

Viruses in Foods: Developments over the last year

Food Safety Summit, 2024
May 8, 2024

Lee-Ann Jaykus, Ph.D.

William Neal Reynolds Distinguished Professor Emeritus
North Carolina State University

Healthy People 2030: Workgroup Overview

Department of Health and
Human Services

Healthy People 2023

Healthy People 2030
Foodborne Illness Reduction

Norovirus at Retail

GOAL

Increase the implementation of effective employee health policies and practices within the retail food industry.

OUTCOME

Reduction in norovirus outbreaks in retail settings

PARTNERING

FDA/CDC MOU, New Era for Smarter Food Safety, Retail Regulatory Association Collaborative, CFP Food Safety Management Systems, CFP Food Safety Culture Committee group members from regulatory, industry, federal government, academia, and associations

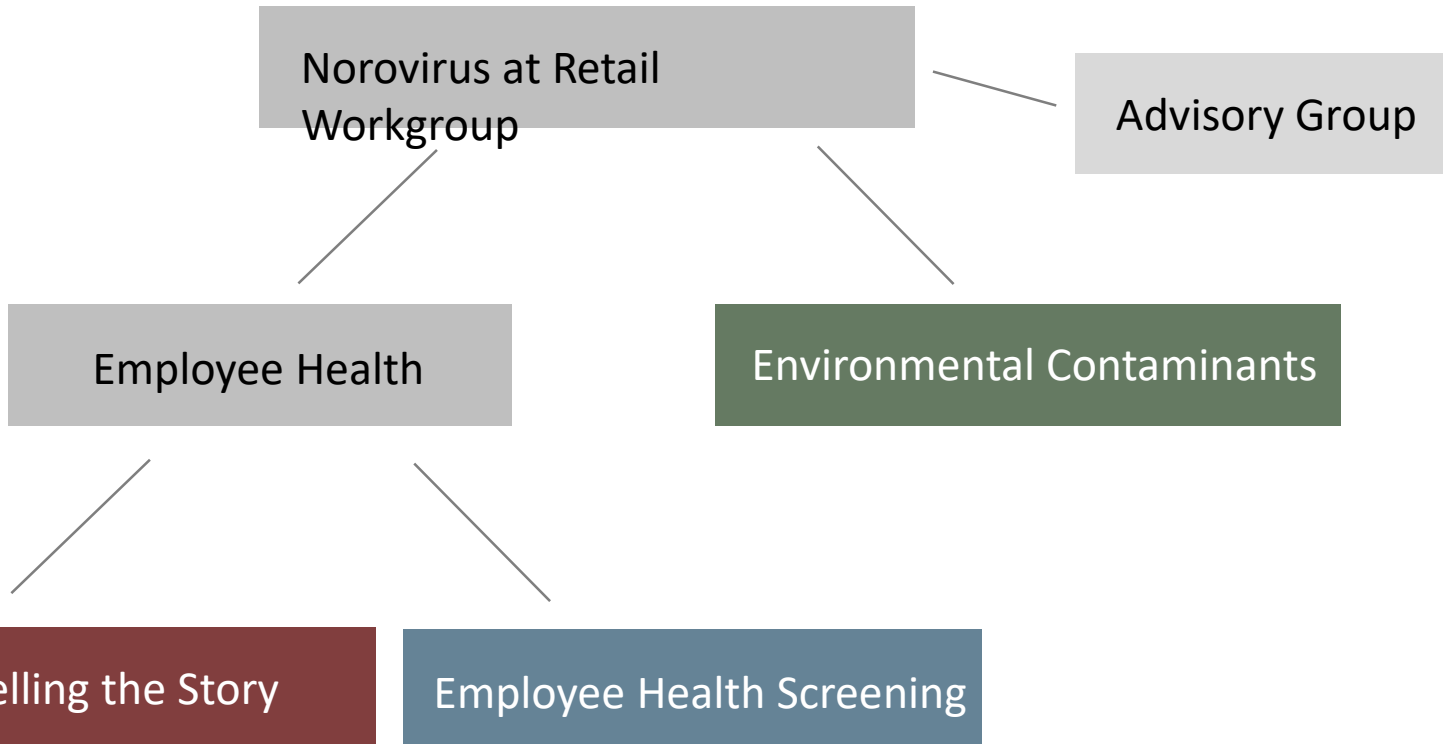
The Vision

turning research into action



Subcommittees

ORGANIZATION



CREATION

Last in-person meeting showed the need for 3 goals for the group to focus on. This was to narrow the scope of the work to have a significant impact.

Telling the Story



CHARGE

Inform and assess the development of employee health communication tools, that target industry and regulators, for the AFDO Norovirus Resource Center



ACCOMPLISHMENTS/GOALS

- Created spreadsheet with available employee health tools and
 - Hosted discussion groups to understand resources needs
 - Complete resource gap analysis
 - Organize resources to keep on AFDO website

Employee Health Screening



CHARGE

Inform and assess the development of employee health screening tools targeting industry and regulators to exclude sick workers through engagement of various food safety stakeholders



ACCOMPLISHMENTS/GOALS

- Gathered employee health screening tools
- Understand what industry is using (screening vs. reporting)
 - Gather more information from industry
- Review interactive FDA/CDC norovirus tool

Environmental Contaminants



CHARGE

Identify and apply achievable, effective tools to aid in the fight against norovirus spread



ACCOMPLISHMENTS/GOALS

- Hosted webinar on disinfection efficacy
- Identify existing environmental contamination tools/resources
- Survey to identify critical knowledge and research gaps
- Collaborate with EPA on sanitizer/ disinfectant labeling

International Food Safety Guidelines

- Codex Alimentarius: International body that produces uniform international food standards, guidelines and codes of practice that contribute to the safety, quality and fairness of international food trade
 - Protecting consumer health
 - Removing barriers to fair trade
- CCFH—Codex Committee on Food Hygiene
- Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment (JEMRA)
- Initial consultation in 2007

GUIDELINES ON THE APPLICATION OF GENERAL PRINCIPLES OF FOOD HYGIENE TO THE CONTROL OF VIRUSES IN FOOD

CAC/GL 79-2012

- The primary purpose of these guidelines is to provide direction on how to prevent or minimize the presence of human enteric viruses in foods, more specifically, Hepatitis A Virus and Norovirus. This guideline is applicable to all foods, with a focus on ready-to-eat food, from primary production through to consumption, for the control of human enteric viruses. It also contains an annex on the Control of Hepatitis A Virus (HAV) and Norovirus (NoV) in Bivalve Molluscs (Annex I) and an annex on the Control of Hepatitis A Virus (HAV) and Norovirus (NoV) in Fresh Produce (Annex II)

2023-2024 JEMRA Expert Consultation

Scientific advice to inform the review of the guidelines focusing on:

1. An up-to-date review of the foodborne viruses and relevant food commodities of highest public health concern;
2. A review of the scientific evidence on prevention and intervention measures and the efficacy of interventions in the food continuum;
3. A review of the analytical methods for relevant enteric viruses in food commodities;
4. A review of scientific evidence on the potential utility of viral indicators or other indicators of contamination; and
5. A review of the various risk assessment models with a view towards constructing more applicable models for wide use among member countries, including a simplified risk calculator

Expert Consultation #1, Sept. 18-22, 2023

Question #1, Public health burden: Expert elicitation/risk ranking

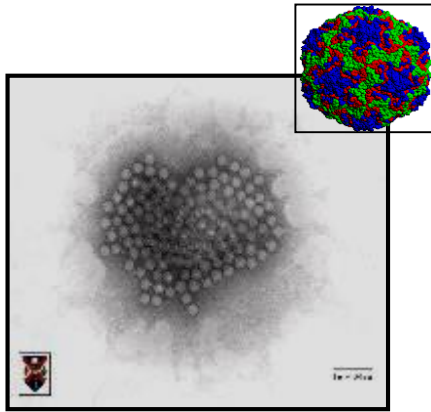
Human norovirus was identified as the leading cause of viral foodborne illness, followed by hepatitis A and hepatitis E viruses. Hepatitis A virus and hepatitis E virus were ranked equally but higher compared to norovirus in terms of clinical severity. When considering both frequency and severity, the ranking for these viruses fell into three groups as follows:

1. norovirus
2. hepatitis A virus and hepatitis E virus ranked in order
3. rotavirus, sapovirus, enterovirus, astrovirus, and enteric adenovirus ranked in order.

The Expert Committee considered commodities from a global perspective, and identified the virus-commodity pairs of highest global public health burden associated with specific viruses:

Norovirus	Hepatitis A virus	Hepatitis E virus
1. Prepared food	1. Shellfish*	1. Pork
2. Frozen berries*	1. Frozen berries*	2. Wild game
2. Shellfish*	1. Prepared foods*	

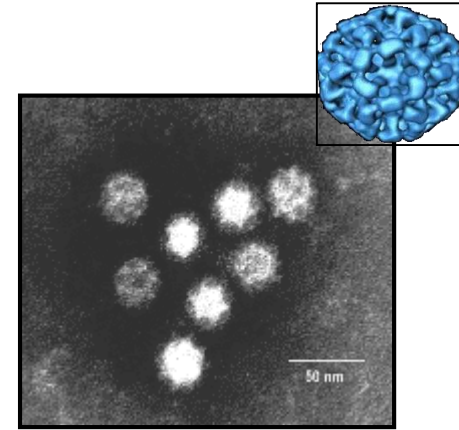
Enteric viruses of Epidemiological Significance



Hepatitis A virus

-Picornaviridae

- Usually self-limiting hepatitis syndrome
- Most severe of the foodborne viral diseases

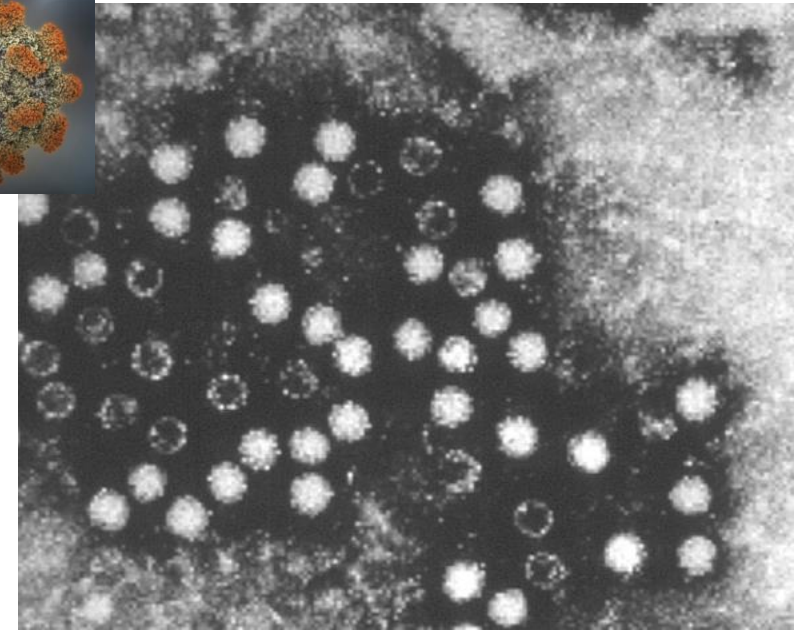
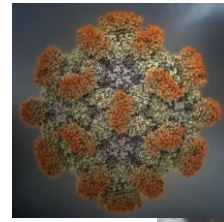


Noroviruses

Caliciviridae

- Self-limiting vomiting and diarrhea in adults
- Leading cause of viral foodborne disease

Hepatitis E virus (HEV)



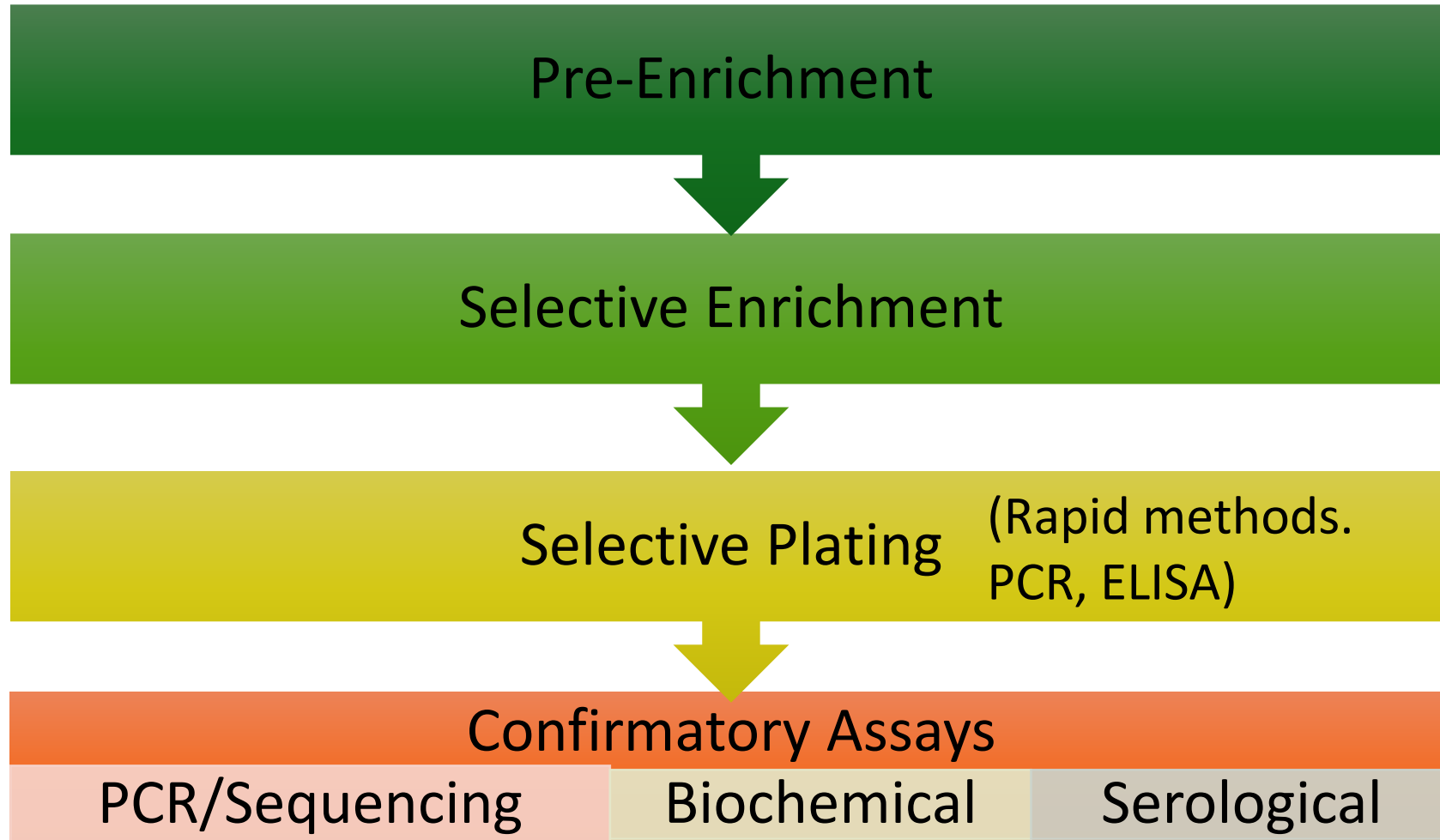
- Zoonotic with asymptomatic animal reservoirs
 - Swine
 - Game animals
- Emerging and under-reported, under-studied
- Causes acute hepatitis in immunocompromised, often with severe chronic sequelae, liver or neurological
- Undercooked pig products, esp. raw or undercooked products containing liver or blood of greatest concern

Expert Consultation #1, Sept. 18-22, 2023

Questions #3 and 4, Analytical methods and indicators

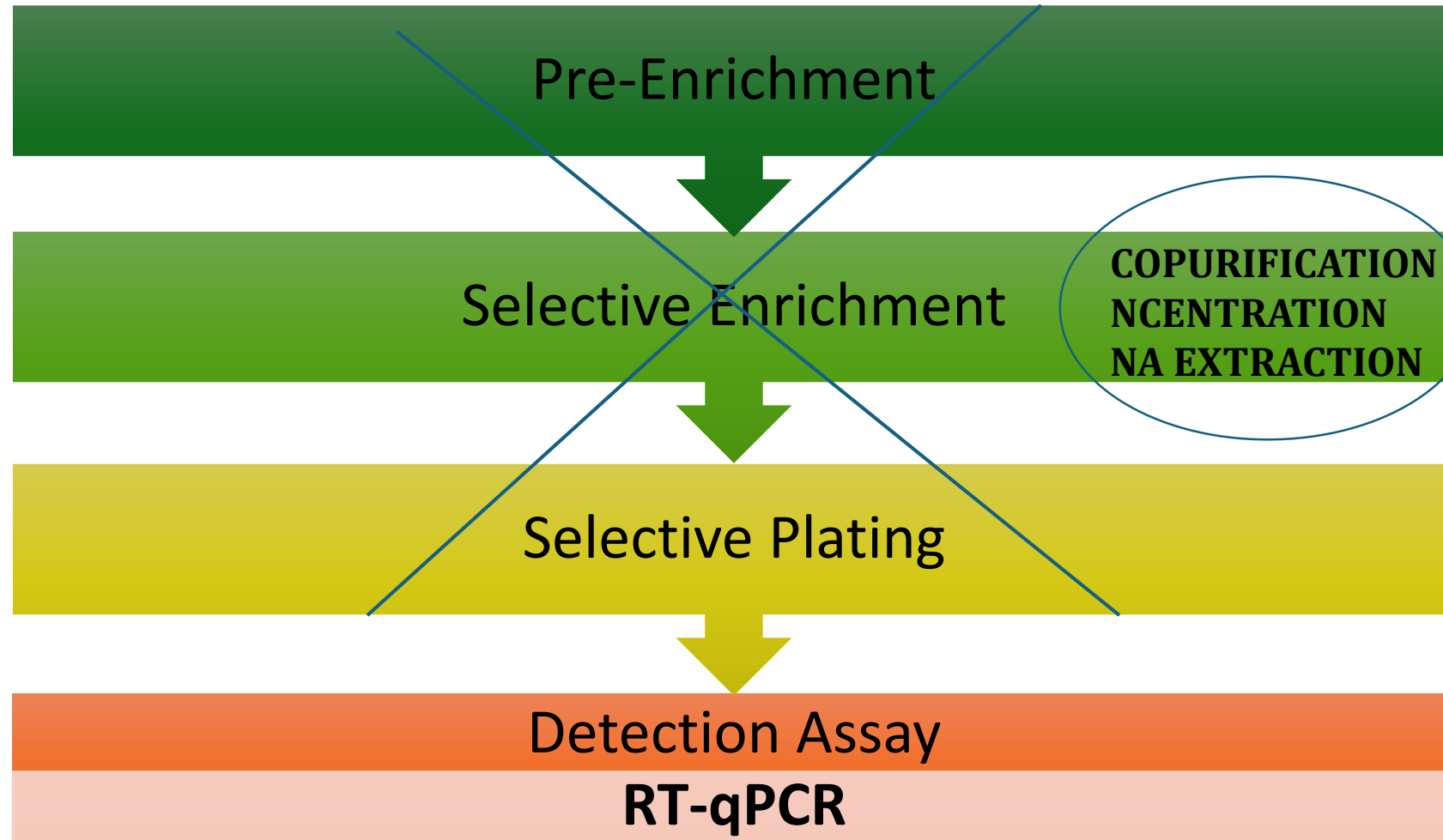
- Progress made in establishment of validated international standard method (ISO 15216)
- Commodities covered
 - Molluscan shellfish
 - Soft fruits
 - NOT RTE foods
- FDA BAM (Bacteriological Analytical Manual, Chapter 26) by U.S., similar commodities covered
- Commercial labs offering testing use the ISO, a few also offer the FDA
- Several indicators for viral contamination have been investigated, but none have sufficient data for current recommended use.

Culture-Based Detection of Bacterial Pathogens in Foods—GOLD STANDARD



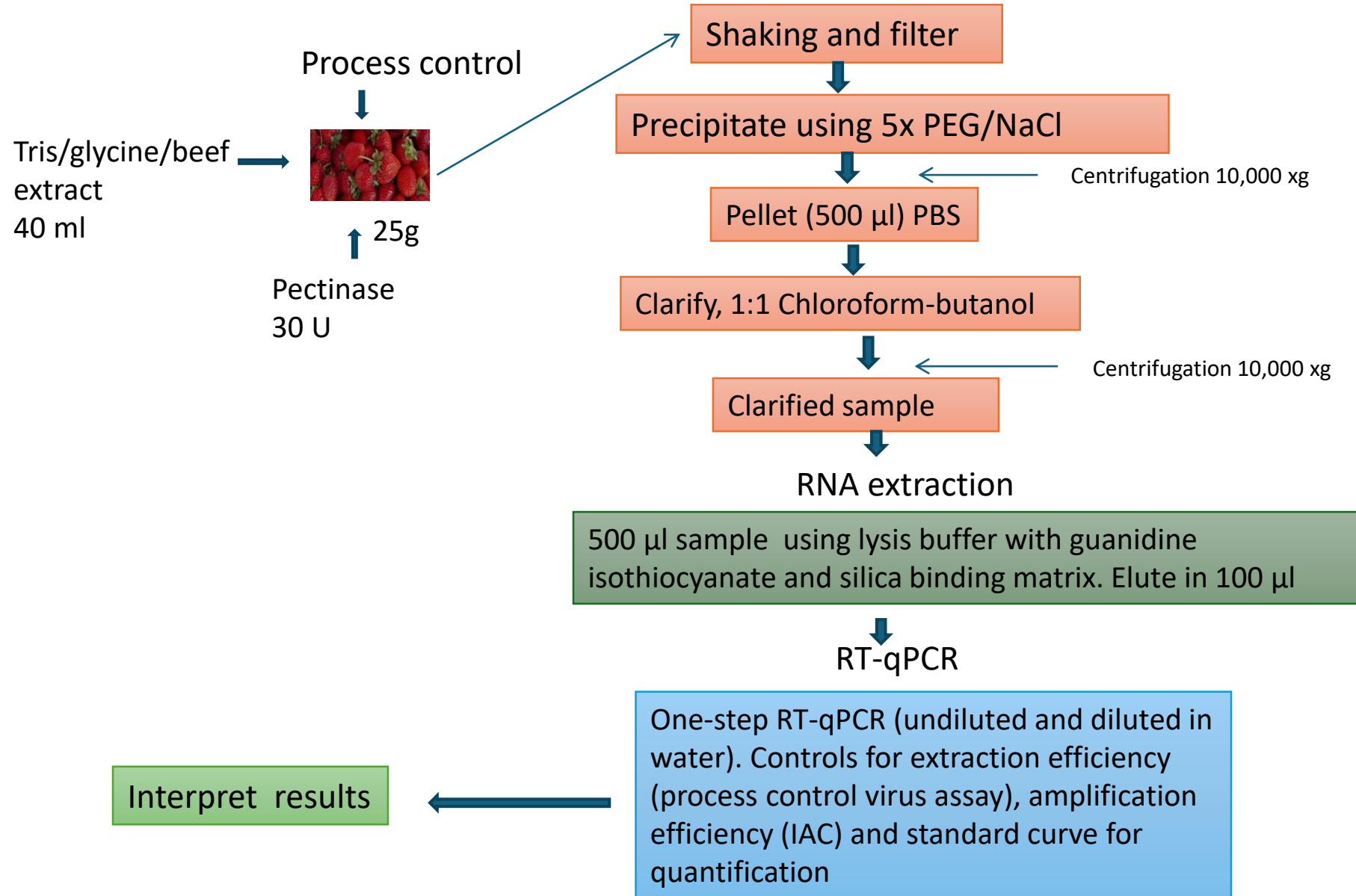
IN THE END,
THERE IS A
VIABLE
CULTURE
AVAILABLE

Culture-Based Detection of Bacterial Pathogens in Foods—GOLD STANDARD



IN THE END,
THERE IS NO
CULTURE
AVAILABLE;
ONLY A SMALL
PIECE OF
NUCLEIC ACID

Virus extraction and detection from berries, ISO method



Complexities of Virus Testing Methods

- Must concentrate and purify viruses from berries before detection
 - Complicated, expensive, time consuming, takes highly trained personnel
 - Not efficient (virus loss and residual matrix)
- **Limitations to detection method (RT-qPCR)**
 - Matrix-associated inhibition and non-specific amplification
 - Potential for cross-contamination
 - **Interpretation issues, i.e., what constitutes a “positive” test for the presence of virus**
 - Methods of confirmation
- **The “infectivity dilemma”**
- **Relationship between detection of viral RNA and risk**

Expert Consultation #1, Feb 12-16, 2024

- Question #2, Prevention and Intervention measures
- Based on Meeting #1, deliberations focused on virus-commodity pairs ranked as greatest of public health concern:
 - Human norovirus (hNoV)
 - Prepared foods (1)
 - Frozen berries and molluscan shellfish (2)
 - Hepatitis A virus (HAV)
 - Molluscan shellfish, frozen berries, prepared foods (1)
 - Hepatitis E virus (HEV)
 - Pork (1)
 - Wild game (2)

Prevention and Intervention Strategies

- Prevention is the primary focus
- Inactivation strategies secondary
- By contamination route:
 - (A) Human fecal contamination of waters (hNoV and HAV)
 - (B) Poor personal hygiene practices of food handlers (hNoV and HAV)
 - (C) Zoonotic spread (HEV)
- By commodity
 - Molluscan shellfish (A)
 - Prepared foods (B)
 - Frozen berries (A) and (B)
 - Pork and wild game (C)

Molluscan Shellfish

- Prevention
 - Sanitary surveys
 - Male-specific coliphages as indicators
 - More effective tertiary wastewater treatment (infrastructure?)
 - Climate change impacts
- Inactivation
 - Discard or divert contaminated product to processing
 - Depuration (not completely effective)
 - Relaying (21+ days)
 - Heat, HPP; as long a process is validated, organoleptic changes?
 - Emerging processes remain experimental

Prepared and RTE Foods

- Prevention
 - Focus on managing infected or potentially infected food handlers (GHPs)
 - Exclusion
 - Gloving
 - Restroom facilities and use
 - Handwashing
 - Surface disinfection
 - Vomiting and fecal clean-up guidelines
- Inactivation
 - Much left to be done
 - Compliance
 - Efficacy of surface sanitizers
 - Duration of Shedding
 - Use of hand sanitizers?

Frozen (and Fresh) Berries

- Prevention

- Pre-Harvest: GAPs, focus on source water and (irrigation and pesticide) and not permitting use of sewage sludge

- Emerging treatments for water (e.g., ozone, photocatalysis, UV, ultrafiltration); Biochar filtration for reused water

- Harvest: GHPs for pickers

- Processing: GMPs, focus on hygienic practices for workers

- Inactivation

- Discard or divert contaminated product to processing

- Heat: Jams/jellies, effective; juice pasteurization needs validation

- Produce washes, less effective

- Emerging processes remain experimental

Pork and Wild Game

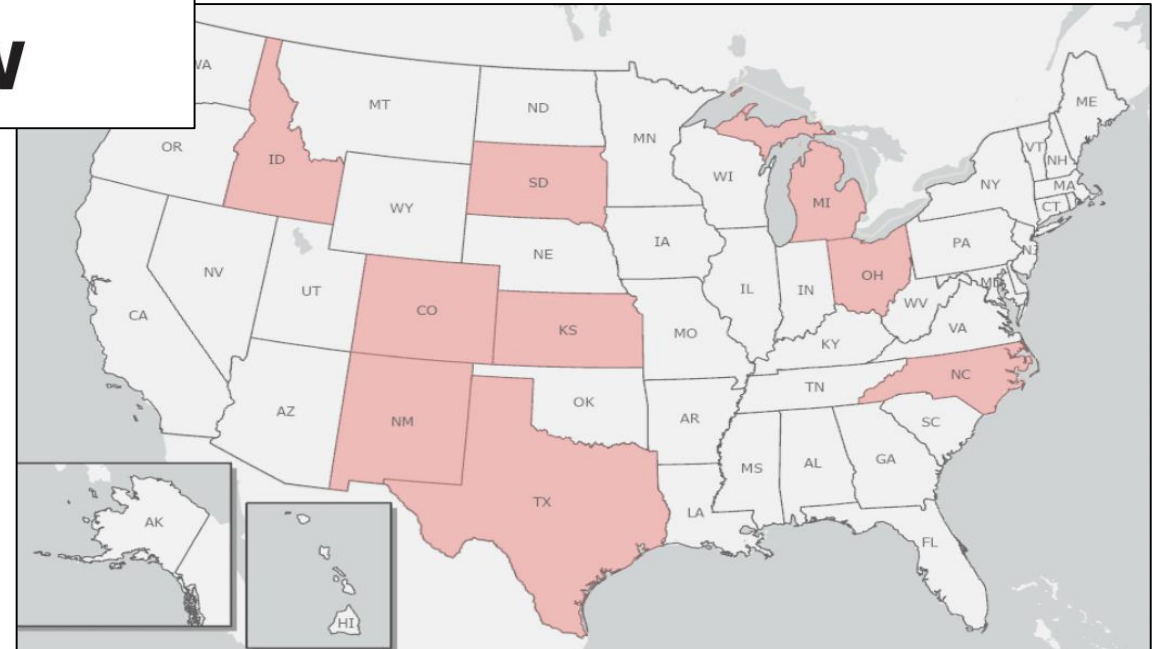
- Prevention
 - Pre-harvest: Prevention of animal infection (i.e., biosecurity measures that include avoiding contact or use of with untreated manures and run-off from farms); surface disinfection
 - Processing: Avoiding use of high-risk tissues in product formulations
- Inactivation
 - Virus highly resistant to heat

HEALTHWATCH

Pasteurization working to kill bird flu in milk and other dairy products, FDA tests find

Eating Beef and Chicken During the Bird Flu Outbreak: What to Know

FDA Finds Bird Flu Traces in a Fifth of Retail Milk Samples. What to Know.



What Does the Science Say

- The virus
- The animals
- The products
- The human cases
- The transmission route
- A role for testing
- The unknowns



Risks Associated with Enteric Viruses in Soft Fruits

Scientific Issues and Policy Implications

Sanjay Gummalla and Lee-Ann Jaykus

May 8, 2024

Food Safety Summit Conference and Expo



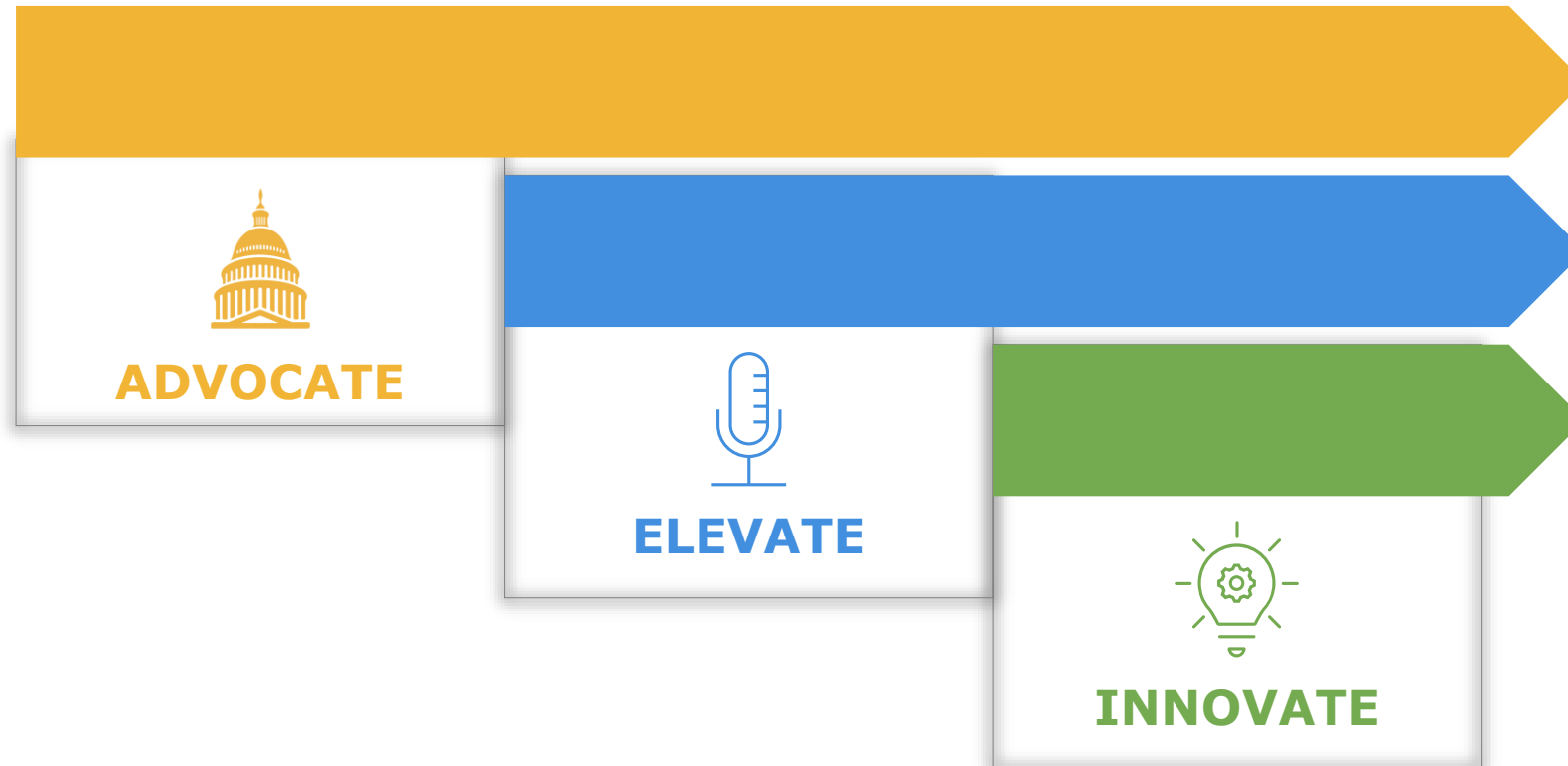
AFFI Strategic Plan

Vision

Frozen foods are essential in a dynamic marketplace.

Mission

AFFI advances the interest of all segments of the frozen food and beverage industry.



Vision: Frozen foods are essential in a dynamic marketplace





Discussion – Human Enteric Viruses in Soft Fruit

- 1) Summary – what we understand from current knowledge about enteric viruses, prevalence, detection, and consumer risk
- 2) The global (frozen) berry supply chain – contamination, mitigation, risk flow
- 3) Surveillance and prevalence studies
- 4) U.S. surveillance and recent outbreaks/recalls
- 5) Requirements industry is being asked to meet from within and from the regulatory community – industry and policy implications
- 6) AFFI's research and supply chain risk management program



What We Understand About Enteric Viruses - Summary

- 1) Hepatitis A and Norovirus are non-cultivable pathogens
- 2) Prevalence, distribution, and level in soft fruits impact sample size and sampling plans
- 3) Current detection assays **cannot**:
 - confirm presence of an intact or complete virus,
 - determine infectious potential,
 - establish public health risk,They are also
 - Lacking standard criteria – for interpretation of results
 - expensive and not without limitations
 - limitations – adequacy, utility, and value
- 4) Persistence in frozen berries through shelf-life – a real problem
- 5) Sampling and testing schemes, and regulatory policies – varied across the world

GLOBAL Frozen Berry Supply Chain

- 1. Distribution in a contaminated lot
- 2. Prevalence in a contaminated lot
- 3. Concentration in a contaminated lot

Overall Prevalence in frozen berries based on literature (0.5%; 1%; 3%)

Contamination Scenarios

- raw sewage used to irrigate on small farm
- infected child defecates on product
- infected workers
- irrigation or wash water may contaminate product
- vomiting incident in IQF facility

FARM Fresh berries intended for freezing

DOMESTIC Supply

- irrigation or wash water may contaminate product
- vomiting incident in IQF facility

FOREIGN Supply

- raw sewage used to irrigate on small farm
- infected child defecates on product
- infected workers

IQF Processor (domestic) receives fresh berries

Cooler Storage (1-2 days)

- Farm D
- Farm E
- Farm F

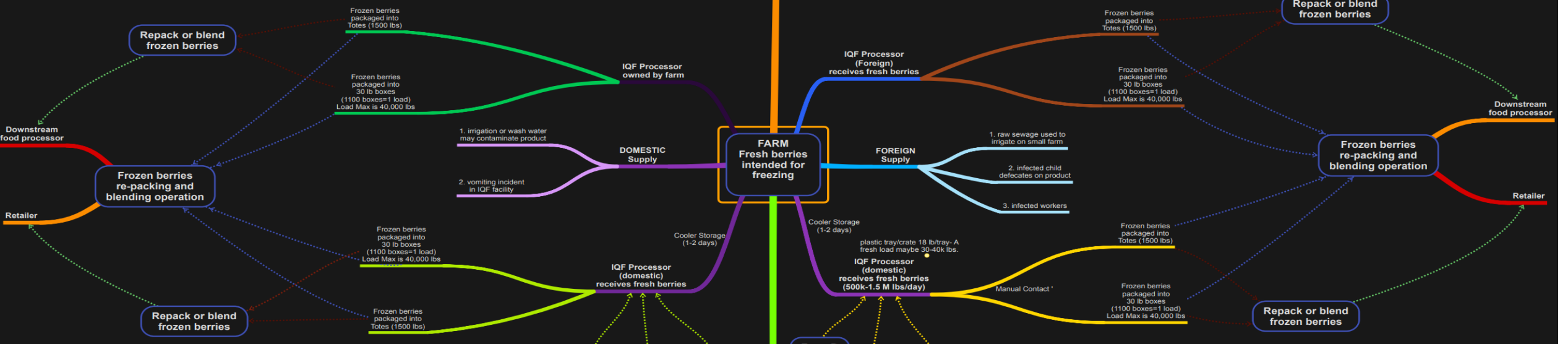
IQF Processor (foreign) receives fresh berries

Cooler Storage (1-2 days)

- Farm A
- Farm B
- Farm C

Harvesting and Processing Considerations

- Manual or Mechanical Harvesting
- Drip irrigation vs other high risk methods
- Water application - risks of direct on fruits
- Berries washed or Not
- Open Source but covered source of water vs well water vs river or creek



Note: Consider blending of frozen fruits from multiple farms!

GLOBAL Frozen Berry Supply Chain

IQF Processor (Foreign) receives fresh berries

Few to 100s of farms supplying to IQF Processing Facility

FOREIGN Supply

- 1. raw sewage used to irrigate on small farm
- 2. infected child defecates on product
- 3. infected workers

Frozen berries packaged into Totes (1500 lbs)

Frozen berries packaged into 30 lb boxes (1100 boxes=1 load) Load Max is 40,000 lbs

Repack or blend frozen berries

Repacking/blending of frozen berries

Comingling of berries – IQF processing

Frozen berries re-packing and blending operation

Downstream food processor

Retailer

er Storage

Global Frozen Berry Supply Chain



In many berry growing regions across the world, EV is endemic to the population.



Importers, brokers and others are not always held to the same standards as packers/processors.



Having international supply chains with limited oversight ability can compound food safety risks.



Audits help inform companies about potential operational food safety risks (not specific to EV) at one point in time and not real-time risk.



Produce margins are low – leaving little room for additional food safety investments/expenses.



FDA has already adopted greater EV surveillance.

Global Frozen Berry Supply Chain



Sourcing from large numbers of small growers to fulfill frozen orders presents traceability challenges and supply chain risks



Testing water, workers and products is costly and has limitations.



Absent a seek and destroy ability, companies are at a loss as to handle EV contamination.



Most companies do not have the combined scientific and technical knowhow to develop inhouse EV solutions.

CFIA – Surveillance Study (2014-2016)

Table 2 Assessment Results of Fresh and Frozen Berries and Frozen Fruit

Product Type	Total Number of Samples	Assessment Results			
		Satisfactory Assessment	Investigative Assessment		
			HAV	NoV(GI)	NoV(GII)
Fresh berries	930	926	0	0	4 (Blackberry, Blueberry (2), Strawberry)
Frozen berries	656	654	0	0	2 (Blueberry, Strawberry)
Frozen fruits	405	404	0	0	1 (Peach)
Total (%)	1991	1984 (99.6%)	0	0	7 (0.4%)

CFIA - Viruses in Fresh Berries and Frozen Fruits April 1, 2014 – March 31, 2016 (final report)

CFIA – Surveillance Study (2016-2022)

	No. of Samples Tested	NoV GI Positives (%)	NoV GII Positives (%)	HAV Positives (%)
Fresh Berries	926	1 (0.11%)	1 (0.11%)	0
Frozen Berries and Pomegranate Arils	3292	3 (0.09%)	10 (0.3%)	0

Steele et al., Intl J. Food Microbiol. 2022. <https://doi.org/10.1016/j.ijfoodmicro.2022.109840>

FDA Surveillance Assignment – Frozen Berries

Enteric Virus Findings in Frozen Raspberries, Strawberries, and Blackberries

	Total	Hepatitis A (HAV)			Norovirus (NoV)		
		Negative	RT-qPCR Positive	Sequenced	Negative	RT-qPCR Positive	Sequenced
Domestic	527	524	3	2	521	4 (2)	3
Imported	995	989	6	5	988	7	4
Total	1522	1513	9	7	1509	11 (2)	7

[US FDA Frozen Berries Surveillance Assignment](#)
(as of July 2023)

U.S. Surveillance and Related Recalls

- 20 positive RT-qPCR findings (14 sequenced)
- All had a Ct > 40; only 1 of 9 replicates positive in all cases (except 2)

In the event that samples are found to be positive for microbial hazards, the FDA will consider regulatory and enforcement options. Enforcement activities include actions to correct and prevent violations, and to remove violative food from the market. The agency will detail any enforcement

Do RT-qPCR and sequencing results deem a sample, positive for the presence of the hazard?

U.S. Surveillance and Related Recalls

Winco Foods, LLC. Recalls Frozen Red Raspberries Because of Possible Health Risk

Kroger Recalls Select Frozen Private Selection Berries for Possible Health Risk

Townsend Farms, Inc., Notifies Costco of Possible Health Risk and Recalls Conventional Frozen Kirkland Three Berry Blend

Cornerstone Premium Foods Voluntarily Recalls Frozen Blackberries Due to Possible Health Risk of Norovirus

Wawona Frozen Food Voluntarily Recalls Frozen Raspberries Due to Possible Health Risk

Alma Pak Voluntarily Recalls Frozen Blackberries Due to Possible Health Risk of Norovirus

Cornerstone Premium Foods Voluntarily Recalls Frozen Blackberries Due to Possible Health Risk of Norovirus

Exportadora Copramar Recalls James Farms Frozen Raspberries Due to Possible Health Risk

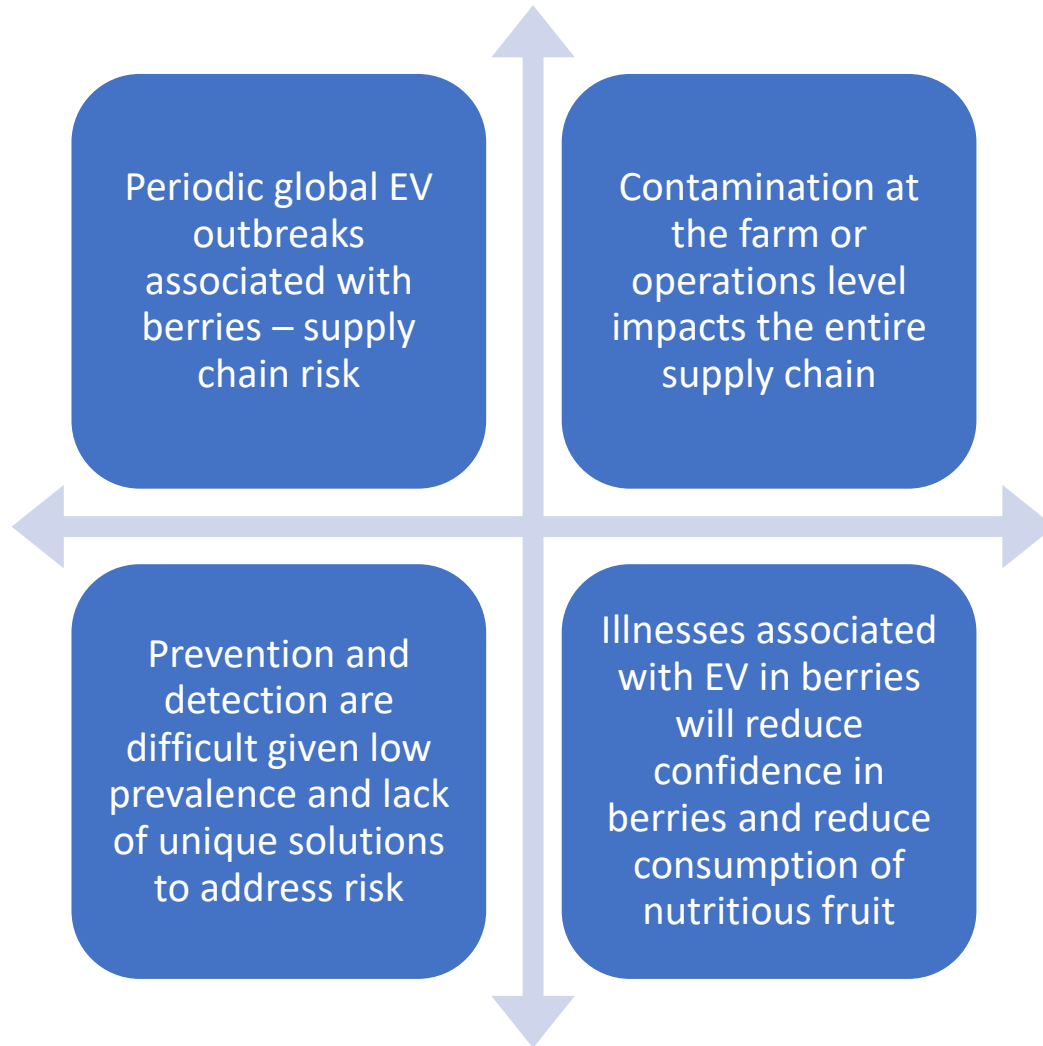
- More than 15 recalls – due to positive nucleic acid findings
- No known epidemiological links
- New regulatory precedents
- First time domestic U.S. harvested berries were implicated – adulterated
- Finding impacted multiple companies, multiple times



Scientific Issues and Policy Implications

- 1) Is presence of genetic material indication of fecal contamination?
- 2) Is presence of genetic material indication of public health risk?
- 3) What is a scientifically sound compliance policy – where intact virus or infectious virus cannot not be determined?

Global Frozen Berry Supply Chain



- In many growing regions across the world, enteric viruses are endemic
- International supply chain compounds food safety risks
- Testing berries has limitations; no protocols for testing water/workers

Two Recent U.S. Outbreaks – Hepatitis A virus

Date Posted	Reference #	Pathogen or Cause of Illness	Product(s) Linked to Illnesses (if any)	Total Case Count	Investigation Status	Outbreak/Event Status	Recall Initiated	Traceback Initiated	On-Site Inspection Initiated	Sample Collection & Analysis Initiated
6/1/2022	1066	Hepatitis A Virus	Strawberries	See Outbreak Advisory	Active	Ongoing See Outbreak Advisory		✓		

Outbreak Investigation of Hepatitis A Virus: Strawberries (May 2022)

FDA's investigation is complete; CDC declares outbreak over.

Public Health Notice: Outbreak of hepatitis A infections linked to imported fresh organic strawberries

10 illnesses in Canada and 18 illnesses in the U.S.

3/1/2023	1143	Hepatitis A Virus	Frozen Strawberries	See Advisory	Active	Ongoing See Advisory	See Advisory	✓	✓	✓
----------	------	-----------------------------------	---------------------	------------------------------	--------	---	------------------------------	---	---	---

Outbreak Investigation of Hepatitis A Virus Infections: Frozen Strawberries (February 2023)

Additional recalls for products sold at Walmart, Costco, and HEB. Do not eat recalled Frozen Strawberries. FDA's investigation is ongoing.

9 illnesses in the U.S.



What We Know About the 2022 and 2023 Outbreaks

Based on epidemiological data collected by CDC, 9/9 (100%) people who provided information about what they ate before becoming ill reported eating frozen organic strawberries.


FDA's traceback investigation identified a common supplier of the frozen organic strawberries. Strawberries used by this supplier were imported from certain farms located in Baja California, Mexico, in 2022.

Additionally, the strain of hepatitis A virus causing illnesses in 2023 is genetically identical to the strain that caused the outbreak of hepatitis A virus infections in 2022, which was linked to fresh organic strawberries imported from Baja California, Mexico, and sold at various retailers.

<https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-hepatitis-virus-infections-frozen-strawberries-february-2023>)

- 1) No root cause analysis, source of contamination, or potential corrective action**
- 2) No virus was detected in product**

Cascade of Regulatory Testing – Expanded Globally

 Fox News
<https://www.foxnews.com/health/strawberry-recall-...>

Strawberries recalled due to hepatitis A outbreak across Taiwan blueberries also tainted with hepatitis A

 rti.org.tw
<https://en.rti.org.tw/news/view>

Taiwan to halt imports of strawberries - News

 CBS News
<https://www.cbsnews.com/MoneyWatch>
FDA expands frozen strawberries recall over possible hepatitis A risk

The New York Times

Frozen Strawberries Recalled Over Hepatitis A Risk

<https://www.taiwannews.com.tw/news>
Taiwan strawberries from Mexico test positive for hepatitis A. FDA to expand testing of Costco Taiwan frozen berry inspections until it is confirmed safe.



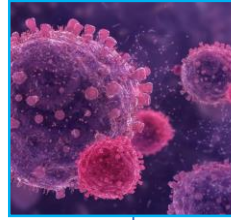
Research and Risk Management Needs

- Standardize international methods, or equivalency between ISO/FDA
- Infectivity assays
- Persistence of RNA in the environment – potential for detection
- Cultivation research
- RCA – If we are going to find a positive, we need to do something about it!
- Risk assessment work – contamination scenarios
- Infectivity dilemma

**These data need to be taken in to account
so we need to prioritize the research**

**Regulatory or industry disposition does not need to be based on the
supposition that the finding of a single nucleic acid copy is a public health risk**

Frozen Berry Supply Chain – Enteric Viruses



Supply Chain Resilience

Scientific outreach across stakeholders – testing practices

USDA research grant (proxy infectivity assays)

Collaborate with CPS research committee to emphasize research needs

AOAC – Advisory committee on methods

EV International Expert Panel

Filling Gaps in Research

Thermal inactivation of enteric viruses (a. Literature review; b. Research)

Chemical inactivation (a. Literature review; b. Research)

Non-thermal inactivation –validation of novel technologies applying multi-hurdle techniques

Prevention and Control

EvIEWS

AFFI – IDS Risk management tool

Real-time dynamic supply chain model

Completed pilot program with industry

Partnerships for implementation

Build and expand globally

Finished Product Testing and Risk Management

FSN | **Food Safety News**
Breaking news for everyone's consumption

Home | Outbreaks | Recalls | Directory | Events | About Us | Media Kit | Contact Us



Is mandatory testing the best approach for managing hepatitis A in berries?

By Guest Contributor on July 12, 2023

FoodSafety
magazine

Are 'Standard' Methods to Detect Non-Cultivable Pathogens in Food and the Environment Fit For Purpose?

Food system stakeholders face inherent challenges in managing non-cultivable foodborne pathogens

By Lee-Ann Jaykus, Ph.D., Jennifer McEntire, Ph.D., Donald W. Schaffner, Ph.D., Sanjay Gummalla, Ph.D.





Managing Risk

Routine Testing

- Reactive
- More likely to detect only high prevalence and high load scenarios
- Cannot determine reason for a positive
- Difficult to take corrective action

Risk Management

- Proactive
- More likely to identify opportunities for low prevalence events
- Evaluates behaviors, situations
- Aim to avoid needing to take corrective action
 - Testing may play a role



EViews: AFFI – IDS Risk Management Tool

Concept

- Software tool: online, real-time, predictive modeling
- Supply chain risk: NOT a risk assessment as defined by risk assessors; enteric-virus specific
- Data collection and analysis: dynamic across the supply chain intended to serve as an early warning system
- Pilot implementation: tested with >60 supply chain nodes

Prevention and Control

- Focus resources toward areas of greatest risk
- Proactive approach to food safety
- Gain supply chain insights
- Implement targeted risk mitigation measures



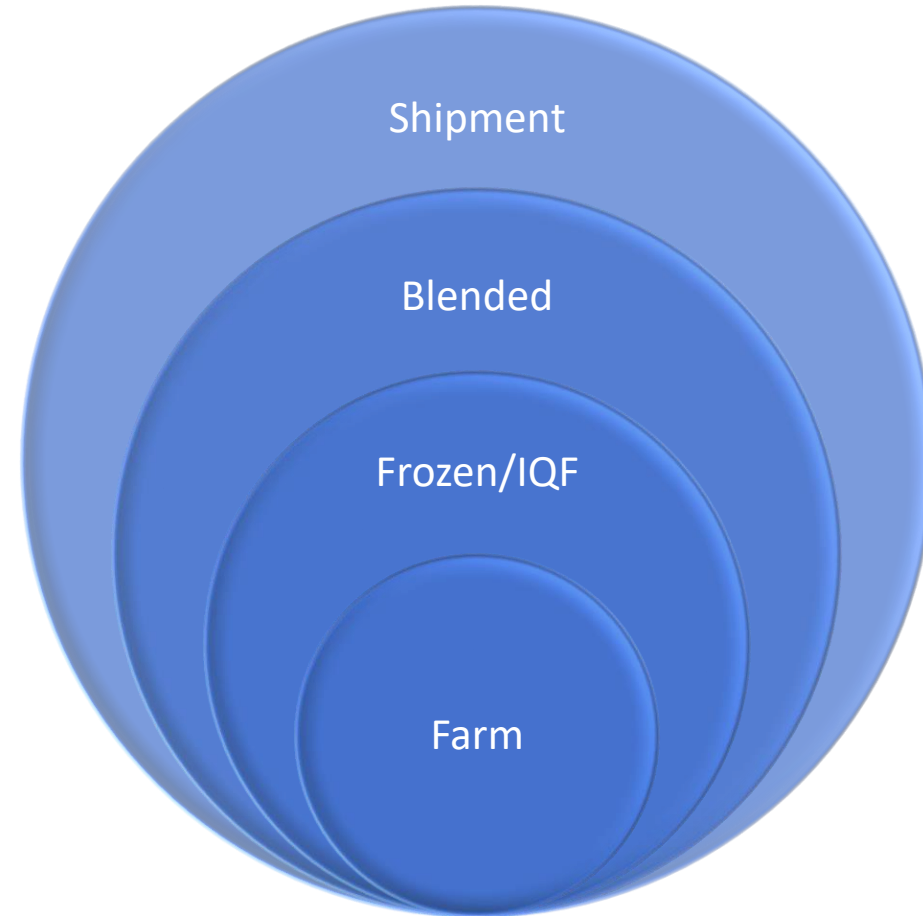
NOT



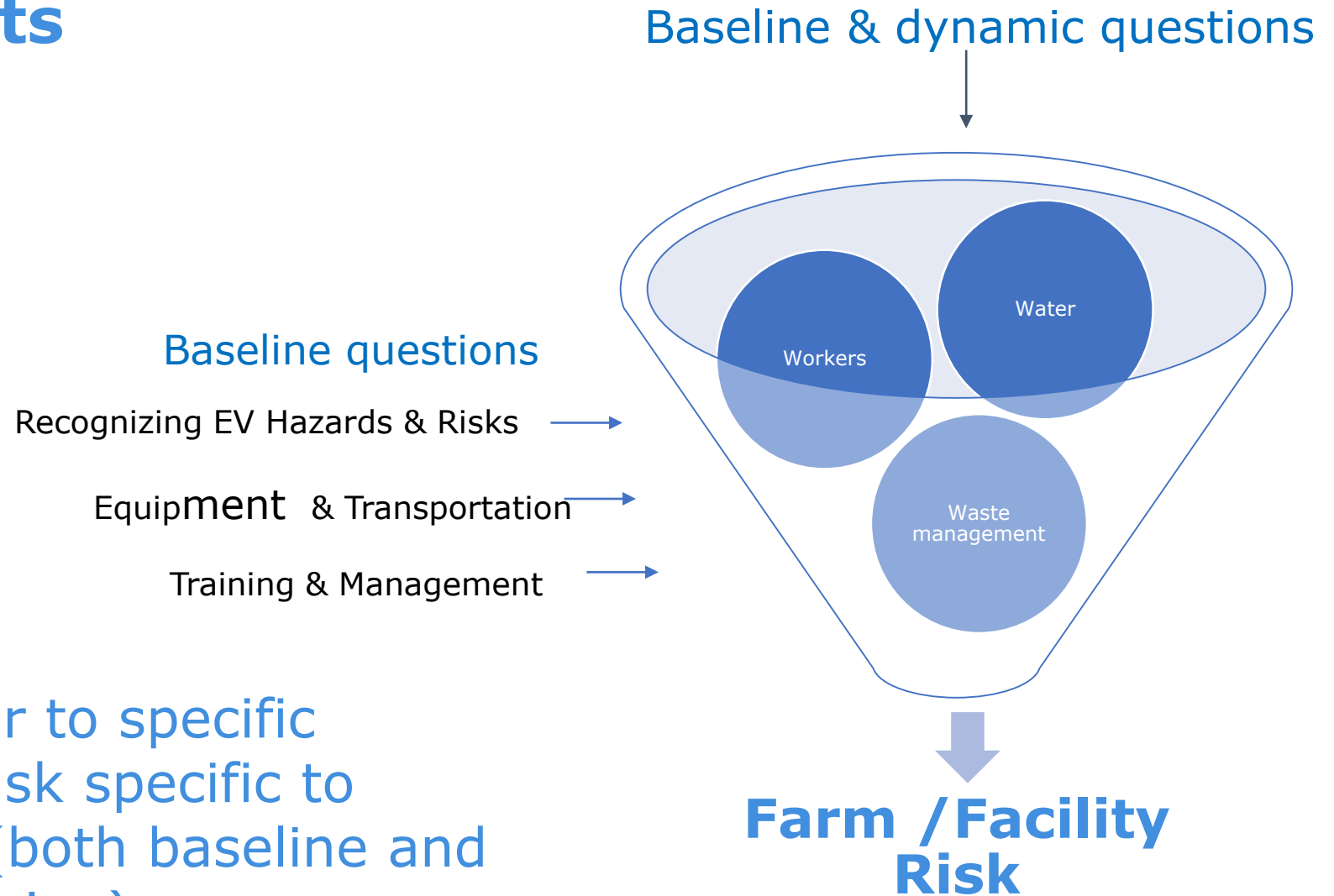
Scope

Ability to drill down to see risk at all levels in the supply chain

- Actionable data starts at each operation
- External data supplements operation data
- Data is then connected across operations in the supply chain

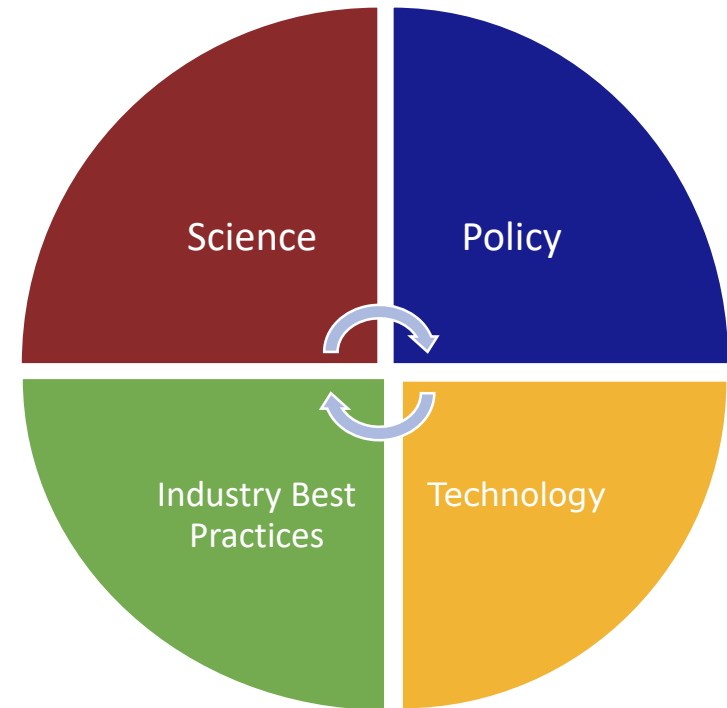


Key Components



Drill down further to specific contributors to risk specific to enteric viruses (both baseline and real-time monitoring)

AFFI Enteric Virus Prevention and Control Resources



- <https://affi.org/safety/>
- <https://affi.org/safety/enteric-viruses-control-program/>

FoodSafety Consortium

Presented by *AFFI* & Food Safety Tech

- The American Frozen Food Institute (AFFI) and Food Safety Tech proudly announce their partnership on the 13th Annual Food Safety Consortium
- The event is an invaluable opportunity to engage with leading experts, exchange insights and collectively advance best practices in food safety
- AFFI members receive discounted pricing on event registration and pre-event workshops. Contact info@affi.com for the discount code.

October 20-22, 2024
Crystal Gateway Marriott
Arlington, VA

Learn more and register at <https://foodsafetyconsortium.org/>



Questions

