FSMA Affect on Pacific Gateway's Small Acreage Farmers

Jari Sugano, Jensen Uyeda, Joshua Silva, Lynn Nakamura-Tengan and Luisa Castro
University of Hawaii at Manoa
College of Tropical Agriculture and Human Resources

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COOPERATIVE EXTENSION
UNIVERSITY OF HAWAI'I AT MĀNOA
COLLEGE OF TROPICAL AGRICULTURE AND HUMAN RESOURCES

FSMA

Food Safety Modernization Act

GAP

Good Agricultural Practices

Food Safety Modernization Act (FSMA)

- Signed into law by President Obama (1.4.2011), effective as of 1/26/16

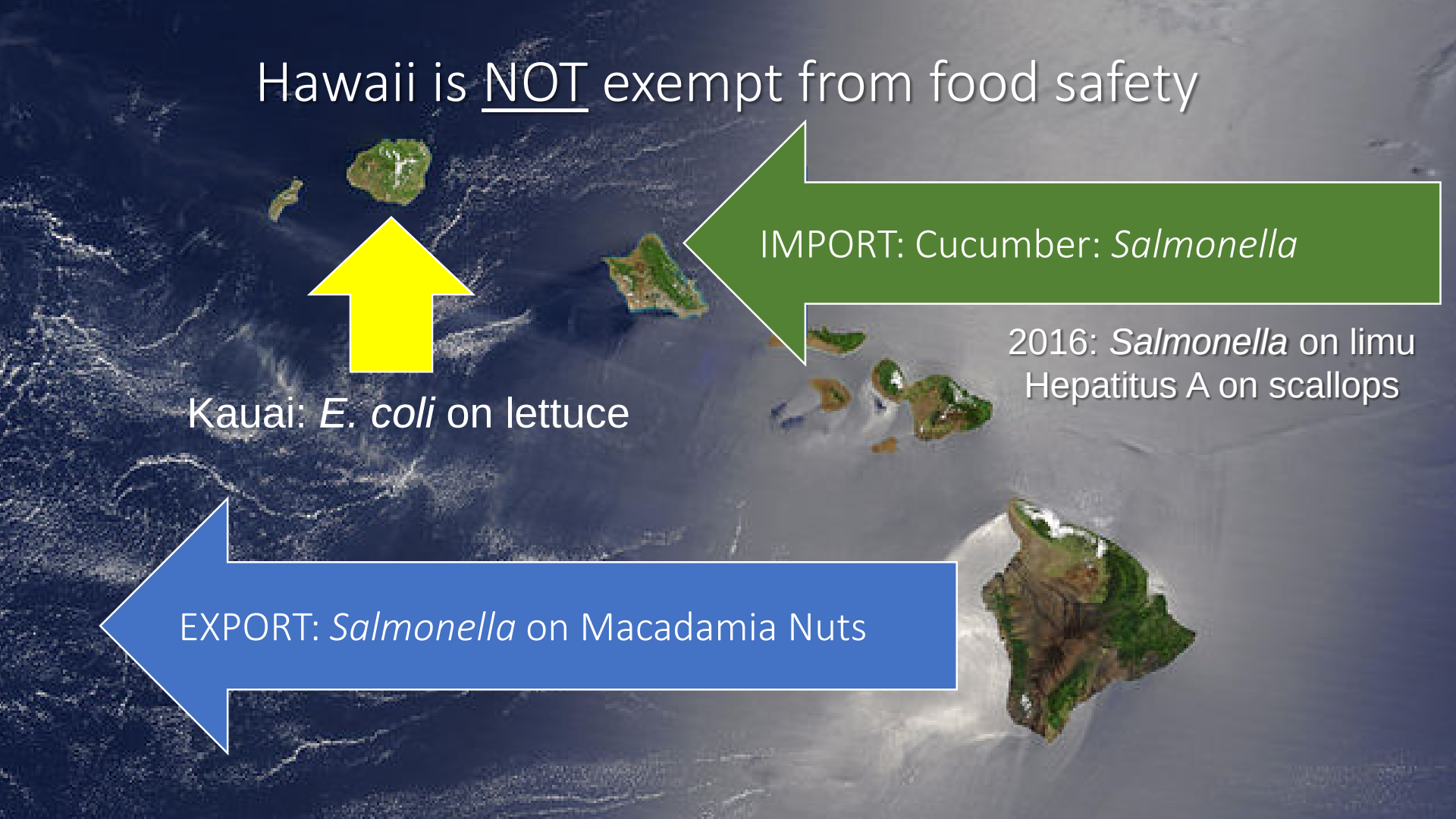
  - Create a safe U.S food supply
  - Preventive vs reactive
  - Domestic and import production

Why is FSMA Necessary? Prevention.

- Illnesses
- Hospitalization
- Lifetime disorders
- Death

Source: CDC website, November 5, 2014

Hawaii is NOT exempt from food safety



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

Sprouts are covered under a different set of rules

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)

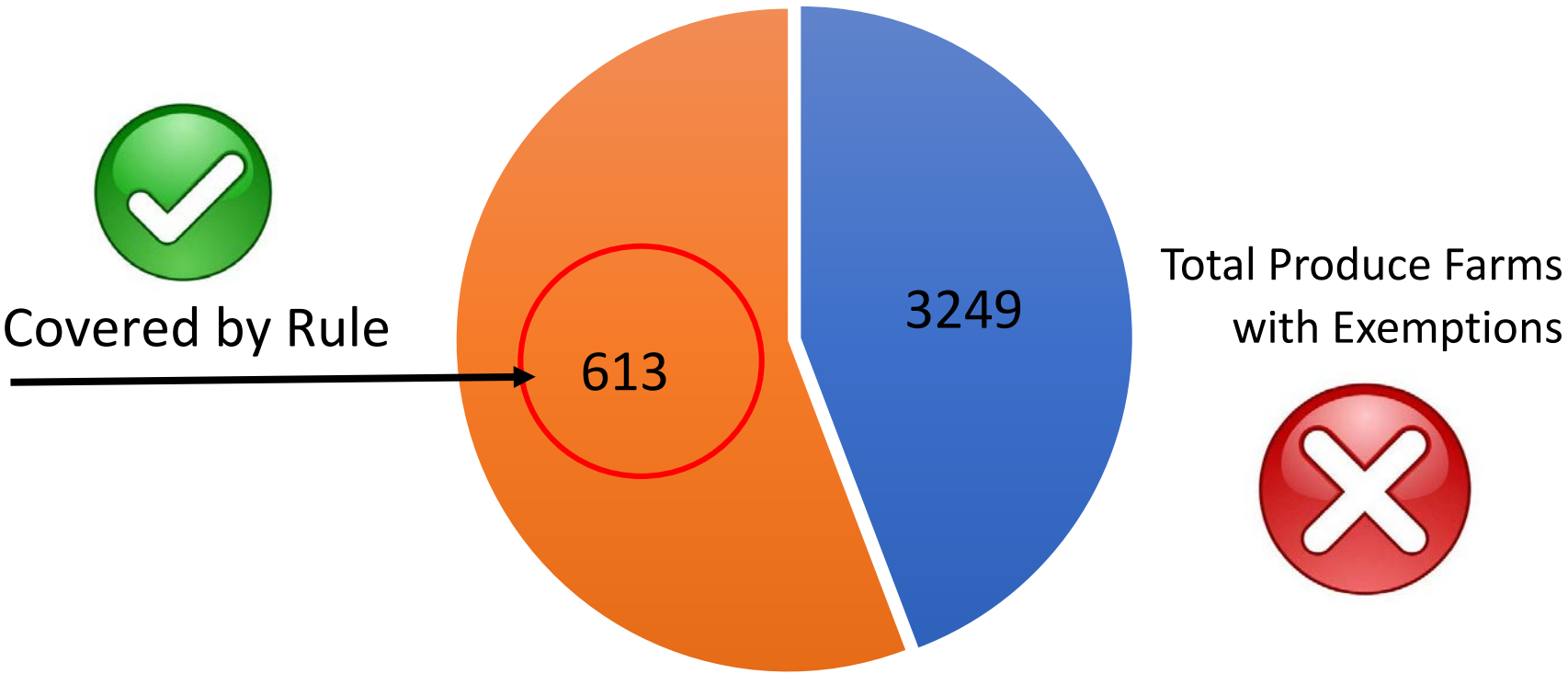
Good Agricultural Practices (GAP)

USDA / FDA (1998)
Educational

Question:
Does FSMA Affect Our Farmers?

PACIFIC GATEWAY CENTER

Hawaii Produce Farms with Food Sales = 3,862 of 7,000



Estimates by Dr. Luisa Castro, Hawaii State Department of Agriculture based *on 2012 U.S. Census of Agriculture data provided by the National Agricultural Statistics Service (NASS) for the National Association of State Departments of Agriculture (NASDA) in August 2015.*

"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

Possible Exemptions to FSMA

- Personal or on farm consumption
- Crop Type
- Annual Sales
- Direct Sales
- Sent to commercial processor

Crop Type is Commonly Eaten Raw

Exemption: Crop Type: Rarely Eaten Raw

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

Micro Exemption-Annual Sales

- Annual Sales < 25K over 3 years
- Produce sales
- Keep records for evidence

Qualified Exemption

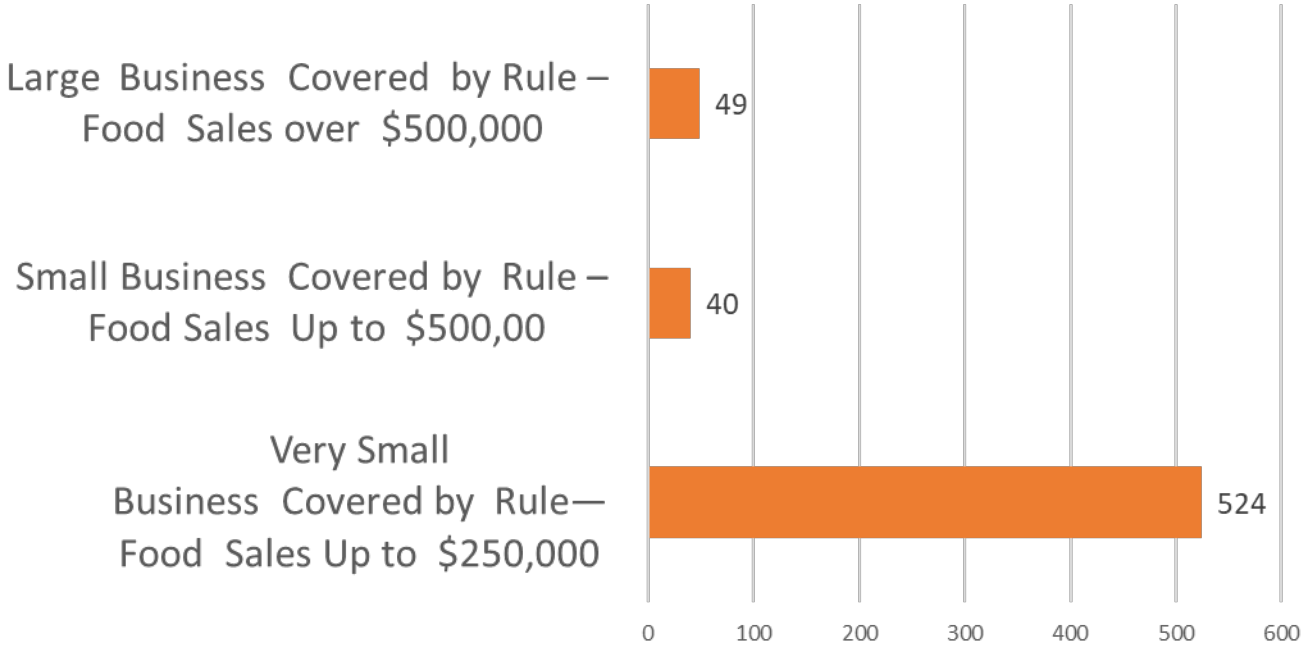
Tester-Hagan Amendment

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

Example: Lihue to Kona
274 miles


YES

Hawaii Farms Subject to FSMA by Size



Majority of Sales to Wholesalers & Exports

YES

Many farms with an average annual monetary value of produce sold (over past 3 years) of no more than $500,000 in which majority of sales are not direct to consumers will be covered by this rule such as those that sell to wholesalers and exporters

Review of Exemptions

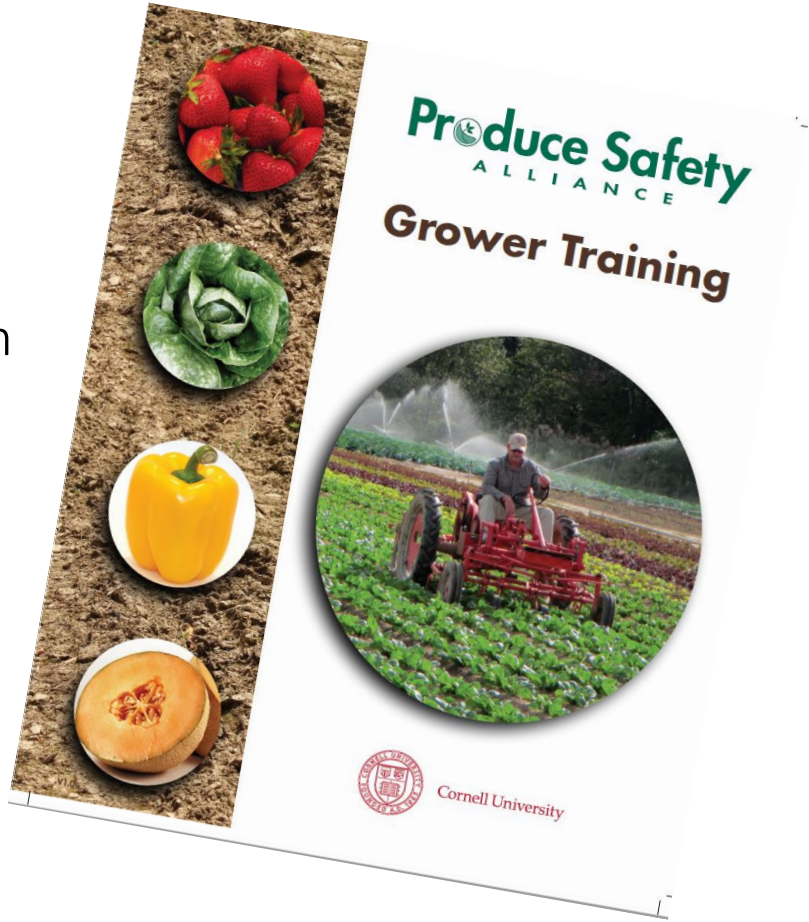
Crop Type	• Produce rarely eaten raw are not covered under FSMA Produce Rule
Personal /On Farm Use	• Personal or on farm consumption
Annual Sales	• **Total** produce sales of $25,000 or less • No restriction on distribution
Distribution/Distance	• Less than 500K in annual sales • Direct to end user within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

Despite Exemptions…

- Subject to the requirements of record keeping (2 years)
  - Sales receipts
  - Verification that your farm meets the exemptions
  - Labels with farm information

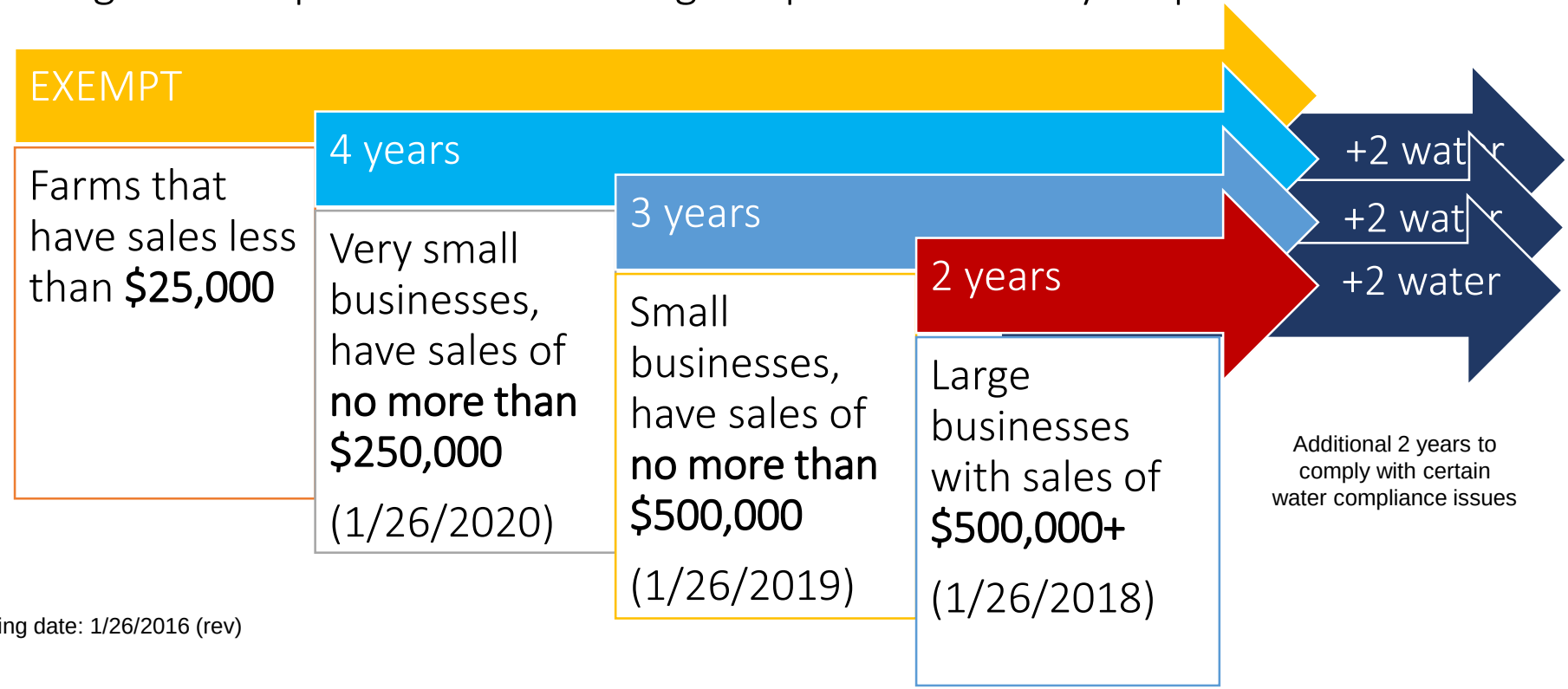
Educational Requirement

- At least 1 supervisor from the farm must complete food safety training at least equivalent to the standardized curriculum before compliance date
  - i.e., PSA training



Farm Size Considerations for Compliance

Average annual produce sales during the previous three year period



Starting date: 1/26/2016 (rev)

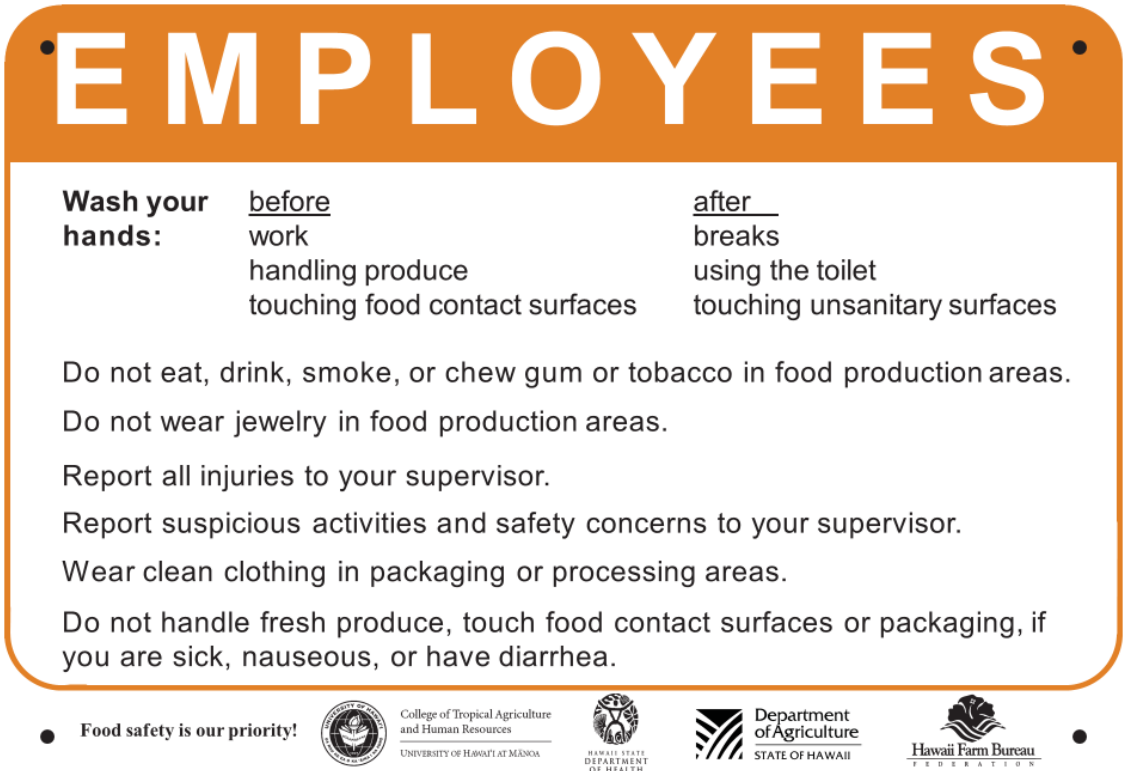
Human Health & Hygiene

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

Educator Training Program

- Refresher training annually or when problem arises
- Supervised by a qualified person
- Requires a process for documenting training



Visitors

- Must educate visitors of farm's food safety policy
- Must provide access to toilet and handwashing facilities

Restroom Facilities

- Accessible toilet facilities
- Properly located
- Well supplied
  - Toilet paper, single use towels, basin, potable water, soap, etc.
- 1 facility per 20 workers per ¼ mile (OSHA rule) of working area
- Cleaned regularly & documented

In Field-Acceptable

In Field-Acceptable


Recordkeeping

Training and policy for personnel health and hygiene

Photo: J. Uyeda

Equipment

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

No more wood


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
5-8 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

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

Source: J. Hollyer

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 Meets Microbial Standards

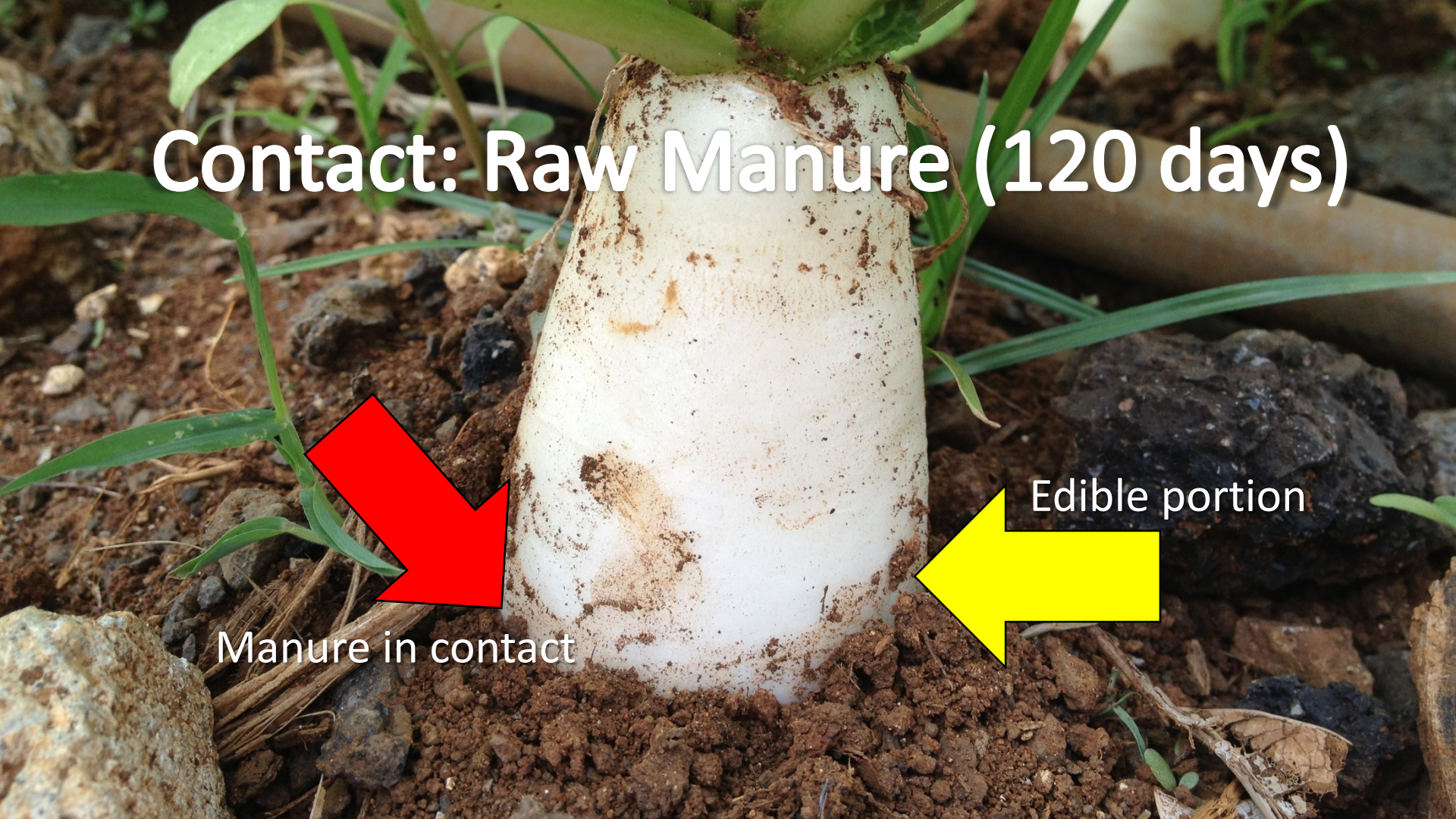
- Two scientifically valid composting methods that meet these standards
    - Static composting (131°F, 3 days), curing
    - Turned composting (131°F, 15 days), 5 turnings and curing
- Establish and maintain records of process

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

Example: Manure meets USDA NOP Rule

- 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

Non-Contact: Raw Manure (90 days)


Contact: Raw Manure (120 days)
Edible portion
Manure in contact

FSMA: Agricultural Water[1]

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

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

FSMA accounted for water risk assessment

Irrigation Method

High Risk

Overhead

Furrow

Drip

Low Risk

Municipal

Well

Surface

Water Source

High Risk

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

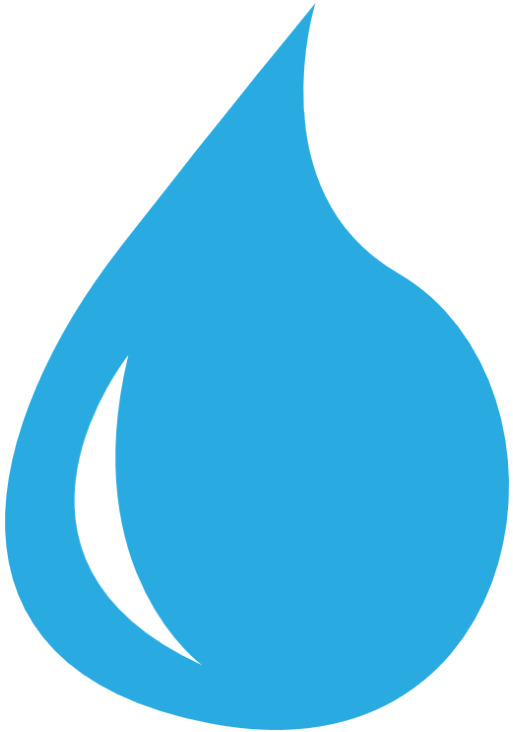
Surface Water
Exposed
Higher Risk

FSMA Agriculture Water Sampling

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

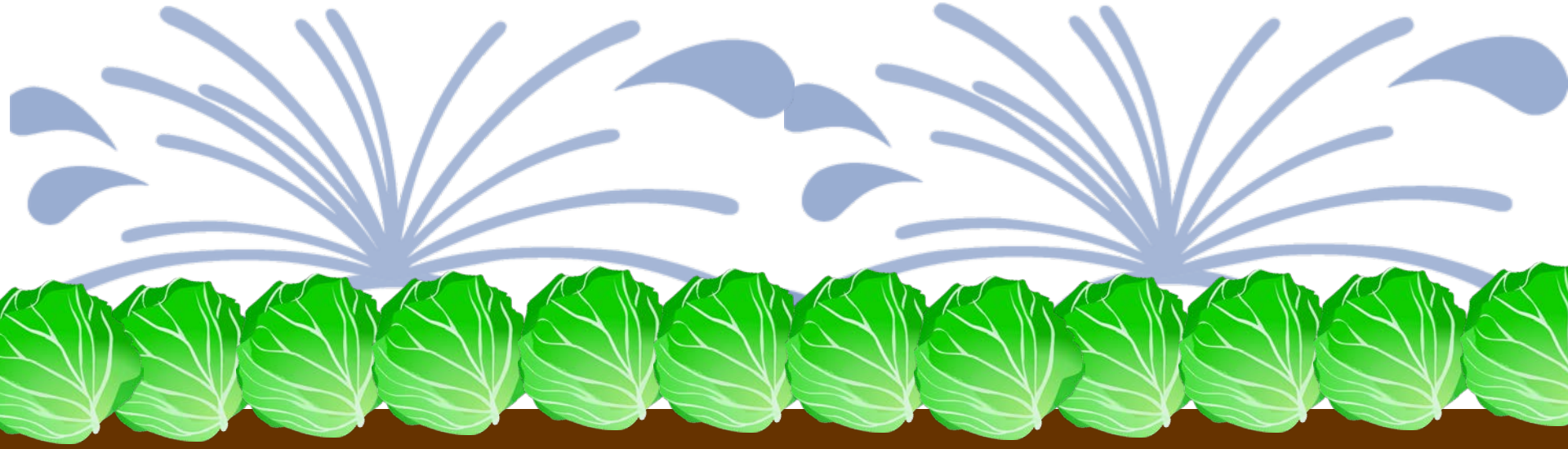
FDA has increased the number of “scientifically valid” water testing methods and “at least equivalent to the method of analysis in § 112.151(a) in accuracy, precision, and sensitivity[1] on September 11, 2017.

As close in time to harvest



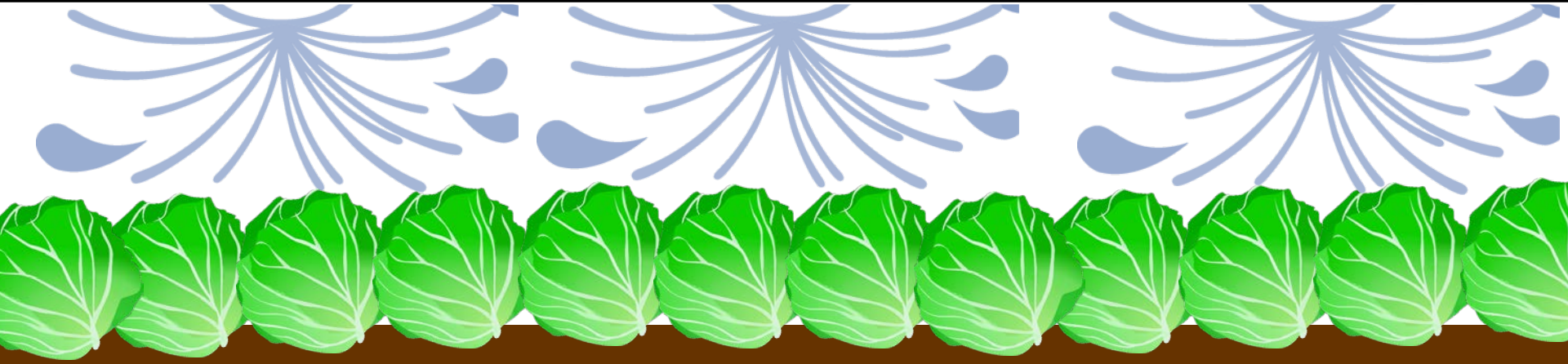
Water contact with crop determines if water is "agricultural water" under FSMA

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



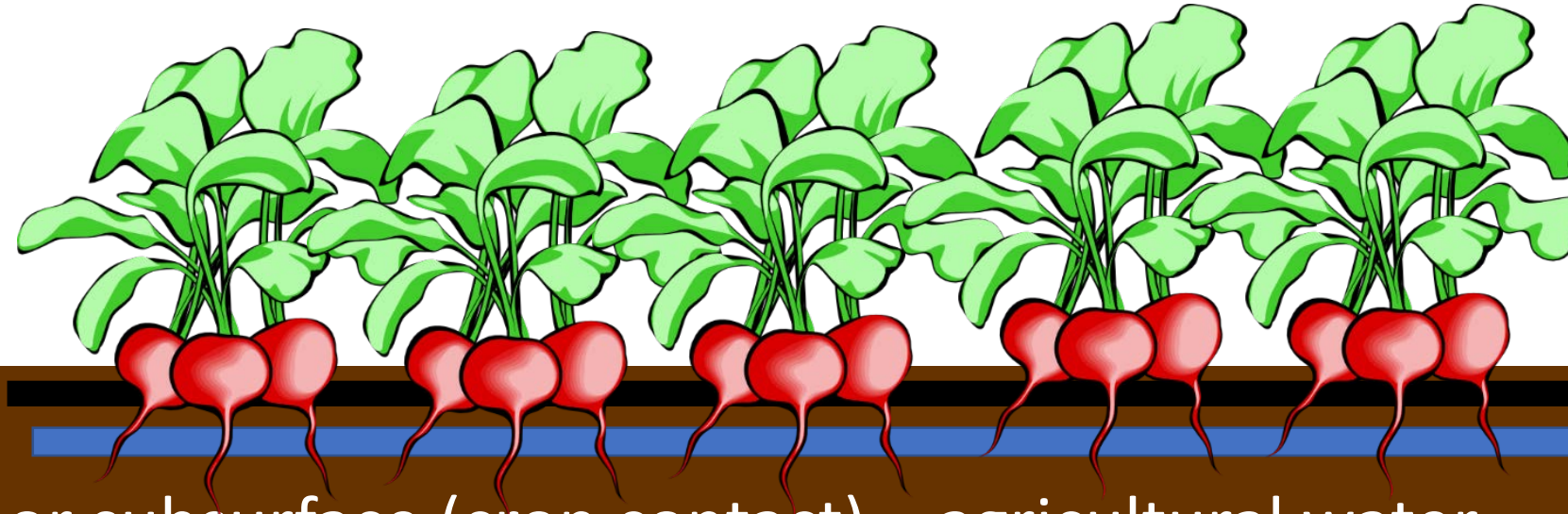
Overhead irrigation (crop contact) = agricultural water

Ex. Spray Boom



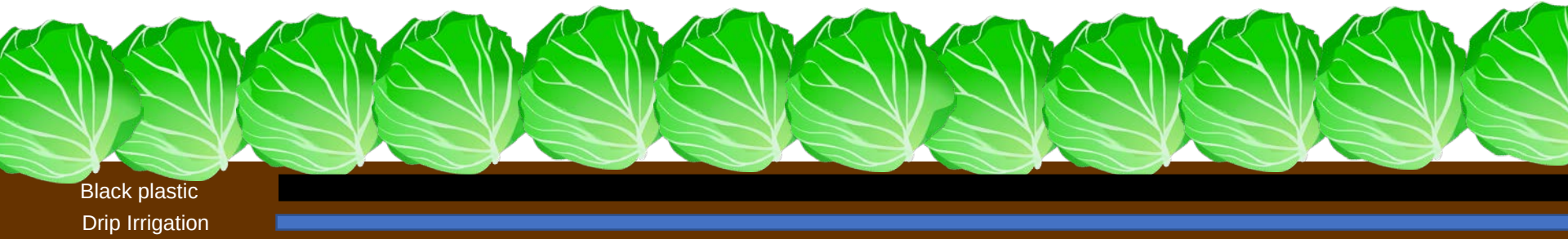
Spray solution (crop contact) = agricultural water

FSMA "agricultural water" definition is based on crop contact



Drip or subsurface (crop contact) = agricultural water

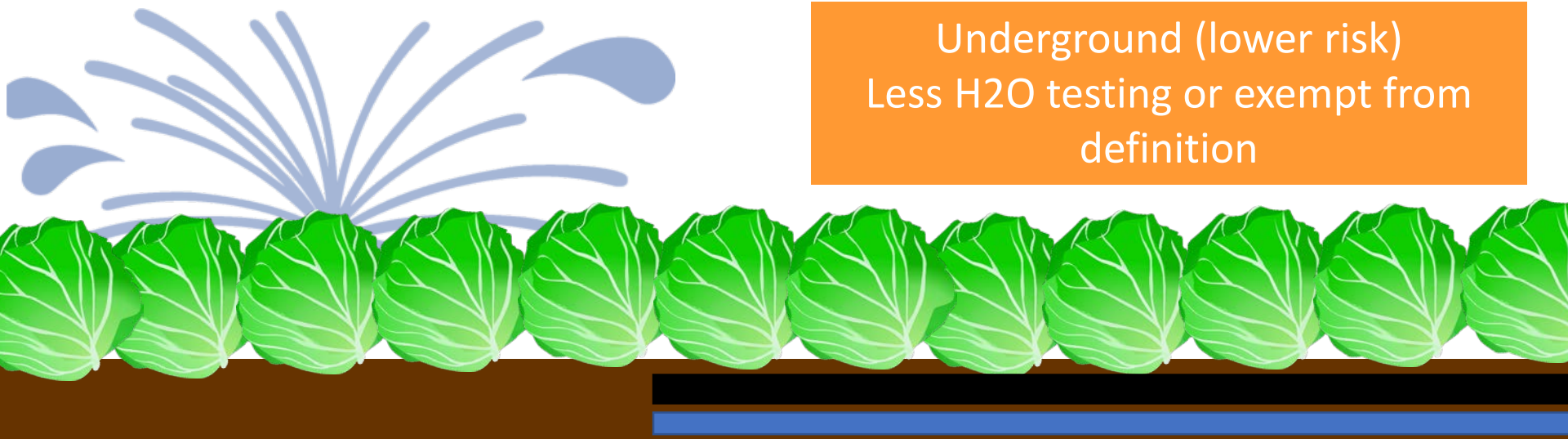
FSMA "agricultural water" definition is based on crop contact



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)

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

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

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*)

Compliance: Record Keeping

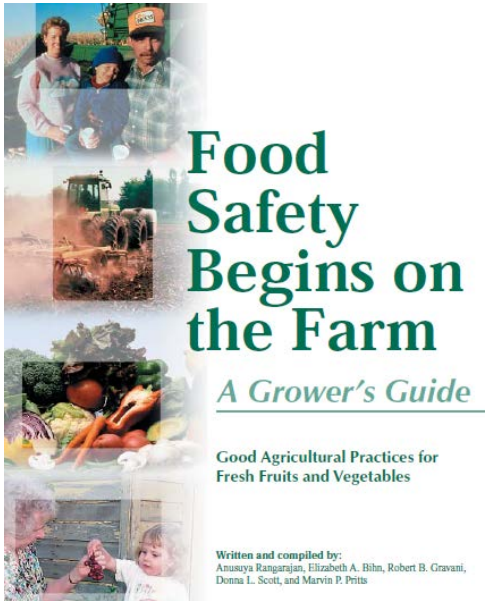
- Records need to be maintained for 2 years
  - Farm plans
  - Standard operating procedures (SOP)
  - Sign and dated after reviewed

https://gaps.cornell.edu/educational-materials/decision-trees/log-sheets-sops

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

FSMA 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

For More Information

Jari S.K. Sugano
University of Hawaii at Manoa
College of Tropical Agriculture and Human Resources
Department of Plant and Environmental Protection Sciences
Wahiawa Extension Office
suganoj@ctahr.hawaii.edu
622-4185

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