

FDA Produce Safety Education and Outreach Workgroup:

Identified knowledge gaps to address through education and outreach
(2017-2020)

Workgroup members:

1. Audrey Draper, USDA/AMS
2. Wendy Johnnecheck, Ph.D., ORA/PSN
3. Kate Allen, ORA/PSN
4. Faz Shakir, OFS/DPS
5. Mauricio Castelo, Ph.D., OFS/DPS
6. Doreen Gubbay, ORA/OP

Rachael Kozolup, M.S., Consumer Safety Officer, Fresh Produce Branch, Division of Produce Safety

Diane Ducharme, Ph. D., Produce Safety Expert, Fresh Produce Branch, Division of Produce Safety

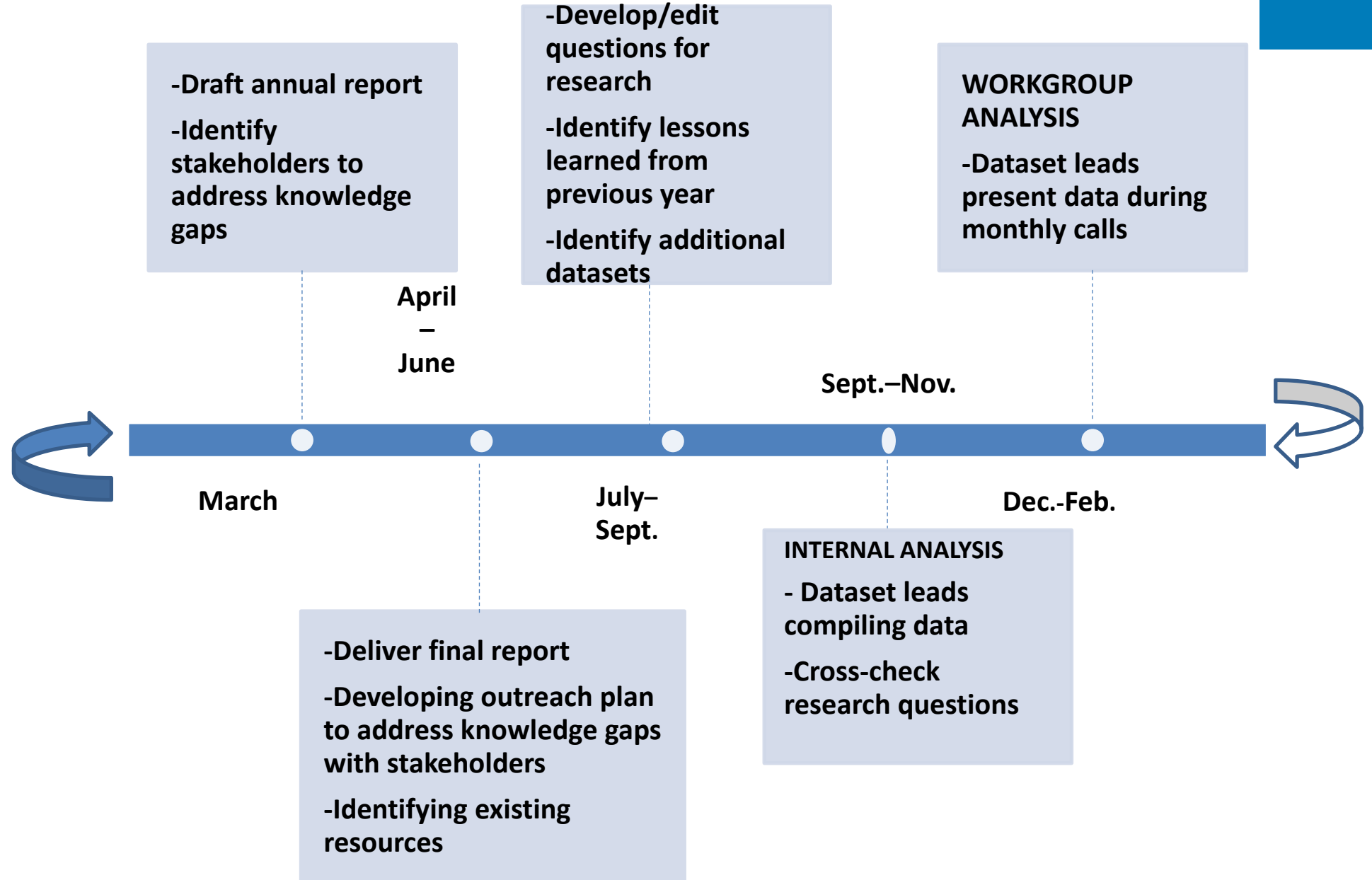
Agenda

- Data briefing of year 1 results
- Discussion of produce safety knowledge gaps
- Next steps for addressing produce safety knowledge gaps with stakeholders

Purpose and Goals

- Identify knowledge gaps that exist from the implementation of the Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption
 - Identify industry knowledge gaps through a variety of data sources,
 - Develop research questions based on knowledge gaps, and
 - Prioritize gaps to address through the development of materials through FDA development or external partners
- Providing education and outreach materials to the produce industry assists in obtaining compliance with the PSR; Improve on-farm food safety culture; and mitigate foodborne illness outbreaks

Workflow



Data Sets



	Data Sets	No. of Records	No. of comments	2017	2018	2019	2020
	Domestic						
1	FDA PSR Inspection Data	157	543			April 1	July 31
2	On-Farm Readiness Reviews (OFRR)	1203	*		December		March
3	Regulator Technical Assistance Network (rTAN)	441	94			April	September
4	Informal Technical Assistance Network (TAN)	184	184		January	December	
5	FDA Food Safety Modernization Act Technical Assistance Network (FSMA TAN)	542	467	September			July
6	U.S. Department of Agriculture (USDA) Good Agricultural Practices (GAPs) Audits	851	126		October 1	September 30	
7	State Cooperative Agreement program inspectional data (CAP)	60	381		July 1		June 30
	International						
8	FDA PSR Inspection Data	48	116			April 1	July 31
9	On-Farm Readiness Reviews (OFRR)	27	72			May	January
	Totals	3513	1983				

Table 1: Produce safety data sets (n=9) utilized for analysis of the Produce Safety Rule gap in knowledge from 2017 – 2020.

Identified areas of knowledge gaps or limited compliance

Provisions	Subpart	International	Domestic	Total
§112.1-112.7	Subpart A: General Provisions ★	0%	20%	18%
§112.11-112.12	Subpart B: General Requirements	3%	1%	1%
§112.21-112.30	Subpart C: Personnel Qualifications and Training ★	18%	11%	12%
§112.31-112.33	Subpart D: Health and Hygiene	5%	7%	7%
§112.41-112.49	Subpart E: Agricultural Water	9%	7%	7%
§112.51-112.84	Subpart F: BSAAO and Human Waste	1%	3%	2%
§112.81-112.84	Subpart I: Domesticated and wild animals	3%	2%	2%
§112.111-112.116	Subpart K: Growing, Harvesting, Packing, Holding Activities	6%	7%	7%
§112.121-112.140	Subpart L: Equipment, Tools, Buildings, and Sanitation ★	47%	27%	29%
§112.151-112.153	Subpart N: Analytical Methods	0%	3%	3%
§112.161-112.167	Subpart O: Records ★	9%	13%	12%
Total of comments		188	1795	1983

Table 2: Frequency of the Produce Safety Rule provisions from the produce safety data sets (n=8) indicating knowledge.

Summary list of topic areas across data sources (n=8) into PSR Subpart Summary

§112.1-112.7	Subpart A General Provisions
§112.1, §112.2	Identifying covered and non-covered produce
	Activities allowed under farm definition and secondary activities farm- Trimming V. cutting; mixing V. blending
	Classifying a qualified end-user
	Determining coverage
§112.11-112.12	Subpart B General Requirements
§112.11	General requirement to prevent foreseeable food safety hazards
	Total coliforms and/or generic E. coli detected in water used for hand washing, produce washing, or cleaning/sanitation activities
	Use of untreated surface water for equipment cleaning/sanitation
	Compromised water systems due to spigot/backflow configuration
§112.21-112.30	Subpart C Personnel Qualifications and Training
§112.21(a)	Personnel receiving adequate training at least once annually
§112.21(b)	Employee qualifications of education, training, experience
§112.22 (b)	Training requirements for harvest employees
	Not trained to recognize and not harvest potentially contaminated produce
§112.22(b)	Not trained to inspect harvest containers
§112.22(c)	Training requirements for supervisors
§112.22	Minimum training content
§112.22(a)	Lack of information on recognizing health symptoms/illness
§112.22(a)	Lack of information on food safety and hygiene
§112.22(b)	Lack of training for specific duties
§112.30	Records
	No topics documented
112.30 (b)	No records for employees and/or contracted employees

PSR

Subpart Summary (Cont'd)

§112.31-112.33	Subpart D Health and Hygiene
§112.31	Applicable Health Conditions
§112.32	Hygienic practices
	Harvest employees not washing hands prior to harvest
	Employees eating in harvest area
	Storage of personal items in contact with produce
	Jewelry
§112.32	Glove use and glove policy
	General lack of workers not following farm policies
§112.33	Visitor policies
§112.41-112.49	Subpart E Ag. Water
§112.41	Ag. Water definition
	Compliance Dates
§112.42	Inspect water systems
§112.43	Treatment
§112.44	Microbial profile
§112.45	Corrective measures
§112.48	Recirculated water quality
§112.51-112.84	Subpart F BSAAO and Human Waste
§112.52	Handling, conveying, storing
§112.54	Application methods
§112.56	Minimizing contact with covered produce after application
§112.60(b)(1)	External treatment records
§112.60(b)(2)	Internal treatment records

PSR

Subpart Summary (Cont'd)

§112.81-112.84	Subpart I Domesticated and wild animals
	Grazing, working animals, animal intrusion
§112.83(b)(1)	Assessment of growing areas
§112.83(b)(2)	Evaluate harvesting
	Adjacent land
§112.111-112.116	Subpart K Growing, Harvesting, Packing, Holding Activities
§112.111	Covered and excluded produce
§112.112	Measures prior to and during harvest
	Observed feces on produce
§112.113	Handling harvested produce
	Placing packing materials on the ground
	Cut surfaces of produce coming into contact with the ground
	Produce coming into contact with the ground
	Produce in contact with non-food contact surfaces
§112.114	Dropped covered produce
	Unclear about definition of DCP
§112.114	Confusion about applicability of 112.114 during and after harvest
	Harvested produce still attached, coming into contact with the ground
	Dropped produce during harvest, picked back up
§112.116(a)	Food-packing (including food packaging) material-Inadequate
	Reusing cardboard containers
§112.116(b)	Food-packing (including food packaging) material-multi-use
	Lack of cleaning for reusable food packing materials
	Storage of harvest bins/bags/baskets
	Harvest containers contacting the ground
	Inadequate cleaning and sanitizing of reusable containers

PSR Subpart Summary (Cont'd)



§112.121-112.140	Subpart L Equipment, Tools, Buildings, and Sanitation
	Definition of food contact surface
	Lack of cleaning and sanitizing step
§112.123	General requirements regarding equipment and tools
§112.123(b)(2)	Equip & tools – storage
	Insanitary storage of knives, gloves, and other food contact surfaces
	Hoses used for covered activities on the floor
	Employees storing food contact items at home
§112.123(d)(1)	Food contact surface sanitary inspection and maintenance
	Sanitizing without a cleaning step
	Lack of cleaning/sanitizing for food contact surfaces (pressure washing w/out detergent, sanitizer wipes without debris removal, etc.)
	season only and storing outside between seasons, observed soil/debris on food
	Calibration
§112.126	Requirements (size, construction, design) for buildings
	Condensate, standing water
§112.128	Pest Control
§112.129	Toilet Facilities
§112.130(c)	Waste from handwashing facilities
	Leaking or nonexistent catch basins for gray water
	No trash can for paper towel or trash can requires hand contact to open
§112.130(b)	Hand-washing facilities supplies
	Lack of drying devices or insanitary storage of drying devices (require handling for use, stored in contact with insanitary surfaces, etc.)
	Lack of soap and/or using sanitizer in place of soap
	Lack of running water
§112.131	Inadequate portable toilet spillage emergency plan
§112.140	Equipment, cleaning, sanitizing records

PSR

Subpart

Summary

(Cont'd)

§112.151-112.153	Subpart N Analytical Methods
§112.151	Methods
	Hold times
	Lab accreditation
	MPN V. CFU
§112.161-112.167	Subpart O Records
§112.161(a)	Records requirements
§112.161	Supervisor review of records
	Missing records
	Inadequate recordkeeping

Questions to research

1. What are the biggest knowledge gaps affecting growers ?

2. Are there domestic versus international differences in knowledge gaps?

3. Are there differences seen in the data set as comparison with On-farm and Off-farm Stakeholder Engagement

4. What are the comments that directly impact public health?

5. Are there common practices leading to repeat comments on multiple farms?

In the Future:

Is commodity specific information important to identify different practices that may be problematic for implementation?

What parts are frequently non-compliant during USDA audits as compared to the FDA requirements for non-compliance?

Does farm size impact comments? Are there regional differences?

Can the knowledge gaps be attributed based on differences audience-types (e.g. growers vs. Regulators vs. Educators)

Is there data to support the question of is there a food safety culture that supports knowledge?

Identification of knowledge gap or what is occurring because of a concern with changing industry practice

Summary of off-farm stakeholder engagement

- The off-farm engagements include 3 data sets
 - FSMA TAN
 - rTAN
 - Informal TAN
- Account for 38% (745/1961) of the comments
- Shift in frequency for these records to
 - Subpart A (49%)
 - Subpart E (15%)
 - Subpart L (9%)



Summary of on-farm stakeholder engagement

- On-farm five data sets, includes 5 data sets
 - International OFRR
 - PSR Inspection Data (International and Domestic)
 - USDA Audit
 - State CAP
- Accounting for 62% (1216/1961) of the comments
- Frequency across Subparts:
 - Subparts L (42%)
 - Subpart O (20%)
 - Subpart C (16%)



Impacts to public health



Qualitative assessment of risk for PSR – focus
on SAHCODH



Quantitative summary of snap shots in time



Specific provisions



Impacts to public health

whole farm - food safety
culture perspective

Egregious conditions and
limitation of data

Data to support repeat compliance issues



Inaugural report for quantitative analysis of knowledge gaps



Data to support the identification of repeat compliance issues



Educational process should be cumulative



Determining a method to link these educational experiences to specifics

Prioritization of knowledge gaps and caveats

- For all data sets, priority subparts are:
 - Subpart L: Equipment, Tools, Buildings, and Sanitation
 - Subpart A: General Provisions
 - Subpart C: Personnel Qualifications and Training
 - Subpart O: Records
- Caveats
 - Data sets analyzed include variety of time periods
 - Data sets included qualitative and/or only quantitative data
 - Data sets are not presented individually nor does this data represent specific state or country information

Next Steps

Share

Share with FDA internal offices

- Identify other data streams
- Identify other questions that would be helpful with the primary focus of identifying educational gaps
- Can these data be beneficial in other ways?



Share

Share with identified external stakeholders

- Identify existing resources & potential for development of new materials addressing gaps in knowledge



Thank you

Contact Information

Rachael Kozolup, M.S.
Consumer Safety Officer
Division of Produce Safety | Fresh Produce Branch

Center for Food Safety and Applied Nutrition
Office of Food Safety
U.S. Food and Drug Administration
Tel: 240.402.2188
Rachael.Kozolup@fda.hhs.gov

Diane Ducharme, Ph.D.
Produce Safety Expert
Produce Safety Network | Southern Region
Division of Produce Safety | Fresh Produce Branch

Center for Food Safety and Applied Nutrition
Office of Food Safety
U.S. Food and Drug Administration
Tel: 301.796.7083 Mobile: 240.535.7543
Diane.Ducharme@fda.hhs.gov