrusion and contamination events
- All corrective actions taken

Worker/Visitor Health & Hygiene

Workers Are A Food Safety Concern

Because They…

- **Can carry human pathogens**
  - *Shigella*, Hepatitis A, Norovirus, and others
- **Can spread human pathogens**
  - Harvest and pack with their hands
  - Fecal-oral route
- **Require training to reduce risks**
  - Proper handwashing
  - How to handle illnesses and injuries

Routes of Contamination

Feces

Clothing

Hands

Footwear

Tools & Equipment

Illness & Injury

Importance of Training Workers

- **Fresh fruits and vegetables often receive no additional processing (such as cooking); contamination with a pathogen can result in illness when the produce is consumed**
- **Workers need to use food safety practices to reduce produce safety risks**
- **Food safety practices are learned so training is key to successful implementation**

Potential Training Challenges

- **Time for training**
- **Language**
- **Literacy level**
- **Training mid-season**
- **Variation in hygiene practices and expectations**
- **Misconceptions/misperceptions**

Ensuring training methods are effective

Visitors

- **Growers must:**
  - Make visitors aware of the farm's food safety policies
  - Provide access to toilet and handwashing facilities

- **Other key information for visitors should include:**
  - Areas of the farm they are allowed to visit
  - The importance of not visiting the farm when ill
  - How to wash their hands
  - Instructions to keep pets at home

Training Programs Must Include

- **Principles of food hygiene and food safety**
- **Recognizing symptoms of foodborne illness and the importance of personal hygiene for all personnel and visitors**
- **Other training relevant to the worker's job**

Worker Illness

- Workers who are sick or show signs of illness can contaminate fresh produce
- Ill workers must not handle fresh produce
- Symptoms of illness can include:
  - Nausea
  - Vomiting
  - Diarrhea
  - Fever
  - Jaundice

Resources

Resources

- **NDA and DFI applied for a cooperative agreement with FDA**
- **Trainings are scheduled for February-April 2018 and will be ongoing for 2-3 years**
- **This will include trainings for those that must comply and for those simply interested**

PSR Oversight

- **NDA will be developing a regulatory program in conjunction with FDA**
- **In the meantime, ongoing trainings, on-site field assessments, on-line tools, etc will be established to help produce growers**

Resources

- **We need to find out how best to help you**
- **Surveys will be issued to identify the range of produce grown, education preferences, specific needs, etc.**
- **The producer certificate registration program will be used as a tool for obtaining this information**
- **Will also help with capturing state statistics on specialty crop production**

Resources

- **DFI will serve as a working model on how to comply with FSMA, PSR**
- **We will collaborate in creating resources and hosting class-room and field trainings**
- **We are here to help and are grateful for all you do!**

Contact Info

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