ALSTON & BIRD

"Environmental Challenges and Impacts on Product Safety"

Sam Jockel – Alston & Bird

2022 FOOD AND DIETARY SUPPLEMENT SAFETY AND REGULATION CONFERENCE

FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR FOOD SAFETY & APPLIED NUTRITION

March 5, 2021

Dear Baby and Toddler Food Manufacturers and Processors:

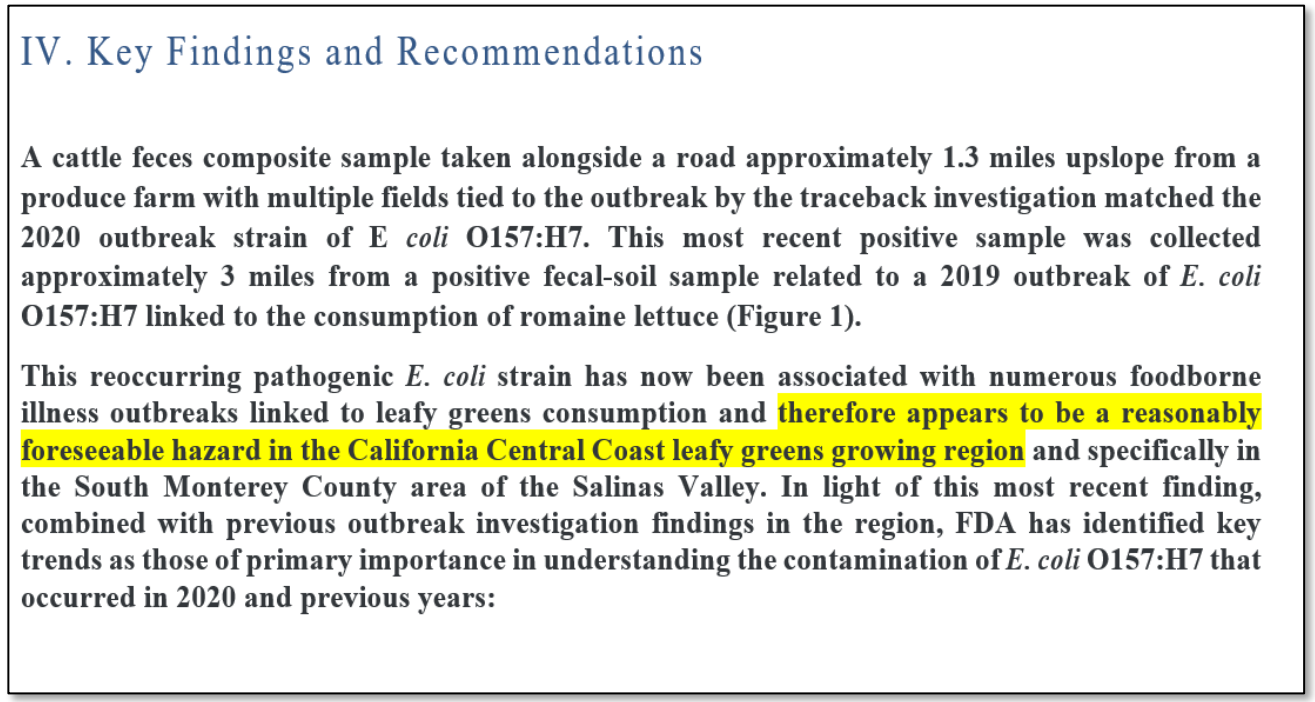
The U.S. Food and Drug Administration (FDA or "we") is taking this opportunity to remind all baby and toddler food manufacturers and processors covered by the preventive control provisions of the rule *Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food*, issued on September 17, 2015 (80 Fed. Reg. 55908), of your responsibility under the rulemaking to consider chemical hazards that may be present in foods when conducting your hazard analysis. See 21 CFR 117.130(b)(1)(ii). Similarly, baby and toddler food manufacturers covered under other food safety regulations requiring a hazard analysis, such as 21 CFR Parts 120 and 123, should consider chemical hazards that may be present in a food when conducting a hazard analysis. We are reminding you of this responsibility in light of a report released on February 4, 2021, by the U.S. House of Representatives Committee on Oversight and Reform Subcommittee on Economic and Consumer Policy that raises important questions on what more can be done to reduce toxic elements in baby food.

Developments: Heavy Metals in Baby Foods

- "Baby Foods Are Tainted with Dangerous Levels of Arsenic, Lead, Cadmium, and Mercury," House Committee on Oversight and Reform Subcommittee on Economic and Consumer Policy
- Baby Food Safety Act
- FDA's "Closer to Zero" Action Plan
- State AG Enforcement
- Consumer Class Action Litigation
- Industry Response

Produce Safety

- Heavy metals, Prop 65 activity
- Biological hazards
  - FDA's Report on the Investigation into the Fall 2020 outbreak of E. coli O157:H7 illnesses
    - "reasonably foreseeable hazard"
    - "geographical region of interest"/"reoccurring region"
  - FSMA Proposed Rule on Agricultural Water



IV. Key Findings and Recommendations

A cattle feces composite sample taken alongside a road approximately 1.3 miles upslope from a produce farm with multiple fields tied to the outbreak by the traceback investigation matched the 2020 outbreak strain of E *coli* O157:H7. This most recent positive sample was collected approximately 3 miles from a positive fecal-soil sample related to a 2019 outbreak of *E. coli* O157:H7 linked to the consumption of romaine lettuce (Figure 1).

This reoccurring pathogenic *E. coli* strain has now been associated with numerous foodborne illness outbreaks linked to leafy greens consumption and therefore appears to be a reasonably foreseeable hazard in the California Central Coast leafy greens growing region and specifically in the South Monterey County area of the Salinas Valley. In light of this most recent finding, combined with previous outbreak investigation findings in the region, FDA has identified key trends as those of primary importance in understanding the contamination of *E. coli* O157:H7 that occurred in 2020 and previous years:

A Note on PFAS

- **FDA**: Total Diet Study
- **Congress**: Keep Food Containers Safe from PFAS Act
- **White House**: Executive Order on Catalyzing Clean Energy Industries and Jobs Through Federal Sustainability
- **States**: Various prohibitions and restrictions in food packaging

Thank you!

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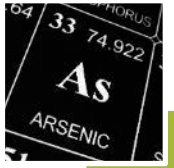
Heavy Metals and Foods

Marisa Kreider, PhD, DABT

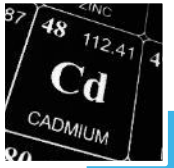
Together we will do great things

Hazards of Heavy Metals in Foods



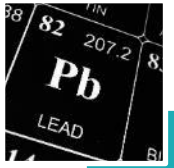
Arsenic

- IARC Group 1 carcinogen
- Prop 65 DART hazard
- RfDs and slope factors
- Naturally occurring in soil



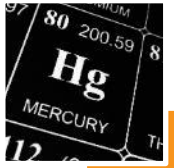
Cadmium

- IARC Group 1 carcinogen
- Prop 65 DART hazard
- RfDs
- Naturally occurring in soil



Lead

- IARC Group 2A carcinogen
- Prop 65 DART hazard
- RfDs and slope factors
- Naturally occurring in soil



Mercury

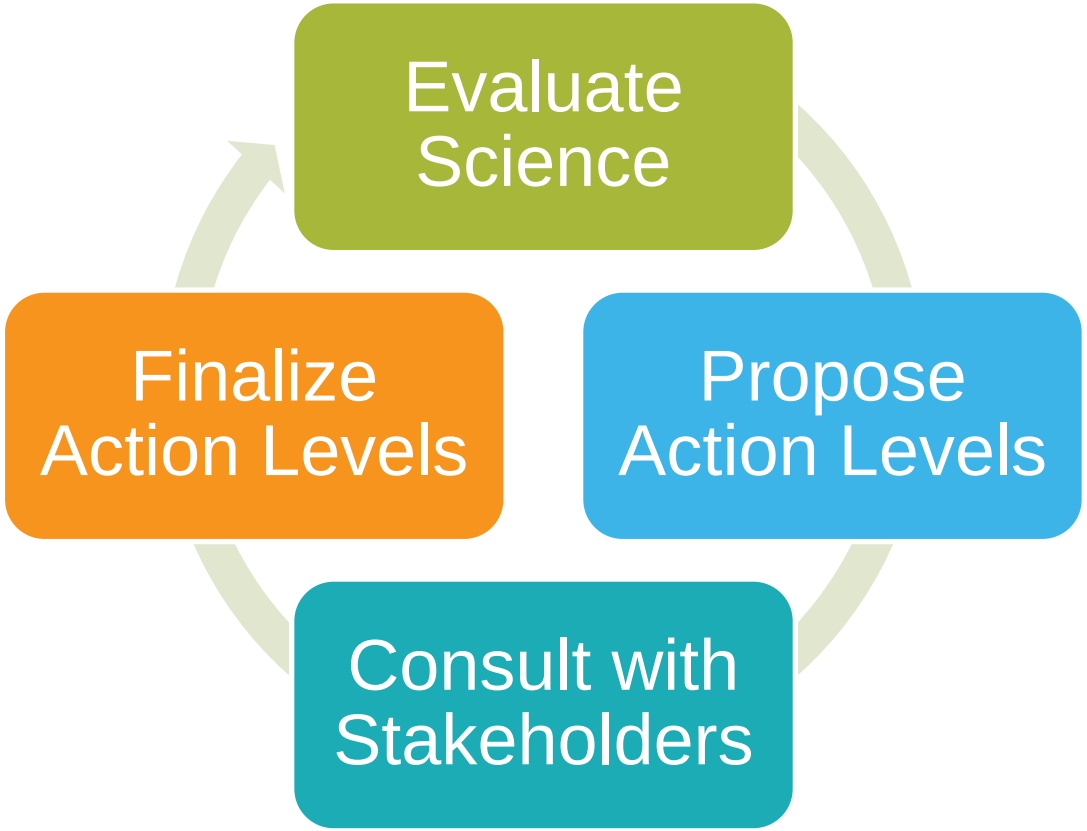
- Mercury
- MeHg IARC Group 2B carcinogen
- Prop 65 carcinogen and DART hazard
- RfDs
- Naturally occurring in soil

Considerations when Characterizing Risk from Heavy Metals

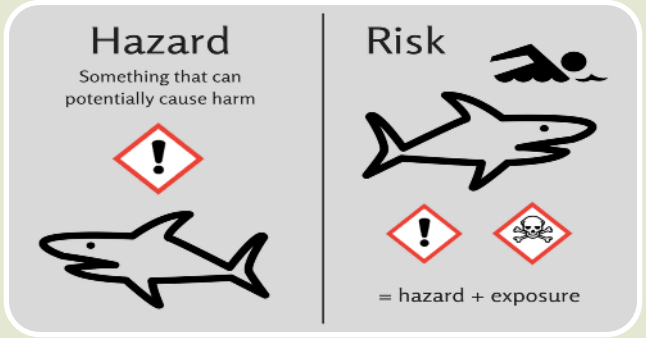
- Potential health risk can be predicted, depending on concentration in food product, specific product, and assumptions regarding intake
- Important to contextualize risk
  - “Baby foods” versus whole foods
  - Risk compared to other known risks or possible benefits
- Risk reduction versus risk elimination

Regulation of Heavy Metals in Foods

- Lack of enforceable limits on most heavy metals in foods at federal level
- FDA Closer to Zero Action Plan
  - Aims to make continual improvements over time in reducing levels of toxic elements in food
  - Encourage best practices in industry
  - Increasing compliance and enforcement
  - Monitor progress
  - Avoid unintended consequences (e.g. elimination of foods with nutritional benefits)



Challenges with Heavy Metals in Foods



Sensitivity of children

Media focus on detection of hazards vs. risk

Lack of appreciation for ubiquitousness of heavy metals in foods

Strategies for Risk Management across Stakeholders

Raw Materials

- Sourcing in areas with limited sources of exogenous contamination
- Sourcing during specific seasons
- Monitoring of raw ingredient heavy metal concentrations

Manufacturing

- Monitoring finished product heavy metal concentrations
- Dilution with low risk foods
- Investigating and/or introducing treatment of high risk foods

Risk Communication

- Communication regarding practices to minimize exposure to heavy metals in foods
- Transparency with consumers

Consumer Risk Management

- Limiting food intake on high risk foods
- Eating a balanced diet

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PFAS and Foods

Marisa Kreider, PhD, DABT

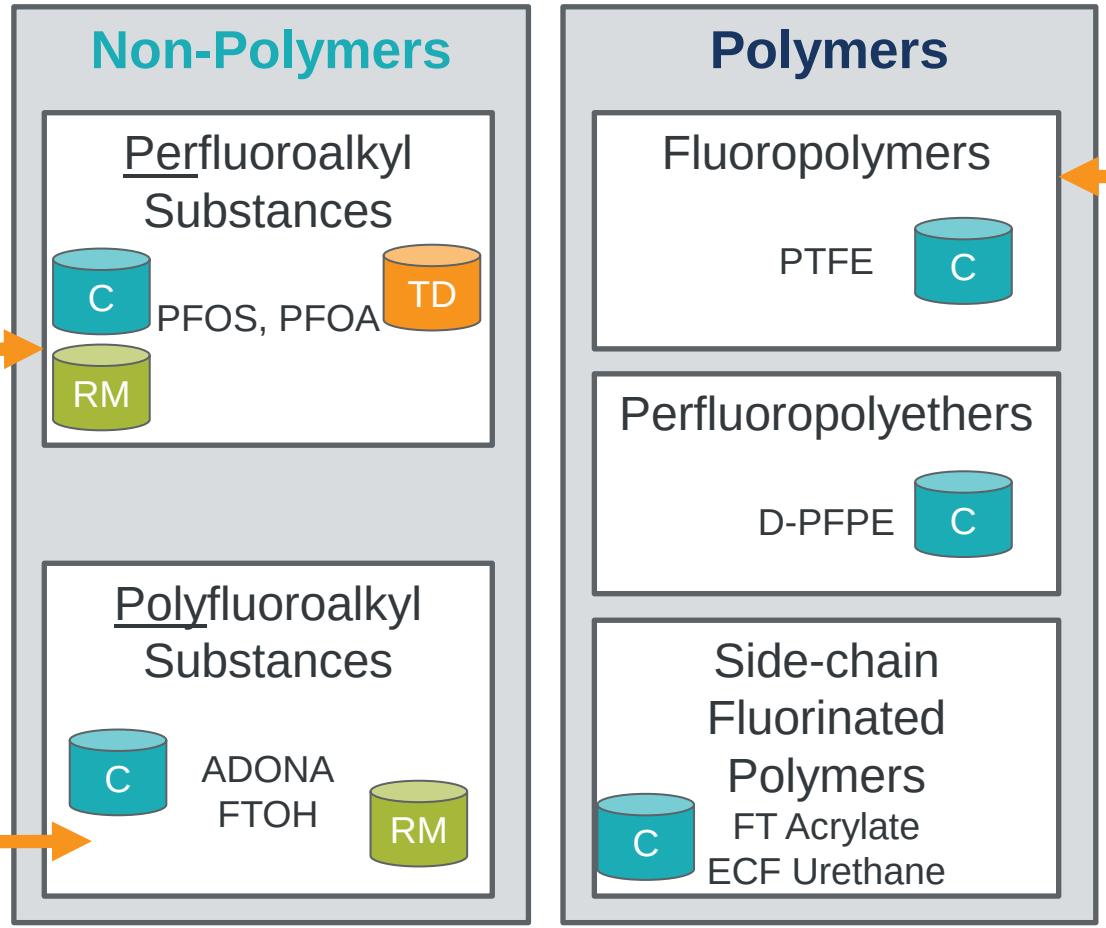
Together we will do great things

Introduction to PFAS

~5,000 PFASs!

Perfluorinated carboxylic acids: fire fighting foam, personal care products, carpet care

Fluorotelomer alcohols, polyfluoroalkyl phosphate esters (PAPs): food contact materials (FCMs)



Teflon pans, specialty plastics, weatherproof clothing/gear, FCMs

RM Raw Materials

C Commercial Products

TD Terminal Degradation Products

Source: Fluorocouncil

PFAS Characteristics

- Ubiquitously found in the environment
- Environmentally and biologically persistent
- PFAS family toxicity information informed by relatively small subset of PFAS
  - PFOA and PFOS proposed as carcinogens and developmental/reproductive hazards; others under evaluation
- Voluntary phase-outs of some PFAS

PFAS in Foods

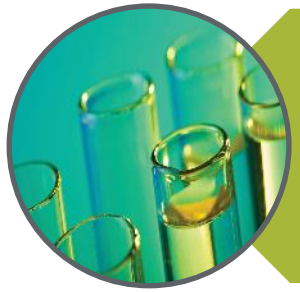
Uptake in Food Supply + Transfer from FCM = PFAS in Foods

- Food is primary source of PFAS exposure in US in most populations
- FDA approved uses of PFAS in FCM
- Individual states enacting bans on PFAS in FCM
  - CA, CT, MN, ME, CT, NY, WA
  - Scope varies by state

PFAS Exposure from Foods: FDA Study

- FDA recently released data on measurement of PFAS in foods as part of Total Diet Study
- Largely not detected in foods (167 total foods tested)
  - Small sample sizes
  - 16 PFAS tested
  - Exceptions included canned tuna, protein powder, and fish sticks
  - Follow-up study planned with targeted analysis of seafoods most commonly consumed in US diet
- Conclusion by FDA: “no scientific evidence that the levels of PFAS found in the TDS samples tested since 2019 indicate a need to avoid any particular foods in the general food supply.”

Challenges with PFAS in Foods



Analytical Detection Limits vs. “Health Benchmarks”

Use of Recycled Content in FCM

Ubiquitous Presence of PFAS in Environment

CALIFORNIA LGMA

COMMITTED TO SAFE LEAFY GREENS

BRINGING FARMERS TOGETHER TO MAKE LETTUCE AND LEAFY GREENS SAFER

MEMBER
CA Leafy Greens
CDFA CERTIFIED
CALeafyGreens.ca.gov
SM

PUBLIC PRIVATE PARTNERSHIP

- Instrument of the State of California
- Funded by industry | overseen by CDFA
- LGMA uses USDA-trained, CDFA auditors
- CDFA auditors are paid by the LGMA, not the company being audited

cdfa
CALIFORNIA DEPARTMENT OF FOOD & AGRICULTURE

USDA

HOW THE LGMA WORKS:

1. VERIFIES FOOD SAFETY PRACTICES
2. ENFORCES THROUGH GOVERNMENT AUDITS
3. REQUIRES A COMMITMENT TO CONTINOUS IMPROVEMENT

CROPS / COMMODITIES

The LGMA program covers 14 different types of leafy greens:


Arugula


Baby Leaf


Butter Leaf


Green Cabbage


Escarole


Green Leaf


Iceberg


Kale


Red Cabbage


Savoy Cabbage


Chard


Endive


Red Leaf


Romaine


Spinach


Spring Mix

LGMA MEMBERS

- Membership is voluntary, but member rules are mandatory
- Approximately 90 members
- Three major growing regions

LGMA MEMBERS

- Sister program in Arizona
- LGMA members in AZ and CA produce over 90% of the Nation's lettuce and leafy greens

THE FOOD SAFETY PRACTICES COVER SEVERAL AREAS, INCLUDING:

General Requirements

Member companies are required to have a complete food safety compliance plan, an up-to-date list of growers, and a written trace back program.

Environmental Assessments

Pre-season and pre-harvest assessments are required to make sure conditions that can affect food safety, such as animal intrusions, flooding, proximity to animal feeding operations, etc. are not present, or have been properly mitigated.

Water Use

Extensive testing and record-keeping for all sources of water used in the production of leafy greens are required.

Soil Amendments

Extensive testing, certification and record keeping for soil amendments, including compost and fertilizers, are required by the program.

Work Practices and Field Operations

Field audits verify that farmers are in compliance with the program's requirements in the areas of worker practices and field sanitation.

The LGMA food safety practices are grounded in the latest food safety science, and are updated as new research and information becomes available.

FSMA PRODUCE SAFETY RULE COMPLIANT

LGMA certification equals Food Safety Modernization Act Produce Safety Rule (PSR) compliance. In August of 2017, the LGMA programs in California and Arizona updated their food safety practices to meet or exceed PSR requirements. Since January of 2018, every LGMA audit that is conducted verifies that member companies are in compliance with PSR.

FDA Report April 8, 2021

- Fall 2020 outbreak
- E. coli 0157:H7
- 40 illnesses – 20 hospitalized, 4 HUS
- Reasonably Foreseeable Hazard
- Recurring strain of concern
- Cattle feces 1.3 upslope miles from produce field
- One Health – interconnection between people, animals, plans and their shared environment

The Challenge

- 88,000 head of cattle in Monterey County
- How do we co-exist safely?
- Efforts include:
  - CA Ag Neighbors
  - Vaccination trials
  - Western Growers data collection

Data Gaps

- How did it get there?
- How long does it last?
- How do we rid/kill it?
- What are potential mitigation solutions?
- For example –
- 1.3 miles from produce field – wind, water, animal, bird, other?
- 100,000 head versus 50,000 head versus 1,000 head versus 50 head - Buffer distance

LGMA Actions

- Focus on the Four W's – waste, water, wildlife, workers
- Water update 2020
- Type A and B
- Compost and soil amendments 2021
- Adjacent land use 2021
- Pre-Harvest testing 2022
- Root Cause Analysis 2021
- Harvesters 2020
- Traceability 2018

RESPONDING TO OUTBREAKS: FOOD SAFETY STANDARDS UPDATES

2018: ADJACENT LAND / WATER / ENVIRONMENT / HARVEST / TRACEABILITY

Increased required buffer distance for fields to:

- At least 1,200 feet from concentrated animal feeding operations (CAFOs) with 1,000 – 80,000 animals
- At least 1 mile from CAFOs with more than 80,000 animals

Updated equipment sanitation requirements:

When changing fields or commodities: clean and sanitize | End of the day: clean and sanitize | Before harvest each day: inspect and clean or sanitize again if necessary

Additional environmental assessment required for unusual weather events like flooding, frost or wind, similar to what the Yuma region experienced

Formalized requirement for lot data to aid traceback investigations

2019: WATER

New approach to agricultural water:

1. Risk assessment required for sources, storage and delivery systems
2. Risk-based water classifications (Type A & Type B)
3. Type B water that touches the edible portion of a crop within 21 days of harvest must be treated to meet the following microbial quality standard:

There must be no detectable generic E. coli in at least 2 of 3 samples. One sample can have up to 10 MPN of generic E. coli

2020: WATER / HARVEST

- Water used for overhead application of crop treatments must meet Type A microbial quality standards
- New best practices for furrow and drip irrigation water

- Required harvesters to prevent cut end of product from contacting the ground
- Best practices for cleaning and sanitizing harvest equipment, containers, tools and bathroom facilities became requirements

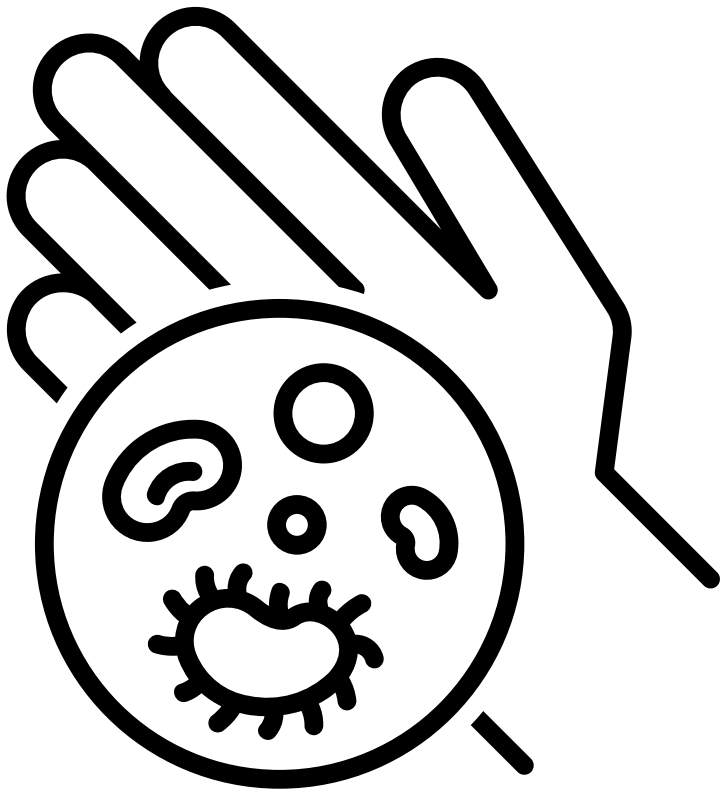
2021: ADJACENT LANDS / ROOT CAUSE / SOIL

- Issued LGMA Preharvest Testing Guidance document for crops grown with animals present on adjacent lands
- Pre-harvest testing to become a requirement*
- Adjacent Land Risk Assessment Tool launch*

- Root Cause Analysis required*

- Major revision to Soil Amendments & Crop Inputs requirements

Emerging Concerns



- Cyclospora
- Listeria – harvesting equipment

The Opportunity

- Address data gaps
- Industry collaboration and data sharing
- FDA working with industry similar to FAA with airline industry
- Data-driven safety agenda
- Collaboration
- Incident reporting
- Investigation support

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