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FSMA

Dissecting the Food Safety Modernization Act (FSMA) Produce Rule & Good Agricultural Practices (GAP)

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College of Tropical Agriculture and Human Resources

Modified: December 11, 2016

FDA FOOD SAFETY MODERNIZATION ACT

Safe Food Handling is a Public Health Concern

- Growing concern about the safety of our U.S. foods system
- Health and sanitation standards are common for food related business
  - Restaurants, meat, egg, poultry, etc.

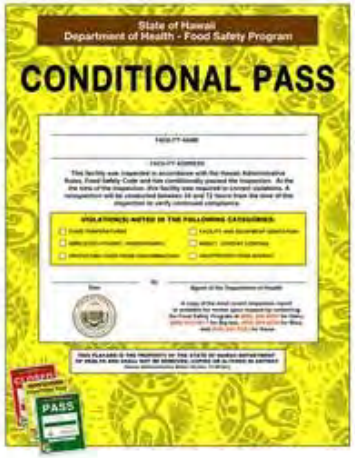


FIGURE 2.

USDA Inspection Mark
Used on raw meat

FDA Food Safety Modernization Act (FSMA)

- Signed into law by President Obama January 4, 2011.
- Published November 27, 2015
- Effective 60 days after (1/26/16)
  - Safety of the U.S food supply
  - Preventive vs reactive
  - Domestic and import production

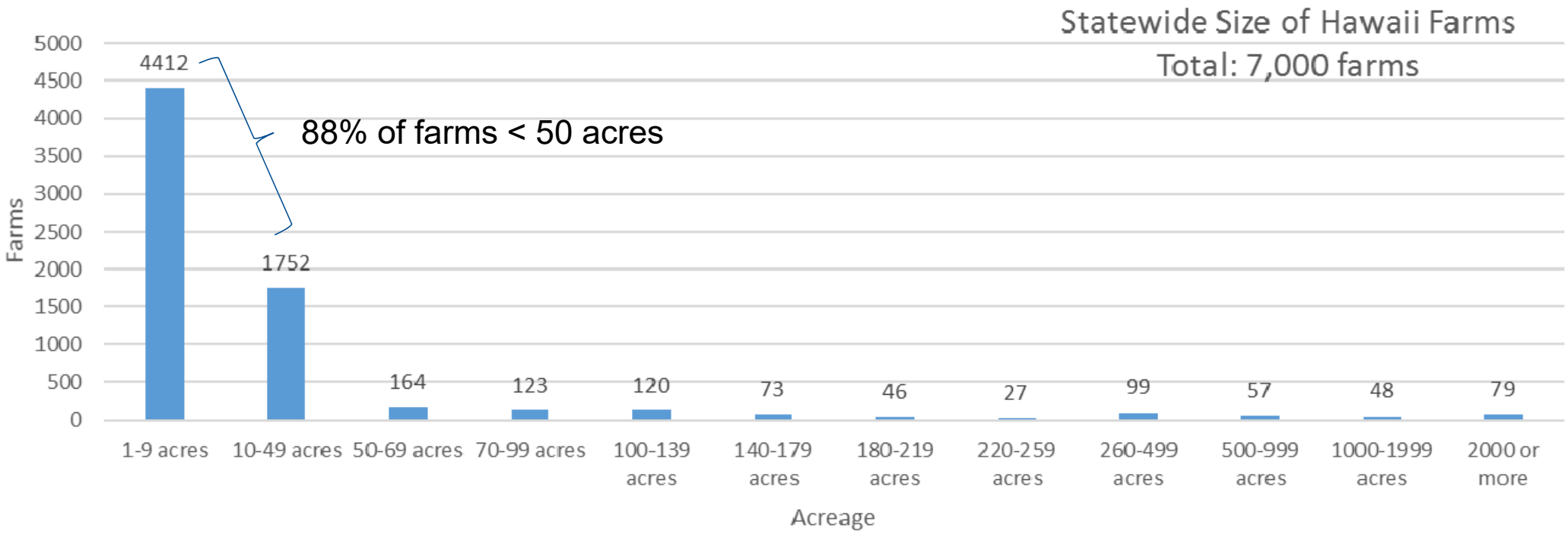
Why is this Necessary?

- Sick
- Hospitalized
- Lifetime disorders
- Die

Source: CDC website, November 5, 2014

Paradigm Shift in Agriculture

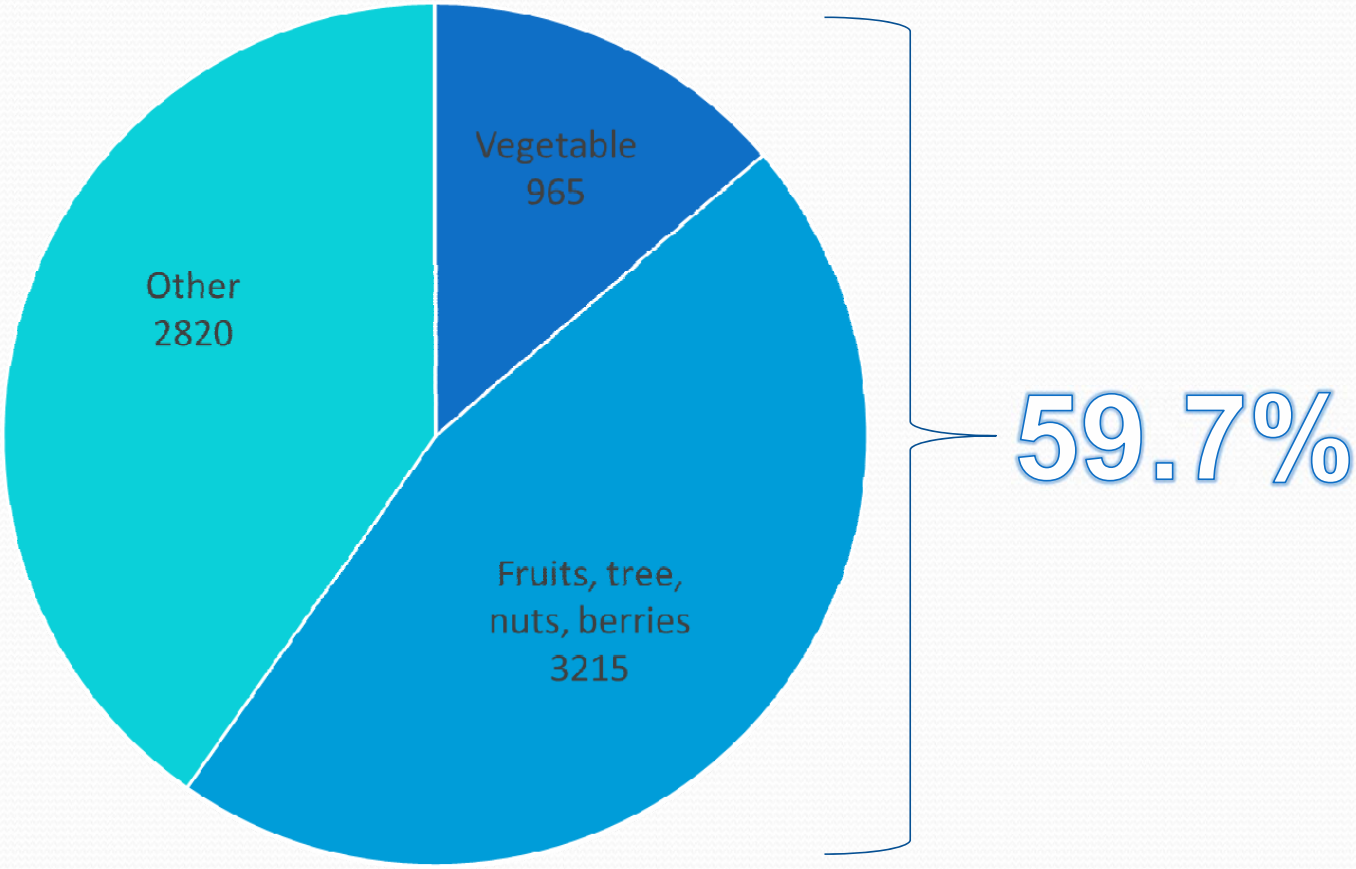
- Farming is changing in Hawaii
  - Increase in small scale farming
  - Changing role of the farmer
- Fruits and vegetables <u>are not</u> exempt from U.S. food safety regulations



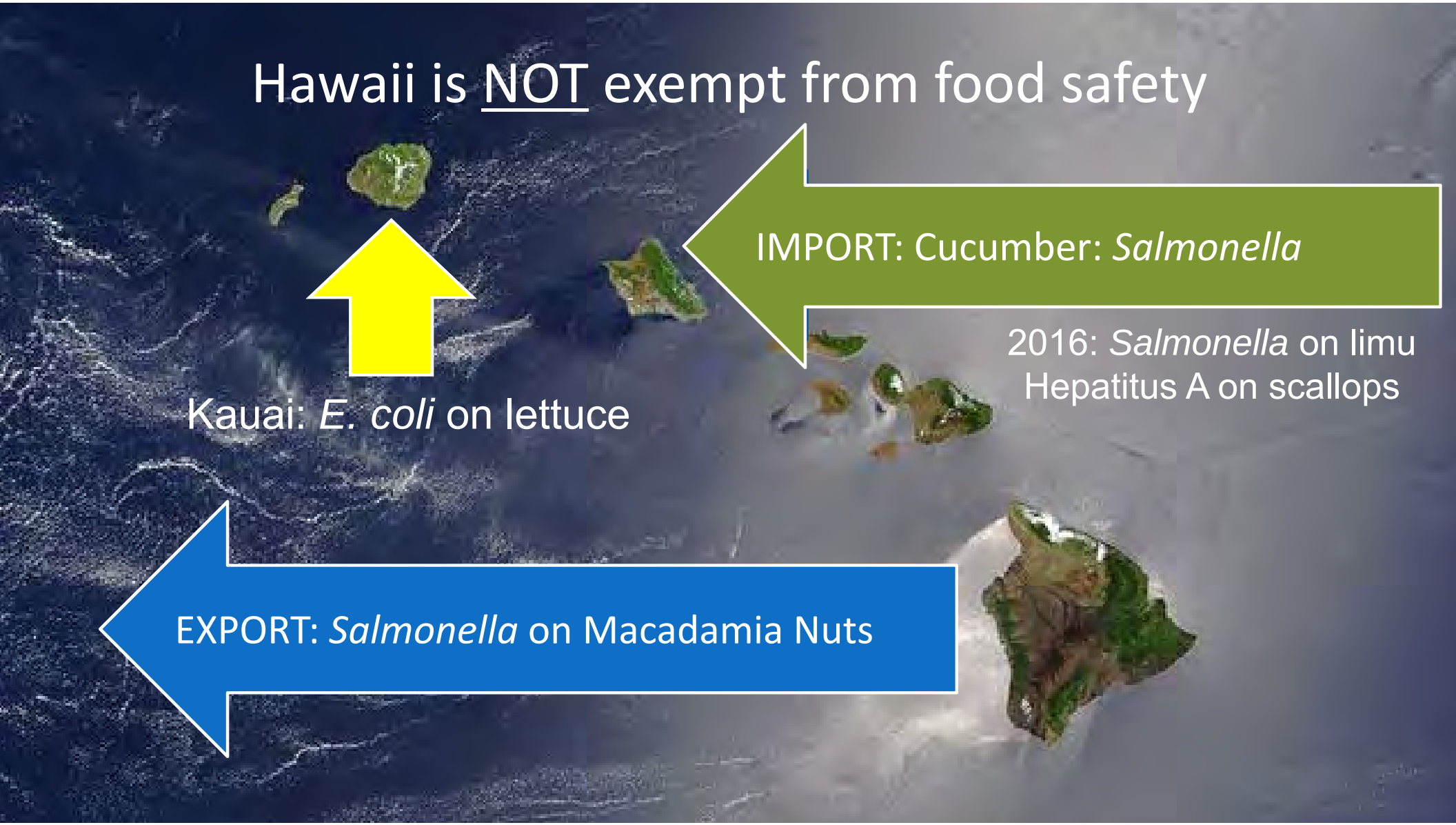
Source: 2012 Census of Agriculture, State Data

For Discussion Purposes:
Includes animals and ornamental crops

Nearly 60% of Hawaii farms are under fruits, nuts and vegetable production



Source: 2012 Census of Agriculture, State Data
Total farms: 7,000


Hawaii is NOT exempt from food safety
IMPORT: Cucumber: *Salmonella*
2016: *Salmonella* on limu
Hepatitus A on scallops
Kauai: *E. coli* on lettuce
EXPORT: *Salmonella* on Macadamia Nuts

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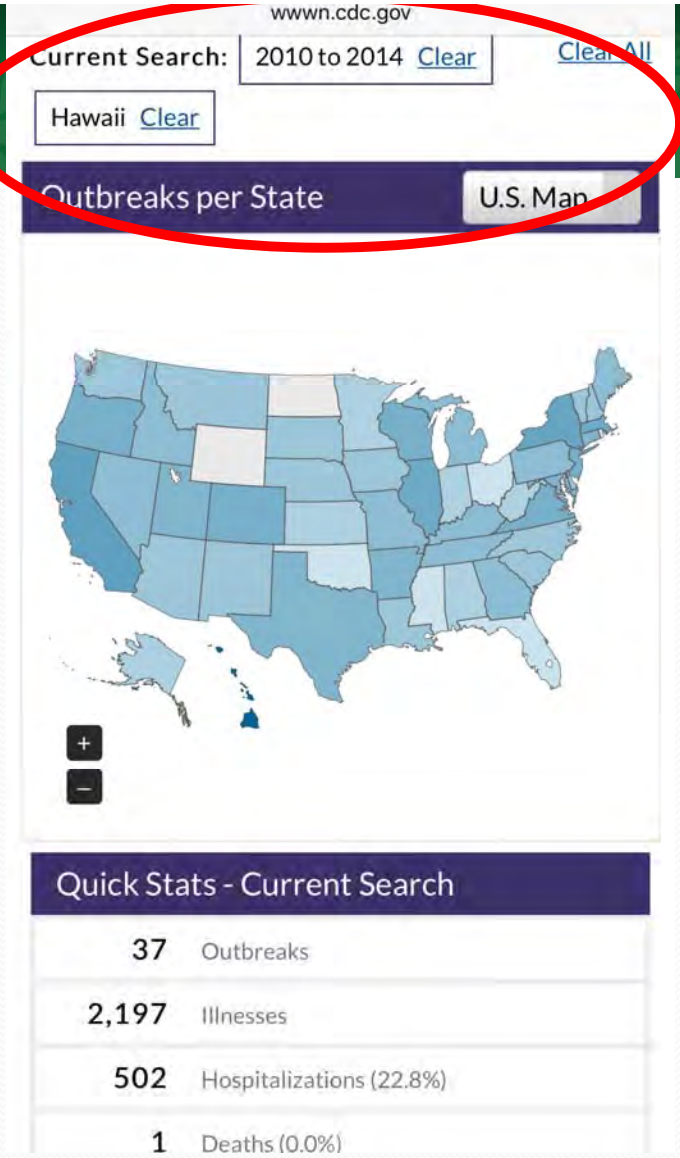
Foodborne Illnesses in Hawaii

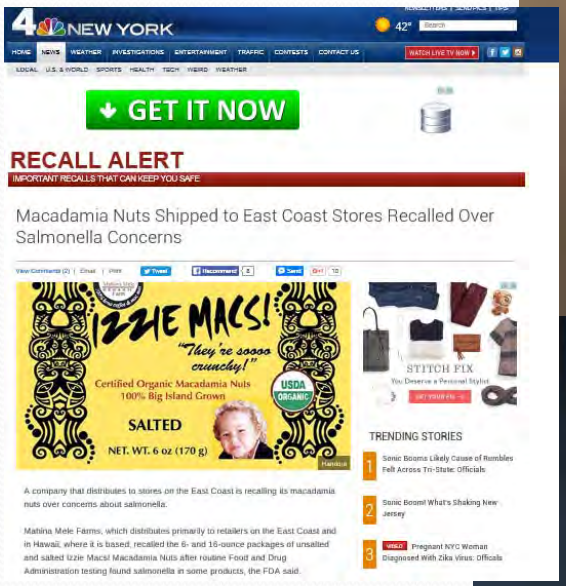
- From 2010-2014 (Hawaii, 4 years)
  - 2,197 food borne illness cases (550/ yr.)
  - 502 hospitalizations (125/ yr.)
  - 1 death (0.25/yr.)
- National (USA, annually)
  - 48 million people get sick
  - 128,000 hospitalizations
  - 3,000 die



Source: From CDC data last updated 10/16/2015

How This May Affect You?

- Recalls
- Bad publicity (viral)
  - Industry effect
- Lawsuits from:
  - Illness
  - Disability
  - Miscarriage
  - Death
- Fines and prison time



How This Can Benefit You?

- Reduce risk
- Minimize illnesses
- Harm reduction plan
- Safeguards high risk areas
- New market opportunities

PRODUCT OF
HAWAII
USA
FOOD SAFETY
CERTIFIED

View our certification records:
www.HIfarmsafe.org

Examples of Hazards in Various Food Related Industries

Physical

Contamination and /or poor food handling practices

Ex. Slivers of glass, hair, nails, nail polish, pieces of jewelry, metal fragments, bandages, etc.

Chemical

Chemicals (pest control, cleaning and sanitizing, etc.) that may come into contact with food & cause contamination.

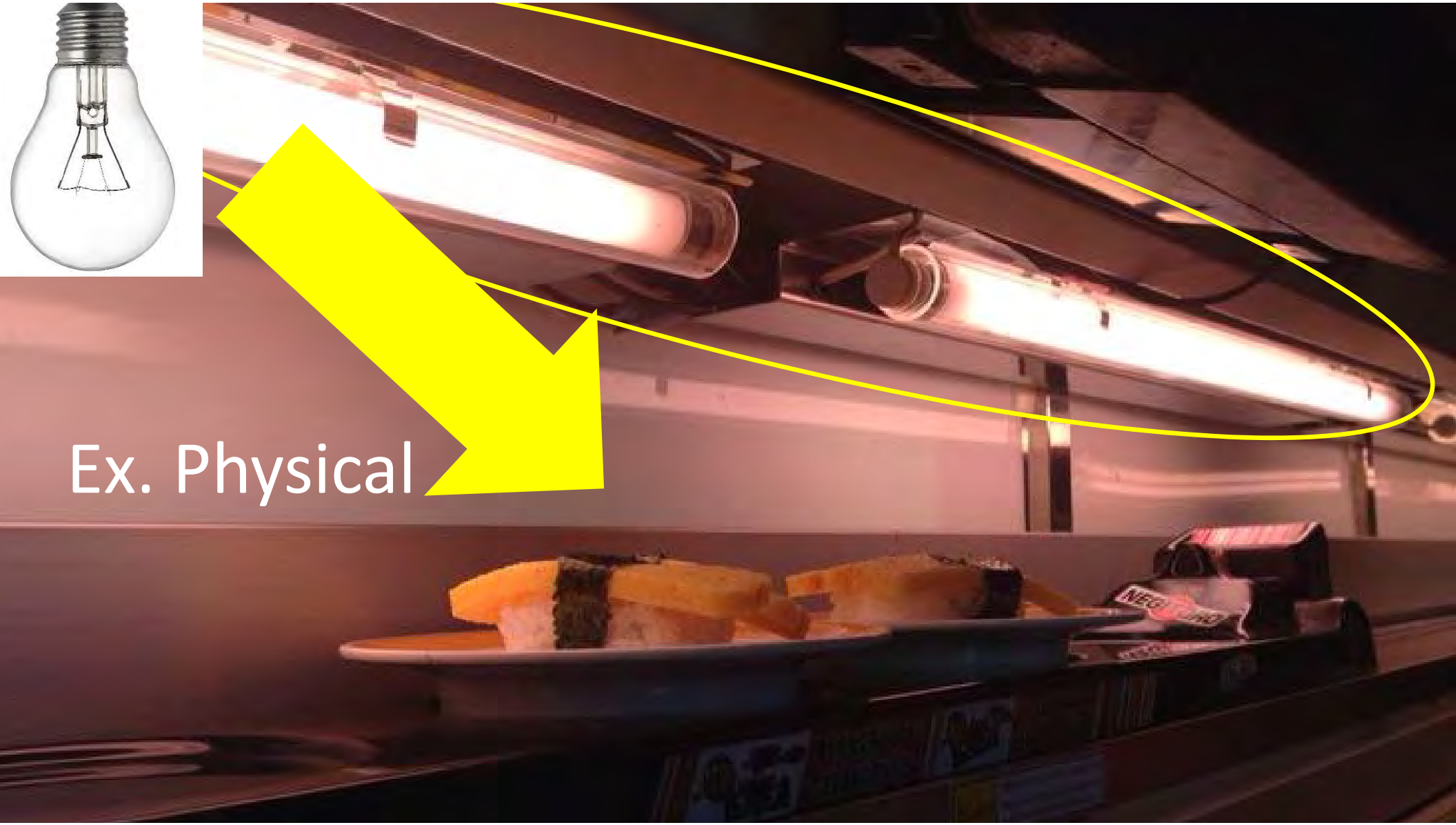
Ex. Allergens, pesticides, sanitizers, lubricants, etc.

Microbial

Found in the air, food, water, soil, animals and the human body which can cause food borne illnesses

Ex. Salmonella, *E. coli* O157:H7, *Listeria*, Hepatitis A, *Campylobacter,* Parasites, nematodes (RLW), etc.

Source: University of Rhode Island, Food Safety Program


Ex. Physical

Ex. Chemical Safeguards

Source: USDA ARS

with fruity raspb

Allergies

Contains egg, gluten and milk
May contain traces of nuts

gredients

buttercre

Ex. Chemical Safeguards


Ex. Microbial, before food was left on counters
How we handle food is changing in the USA

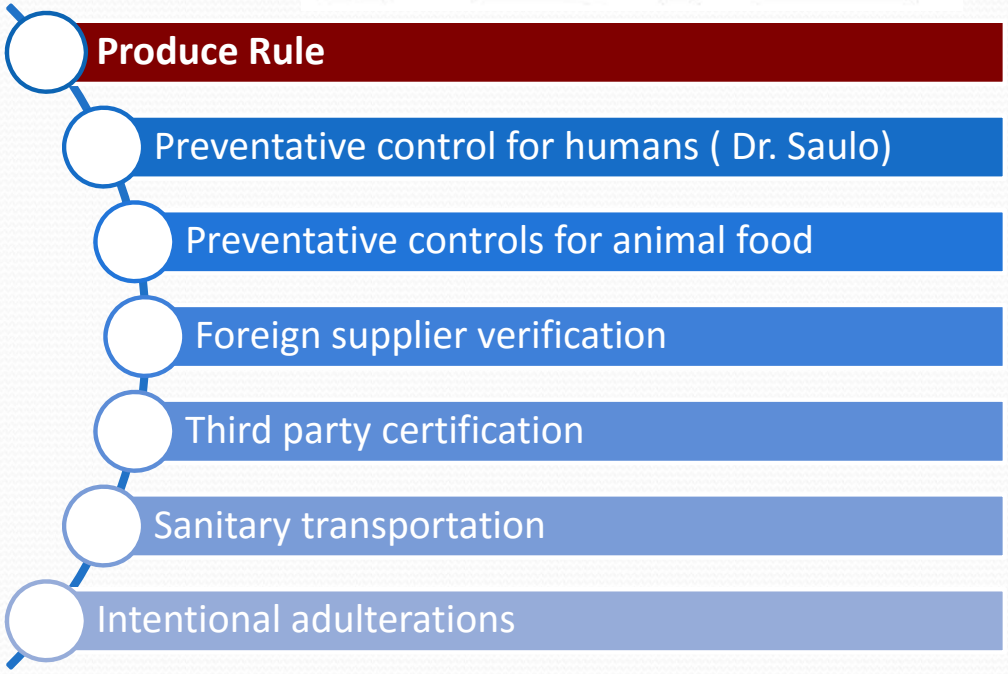
Now: Food placed under heat and time stamped

FSMA Produce Rule (FDA)

- Establishes “science-based” standards for domestic and foreign farms :
  - holding,
  - growing,
  - harvesting, and
  - packing

CTAHR's Farm Food Safety Focus

- To prevent and reduce illness, disability, and death due to contaminated foods
- Disclaimer:
  - We do not have all the answers or fully understand how FSMA will be implemented in Hawaii



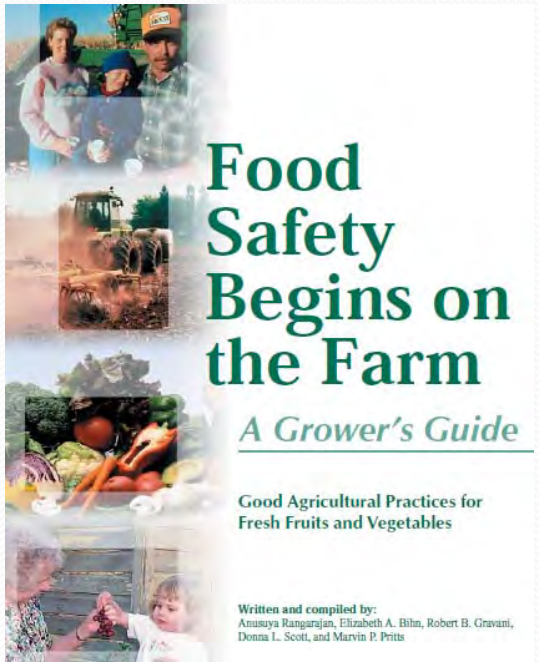
Processing/ Manufacturing FSMA's Preventative Control

Foundation for FSMA Hawai`i: Good Agricultural Practices (GAP)

Established in 1998 by U.S. Food and Drug Administration

- Preventive, science- and experience-based risk-reduction guidelines
- Basic level of food safety for Hawaii farms (1999)
- USDA AMS Audit Program verifies adherence with US. FDA's GAP/GHP guidelines

Source: http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM169112.pdf



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Basic Good Ag Practices

- Water quality & application
- Manure & biosolids
- Worker health & hygiene
- Sanitary facilities
- Field Sanitation
- Packing facility sanitation
- Transportation
- Traceback

http://www.fda.gov/downloads/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/UCM169112.pdf

Guidelines

Mandatory

Good Agricultural Practices (GAP)
USDA / FDA (1998)
Educational / Voluntary

Food Safety Modernization Act
FDA (2015)

Water quality & application → Agriculture water

Worker health & hygiene → Health and hygiene

Manure & bio solids → Biological soil amendments of animal origins

Sanitary facilities → Domestic and wild animals

Field Sanitation
Packing facility sanitation
Transportation → Growing, harvesting, packing and holding activities (includes transportation)

Traceback → Written documentation & record keeping

May be voluntary + added requirements

Mandatory

3rd Party Independent Audits

Primus, NSF, USDA Agricultural Marketing Service, HDOA, etc.
(May be voluntary, but often required by buyers, farmers markets, and distributors)

Food Safety Modernization Act

FDA (2015)

Good Agricultural Practices (GAP)

USDA / FDA (1998)
Educational

3rd Party Independent Audits
(May be voluntary, but often required by buyers, farmers markets, insurance carriers, and distributors)

Examples:

Primus Labs

NSF International

USDA Agricultural Marketing Service, etc.

(2015: HDOA conducts USDA & Primus Lab audits)

3rd Party Group GAP Independent Audit

Group GAP: USDA (2015)

GAP Certified

3rd Party Independent Audit

HDOA does USDA audit in Hawaii

BASIC

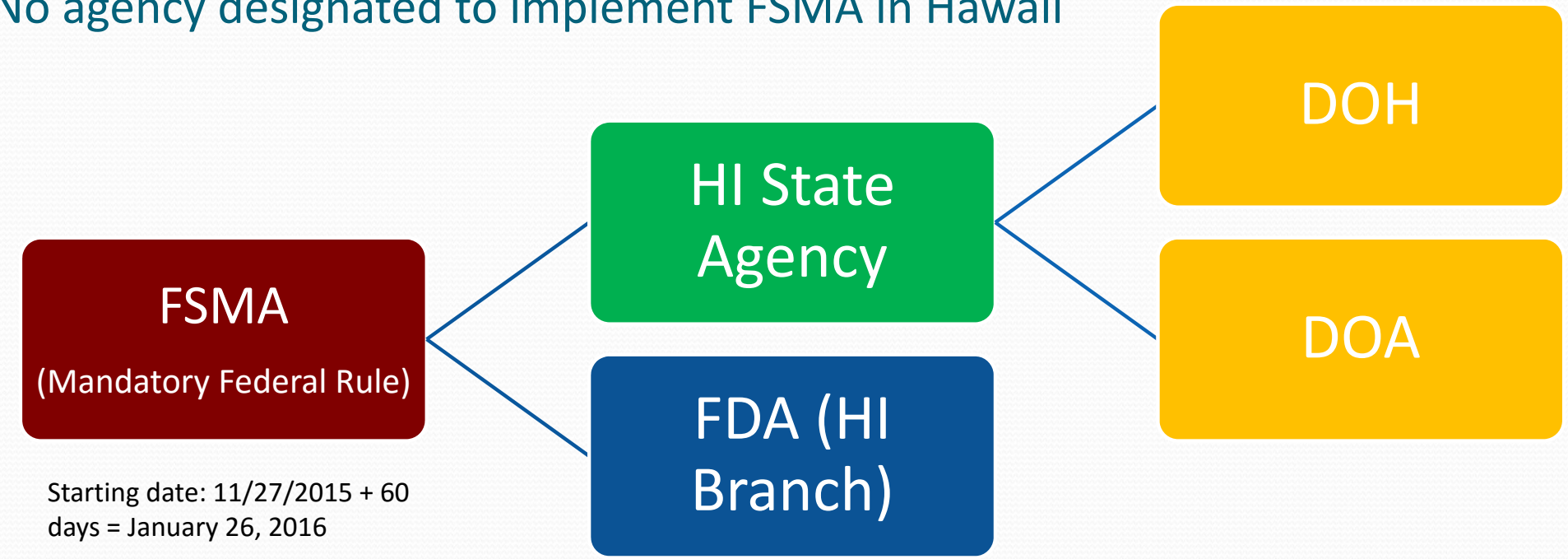
Good Agricultural Practices (GAP)

USDA / FDA (1998)

Educational Guidelines

FSMA Implementation (February 2016)

No agency designated to implement FSMA in Hawaii



Starting date: 11/27/2015 + 60 days = January 26, 2016

Per communication with P. Oshiro (DOH) on January 22, 2016

BIG QUESTION:
Does your farm have to comply with FSMA?

Definition of Farm[1]

- Operation under 1 management
- Not necessarily in 1 contiguous physical location (primary and secondary)
- Activities may include, but not limited to:
  - Pack and hold raw commodities
  - Manufacture and process food
    - Consumed on farm or another farm under same management

[1] FSMA Final Produce Rule. Federal Register. V. 80 no. 228 § 112.3

Average Annual Produce Sales

- Produce sales:
  - Monetary value of covered produce
- Average annual produce sales:
  - Rolling value based on produce sales over the previous 3 years

Despite Being Exempt from FSMA

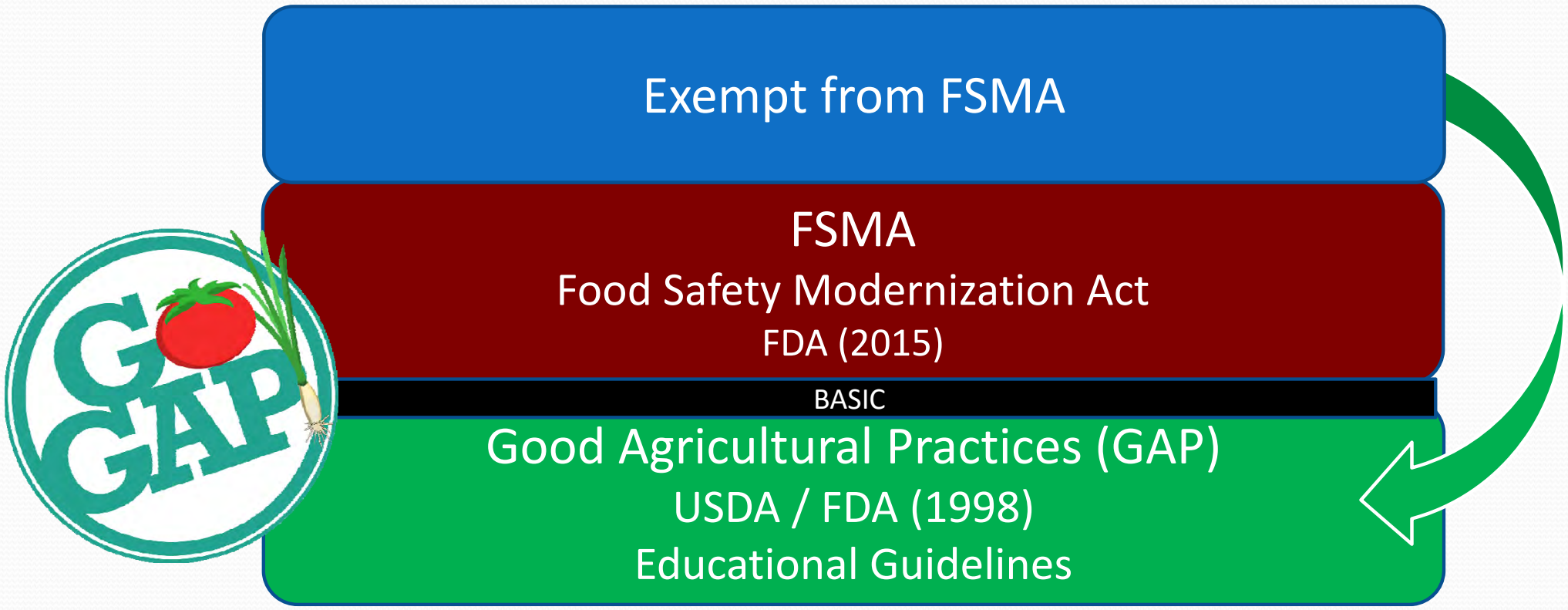
Exempt from FSMA

FSMA

Food Safety Modernization Act

FDA (2015)

.....Follow Good Agricultural Practices



Challenge

FSMA and GAP guidelines differ

"Covered" Produce[1]

- Produce that is subject to the requirements of this Rule
- Harvested or harvestable part of the crop
- Including mixes of intact fruits and vegetables (such as fruit baskets)

1 FSMA Final Produce Rule. Federal Register. V. 80 no. 228 § 112.3

Definition of Produce

- Unless on the Rarely Eaten Raw list it is:
  - Any fruit or vegetable and includes mushrooms, sprouts (irrespective of seed source), tree nuts, and herbs.
  - Produce does not include food grains
    - Examples of food grains include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, and oilseeds.

1 FSMA Final Produce Rule. Federal Register. V. 80 no. 228 § 112.3, 10/31/15

Not Covered: Produce Rarely Eaten Raw[1]

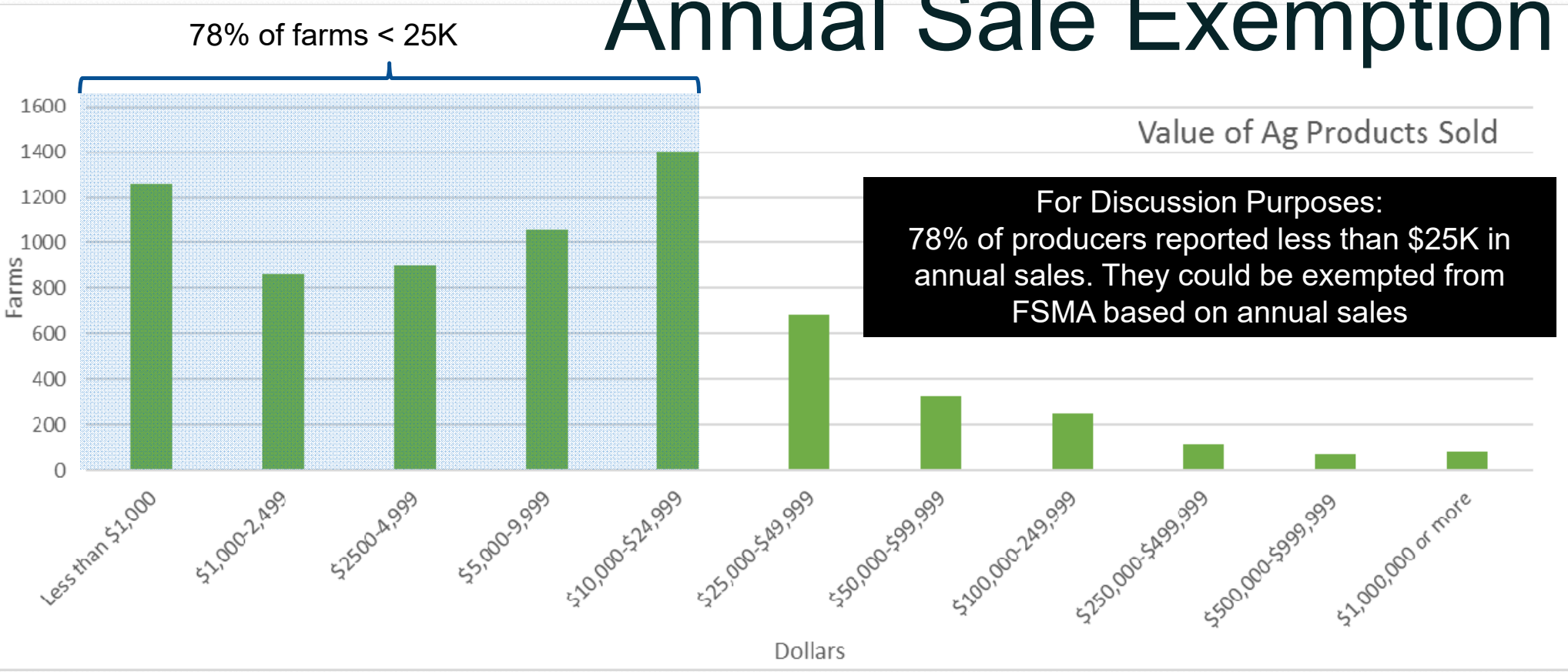
- Asparagus; beans, black; beans, great Northern; beans, kidney; beans, lima; beans, navy; beans, pinto; beets, garden (roots and tops); beets, sugar; cashews; cherries, sour; chickpeas; cocoa beans; coffee beans; collards; corn, sweet; cranberries; dates; dill (seeds and weed); eggplants; figs; ginger; hazelnuts; horseradish; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; squash, winter; sweet potatoes; and water chestnuts.
- All other produce not on exempt list are covered under FSMA

1 FSMA Final Produce Rule. Federal Register. V. 80 no. 228 § 112.2, 10/31/15

Multiple Types of Exemptions

Crop Type	• Produce rarely eaten raw are not covered under FSMA Produce Rule
Personal /On Farm Use	• Personal or on farm consumption
Annual Sales	• Produce sales of $25,000 or less • No restriction on distribution
Distribution/Distance	• Less than 500K in annual sales • Direct to end user within 275 miles
Commercial Processing	• Treated with a validated process • Written assurances from customer

Annual Sale Exemption



For Discussion Purposes:
78% of producers reported less than $25K in annual sales. They could be exempted from FSMA based on annual sales

Source: 2012 Census of Agriculture, State Data

Statutory:

Qualified End User Amendment

- Farm food sales averaging less than $500,000 (3 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 (direct sales) **or**
    - not more than 275 miles away.

Example: Lihue to Kona
274 miles

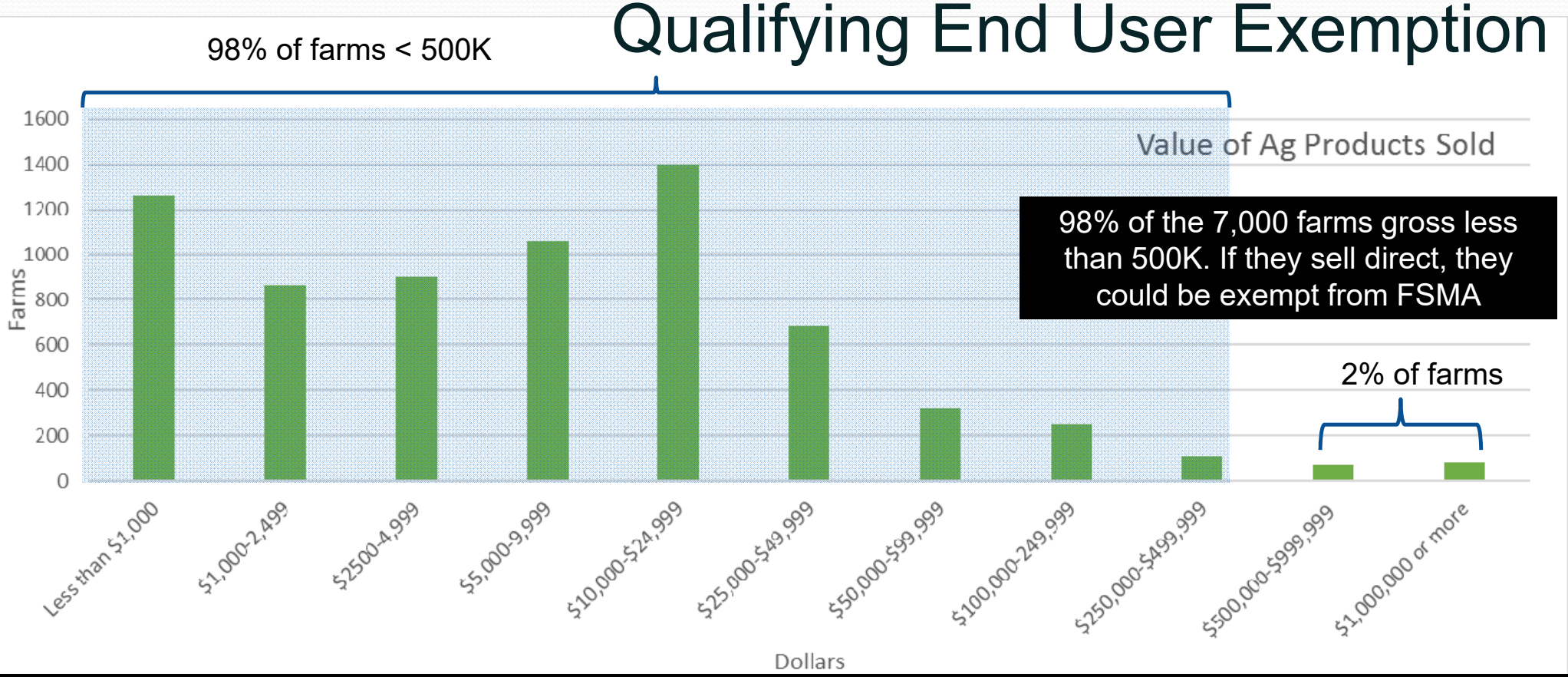
EXEMPTION: Direct Sales

Tester's Amendment

Qualified End User Amendment

- Sales to qualified end users must exceed sales (51%) to other businesses
- Disclosure of farm information and documentation is still necessary

Qualifying End User Exemption



For Discussion Purposes:
Data includes animals and ornamental crops. Does not take into account those who sell to wholesalers or export

Exempt from FSMA, but buyers or insurance carriers may require certification

- 1) Grower maybe <u>exempt</u> from FSMA, but market and/or insurance providers may require USDA or other 3rd party food safety certification
  2) USDA GAP certification and 3rd party agencies follow different rules from FSMA

Withdrawal of Exemptions

- Active investigation of an outbreak of food borne illness linked to farm
- Public health concerns

Despite Exemptions…

- Subject to the requirements of record keeping
  - Sales receipts
  - Verification that your farm meets the exemptions
  - Labels with farm information

No exemption, you MUST comply with FSMA

Crop Type	• Produce rarely eaten raw are not covered under FSMA Produce Rule
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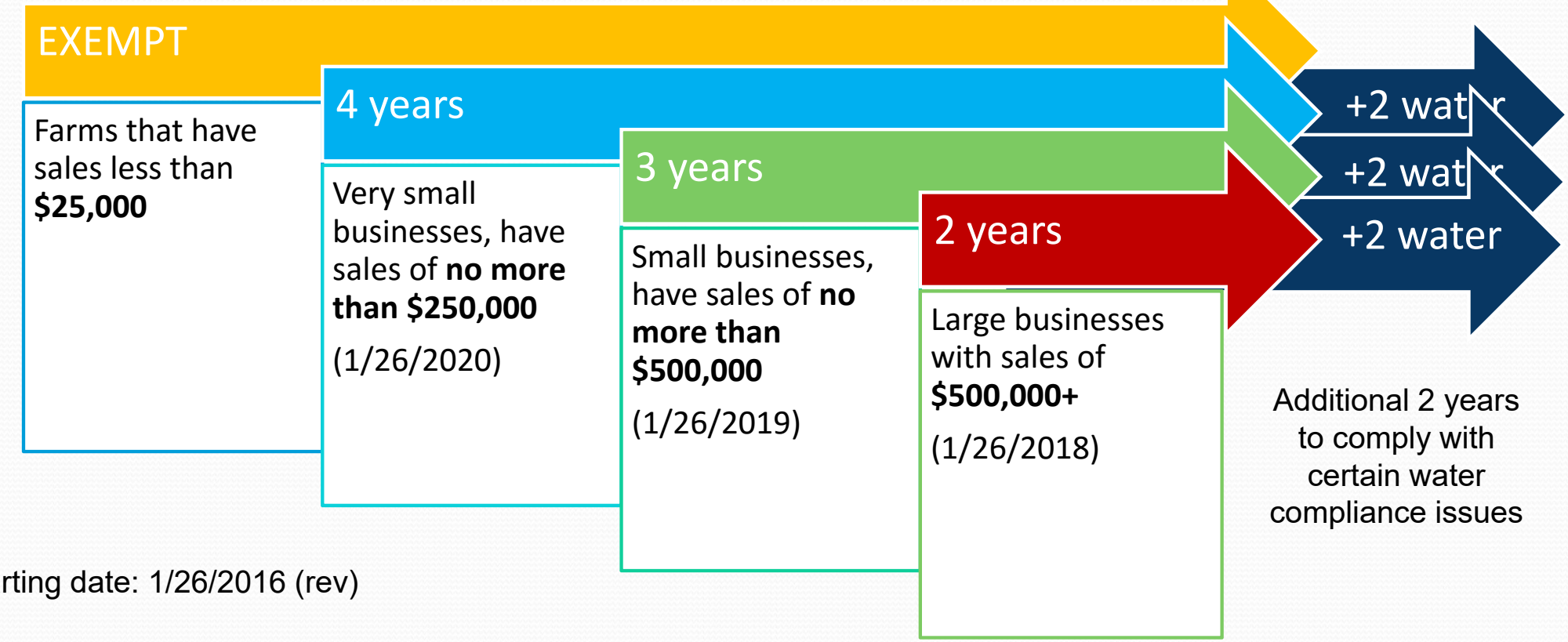
Farm Size Considerations for Compliance

Average annual produce sales during the previous three year period



Starting date: 1/26/2016 (rev)

Key Areas of the FSMA Produce Rule

Routes of possible microbial contamination including:

1. Human health and hygiene
2. Equipment & transportation
3. Domesticated and wild animals
4. Biological soil amendments of animal origin
5. Agricultural water

Similar to GAP

Sprouts are covered under a different set of rules

Human Health & Hygiene

Responsibility to public health

- Good Hygiene Training Program
  - Hand washing
  - Toilet facilities,
  - No eating, smoking, jewelry, etc.
  - No sick employees
  - No open wounds, etc.
- Combination of training, education and experience is REQUIRED

EMPLOYEES

	before	after
Wash your hands:	work	breaks
	handling produce	using the toilet
	touching food contact surfaces	touching unsanitary surfaces

Do not eat, drink, smoke, or chew gum or tobacco in food production areas.

Do not wear jewelry in food production areas.

Report all injuries to your supervisor.

Report suspicious activities and safety concerns to your supervisor.

Wear clean clothing in packaging or processing areas.

Do not handle fresh produce, touch food contact surfaces or packaging, if you are sick, nauseous, or have diarrhea.

Food safety is our priority!

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Department of Agriculture
STATE OF HAWAII

Hawaii Farm Bureau

VISITORS

Follow all posted signs and notices.

Do not handle produce or touch any production equipment while visiting.

Do not eat, drink, smoke, or chew gum or tobacco in food production areas.

Do not wear jewelry in food production areas.

Report all injuries to a company representative.

Wear company supplied safety equipment as instructed.

Food safety is our priority!

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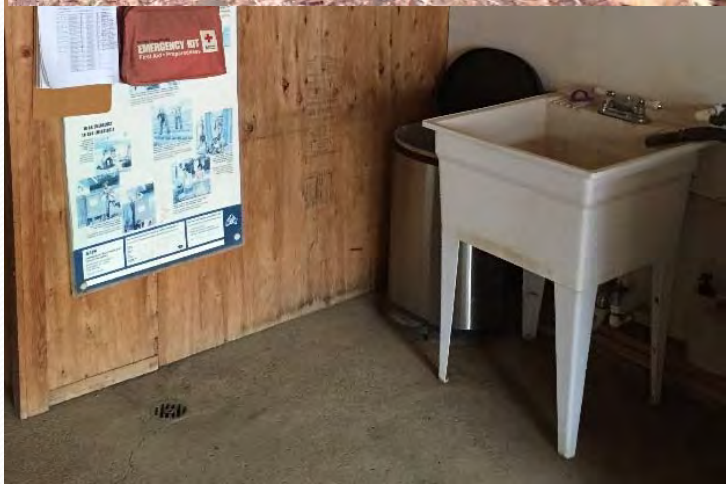
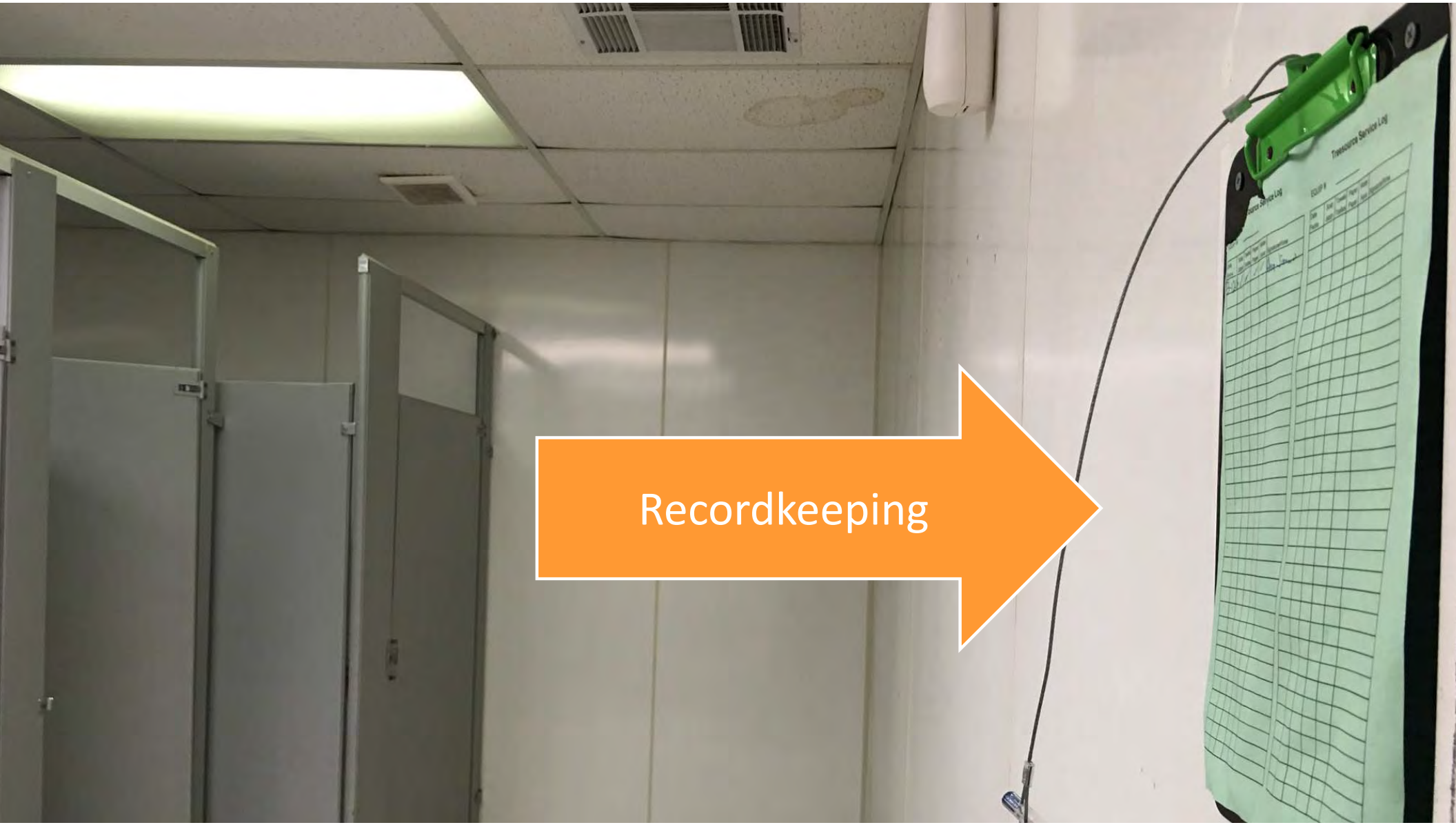
Department of Agriculture
STATE OF HAWAII

Hawaii Farm Bureau

Restroom Facilities

- Accessible toilet facilities
- Properly located
- Well supplied
  - Toilet paper, single use towels, basin, potable water, soap, etc.
- Cleaned regularly




Recordkeeping

In Field-Acceptable

Training and policy for personnel health and hygiene

Photo: J. Uyeda

Equipment

- Cleanable
  - Tools
  - Containers
  - Food surfaces
- Prevent attracting and harboring of pest


Ex. Clean buckets

Packing Facility Sanitation

Equipment and buildings (fully and partially enclosed) must be adequately cleaned and properly maintained

- Clean/sanitize processing equipment
- Maintain cooling system
- Clean product storage area
- Establish pest control system
  - Maintain surrounding area
  - Block access of pest into facility

Photo: J. Uyeda


10-4 LB. BAGS
4-10 LB. BAGS
12-3 LB. BAGS
18-2 LB. BAGS
70-15 100


forma-kool

Transportation

Equipment and vehicles that come into contact with produce must minimize hazards:

- Handler hygiene
- Vehicle cleanliness
  - Odor, soil, debris
- Proper temperature
- Loaded securely

Human Waste

- No human waste except for sewage sludge bio solids in accordance with regulatory EPA requirements
  - Synagro (HI)

Photo: www.planetnatural.com/compost-sewage, http://www.ocsd.com

Biological Soil Amendments (if of animal origin)

- **Are allowable if treated or processed to reduce microorganisms**
  - Undergoes a process that meets scientifically validated standards which have set limits on detectable amounts of bacteria to minimize microorganisms of interest
    - *Listeria monocytogenes*
    - *Salmonella spp.*
    - Fecal coliforms and
    - *E. coli* 0157:H7 (MPN)

[1] FSMA Final Produce Rule. Federal Register. V. 80 no. 228 § 112.54

Example: Composting to meet the Microbial Standards

- Two scientifically valid composting methods that meet these standards
  - Static composting (131°F, 3 days), curing
  - Turned composting (131°F, 15 days), 5 turnings and curing
- Establish and maintain records of process

[1] FSMA Final Produce Rule. Federal Register. V. 80 no. 228 § 1

Biological Soil Amendments (if of animal origin)

- **Allowable, if untreated, however,**
  - [Reserved] FDA has not finalized the Rule on untreated biological soil amendments. FDA is evaluating research on raw manure intervals.
    - They do not object to farmers following the USDA National Organic Program (NOP) Rule
    - They allow untreated soil amendments to be applied in a manner that does not contact covered produce during and after application
    - Establish and maintain records of process
    - Open comment period by May 3, 2016

[1] FSMA Final Produce Rule. Federal Register. V. 80 no. 228 § 112.54

FDA is [RESERVED] on the minimum interval of untreated Biological Amendments of Animal Origins (BAAO)'

(open public comment period offered & closed)

USDA National Organic Program (NOP)

- **§ 205.203 Soil fertility and crop nutrient management practice standard.**
- (c) The producer must manage plant and animal materials to maintain or improve soil organic matter content in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances. Animal and plant materials include:

USDA NOP § 205.203

- (1) Raw animal manure, which must be composted unless it is:
  - (i) Applied to land used for a crop not intended for human consumption;
  - (ii) Incorporated into the soil not less than 120 days prior to the harvest of a product whose edible portion has direct contact with the soil surface or soil particles; or
  - (iii) Incorporated into the soil not less than 90 days prior to the harvest of a product whose edible portion does not have direct contact with the soil surface or soil particles;

FSMA Allows for Scientifically Valid Controlled Processes

- Accept scientifically valid controlled physical, chemical, biological or a combination of processes
  - USDA NOP Rule: Use of Raw Manure & Compost
    - Manure in contact with harvestable crop:
      - 120 days between application and harvest
    - Manure not in contact with harvestable crop
      - 90 days between application and harvest


Example: Raw Manure
Harvestable portion
Manure

Raw Manure NOT in Contact with Harvestable Product

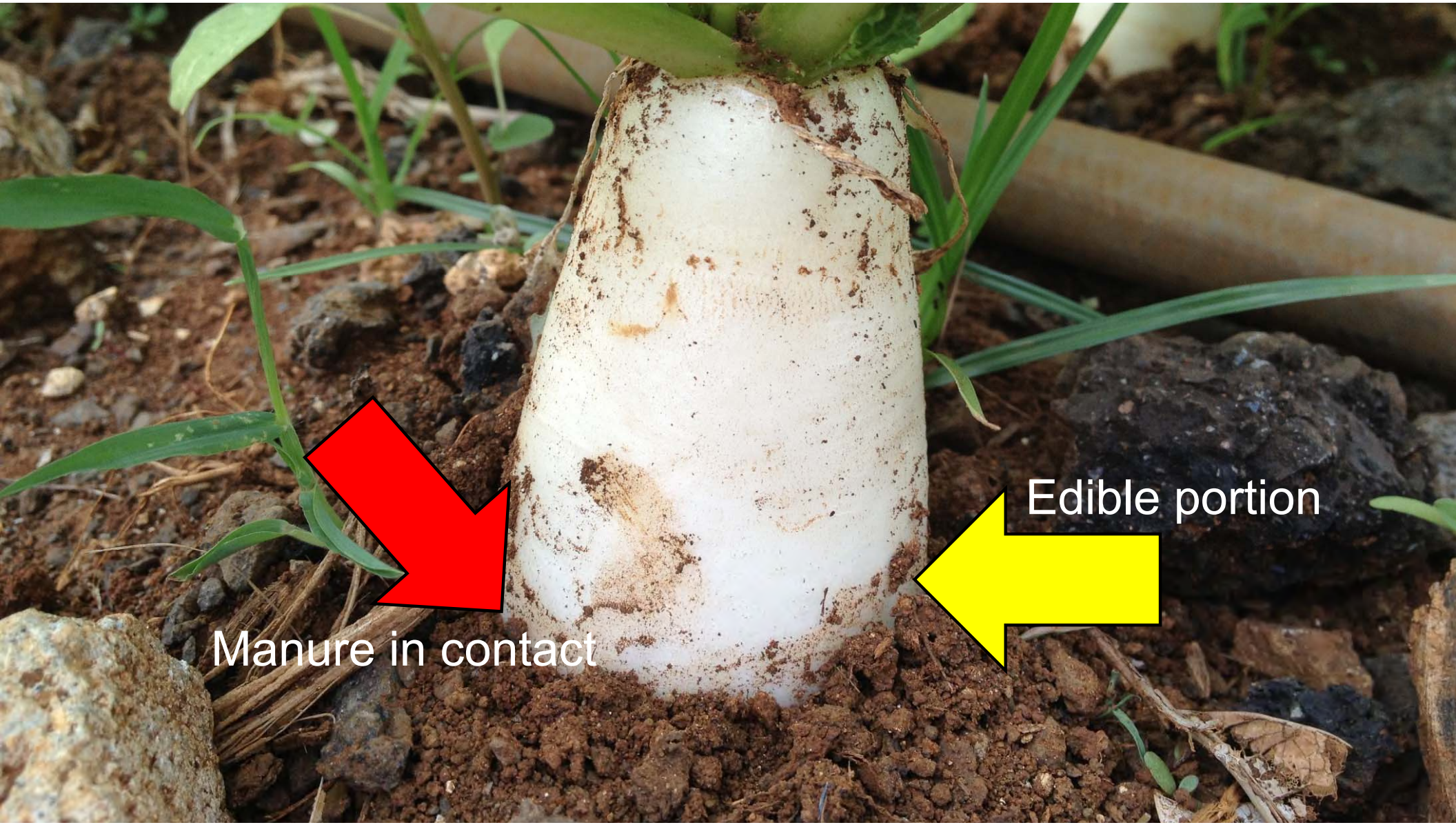
9 months till harvest

Day 65

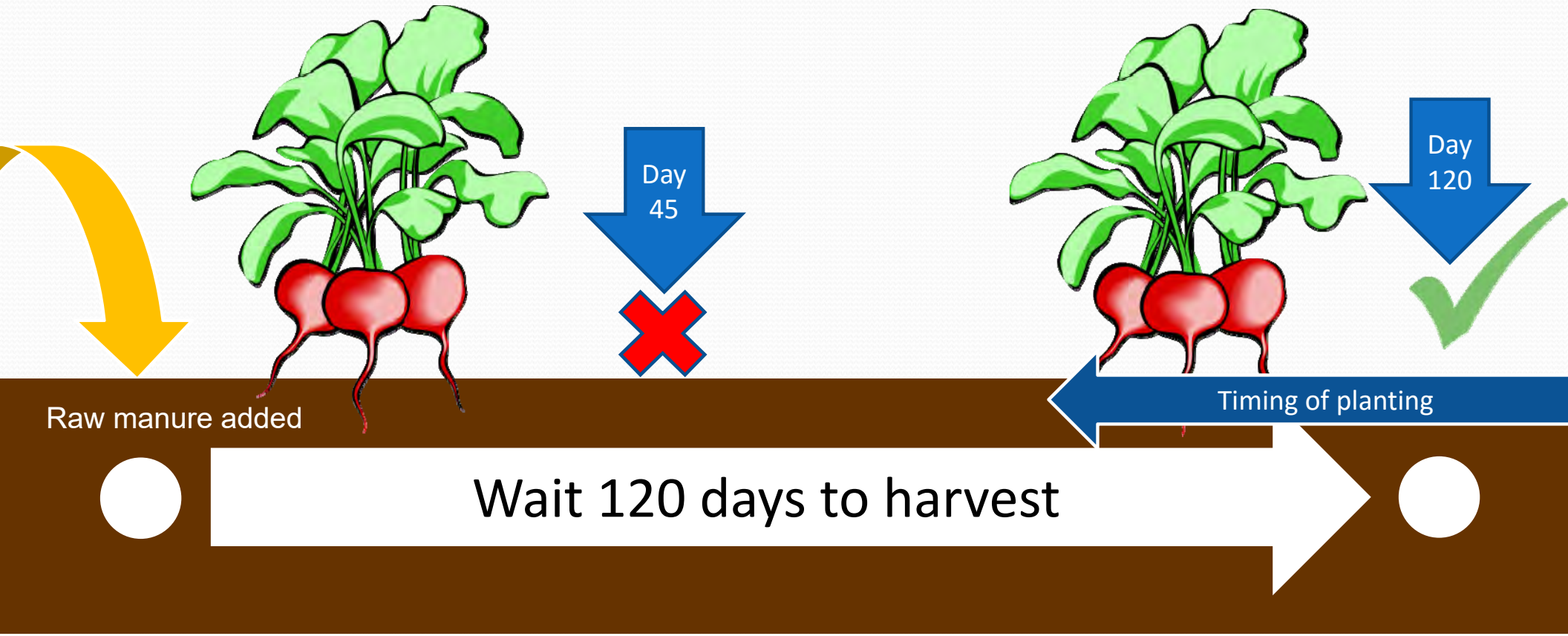
Day 90

Raw manure added

Wait 90 days to harvest


Edible portion
Manure in contact

Raw Manure in Contact with Harvestable Product

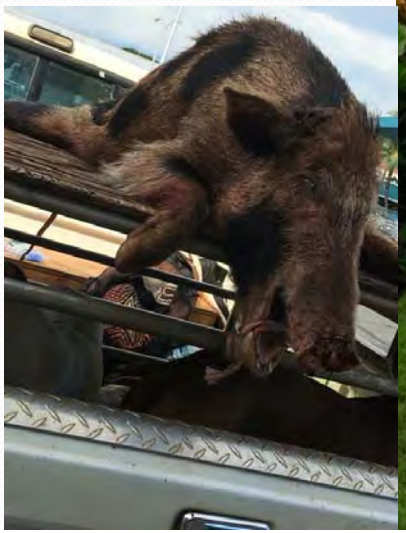


Agricultural Tea using Biological Soil Amendments

- Water extracts of biological materials are allowable if held for 1 hour prior to application and are soil applied
  - Treated tea
    - Compost materials to make the tea have been processed
    - Water must have no detectable *E. coli* in 100 ml of water
  - Un-treated Tea [Reserved]
    - Compost materials to make tea are not processed
    - Untreated water
    - Recombined with untreated amendments
    - Establish and maintain records of process

Domestic and Wild Animals

- FSMA does not require exclusion of grazing, working or intruding animals
- Must take proactive and reasonable steps to prevent produce, production area and food packing area from being contaminated by animals
  - Visible animal excretions




Implementation of reasonable precautions to minimize contamination
Source: J. Hollyer

Industry Request: Evaluation of Local Ag Systems

If there is reasonable probability that the covered produce was contaminated (visible animal excretions) then the grower MUST take measures to NOT harvest the product.

Two commodities of concern: Taro and Watercress

Taro

This is not a aquaculture operation. Wildlife animals (i.e. federally protected birds) often enter the farm system

Possible Exemptions for Taro

Crop Type

- Produce rarely eaten raw are not covered under FSMA Produce Rule

Personal /On Farm Use

- Personal or on farm consumption

Annual Sales

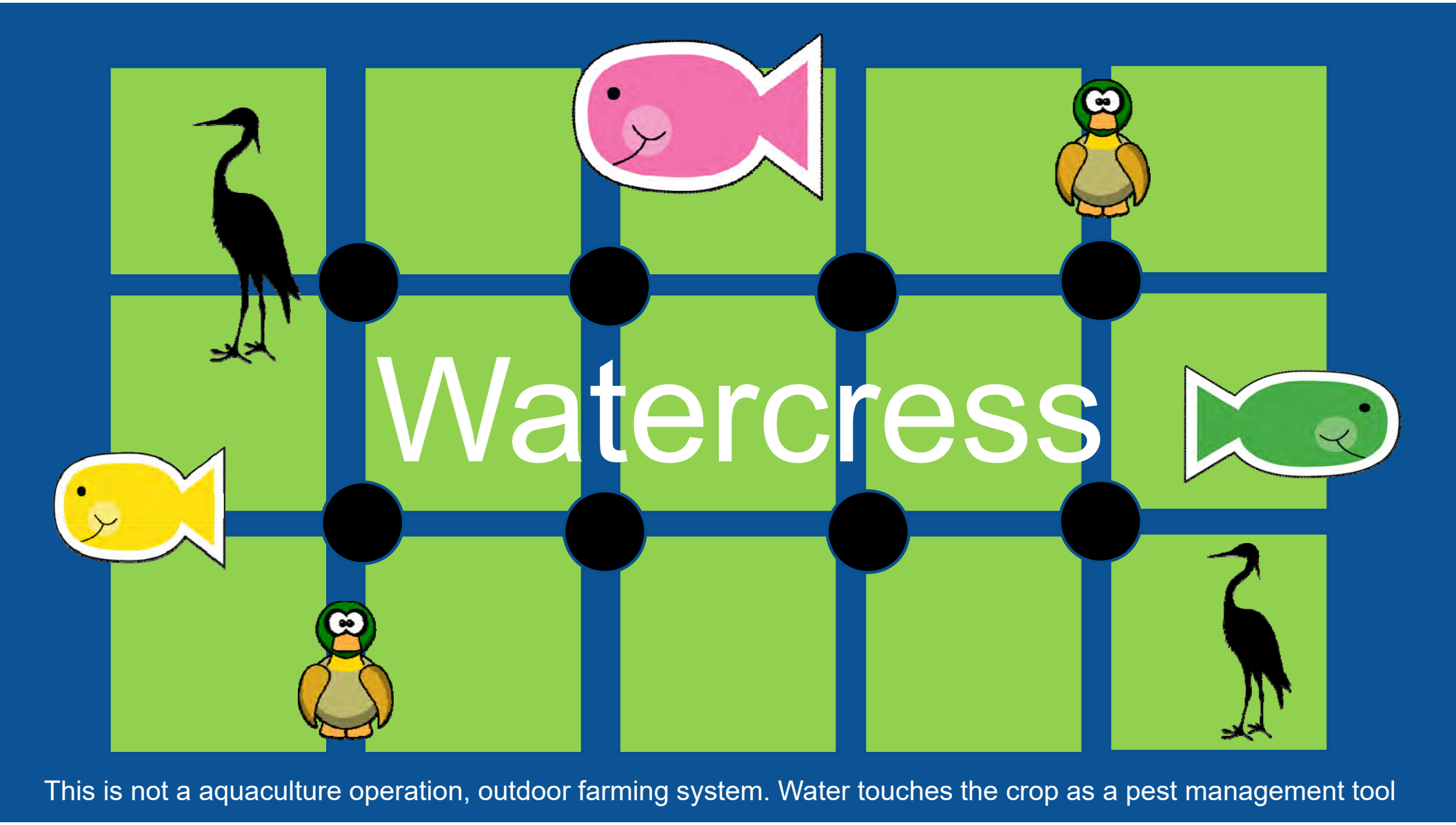
- Produce sales of $25,000 or less
- No restriction on distribution

Distribution/Distance

- Less than 500K in annual sales
- Direct to end user within 275 miles

Commercial Processing

- Treated with a validated process
- Written assurances from customer


Watercress
This is not a aquaculture operation, outdoor farming system. Water touches the crop as a pest management tool

Our Concerns for Watercress

- The application of overhead irrigation (with animals in and entering the water system) in flooded, watercress production systems will be problematic based on review of the FSMA rules
  - Overhead sprinklers are used to deter pest in watercress operations
  - Water that is used to overhead irrigate, has wildlife (fish, crayfish, birds, etc.) entering the system despite efforts to minimize intrusion
  - Reduce contact with untreated water, to reduce risk

Possible Exemptions for Watercress

Crop Type

- Produce rarely eaten raw are not covered under FSMA Produce Rule

Personal /On Farm Use

- Personal or on farm consumption

Annual Sales

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Distribution/Distance

- Less than 500K in annual sales
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Commercial Processing

- Treated with a validated process
- Written assurances from customer

Biggest Difference Between GAP & FSMA

- Irrigation Water
  - Definition
  - Sampling
  - Treatment options

FSMA accounted for water risk assessment

Irrigation Method

High Risk

Overhead

Furrow

Drip

Low Risk

Municipal

Well

Surface

Water Source

High Risk

GAP: Definition of Agricultural Water

- Agricultural water refers to **water used in the growing environment** for agronomic reasons.
  - Irrigation,
  - Cooling
  - Carrier for fertilizers and pesticides
  - Etc.

Source: Guidelines to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables
http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM169112.pdf

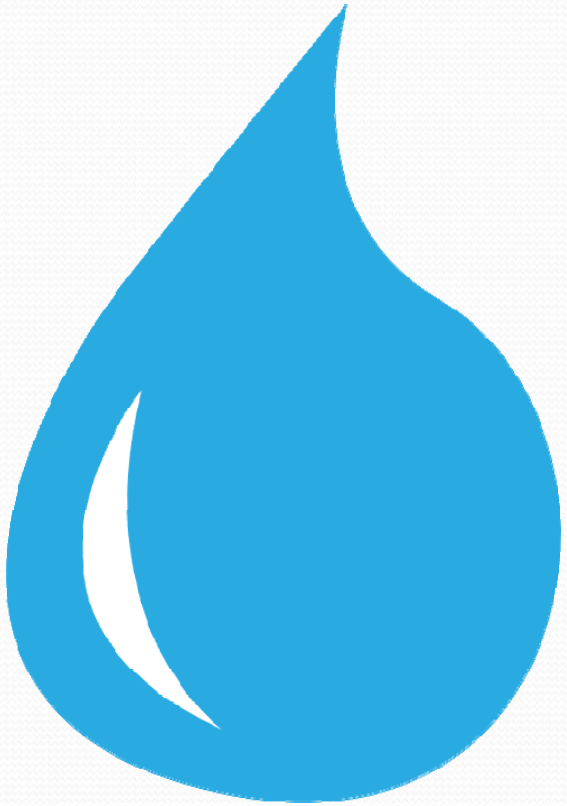
FSMA: Definition of Agricultural Water[1]

- Water used in covered activities where **<u>water is intended to, or is likely to, contact</u>** covered produce.
  - Irrigation
  - Crop sprays
  - Washing & cooling
  - Etc.

1 FSMA Final Produce Rule. Federal Register. V. 80 no. 228 § 112.3

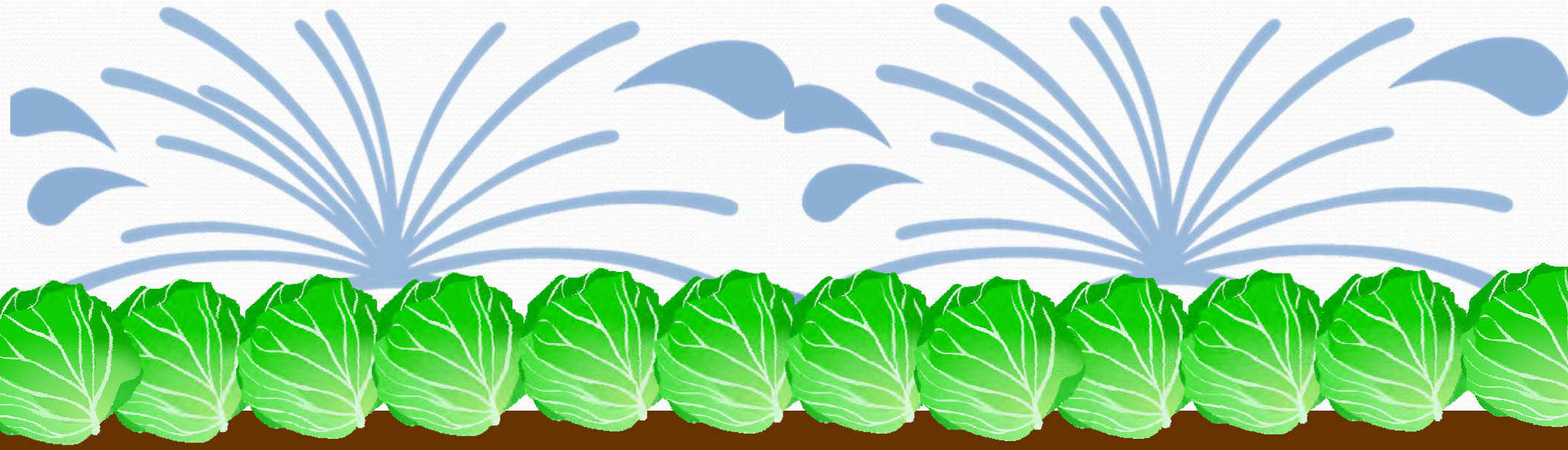
Clarification: No Water Contact with Crop

- Water that is not intended or likely to contact harvestable portion of crop; is not considered "agricultural water" under this Rule
- Question posed to HDOA (2/20/16)
- PSA: Agreed on 2/21/16



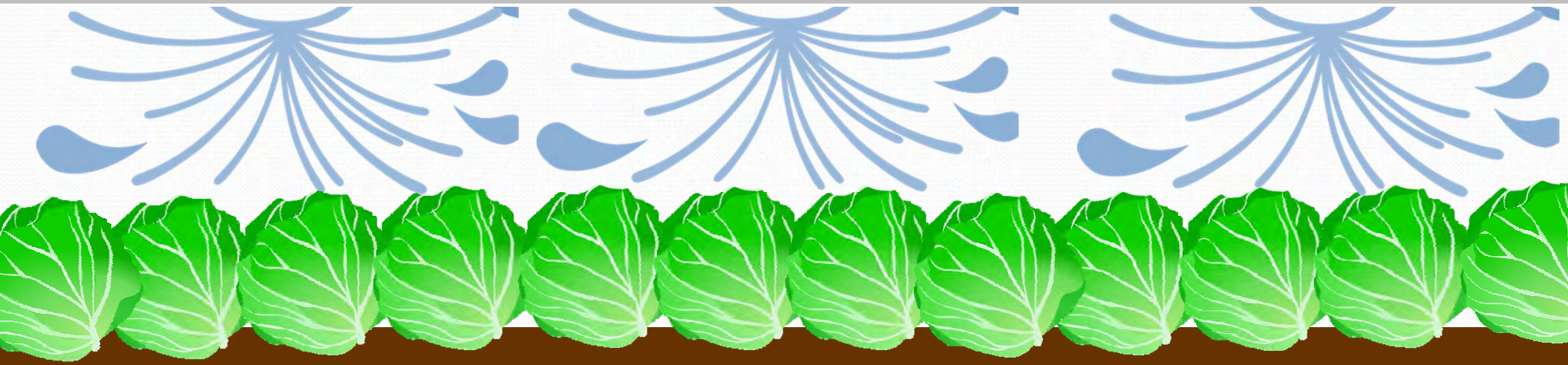
Water contact with crop determines if water is "agricultural water" under FSMA

This is an important definition because agricultural water under FSMA must follow water sampling requirements outlined in this Rule



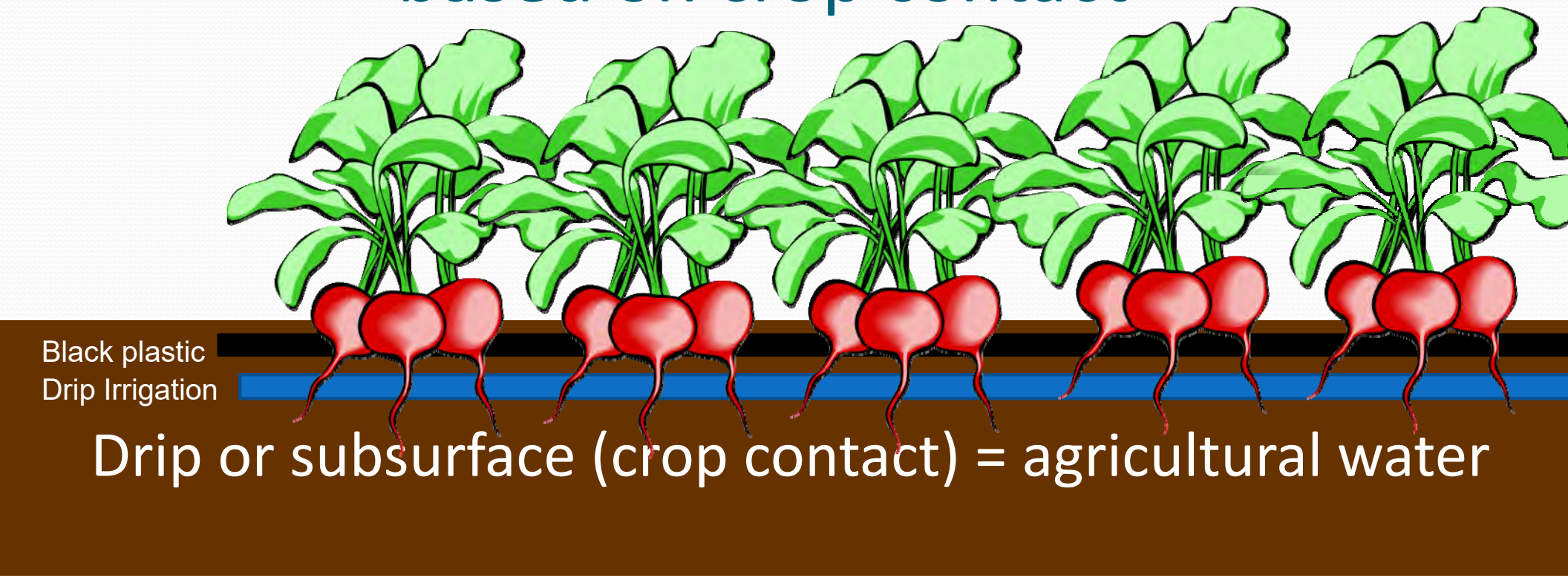
Overhead irrigation (crop contact) = agricultural water

Ex. Spray Boom



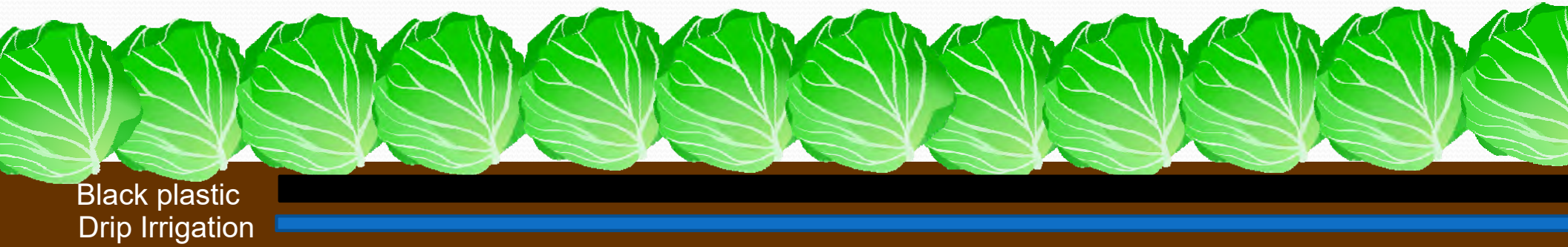
Spray solution (crop contact) = agricultural water

FSMA "agricultural water" definition is based on crop contact



Drip or subsurface (crop contact) = agricultural water

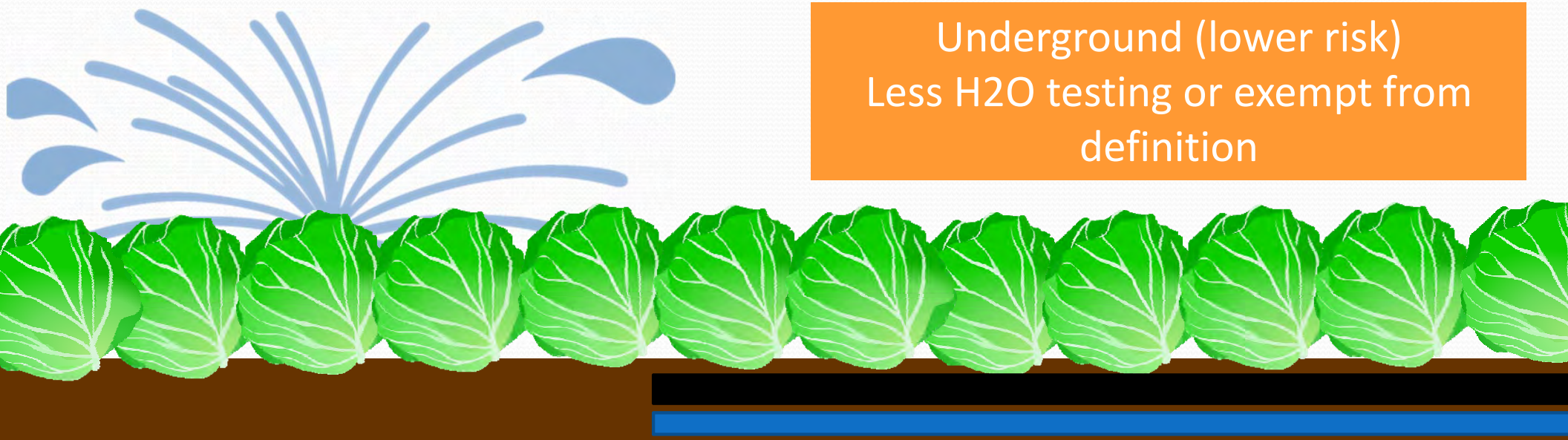
FSMA "agricultural water" definition is based on crop contact



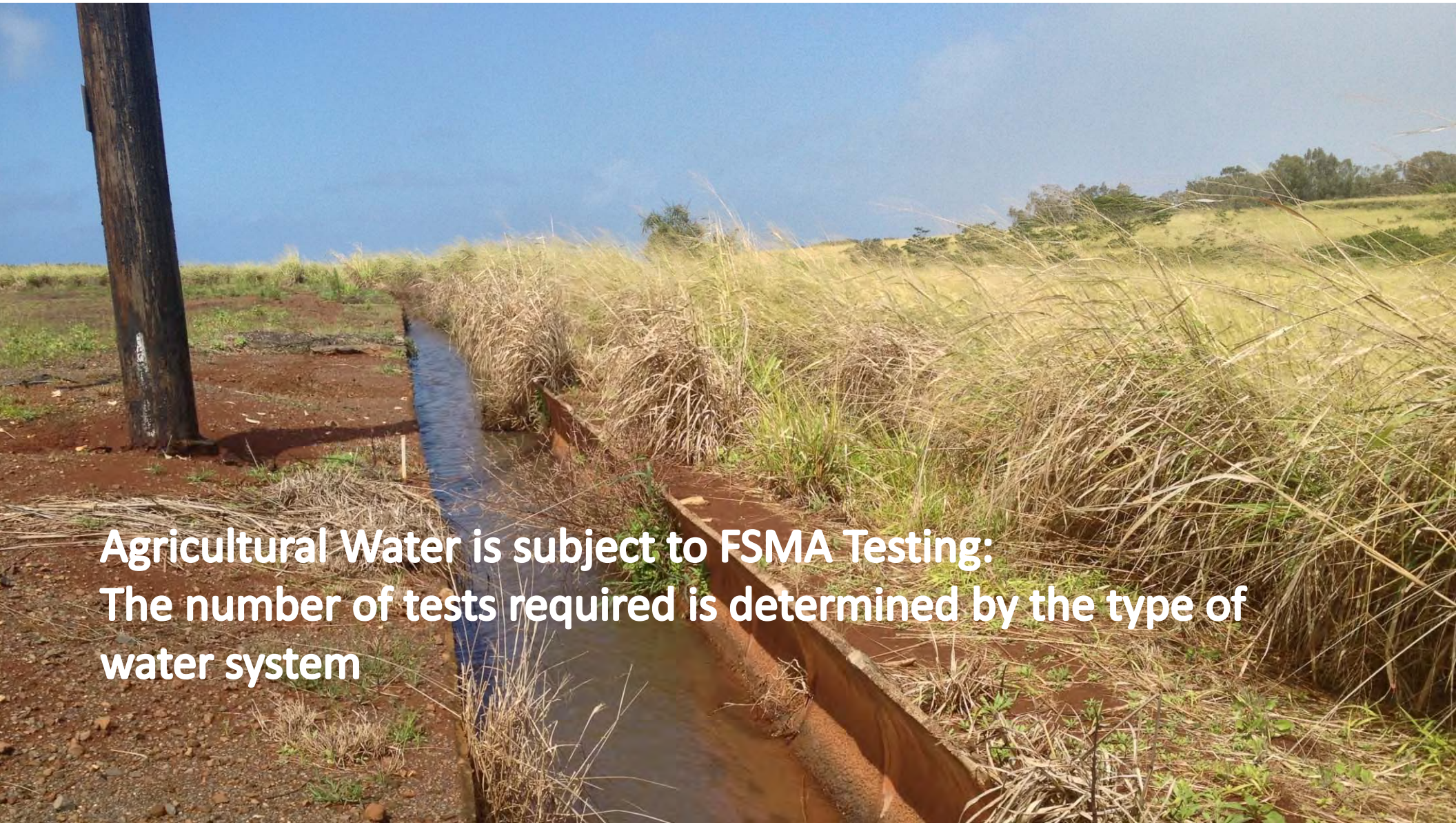
Drip or subsurface (no crop contact) ≠ agricultural water

Overhead (higher risk),
More H2O testing

Underground (lower risk)
Less H2O testing or exempt from definition



Possible movement from overhead to underground with FSMA (less crop contact)


Agricultural Water is subject to FSMA Testing:
The number of tests required is determined by the type of water system

Samples Correlate with Level of Risk

Number of Samples

Board of Water Supply
City and County of Honolulu
630 South Beretania Street
Honolulu, Hawaii 96843
www.boardofwatersupply.com

City Water
Protected & Monitored
Low Risk

Ground or Well Water
Closed
Moderate Risk

Surface Water
Exposed
Higher Risk

Differences in Agriculture Water Sampling

FSMA & GAP DIFFERENCE:
Baseline & Number of Samples / Year

Water Source	FSMA	GAP
Surface	Annual: 5 x / year	Minimum 1 x / year
	Baseline: 20 samples (2-4 yr)	
Ground	Annual: 1 x / year	Minimum 1 x / year
	Baseline: 4 samples (1 year)	
Public Water	Copy of test results or current certificate of compliance	Minimum 1 x / year

As close in time to harvest

FSMA Water Testing: Method 1603

- Method 1603 is the only method that FDA has formally approved for use (in the text of the Rule)
- FDA was not willing to state whether Colilert or Colilert-18, used with Quantitray/2000 MPN format, would be approved methods for generic E. coli in 40 CFR 136.3, alongside method 1603
- Method 1603 has a 6-hour hold time from collection to delivery to the lab (8 hours to analysis)
- There is one testing lab in Hawaii that can offer this test (Manoa)
- It is possible the Recycled Water Branch also does this membrane testing method. UH CTAHR is currently evaluating this method (2016).

Difference Between Method 1603 & Colilert

- Colilert water test is a reagent based test that detects total coliform and *E. coli*
  - Used for drinking water
  - Presence vs. Absence type of test
  - Results read at 24 hours
- Method 1603
  - Recreational & waste water quality test
  - Membrane filtration method
  - Direct count of *E. Coli* in water based on the development of colonies (CFU/100 ml)
  - Within 6 hours of hold time

UH EXTENSION
MĀNOA COLLEGE OF TROPICAL AGRICULTURE AND HUMAN RESOURCES

Water Testing Exceptions

- There is no water testing requirement if you receive water from public water supply system that meets the requirements in the final rule

2015 ANNUAL

WATER QUALITY REPORT

Supplemental Information

A separate report, containing the results of tests performed on samples of your water, accompanies this Supplemental Information.

Board of Water Supply
City and County of Honolulu
630 South Beretania Street
Honolulu, Hawaii 96843
www.boardofwatersupply.com

The water serving Your Location **has been tested and meets all Federal and State standards.** 41810

The water quality monitoring results are presented below.

The water sources serving this address are:

Source Name	Origin of Water	Treatment	Region
a) Mililani Wells I & II	Groundwater	Chlorination, GAC	5
b) Mililani Wells IV	Groundwater	Chlorination	5

Source Water Monitoring

The substances detected in these sources are shown below. If a substance is not shown then it was not detected.

Regulated Contaminants (2)

Contaminant	Sample Year	Unit	Highest Average	Range Minimum	Range Maximum	MCL (Allowed)	MCLG (Goal)	Found in Sources
1,2,3-Trichloropropane	2014	ppb	0.063	ND	0.180	0.600	0.000	a
Chromium	2014	ppb	1.400	1.400	1.400	100.000	100.000	b
Fluoride	2014	ppm	0.085	0.085	0.085	4.000	4.000	a
Nitrate	2014	ppm	1.200	0.390	1.200	10.000	10.000	All Sources

Definitions:

MCL	**Maximum Contaminant Level. The highest level of a contaminant that is allowed in drinking water. MCLs are set as close to the MCLGs as feasible using the best available treatment technology.**
MCLG	**Maximum Contaminant Level Goal. The level of a contaminant in drinking water below which there is no known or expected risk to health. MCLGs allow for a margin of safety.**
GAC	**Granular Activated Carbon Filtration**
Health Advisory	**An estimate of acceptable drinking water levels for a chemical substance based on health effects information. Health advisory is not a legally enforceable standard.**
CFU/100ml	**Colony forming units per 100 milliliter**
mrem/yr	**Millirems Per Year (A Measure of Radiation)**
pCi/L	**Picocuries Per Liter (A Measure of Radioactivity)**
ppb	**Parts Per Billion or Micrograms Per Liter"**
ppm	**Parts Per Million or Milligrams Per Liter**
ppt	**Parts Per Trillion or Nanograms Per Liter**
NQ	**Not Quantifiable (<means \"less than\")**
NYA	**Not Yet Available**
N/A	**Not Applicable**
ND	**Not Detected**
*	**EPA considers 50 pCi/L to be the level of concern for beta particles**
(1)	**Analysis by the State of Hawaii Department of Health.**
(2)	**Analysis by the Honolulu Board Of Water Supply. Questions, call 808-748-5370.**
LRAA	**Locational running annual average is the average of sample analytical results for samples taken at a particular monitoring location during the previous four calendar quarters.**
MRDL	**Maximum residual disinfectant level: The highest level of a disinfectant allowed in drinking water.**
MRDLG	**Maximum residual disinfectant level goal: The level of a drinking water disinfectant below which there is no known or expected risk to health.**

Unregulated Contaminants (Do not have designated maximum limits but require monitoring)

Contaminant	Tested By	Sample Year	Unit	Highest Average	Range Minimum	Range Maximum	Health Advisory	Found in Sources
Chlorate	(2)	2014	ppb	46.000	46.000	46.000	210.000	a
Chloride	(2)	2014	ppm	16.000	14.000	16.000	250 **	All Sources
Chromium, Hexavalent	(2)	2014	ppb	1.500	0.032	1.500	13.000	All Sources
Sodium	(2)	2014	ppm	14.000	12.000	14.000	60.000	All Sources
Strontium	(2)	2014	ppb	61.000	40.000	61.000	4000.000	All Sources
Sulfate	(2)	2014	ppm	3.900	2.500	3.900	250 **	All Sources
Vanadium	(2)	2014	ppb	16.000	1.300	16.000	21.000	All Sources

** Secondary Maximum Contaminant Levels (SMCLs) are standards established as guidelines to assist public water systems in managing the aesthetic quality (taste, odor and color) of drinking water. EPA does not enforce SMCLs.

Distribution System Monitoring

Disinfection By-Products (2)

System Name	Contaminant	Unit	Range Min	Range Max	Highest LRAA	MCL (Allowed)	MCLG (Goal)
Mililani	Total Trihalomethanes	ppb	0.00	0.00	0.00	80	None

Microbial Contaminants (2)

System Name	Contaminant	Unit	Found	MCL (Allowed)	MCLG (Goal)	Violation	Source of Contaminant
Mililani	Total Coliform	% of positive samples	1.89 ***	5%	0	No	Naturally present in the environment

***Highest monthly percentage of positive samples

Residual Chlorine

System Name	Sample Year	Unit	Lowest Monthly Average	Highest Monthly Average	Running Annual Average	MRDL	MRDLG
Mililani	2014	ppm	0.20	0.28	0.20	4	4

Lead/Copper Testing (2)

Contaminant	Sample Year	Unit	90th Percentile Reading	Action Level	# Samples Above Action Level
Copper	2012	ppm	0.240	1.300	0
Lead	2012	ppb	0.630	15.000	0

No violations found for calendar year 2014

Date Report Printed: 6/8/2015

Clean Water Related Activities

- Processes where no *Escherichia coli* (*E. coli)* should be detected.
  - Hand washing (during and after harvest)
  - Water on food contact surfaces
  - Water that directly contacts produce (including ice) during or after harvest
  - Water used for sprouts (*Salmonella*, *Listeria*, *E. coli*)

Industry Request: Evaluation of Aquaponics

No Exemptions for Aquaculture

- FSMA does not prohibit aquaponics or hydroponically grown crops
- There are no water exemptions for aquaponic grown crops despite the argument of fish not carrying *E. coli*.
- However, it is possible to argue that the water be excluded as ag water under FSMA if the grower can keep the aquaponic water from touching the targeted crop

FSMA/GAP Different Guidelines

Separate Aquaponics Criteria for USDA GAP Certification

USDA GAP Certification of Aquaponics

- 3rd party certifications can have additional USDA AMS Interim Guidelines regarding water requirements that are different from FSMA
- USDA requires a separation between the fish and crop
- USDA requires a filter or sanitation process

USDA

United States Department of Agriculture

Agricultural Marketing Service, Fruit & Vegetable Program, Specialty Crops Inspection Division

Interim Guidance for Agreeing to Perform Aquaponics Facility Audits

1.0 Responsible Parties:

Auditors, Supervisors, Federal Program Managers, and Audit Programs Section Staff

2.0 General Information:

We are again receiving some requests to perform GAP GHP audits on aquaponics operations. As a reminder, here are some of our guidelines to share about auditing aquaponics operations.

- These types of operations can be approved for being audited on a case by case basis.
- The farm or operation should submit a summary of the fish growing and plant growing operation. A flow chart showing the places and processes that the water passes though is a very helpful summary.
- We will not certify aquaponics operations where the fish are living under the plants in the same tanks.
- We have certified aquaponics operations where the fish are kept in tanks separate from the plant, the water is filtered and sanitized before it is used in the plant beds, and the fish tanks are physically separated from the plants so there can be no cross contamination by spilled or leaking water.
- The water sanitation included ultraviolet light to clean the water. There may be other good sanitation methods such as ozonation or chlorine. The auditor will need to look at the water test documents to see if they are working.
- Some good SOP's we have found are: Persons handling the fish or fish equipment cannot handle the plants or plant water and equipment without sanitizing their hands. Aprons worn in the fish area and plant area are kept separate.
- There are SOPS that prohibited edible portions of plants that come in contact with the water from being packed.
- Tests on the water in the plant growing area were routinely done (monthly or more often).

Meeting the above criteria does not guarantee USDA certification. Each operation is different and will have different risk factors.

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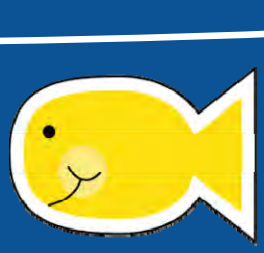
PRODUCE

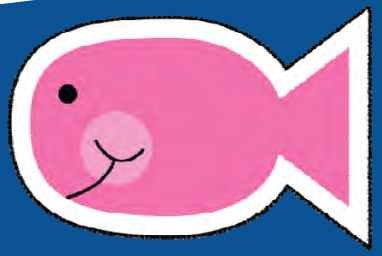
Remediation

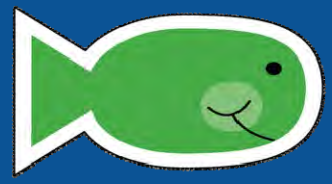
PRODUCE

Ex: USDA AMS Certification Requirements

Aquaponically grown produce







Water does not touch the harvestable portion of the crop, this may fall under “agricultural water” (per the FSMA rule comments section)

Industry Request:
Where does Recycled Water Fit into FSMA?

Recycled Water

Treated wastewater that by design is intended or used for a beneficial purpose.

Source: Hawaii State Department of Health, Guidelines for the Treatment of Recycled Water
http://health.hawaii.gov/wastewater/files/2016/03/06_V2_RW-Projects.pdf
Photo credit: http://www.hawaiireporter.com/trial-run-city-will-haul-excess-sewage-sludge-to-ewa-plant/123

Recycled Water on Edible Crops

- Current unknowns with waste water solution:
  - Chemicals
  - Pathogens
  - Hormones
  - Etc.

Photo Source:
http://www.crescentmfg.net/Products.htm
http://medimoon.com/2014/05/electronic-monitoring-documents-lack-of-medication-adherence-in-patients-with-glaucoma

Three Grades of Recycled Water

- R1 (Highest grade of recycled water)
  - Waste water has undergone 1) oxidation, 2) filtration and 3) disinfection
- R2
  - Waste water has undergone 1) oxidation and 2) disinfection
- R3
  - Waste water has undergone 1) oxidation only

Source: Hawaii Administrative Rules [HAR], Ch 62, section 11

Which Comes First?

FSMA or DOH Hawaii Administrative Rules

Review: Interpretation
FSMA: No Water Contact

- Water that is <u>not intended or likely to contact harvestable portion of crop;</u> is not considered “agricultural water” under FSMA

Suitable Irrigation Use According to DOH Guidelines

- R1-highest grade
  - All landscape and agricultural irrigation via spray, surface drip or subsurface drip irrigation.
- R2
  - Drip irrigation is allowed for above ground food crops (such as fruit trees) where the edible portion of the crop has minimal contact with the recycled water
- R3
  - Not allowed for edible crops

FSMA: Agriculture Water Thresholds

- FSMA: EPA Recreational Water Standards
  - Geometric mean (GM) is **126 CFU or less** of generic *E. coli*/ 100 ml of water AND
  - Statistical Threshold Value (STV) is **410 CFU or less** generic *E.coli* in 100 ml/ water

E. coli	Geometric Mean	Single Water Sample	Statistical Threshold Value (STV)	
FSMA	126 CFU or less/ 100 ml		410 CFU or less / 100 ml	
R1	2.2 CFU / 100 ml / 7 days	23 CFU / 100 ml		No sample shall exceed 200 / 100 ml
R2	23 CFU / 100 ml / 7 days			No sample shall exceed 200 / 100 ml

Under FSMA, it is possible that R2 could also be used on the harvestable portion of the crop, despite the DOH guidelines, if *E. coli* water levels are under the FSMA threshold. Recycled water branch conducts *E. coli* membrane water testing.

R 1 would qualify for FSMA "ag water" and fit within DOH guidelines

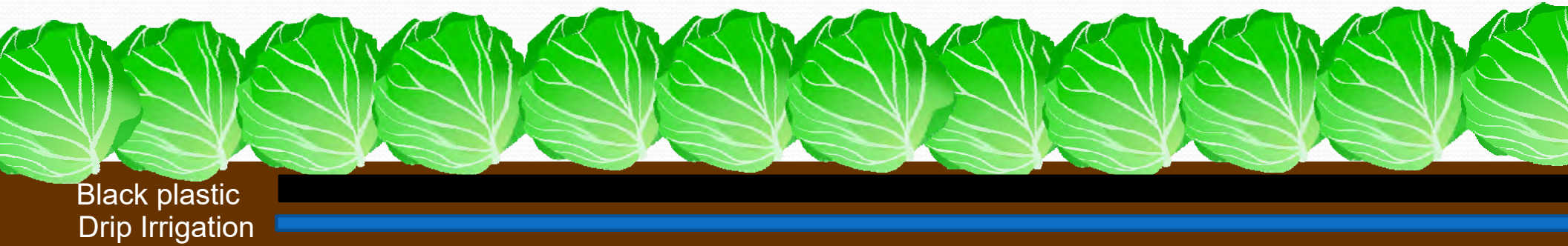
Overhead irrigation = agricultural water

DOH allows R1 water to touch the crop

R 2 could potentially qualify as "ag water" if it meets FSMA water testing criteria, but conflict with DOH guidelines

DOH guidelines do not allow R2 water to touch crop

Under FSMA, it is possible the R3 could be used and not qualify as "ag water" but its use would be against DOH guidelines



Drip or subsurface (no crop contact) ≠ agricultural water

DOH guidelines do not allow R3 to be used on edible crops

Recycled Water Under FSMA

- Interpretation
  - Overhead and spray solutions could put recycled water into the agricultural water category. Growers would have to comply with required FSMA water testing.
    - R2 could potentially meet the FSMA *E.coli thresholds as FSMA does not take into account filtration, (just CFU/ml)*
  - Drip irrigation: If growers move to drip or sub surface irrigation, where the water does not touch the crop, then under FSMA, recycled water (R1, R2, and R3) would not be considered agricultural water and not subject to the water testing requirements
  - Federal law could change the way growers utilize recycled water and allow for greater recycled water use

Challenge

DOH Recycled Water Guidelines and FSMA definitions on water use are different

Considerations for Recycled Water Use

- More discussion is needed to advise growers whether they should 1) follow FSMA guidelines or 2) abide by DOH Recycled Water Guidelines
- Due to the uncertainty of this issue, in a conversation with C&C BOW & DOH, the recommendation is to follow the water rule that is more stringent
- Federal law supersedes state law, but DOH Recycled Water Guidelines are more stringent than FSMA
- For now, we suggest recycled water use should follow the DOH guidelines until we have a better handle on FSMA implementation in Hawaii

Differences in Agriculture Water Sampling

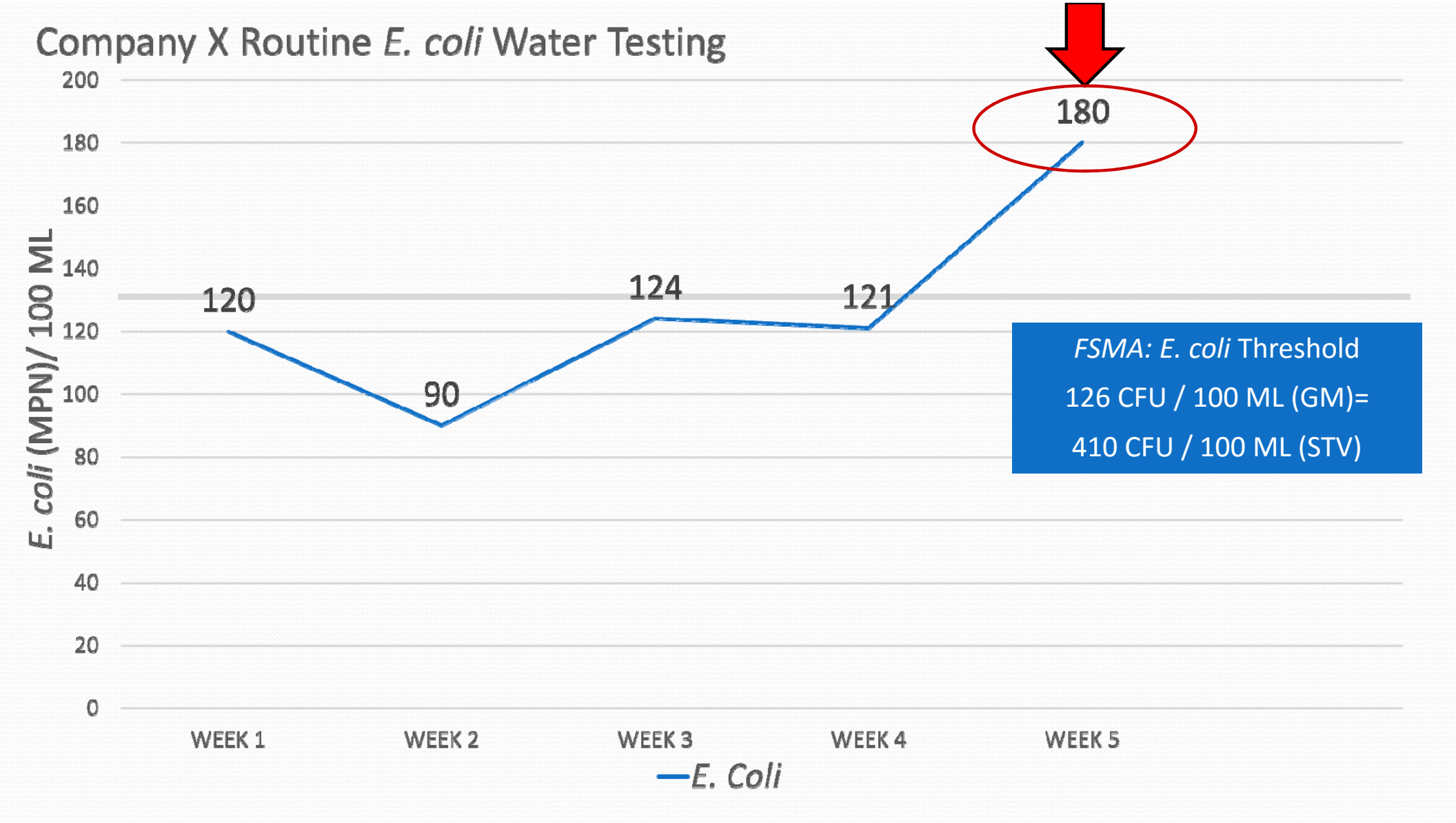
Water Source	FSMA
Surface	Annual: 5 x / year
	Baseline: 20 samples (2-4 yr)
Ground	Annual: 1 x / year
	Baseline: 4 samples (1 year)
Public Water	Copy of test results or current certificate of compliance
Recycled Water (i.e. overhead/spray solution)	Unknown (would this fall under municipal?)

As close in time to harvest

Agriculture Water Thresholds

- FSMA: EPA Recreational Water Standards
  - Geometric mean (GM) is **126 CFU or less** of generic *E. coli*/ 100 ml of water AND
  - Statistical Threshold Value (STV) is **410 CFU or less** generic *E.coli* in 100 ml/ water

- GAP Previous Audit Standards
  - Geometric mean (GM) is **126 CFU or less** of generic *E. coli*/ 100 ml of water
  - No more than **235 CFU** generic E. coli per 100 ml for any single water sample


Company X Routine E. coli Water Testing
200
180
160
140
120
100
80
60
40
20
0
E. coli (MPN)/ 100 ML
120
90
124
121
180
WEEK 1
WEEK 2
WEEK 3
WEEK 4
WEEK 5
E. Coli
FSMA: E. coli Threshold
126 CFU / 100 ML (GM)=
410 CFU / 100 ML (STV)

Calculating Rolling Geometric Means

Michelle Danyluk[1], Soohyoun Ahn[2], Renée Goodrich[2], and Keith Schneider[2]
[1]University of Florida, Citrus Research and Education Center, Lake Alfred, FL, [2]Food Science and Human Nutrition, Gainesville, FL

120
90
124
121
180

Rolling Geometric Mean

120+90+124+121+180= 635

635/5= Average

124 CFU/ 100 ml

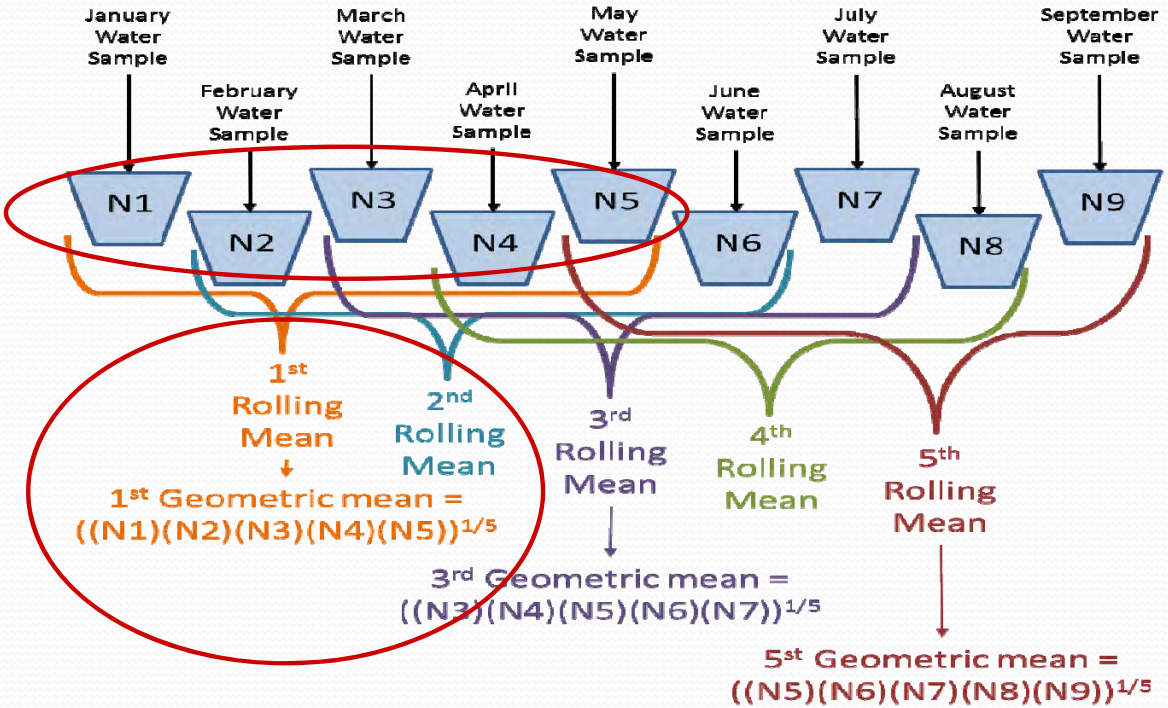


Figure 2. Agricultural Water – What is a Rolling Geometric Mean?

Geometric Mean Calculator

Calculator | Tutorial | Formula | Code | Download

An online statistical Geometric Mean calculator to find the geometric mean value of the given numbers or statistical data when all the quantities have the same value. It is the average of a relevant set of quantities multiplied together to produce a product. It is also referred as compounded annual growth rate since, the average rate of return values are calculated based on the product of the terms. Find the geometric mean value for a given data using this calculator.

Find the Geometric Mean Value

Enter all the numbers separated by comma (,)
E.g: 13,23,12,44,55

Calculate | Reset

Total Numbers:

Geometric Mean:

Code to add this calci to your website

Ask a Question

Add Your Question

Reset | Ask

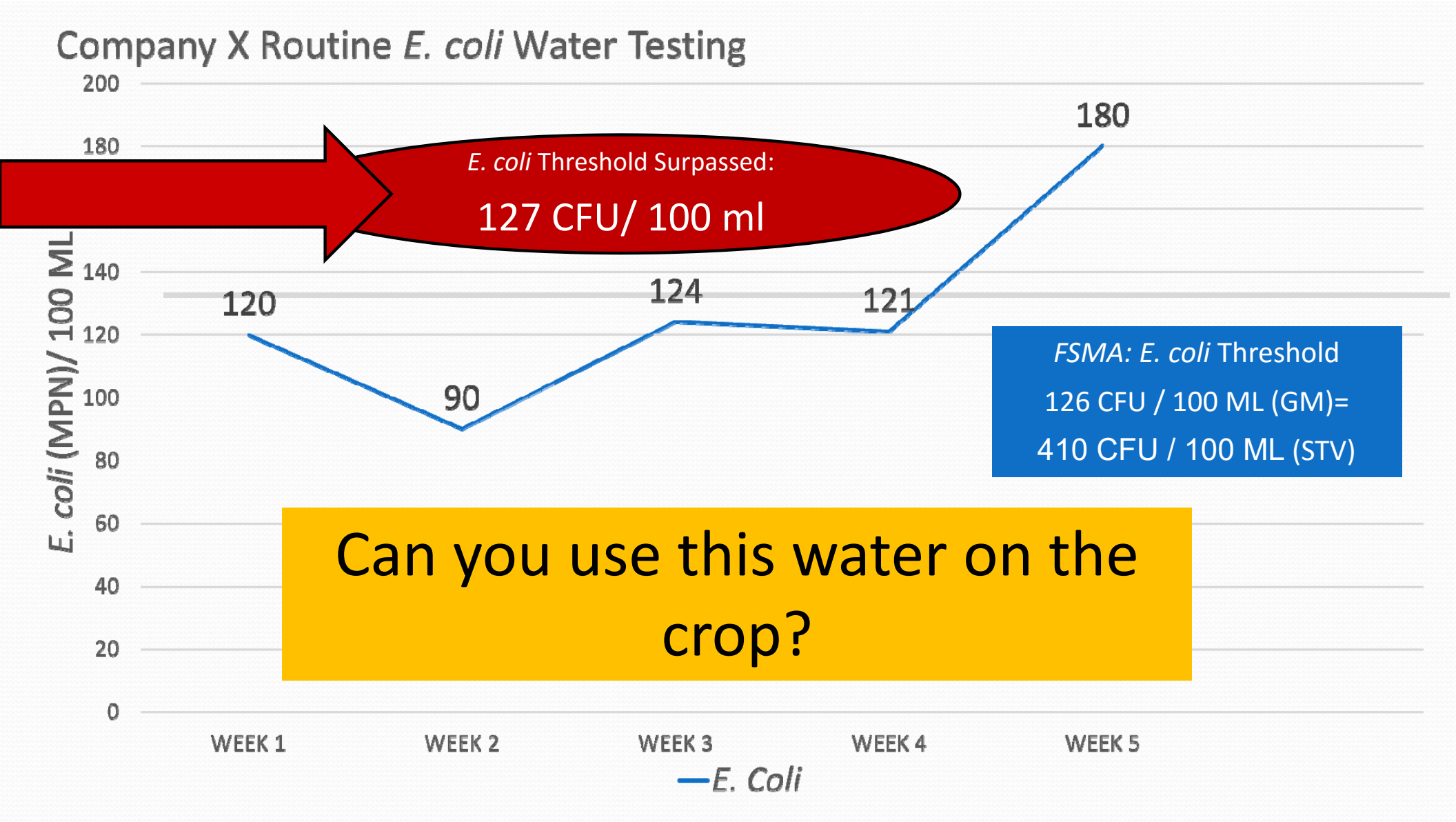
Top Calculators

Age Calculator

Mortgage

Water Remediation Options

- If water does not meet FSMA criteria or exceeds thresholds, corrective action is required:
  - **Passive treatments:**
    - Longer harvest time to allow for microbes to die off in the field (die off rate (log))
    - Longer harvest time to allow for microbes to die off between harvest and end of storage
  - **Active Treatment:**
    - Treating the water


Company X Routine E. coli Water Testing
200
180
140
120
100
80
60
40
20
0
E. coli (MPN)/ 100 ML
E. coli Threshold Surpassed:
127 CFU/ 100 ml
120
90
124
121
180
FSMA: E. coli Threshold
126 CFU / 100 ML (GM)=
410 CFU / 100 ML (STV)
Can you use this water on the crop?
WEEK 1
WEEK 2
WEEK 3
WEEK 4
WEEK 5
E. Coli


STOP

Option 1

Passive Treatment Actions

Determine and implement the time interval log reduction by calculating the microbial die off rate between the last irrigation and harvest

Passive Treatment Actions

Last irrigation

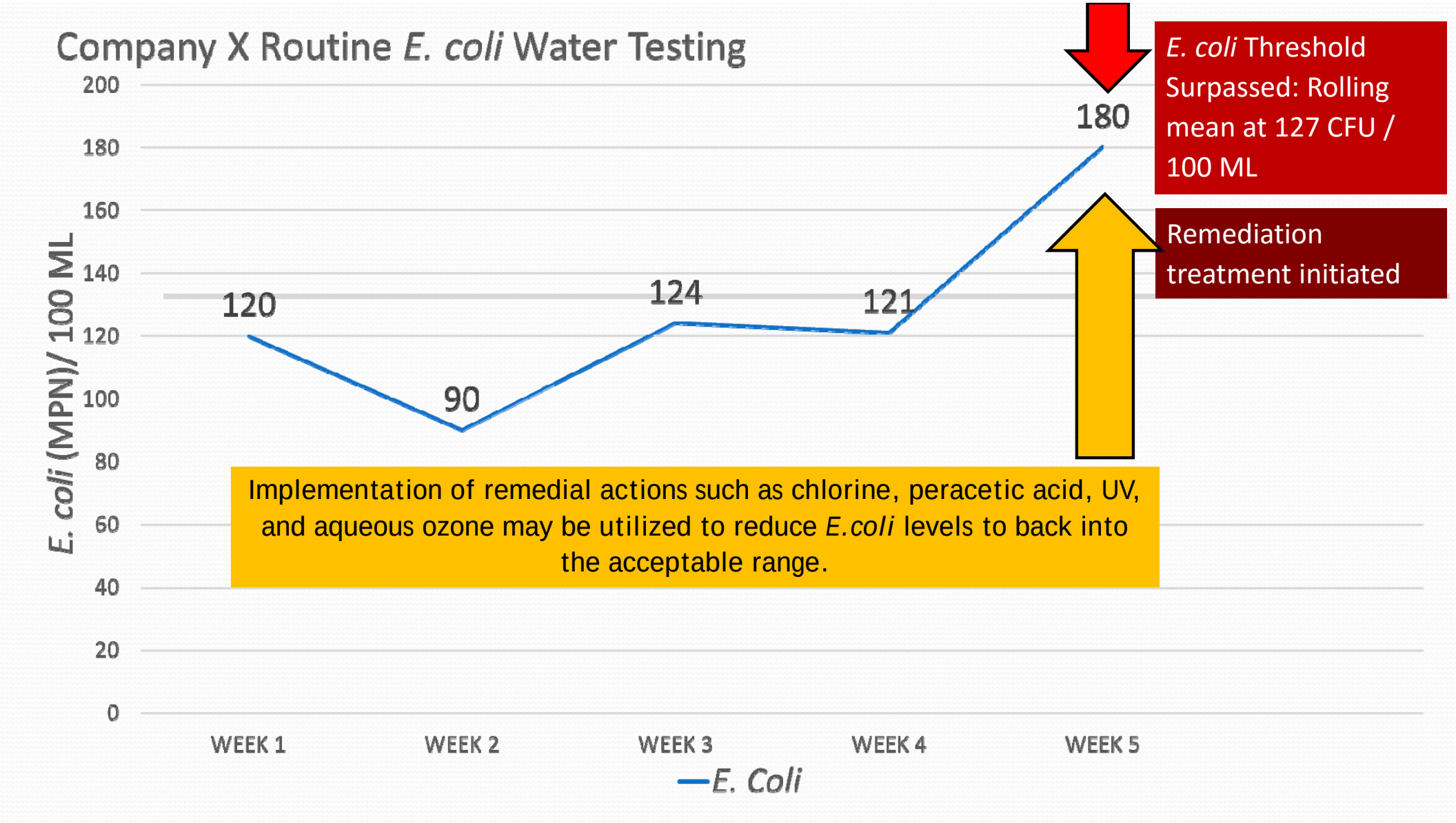
Harvest

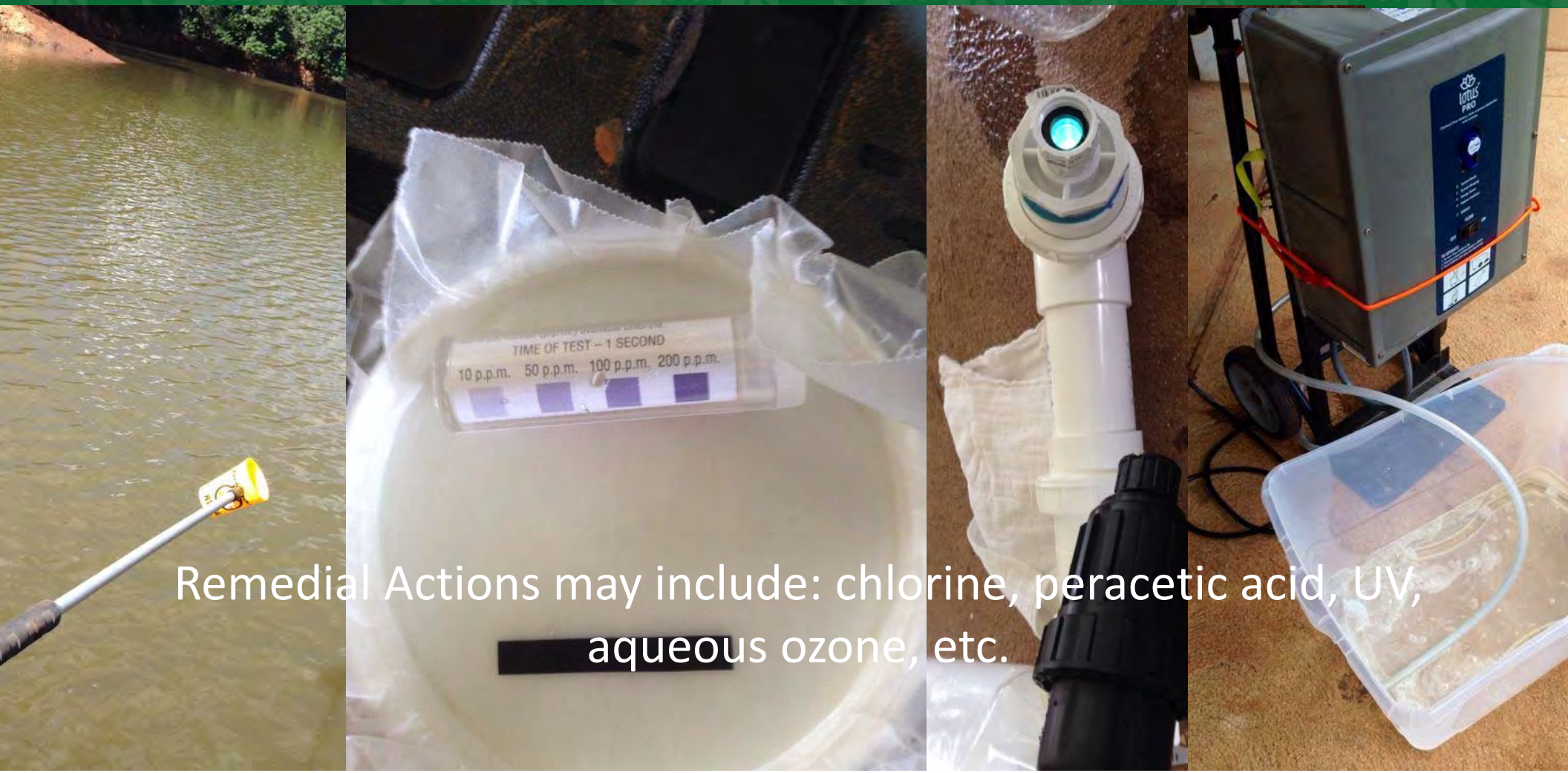
Local Research is Needed

0.5 log / day reduction in microbial / 4 days (max)

Based on microbial die off rate

Option 2


Company X Routine E. coli Water Testing
E. coli (MPN)/ 100 ML
200
180
160
140
120
100
80
60
40
20
0
120
90
124
121
180
WEEK 1
WEEK 2
WEEK 3
WEEK 4
WEEK 5
E. Coli
E. coli Threshold Surpassed: Rolling mean at 127 CFU / 100 ML
Remediation treatment initiated
Implementation of remedial actions such as chlorine, peracetic acid, UV, and aqueous ozone may be utilized to reduce E.coli levels to back into the acceptable range.

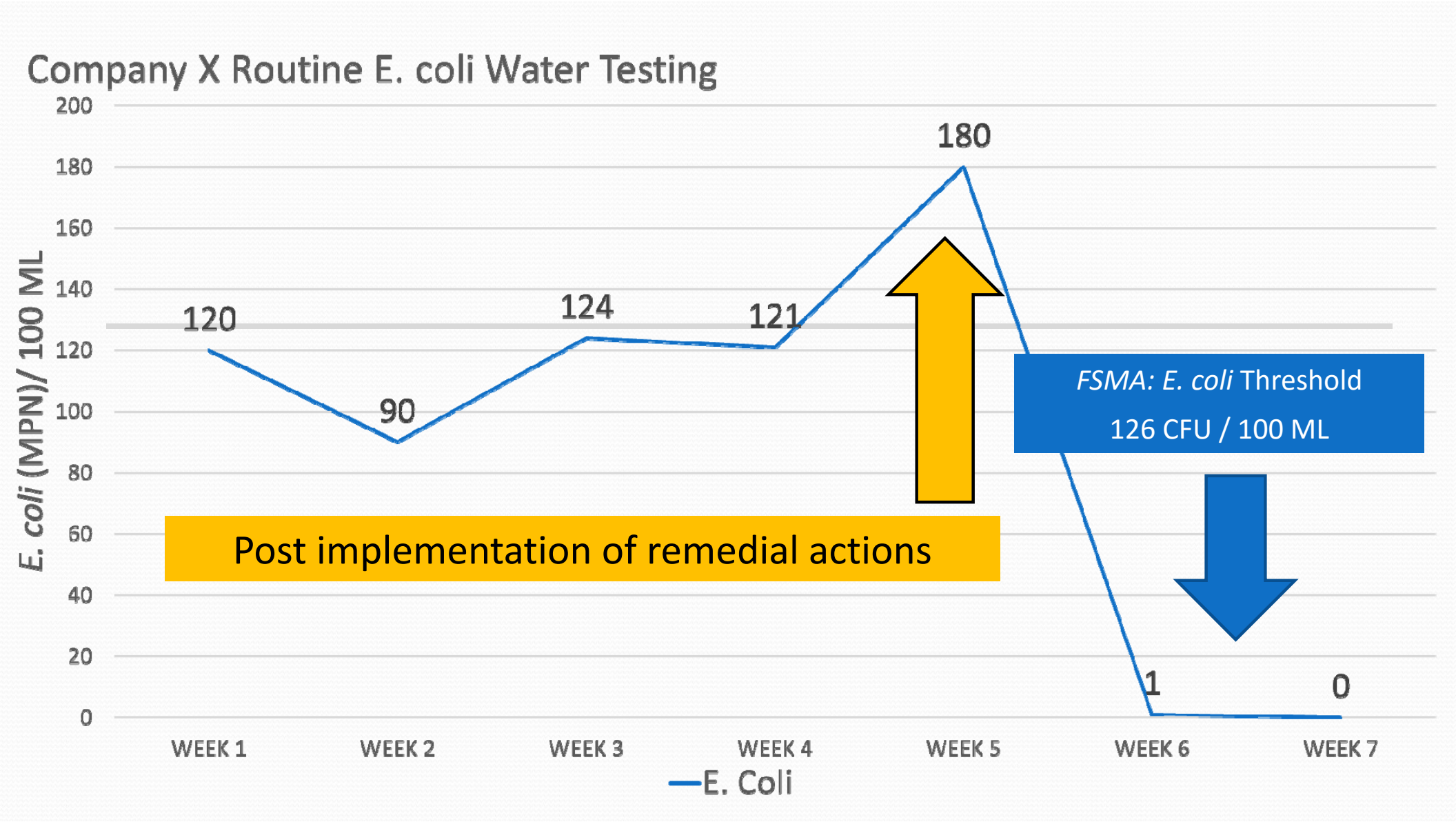


Remedial Actions may include: chlorine, peracetic acid, UV, aqueous ozone, etc.

Evaluation of Remedial Water Treatments

Treatment	Beginning E. coli	Ending E. coli	ORP
Chlorine: 200 ppm	130	1	600
Chlorine: 200 ppm	130	1	661
Chlorine: 400 ppm	130	1	620
UV	130	<1	495
Aqueous ozone: 25% 1 ppm	<200	83	523
Aqueous ozone: 50% 1 ppm	<200	6	462
Aqueous ozone: 75% 1 ppm	<200	<1	359
Aqueous ozone/ UV	130	<1	495
Peracetic acid: 3 ppm	200	<1	332

J. Sugano, J. Uyeda, S. Fukuda, and J. Odani, August 2014


Company X Routine E. coli Water Testing
E. coli (MPN)/ 100 ML
200
180
160
140
120
100
80
60
40
20
0
120
90
124
121
180
1
0
WEEK 1
WEEK 2
WEEK 3
WEEK 4
WEEK 5
WEEK 6
WEEK 7
E. Coli
Post implementation of remedial actions
FSMA: E. coli Threshold
126 CFU / 100 ML

“Agriculture Water” requirements under FSMA is the key difference between FSMA and GAP

Agriculture Water Considerations to Lower Risk

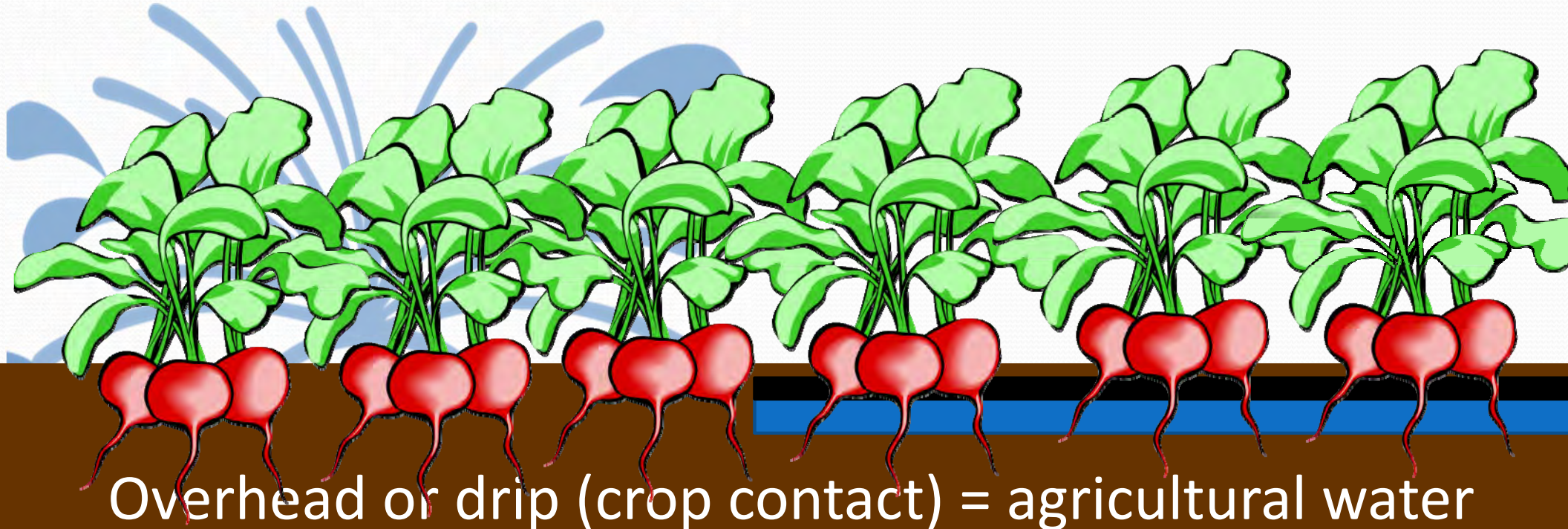
- Change water contact with crop
  - Transition from overhead to drip irrigation
- Water contact systems:
  - Preventative:
    - Implement filtration & water remediation treatment systems close to the point of use
  - Reactive:
    - Select a passive or active water remediation, corrective action program when thresholds are exceeded
  - Consider municipal based water systems
- Evaluate crop selection

Overhead (higher risk),
More H2O testing

Underground (lower risk)
Less H2O testing or exempt from definition

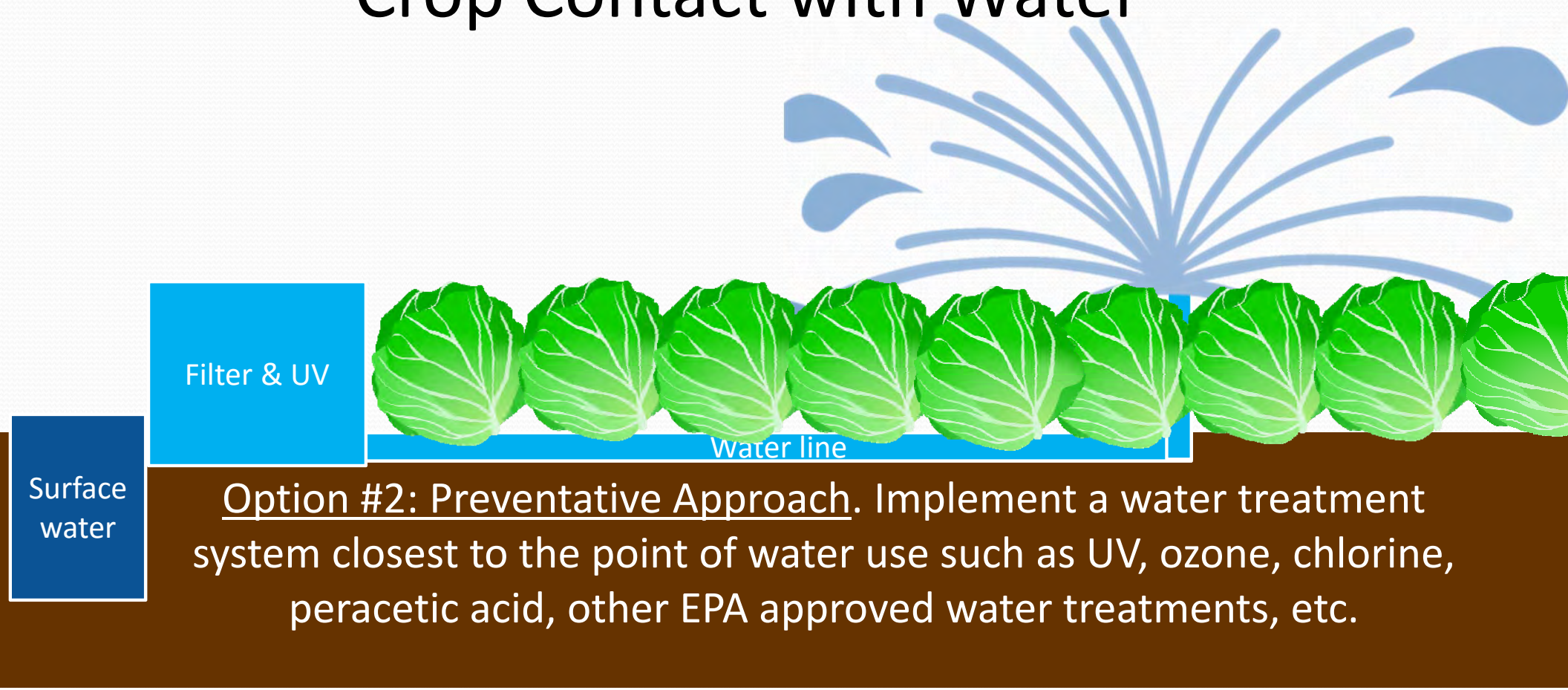
Option #1: Change the contact with water

Crop contact with water cant be avoided?



Overhead or drip (crop contact) = agricultural water

Crop Contact with Water



Option #2: Preventative Approach. Implement a water treatment system closest to the point of water use such as UV, ozone, chlorine, peracetic acid, other EPA approved water treatments, etc.

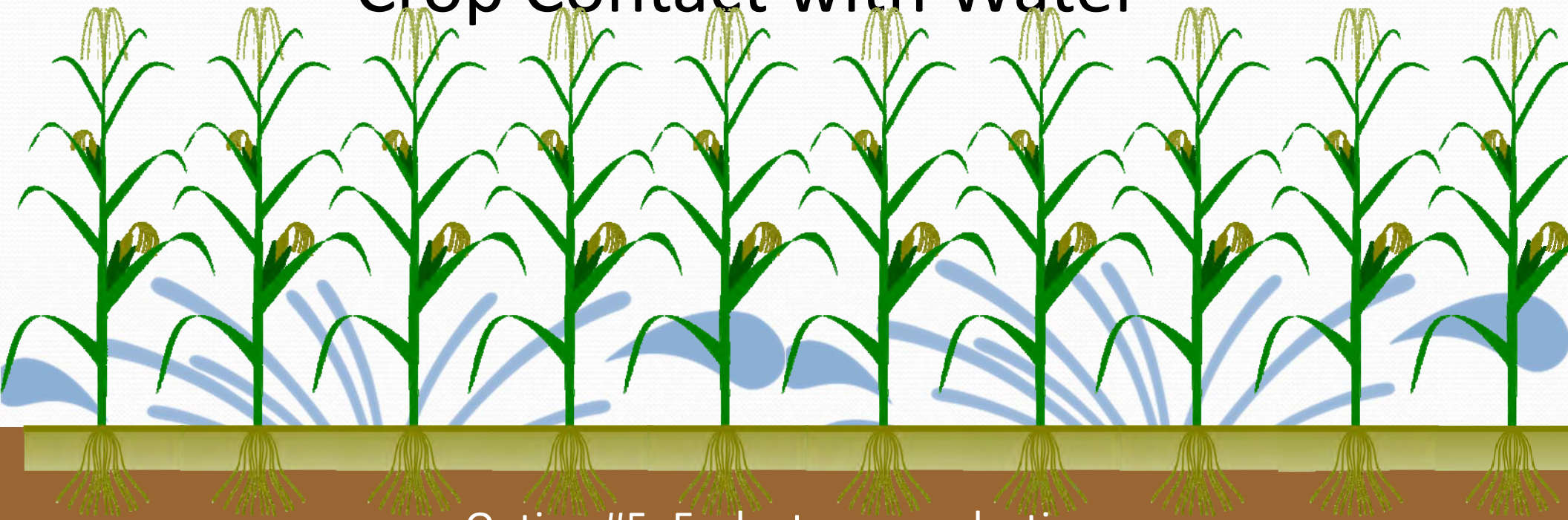
Crop Contact with Water

Option #3: Reactive Approach: Monitor water according to FSMA Rule and have a corrective action plan when thresholds are surpassed, such as UV, ozone, chlorine, peracetic acid, etc.

Crop Contact with Water

Option #4: Consider county or municipal water systems, including R1 recycled water. Evaluate the cost associated with use.

Crop Contact with Water



Option #5: Evaluate crop selection

Review list of crops not covered under FSMA to lower risk

Ex. Municipal Water-Ag Rate

Agricultural * (Monthly Per Account)	January 1, 2012	July 1, 2012	July 1, 2013	July 1, 2014	July 1, 2015
Block 1 (Gallons) First 13,000 or any part thereof	$3.06	$3.35	$3.68	$4.03	$4.42
Block 2 (Gallons) Over 13,000	$1.31	$1.43	$1.57	$1.72	$1.89

Non-Potable **	January 1, 2012	July 1, 2012	July 1, 2013	July 1, 2014	July 1, 2015
All Usage	$1.71	$1.88	$2.06	$2.26	$2.47

* To obtain Agricultural Quantity Charges, a service holder must submit a written application each fiscal year to the Board of Water Supply and furnish satisfactory proof that they are engaged in crop production, stock raising or dairy farming on a commercial basis. Each approved application shall continue in effect entitling the service holder to these charges for the remainder of the fiscal year, until they cease the activities entitling them to these charges, or until new charges are established.

** The Nonpotable Quantity Charge effective from July 1, 1993 shall not supersede

Record Keeping

- Records need to be maintained for 2 years
  - Farm plans
  - Standard operating procedures (SOP)

Confusion for Growers:
Different requirements between FSMA, GAP and 3rd Party Groups

Voluntary, but market driven. Vendors require various food safety certifications from producers

Federally mandated, but without a regulatory or certification component as of 2016

3rd Party Independent Audits

Primus, NSF, USDA Agricultural Marketing Service, HDOA, etc.
(May be voluntary, but often required by buyers, farmers markets, insurance carriers, and distributors)

Food Safety Modernization Act
FDA (2015)

Good Agricultural Practices (GAP)
USDA / FDA (1998)
Voluntary

Closing the GAP

We expect, FDA will merge FSMA and GAP guidelines

Food Safety Modernization Act
FDA (2015)
Mandatory

Good Agricultural Practices (GAP)
USDA AMS conducts audits based on FDA guidelines
Voluntary (1998)

UH EXTENSION
MĀNOA COLLEGE OF TROPICAL AGRICULTURE AND HUMAN RESOURCES

People, Place, Promise

Exemption or Not:
Hawaii Growers Should Adopt Good Ag Practices (GAP)

- Water quality & application
- Manure & biosolids
- Worker health & hygiene
- Sanitary facilities
- Field Sanitation
- Packing facility sanitation
- Transportation
- Traceback

http://www.fda.gov/downloads/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/UCM169112.pdf

Cornell University **February 27-28, 2016** 1 member of each "covered" farm must undergo educational training under FSMA

UH CTAHR

3rd Party Independent or USDA GAP Audits
(May be voluntary, but also maybe required by buyers, farmers markets, insurance carriers, and distributors)

Produce Safety ALLIANCE
(FDA Approved curriculum)

Food Safety Modernization Act
USDA FDA (2015)

Good Agricultural Practices (GAP)
USDA FDA (1998)

Food Safety: Whole Food System Approach

GOAL
Food Safety

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For more information about statewide workshops:

http://manoa.hawaii.edu/ctahr/farmfoodsafety/about-us/

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