

December 13, 2022



PHYSICAL HAZARDS CONNECTING THE DOTS FROM RECALL TO HAZARD ANALYSIS

GEOFF FARRELL

GLOBAL SENIOR TECHNICAL MANAGER - NSF

AGENDA

- 01 **DEFINE PHYSICAL HAZARDS**
- 02 **RECALLS - PHYSICAL HAZARDS**
- 03 **HAZARD ANALYSIS**
- 04 **PROGRAMS / CONTROLS**
- 05 **BEST PRACTICES**

PHYSICAL HAZARDS

Foreign materials that may be introduced anywhere along the food chain from production to the consumer.

Foreign materials can be introduced by anything or anyone coming in contact with the food i.e. People, storage, transportation.

Foreign materials are considered hazards if they can result in injury or illness to anyone who consumes the food.

PHYSICAL HAZARDS EXAMPLES



RECALLS



Starbucks Espresso drink recalled over metal fragments in product

By News Desk on September 9, 2022

Foster Farms Recalls Fully Cooked Frozen Chicken Patty Products Due to Possible Foreign Matter Contamination

FOSTER FARMS →

FSIS Announcement

WASHINGTON, Oct. 29, 2022 – Foster Farms, a Farmerville, La. establishment, is recalling approximately 148,000 pounds of fully cooked frozen chicken breast patty products that may be contaminated with extraneous materials, specifically hard clear pieces of plastic, the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) announced today.

Tyson Fresh Meats, Inc. Recalls Raw Ground Beef Products Due to Possible Foreign Matter Contamination

TYSON FRESH MEATS, INC. →

FSIS Announcement

WASHINGTON, Nov. 16, 2022 – Tyson Fresh Meats, Inc., an Amarillo, Texas establishment, is recalling approximately 93,697 pounds of raw ground beef products that may be contaminated with extraneous materials, specifically reflective mirror-like material, the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) announced today.



Picture from Melton Borough Council

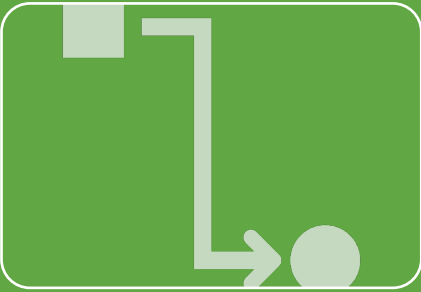
Krispy Kreme fined after metal found in doughnut

By News Desk on September 13, 2022

WALKING IT BACK TO HAZARD ANALYSIS!



This is where it all starts!
The beginning!



It is imperative you understand the products and the physical hazards associated with foods and processes.



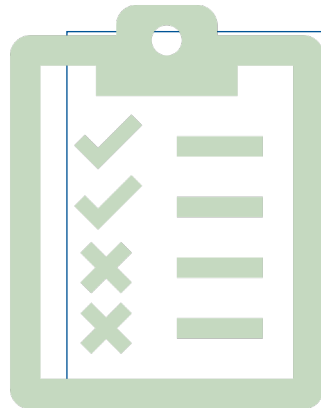
Use a cross functional group

- Employees from all different areas
- Documented production issues i.e., rework, complaint
- External References – publications, industry association

HAZARD ANALYSIS



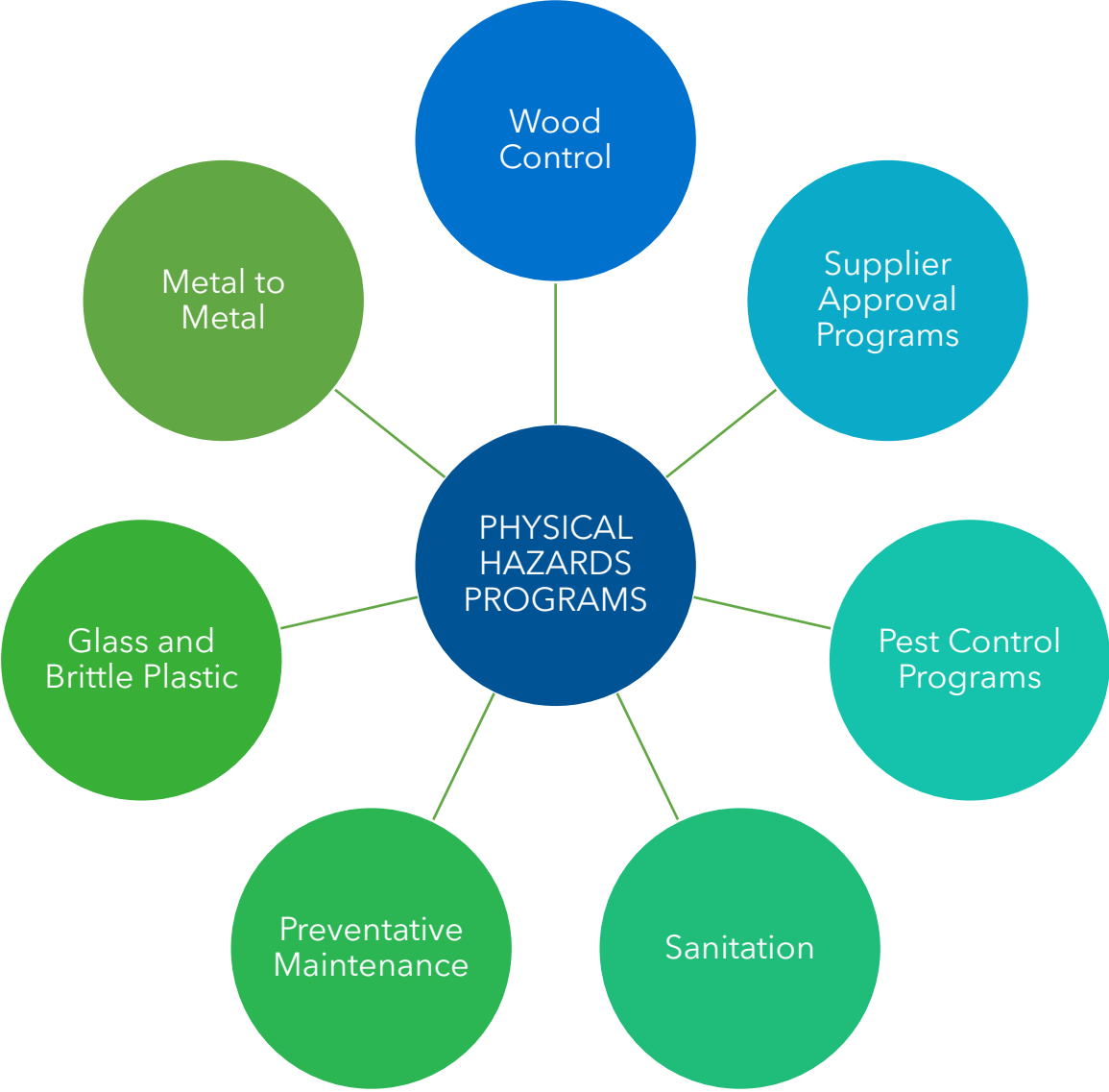
Hazard Identification is critical



Identify all hazards expected or likely to occur

- All inputs – raw materials, ingredients, packaging, additives
- Production Steps – Equipment, Conveyors
- Process Flow
- Employee Flow

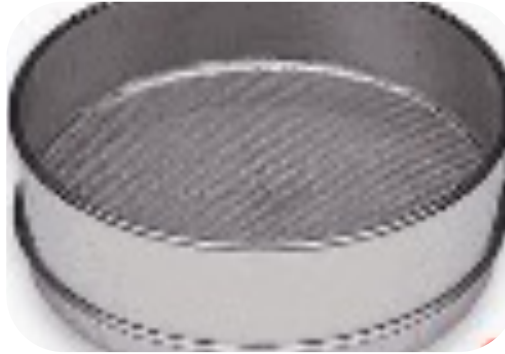
PHYSICAL HAZARDS PROGRAMS



PHYSICAL HAZARD CONTROLS



Metal
Detector



Sifter



Magnets



X-ray



Destoners

PHYSICAL HAZARDS – BEST PRACTICES

GMP Audit Reviews

Management Power Walks – gather all physical hazards

Educate – Monthly list of all physical hazards gathered

Complaint Investigation – focused physical hazard investigation

Physical Hazard Contests

Recall Investigations

Using Certified products and Equipment

Q&A





THANK YOU.

GEOFF FARRELL

GLOBAL SENIOR TECHNICAL MANAGER, NSF



Understanding, Prioritizing, and Preventing Foreign Object Hazards Across Different Food Categories

Wendy Wade White

Industry Manager for Food & Beverage



GaMEP
Georgia Manufacturing
Extension Partnership



Wendy White
Industry Manager for
Food & Beverage

Background:

- B.S. Biology - UGA
- M.S. Food Science – UGA
- 17 Years in Food Manufacturing
- 3 Years in Academia

Certifications:

- HACCP Certificates
- ASQ Certified Quality Auditor
- SQF Practitioner
- BRC Internal Auditor

Lead Instructor:

- Preventive Controls for Human Food (PCQI)
- Foreign Supplier Verification Program (FSVP)
- International HACCP Alliance



GaMEP – Georgia
Manufacturing
Extension Partnership



GaMEP at Georgia Tech: How We Work

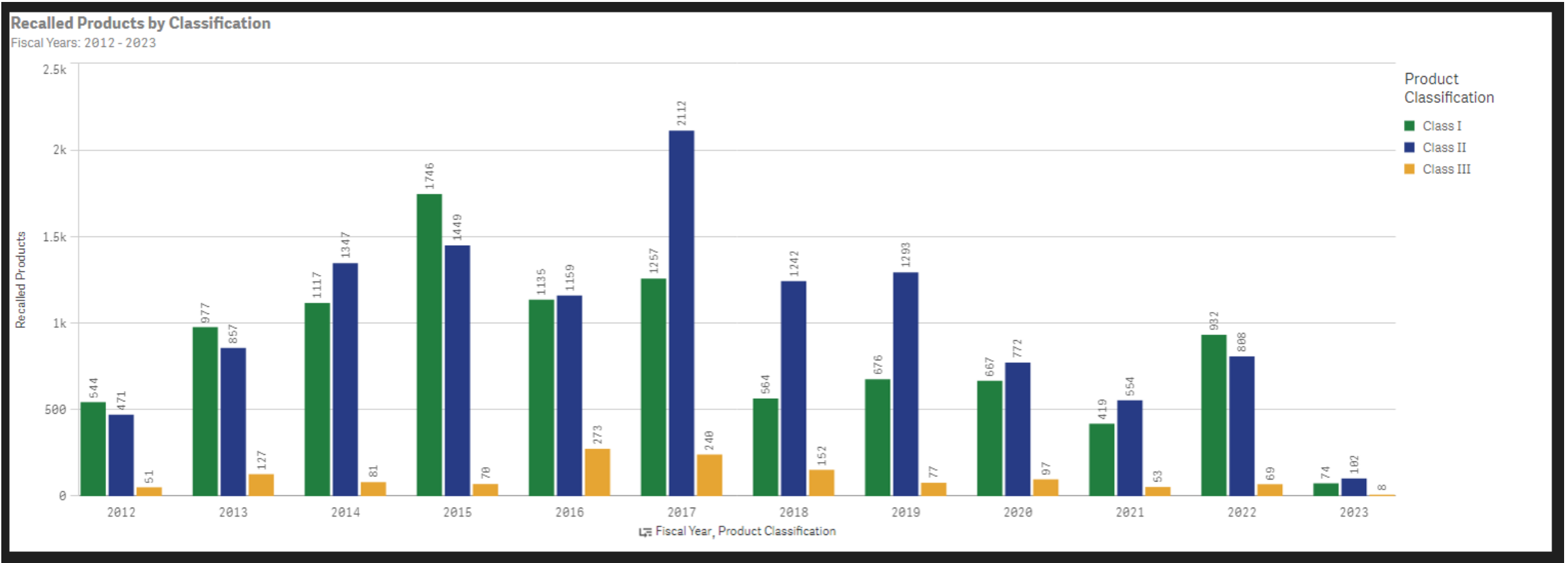
- Consulting Projects
- Training
- Events
- Subjects:
 - Strategy and Leadership Development
 - Process Improvement (Lean 6-Sigma)
 - Quality and Food Safety
 - Energy and Sustainability
 - Cybersecurity
 - Automation and Technology



Agenda

- Overview of foreign object recalls over the past few years
- Specific industries that are predisposed to certain foreign objects
- Understanding contamination pathways for these hazards
- Assessing risk and prioritizing physical hazards
- Utilizing multiple preventive methods (hurdle method) for control
- Empowering your workforce to remain vigilant

Food & Cosmetic Recalls (FDA)

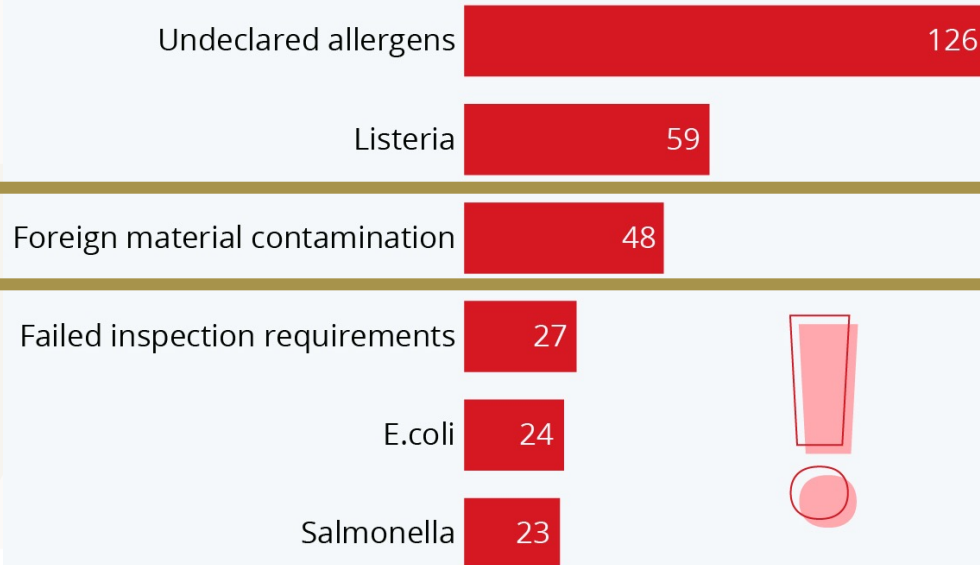


<https://datadashboard.fda.gov/ora/cd/recalls.htm>

2019 Food Recall Snapshot

Why Foods Are Being Recalled

Most common causes for food recalls
in the U.S. in 2019

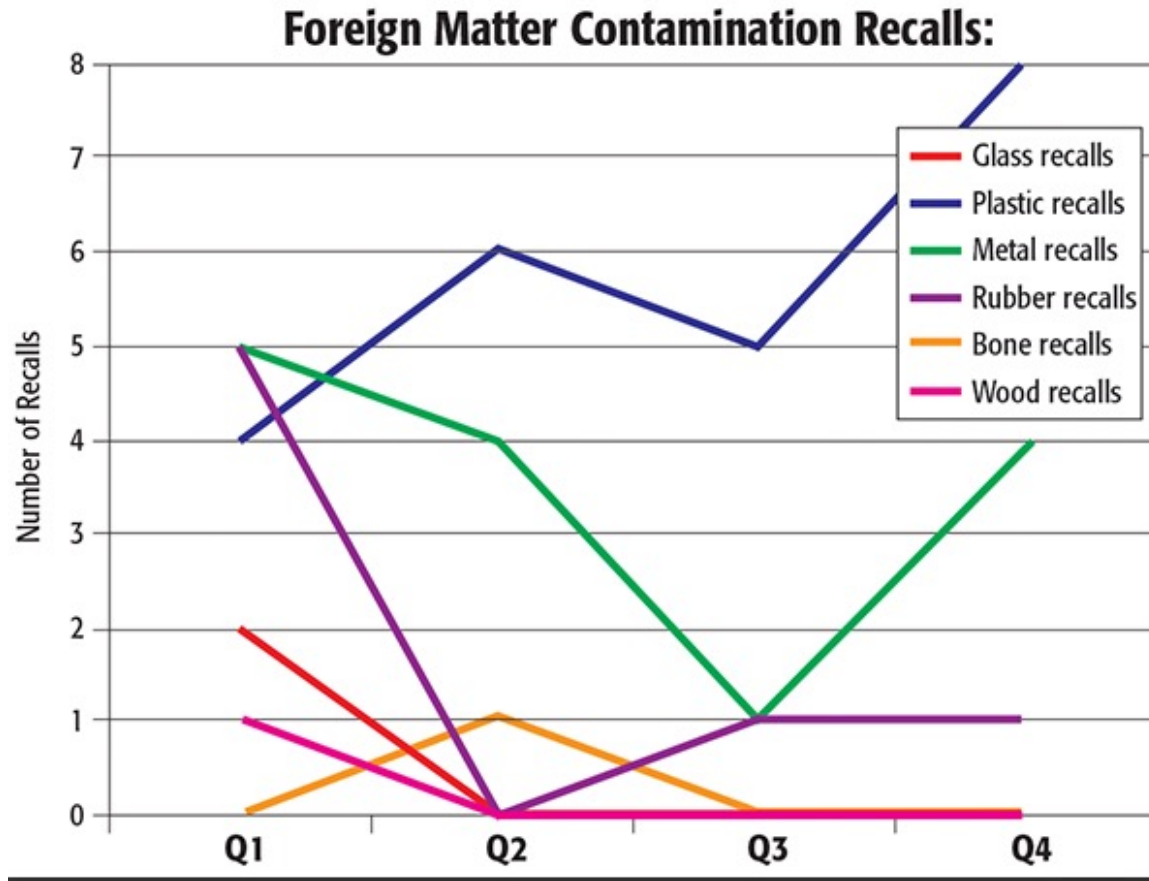


Major recalls listed on USDA, FDA websites only
Sources: USDA, FDA

- Foreign Material is the Third Largest Cause of Recalls.
 - USDA
 - FDA

<https://www.statista.com/chart/20681/us-food-recalls-by-type/>

2019 Food Recall Snapshot



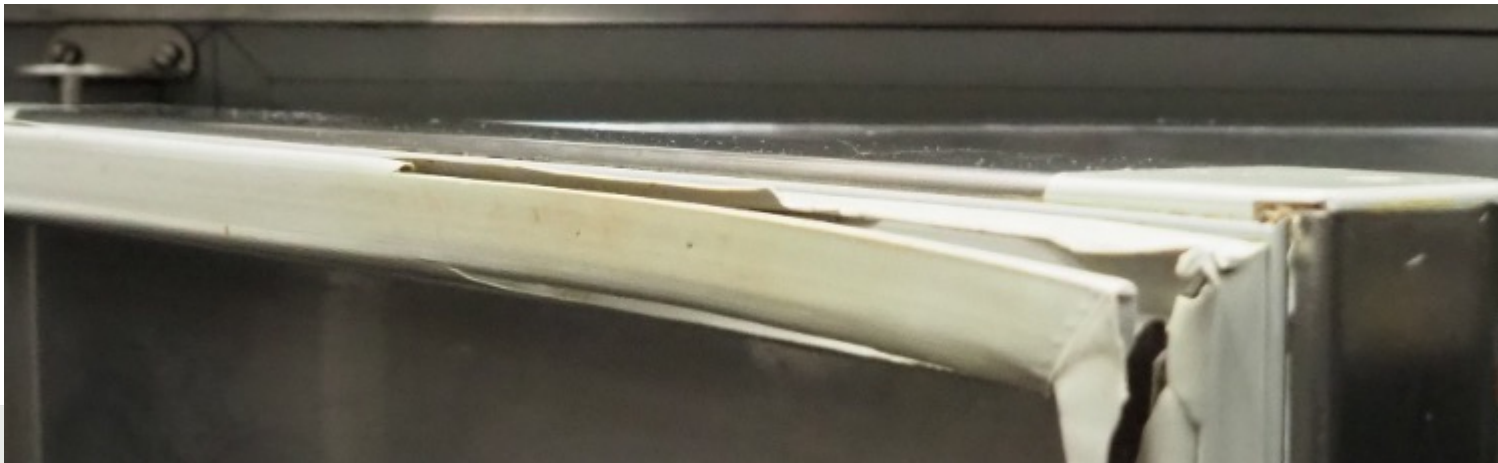
Top Foreign Object Recalls:

1. Plastic
2. Metal
3. Rubber
4. Glass
5. Wood & Bone

<https://www.food-safety.com/articles/6487-a-look-back-at-2019-food-recalls/>

Where Are These Foreign Objects Coming From?

- Plastic
 - Box Liners
 - Containers
 - Pallet Pieces
 - Plastic Shavings from Conveyors
- Metal
 - Metal Shavings from Equipment
 - Metal Parts (nuts & bolts)
- Rubber
 - Broken Gaskets
- Glass
 - Broken Glass from Facility
 - Broken Glass from Packaging
- Wood
 - Pallet Pieces
- Bone



Understanding Your Foreign Object Risk

Industry-Specific Foreign Objects:

- Ground Meats
 - Metal Shavings
 - Soft Plastic
 - Bone
- Produce
 - Peanuts:
 - Stones
 - Lettuce:
 - Hard Plastic
 - Insects & Frogs



Regional Differences

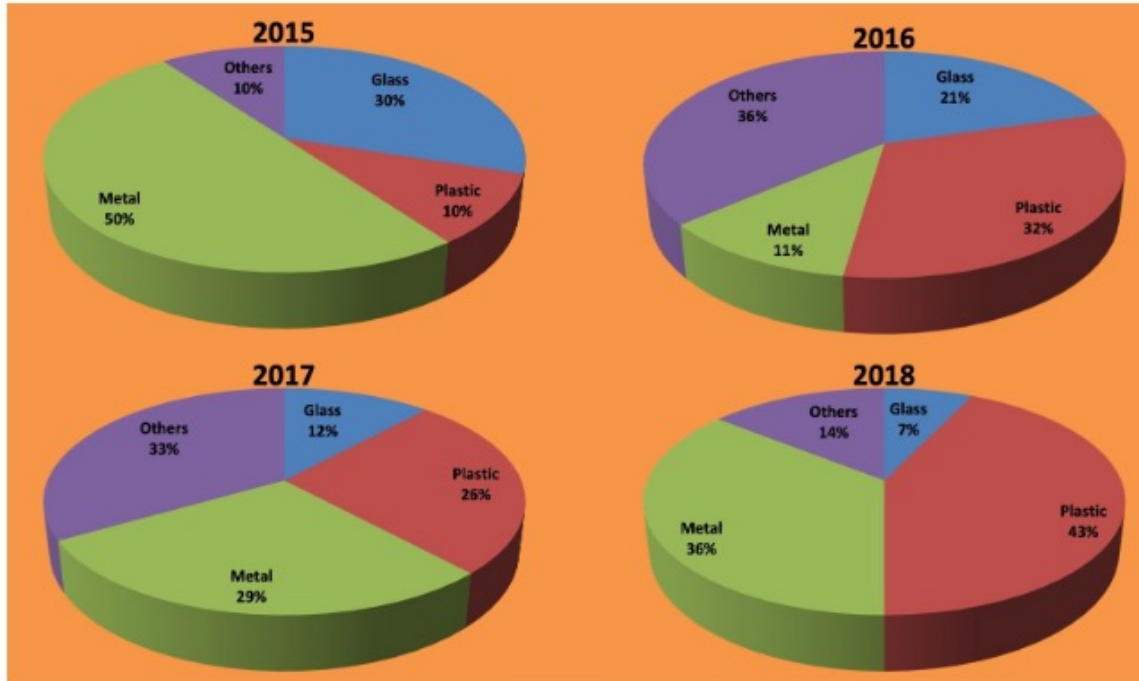


Figure 2 – Foreign Bodies Reported by the Food Drug Administration (USA)

<https://www.theauditoronline.com/the-importance-of-controlling-foreign-matter-in-food-production/>

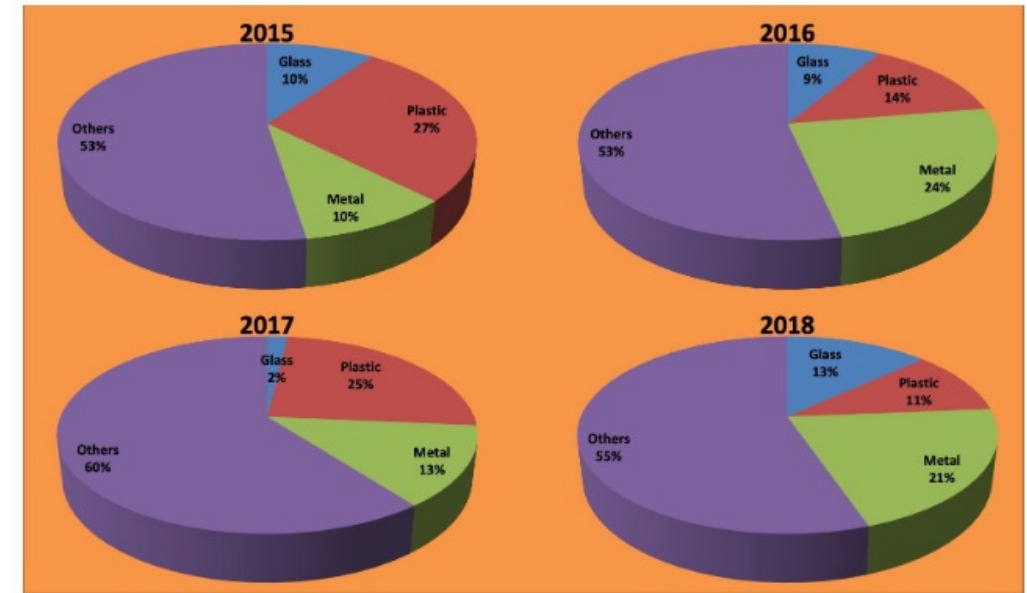


Figure 3 – Foreign Bodies Reported by the Canadian Food Inspection Agency

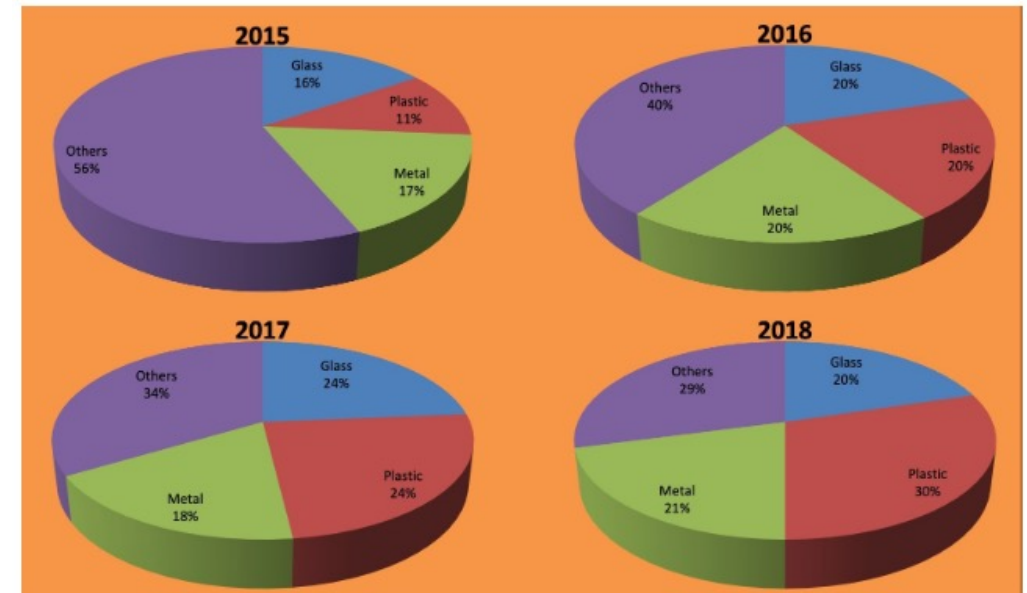
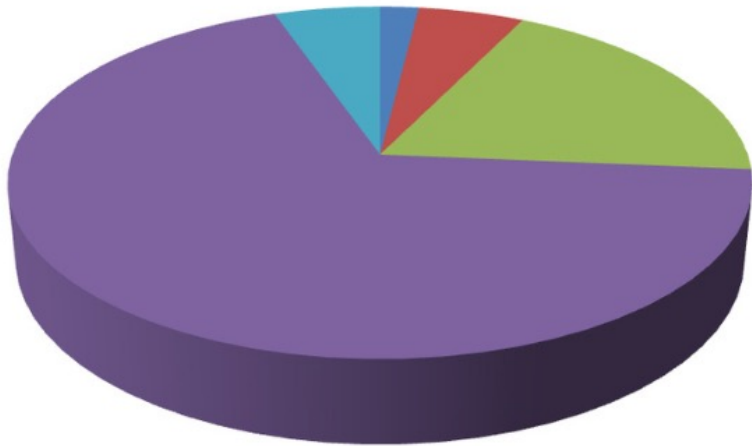


Figure 4 – Foreign Bodies Reported by RASFF (European Union)

Utilize Data to Determine Likelihood

- Industry Data
- Unforeseen Incidents
- Customer Complaints



Category of Complaint	Type of Complaint
Off	Tamper Tab
Off	Glass
Foreign Body	Taste
Chemical Taste	Sickness
Sickness	Poor Seal
Packaging	Quality
Other	

	A	B	C	D	E	F	H	I	J	K	L	M	
1	Customer Complaints Log												
2													
3													
4	Date Received	Complaint Number	Product	Size	Use By / Best Before	Category of Complaint	Type of Complaint	Initial Reply Sent	Target Response By	Date Investigated	Reply Sent to Customer	Customer Name	Customer Address
5	02/01/2019	1	Strawberry	250ml	02/02/2019	Off	Tamper Tab	03/01/2019	09/01/2019	06/01/2019	08/01/2019	Mr A Smith	15 Some Street, Somewhere
6	03/01/2019	2	Banana	500ml	03/02/2019	Foreign Body	Glass	04/01/2019	10/01/2019	07/01/2019	09/01/2019	Mrs J Doe	112 Another Street, Somewhere
7	04/01/2019	3	Strawberry	1000ml	04/02/2019	Chemical Taste	Taste	05/01/2019	11/01/2019	08/01/2019	10/01/2019	Mrs B Smith	22 Some Street, Somewhere
8	05/01/2019	4	Blackcurrant	1000ml	05/02/2019	Sickness	Sickness	06/01/2019	12/01/2019	09/01/2019	11/01/2019	Mr J Doe	39 Some Lane, A Place
9	06/01/2019	5	Raspberry	500ml	06/02/2019	Packaging	Poor Seal	07/01/2019	13/01/2019	10/01/2019	12/01/2019	Mr C Jones	The Cottage, In the Country
10	07/01/2019	6	Chocolate	1000ml	07/02/2019	Other	Quality	08/01/2019	14/01/2019	11/01/2019	13/01/2019	Mr A Smith	15 Some Street, Somewhere
11	08/01/2019	7	Vanilla	250ml	08/02/2019	Off	Taste	09/01/2019	15/01/2019	12/01/2019	14/01/2019	Mrs J Doe	112 Another Street, Somewhere
12	09/01/2019	8	Coffee	1000ml	09/02/2019	Foreign Body	Plastic	10/01/2019	16/01/2019	13/01/2019	15/01/2019	Mrs B Smith	22 Some Street, Somewhere
13	10/01/2019	9	Strawberry	1000ml	10/02/2019	Chemical Taste	Taste	11/01/2019	17/01/2019	14/01/2019	16/01/2019	Mr J Doe	39 Some Lane, A Place
14	11/01/2019	10	Strawberry	500ml	11/02/2019	Sickness	Sickness	12/01/2019	18/01/2019	15/01/2019	17/01/2019	Mr C Jones	The Cottage, In the Country
15	12/01/2019	11	Strawberry	1000ml	12/02/2019	Packaging	Tamper Tab	13/01/2019	19/01/2019	16/01/2019	18/01/2019	Mr A Smith	15 Some Street, Somewhere
16	13/01/2019	12	Banana	1000ml	13/02/2019	Other	Quality	14/01/2019	20/01/2019	17/01/2019	19/01/2019	Mrs J Doe	112 Another Street, Somewhere
17	14/01/2019	13	Vanilla	250ml	14/02/2019	Off	Taste	15/01/2019	21/01/2019	18/01/2019	20/01/2019	Mrs B Smith	22 Some Street, Somewhere
18	15/01/2019	14	Strawberry	1000ml	15/02/2019	Foreign Body	Hair	16/01/2019	22/01/2019	19/01/2019	21/01/2019	Mr J Doe	39 Some Lane, A Place
19	16/01/2019	15	Strawberry	1000ml	16/02/2019	Chemical Taste	Quality	17/01/2019	23/01/2019	20/01/2019	22/01/2019	Mr C Jones	The Cottage, In the Country
20	17/01/2019	16	Blackcurrant	1000ml	17/02/2019	Sickness	Sickness	18/01/2019	24/01/2019	21/01/2019	23/01/2019	Mr F Bloggs	The Shack Shanti Town
21	18/01/2019	17	Blackcurrant	1000ml	18/02/2019	Packaging	Poor Seal	19/01/2019	25/01/2019	22/01/2019	24/01/2019	Mrs A Moaner	Whingy Thatch, Whinetown
22													
	⏪	⏩	Complaint Log	Products	Size	Category of Complaint	Type of Complaint	+					



Prioritize Your Target Foreign Objects

Risk = Significance + Likelihood

1. Metal Shavings = High
2. Bone = Medium
3. Soft Plastic = Medium

<u>Risk Assessment</u>		Likelihood		
		Low	Medium	High
Significance	Low	Low	Low	Medium
	Medium	Low	Medium	Medium
	High	Medium	Medium	High

Foreign Object Controls

Equipment

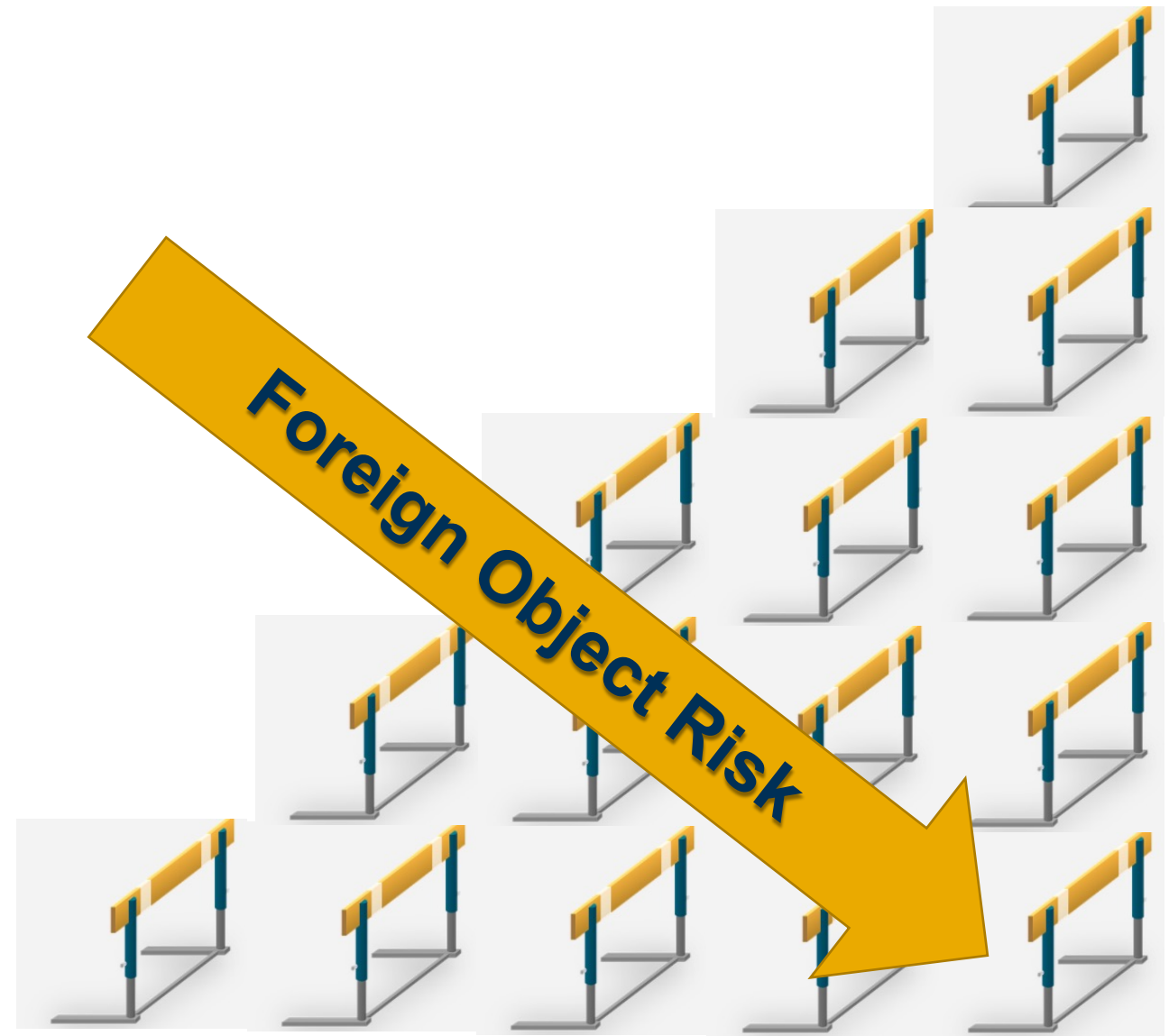
- Screens
- Filters
- Magnets
- Bone-Eliminator
- Metal Detection
- X-Ray
- Optical Sorter

Programs

- Supplier Approval Program
- Raw Material Evaluation
- Visual Inspection
- Glass & Hard Plastic Program
- Metal Detectable Blue Band-Aids

Hurdle Concept

Multiple hurdles can be used together to further reduce the likelihood of contamination.



Food Safety Is Everyone's Job!

- Your employees are your LAST line of defense.
- Train them regularly on your foreign object controls.
- Empower employees to prevent FO contamination:
 - “See Something, Say Something!”
 - Stop the production line if they see contamination



Summary

- Identify the Most Common Foreign Object for Your Process and Product
 - Industry Data
 - In-House Unforeseen Incidents
 - Customer Complaints
- Determine the Best Control for that Object
- Utilize Multiple Controls (Hurdle Concept) to add Extra Protection
- Track Foreign Object Incidents and Review Program
- Train and Empower Employees to Help!

Questions?

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*Scan for my
virtual
business
card*





MYCOTOXINS AND METALS THREATS TO FOOD

Kelly O'Connor
Columbia Laboratories
December 13, 2022

MYCOTOXINS

- Affect a variety of different crops and foodstuffs including cereals, nuts, spices, dried fruits, apples and coffee beans, often under warm and humid conditions
- Can occur either before harvest or after harvest, during storage, on/in the food itself often under warm, damp and humid conditions.
- Most mycotoxins are chemically stable and survive food processing. (and botanical supplement processing)





AFLATOXINS

THE MOST POISONOUS

Aflatoxins are one of the most toxic mycotoxins known. The dominant aflatoxin produced (AFB1) is the most powerful naturally occurring carcinogen, classified as group I by the International Agency for Research in Cancer [34].	Hay/grain cereals oilseeds spices tree nuts Aflatoxin M1 is also found in milk of cows that eat aflatoxin B1 contaminated crops produced by certain moulds (<i>Aspergillus flavus</i> and <i>Aspergillus parasiticus</i>)	The toxins can also be found in the milk of animals that are fed contaminated feed, in the form of aflatoxin M1 genotoxic, meaning they can damage DNA and cause cancer in animal species. cause liver cancer in humans, cause birth defects, and lead to kidney and immune system problems
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OCHRATOXIN A

THE MOST COMMON

Common food-contaminating mycotoxin Formed during the storage of crops 5 August 2022: EU amended regulation (EC) No 1881/2006 to lower the maximum levels of ochratoxin A in certain foodstuffs. Maximum level (µg/kg) ranges: 3,0 – 15 Commodity Specific (a µg is one billionth of a <u>kilogram</u>).	Cereals cereal products, Coffee beans, dry vine fruits, wine and grape juice, spices and liquorice	Primarily data in animals kidney damage
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PATULIN

APPLE JUICE CHEESE

produced by a variety of moulds, particularly <i>Aspergillus</i> , <i>Penicillium</i> and <u><i>Byssochlamys</i></u>	Rotting apples apple product fruit, grains, and cheese apple juice made from affected fruit	In animals: include liver, spleen and kidney damage and toxicity to the immune system In humans: nausea, gastrointestinal disturbances and vomiting
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FUSARIUM FUNGI

DEADLIEST TOXIN

Common in soil – and storage trichothecenes such as deoxynivalenol (DON), nivalenol (NIV) and T-2 and HT-2 toxins, as well as zearalenone (ZEN) and fumonisins (the vomit toxin) deoxynivalenol (DON), also known as vomitoxin * DON has been found in bread, noodles, beer, popcorn, and other foods, causing nausea. The level of fumonisins in a corn product depends on weather conditions. High levels of this toxin occur when hot, dry weather is followed by a period of high humidity. Milling, storage, and manufacturing processes can also affect levels of contamination with fumonisins.	cereal crops: DON and ZEN: WHEAT T-2 and HT-2: OATS	oesophageal cancer in humans, and to liver and kidney toxicity in animals. infertility at high intake levels, particularly in pigs
---	--	--



FUSARIUM FUNGI

FDA LIMITS

Human Foods	
Product	Total Fumonisin (FB ₁ +FB ₂ +FB ₃)
Degermed dry milled corn products (e.g., flaking grits, corn grits, corn meal, corn flour with fat content of < 2.25%, dry weight basis)	2 parts per million (ppm)
Whole or partially degermed dry milled corn products (e.g., flaking grits, corn grits, corn meal, corn flour with fat content of ≥ 2.25 %, dry weight basis)	4 ppm
Dry milled corn bran	4 ppm
Cleaned corn intended for masa production	4 ppm
Cleaned corn intended for popcorn	3 ppm



EVOLVING THREAT

TEMP, CO₂, AW

Main factors for mycotoxin production includes all three factors. CC estimates +2 °C.

LOWER LIMITS

5 August 2022 EU amended regulation (EC) No 1881/2006 to lower the maximum levels of ochratoxin A in certain foodstuffs.

CURRENT CHALLENGE

2003, 2004, and 2012 summer seasons in Italy, where dry and hot weather (>35 °C) contributed to an outbreak of *A. flavus* on crops, previously uncommon

FUTURE CHALLENGES

Increased aflatoxins: drought conditions and rising temperatures (extreme hot dry)-



HOW TO MITIGATE MYCOTOXINS



STORAGE

Store and Dry crops with best practices avoid damage to grains before and during drying, and in storage, as damaged grain is more prone to invasion of moulds and therefore mycotoxin contamination



VENDOR/ SOURCING

Test against the supplier's claims. inspect whole grains for evidence of mould, and discard any that look mouldy, discoloured, or shrivelled



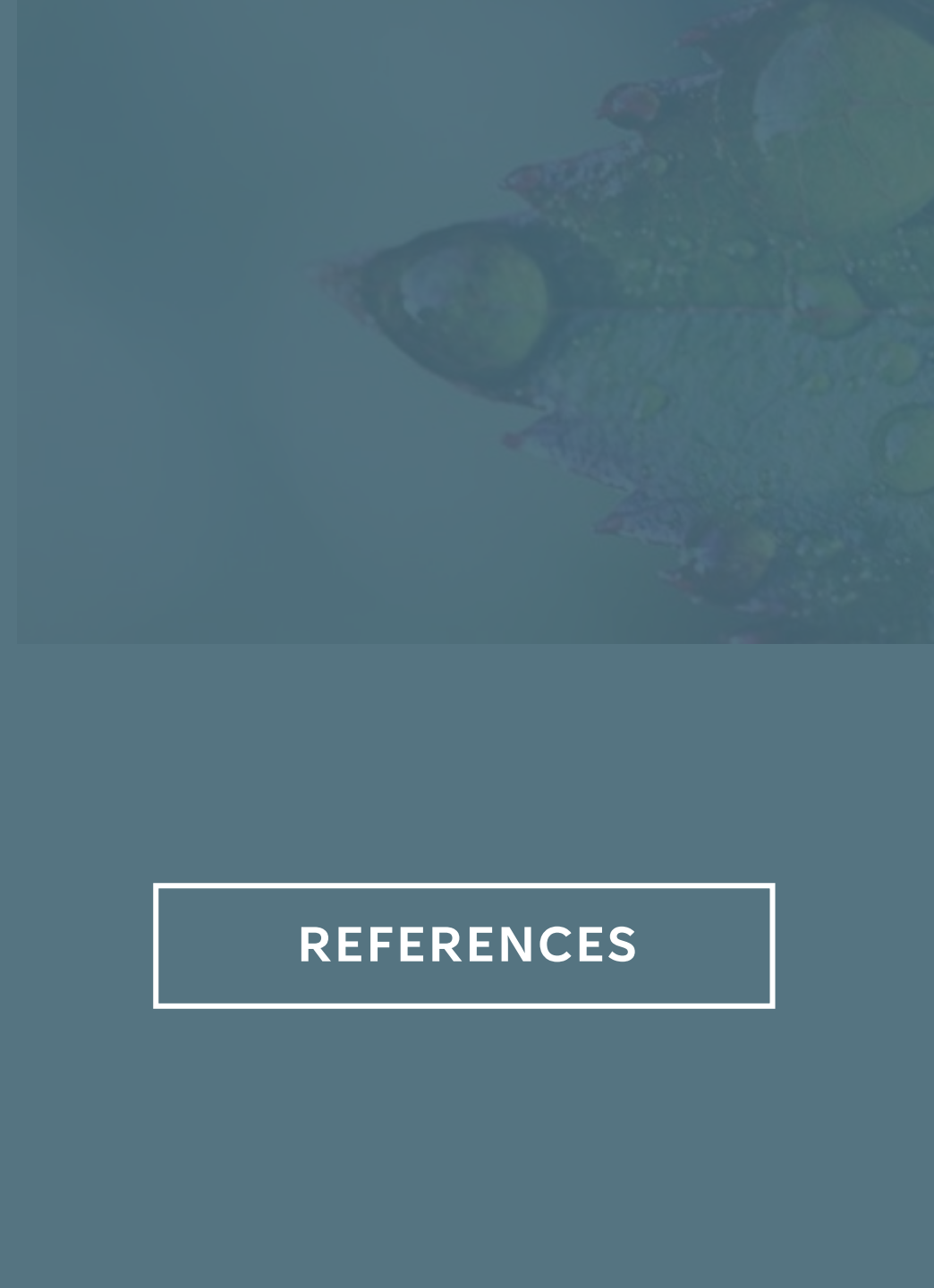
THIRD PARTY TESTED

Testing for Aspergillus, Moulds, Mycotoxins and more with the FDA approved method, reaching EU Action Limits



COMPLIANCE

“by using modern agricultural and processing techniques, companies can reduce the possibility of contamination in their products.”



REFERENCES



[Mycotoxins | FDA](#)

[Mycotoxins \(who.int\)](#) WHO

[EUR-Lex - 32022R1370 - EN - EUR-Lex \(europa.eu\)](#) Commission Regulation (EU) 2022/1370 of 5 August 2022 amending Regulation (EC) No 1881/2006 as regards maximum levels of ochratoxin A in certain foodstuffs (Text with EEA relevance)

[Toxins | Special Issue : Mycotoxins in Relation to Climate Change \(mdpi.com\)](#) MDPI: All manuscripts are thoroughly refereed through a double-blind peer-review process

[Toxins | Free Full-Text | Effect of Temperature, Water Activity and](#)

[Carbon Dioxide on Fungal Growth and Mycotoxin Production of](#)

[Acclimatised Isolates of Fusarium verticillioides and F. graminearum](#)

[\(mdpi.com\)](#)

A landscape photograph of a field with a path and a stormy sky. The foreground is filled with tall, green grass. A path of lighter-colored grass or dirt leads from the bottom right towards the center of the image. In the background, there are rolling hills and a dark, cloudy sky with a hint of light breaking through. The overall tone is somber and atmospheric.

HEAVY METALS



FDA'S CLOSER TO ZERO ACTION PLAN

"Additional funding and legislative proposals will focus specifically on better protecting mothers, infants and young children through contamination limits in food, product testing requirements, notification of anticipated significant interruptions in the supply of infant formula or essential medical foods, as well as modernization of dietary supplement regulation," the FDA stated.

CAUSE AND EFFECT

report released by Congress in 2021 on heavy metals contamination in baby food.

IN ACTION (IRL FOR LEAD)

10 ppb action level for lead in apple juice (Phase one of establishing MRLs)

ESTABLISHING LOWEST POSSIBLE MRLS

1

Evaluate the scientific basis for action levels.

2

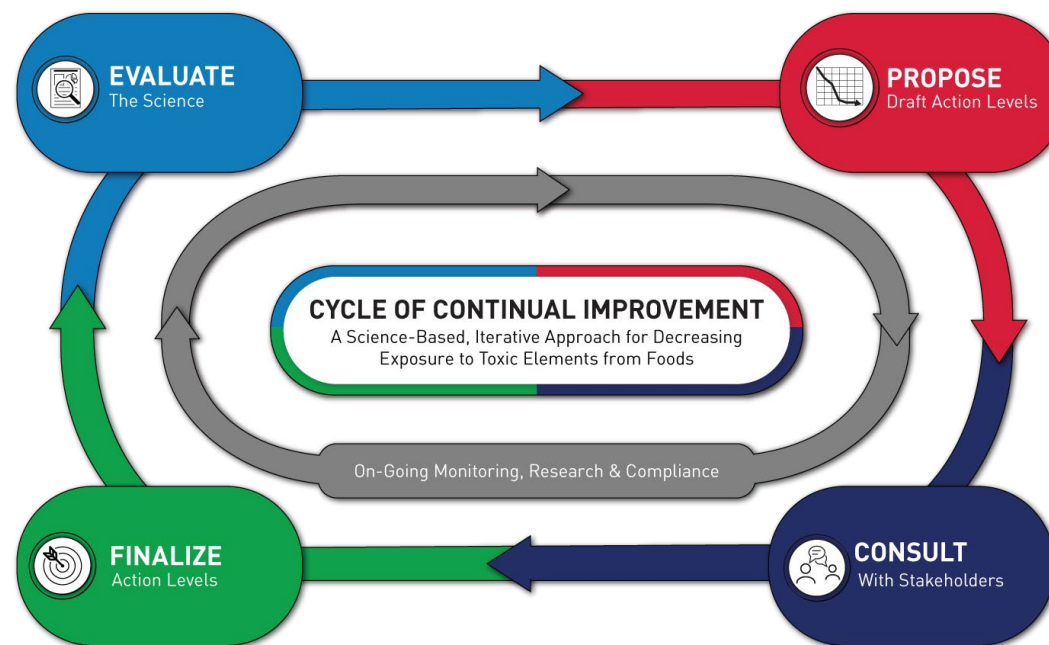
Propose action levels.

3

Consult with stakeholders, including the achievability and feasibility.

4

Finalize action levels.



HEAVY METALS INTRODUCTION



Environmental

Water, Soil



Additives

Nutrients Fertilizer

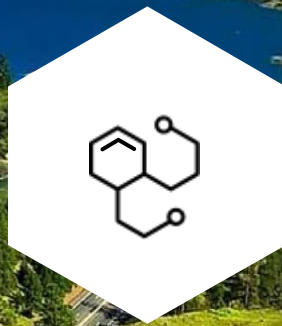
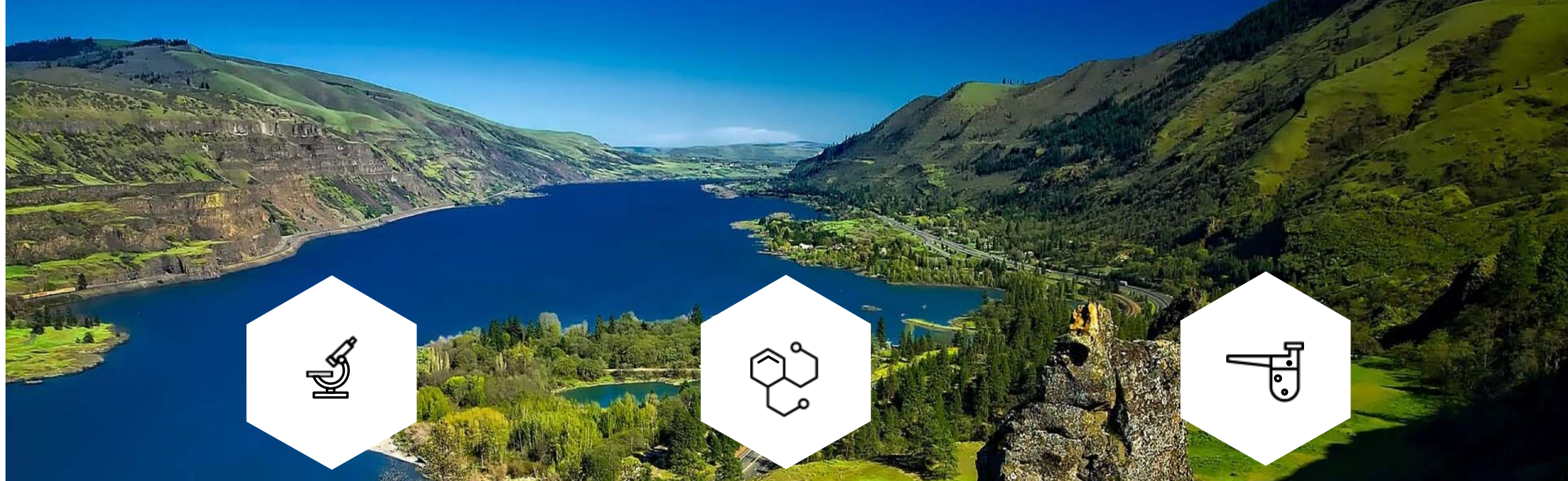


Packaging

Detectors



Product/ Stage	Testing (General)	Testing Considerations
Concentrate/ Extract: Ingredient	Pesticides- Residual Solvents Mycotoxins Potency (optional)- AOAC Nutritional Testing Microbiology: Pathogens	Food Grade Cannabis Safe Homogenization Studies Batch Testing Shelf-life studies
Formulated Products Can limit testing to potency for label verification and microbiology per batch, on the premise that the ingredients were cleared for contaminants testing... and then diluted into the final product. If you don't have COAs/ Spec sheets that meet regulatory requirements on the ingredient, then get the final product tested for a full panel per batch.	Active Ingredients Potency (+/- 10% of claim) Micro for safety (SALM, STEC, TYM, APC) Metals (packaging) – detector vs Full Panel	Micro highly recommended per batch Buyers check for supply chain testing (Vendor Vetting) Layer COAs- contaminants on the ingredient and label verification plus micro on final batches. Provide consolidated test report for client facing summary.



Multiple Commodity Service Lines In-House



- Nutritional
- Nutraceutical
- Microbiological
- Environmental
- Pesticides & Residues
- Commodity Specific
- Pet Food and Feed
- Soil to Sale Cannabis Testing

Trusted Testing since 1996

- 55+ employees with over 150 years of combined analytical experience.
- Members of Tentamus Network
- **ISO 17025 Accredited**
- **CDPHE Accredited**
- **TNI/ ORELAP Accredited**

Accredited Industry leaders

- 2016 – FIRST State accredited cannabis laboratory (ORELAP)
- 2018 – FIRST ISO 17025 accredited cannabis lab in Oregon.
- 2018 – FIRST fully validated cannabis multi-residue screen: +370 analytes
- Method standardization with AOAC

THANK YOU



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A background image of a male scientist with a beard, wearing safety glasses and a white lab coat, working in a laboratory. He is wearing blue gloves and holding a small vial, with a microscope visible in the foreground.

Ethylene Oxide – Recalls and Regulations

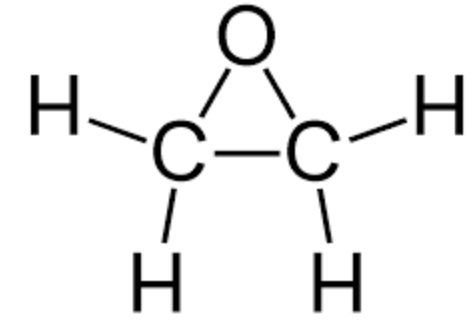
Food Safety Tech's Physical & Chemical Hazards
Virtual Event

Walter Brandl – Mérieux NutriSciences – 2022

Agenda

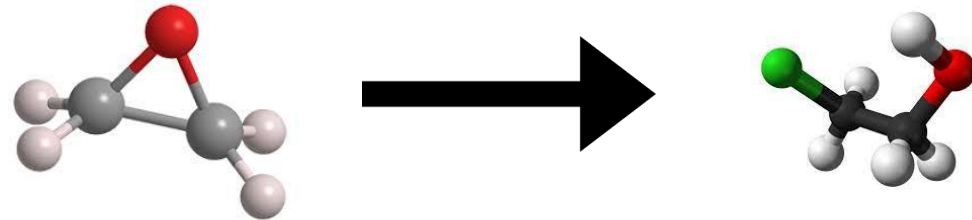
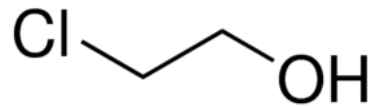
1. What is ethylene oxide? Applications
2. Current Situation Globally
3. North American Situation - Current and looking forward

Ethylene Oxide

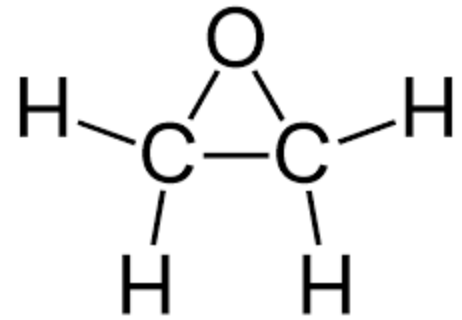


Characteristics

- A simple but strained cyclic ether
- A true gas at room temperature (25 deg C)
- A mobile liquid at 0 deg C.
- Breaks down to 2-chloroethanol (2-CE) in the presence of chlorides

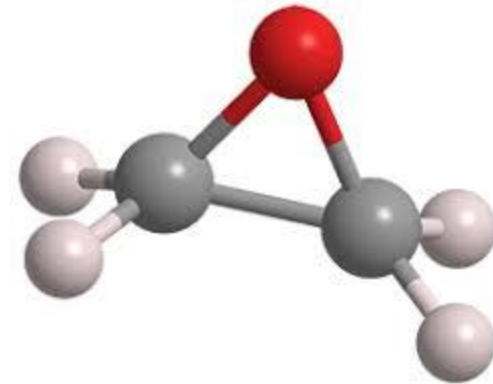


Ethylene Oxide

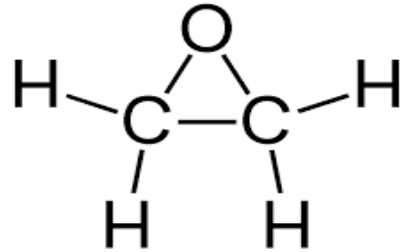
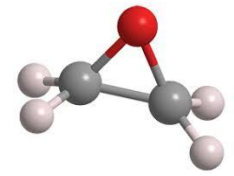


Applications

- 97% of EtO is used for as a precursor to industrial chemicals (anti-freeze, polyester, detergents)
- A reactive molecule used as a surface disinfectant and for heat-sensitive medical equipment
- A sterilant used to reduce microbiological load in sensitive products such as herbs and spices where heat treatment may affect color or flavor
- A fumigant used in nut warehouses, grain bins and the like.

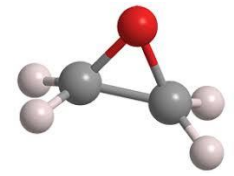


Ethylene Oxide Regulatory Status



- **Banned in most countries in the world**
 - Maximum Residues Limits from 0.01 to 0.1 mg/kg (ppm)
 - Measured as the sum of EtO and 2-CE calculated as EtO
- **Still used in Canada, US and India (and a few others)**
 - MRLs typically 7 ppm for EtO and much higher (940 ppm) for 2-CE

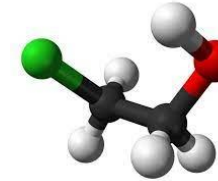
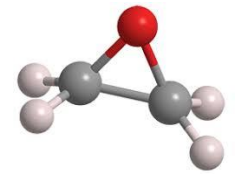
Ethylene Oxide Regulatory Status



RECALLS

- Sesame seeds 2020
 - Over 500 alerts in Europe as many products were affected (breads, hummus, crackers etc.)
- Ice-cream
 - From thickeners (locus bean gum) and flavors (vanilla bean)
- Pet Food

Ethylene Oxide Going Forward

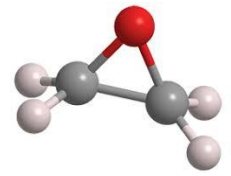
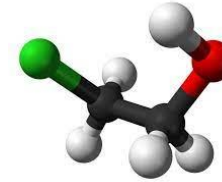


Issues



- Source of 2-CE
 - Some suppliers claim 2-CE is formed naturally from non-EtO sources
- Toxicity of 2-CE
 - While EtO is clearly genotoxic testing on 2-CE has been insufficient and inconclusive

Ethylene Oxide Going Forward



Regardless of Issues:

Canada and the US will continue to phase out the use of Ethylene Oxide for use in food.

MRLs will likely mirror the EU and other jurisdictions, effectively zero tolerance

Fate of 2-CE regulation will hinge on the outcome of genotoxicity testing

Q and (hopefully) A











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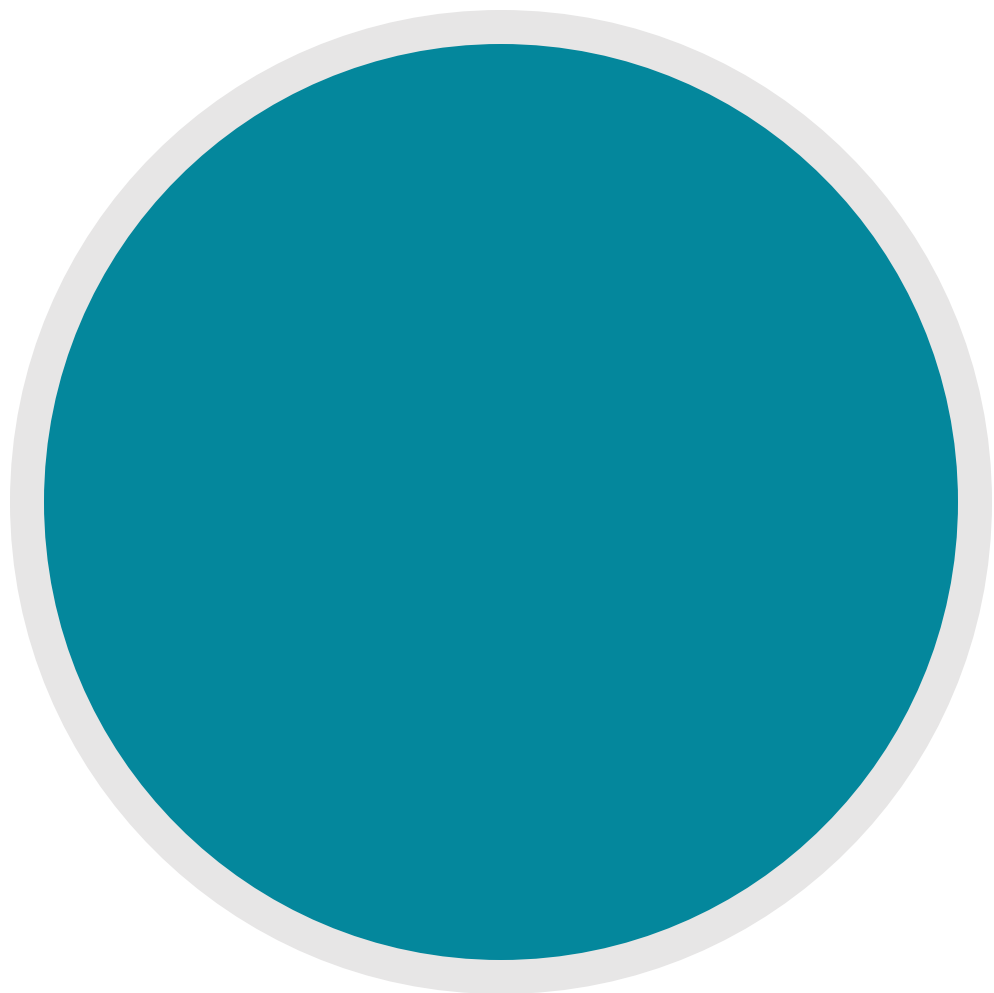


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Better Food. Better Health. Better World.



Thank you

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sed diamloclisi.

The background of the slide is a close-up, slightly blurred photograph of wheat stalks. The stalks are golden-brown and have long, thin awns. The lighting is soft, creating a warm, natural feel.

Undeclared Allergens - Not your usual chemical hazard

Steven Gendel, Ph.D.

Principal

Gendel Food Safety LLC

steve@gendelfoodsafety.com



Introducing Myself

- **Over 30 years in food safety**
- **25 years at FDA CFSAN**
- **Independent consultant and advisor**

What is different?

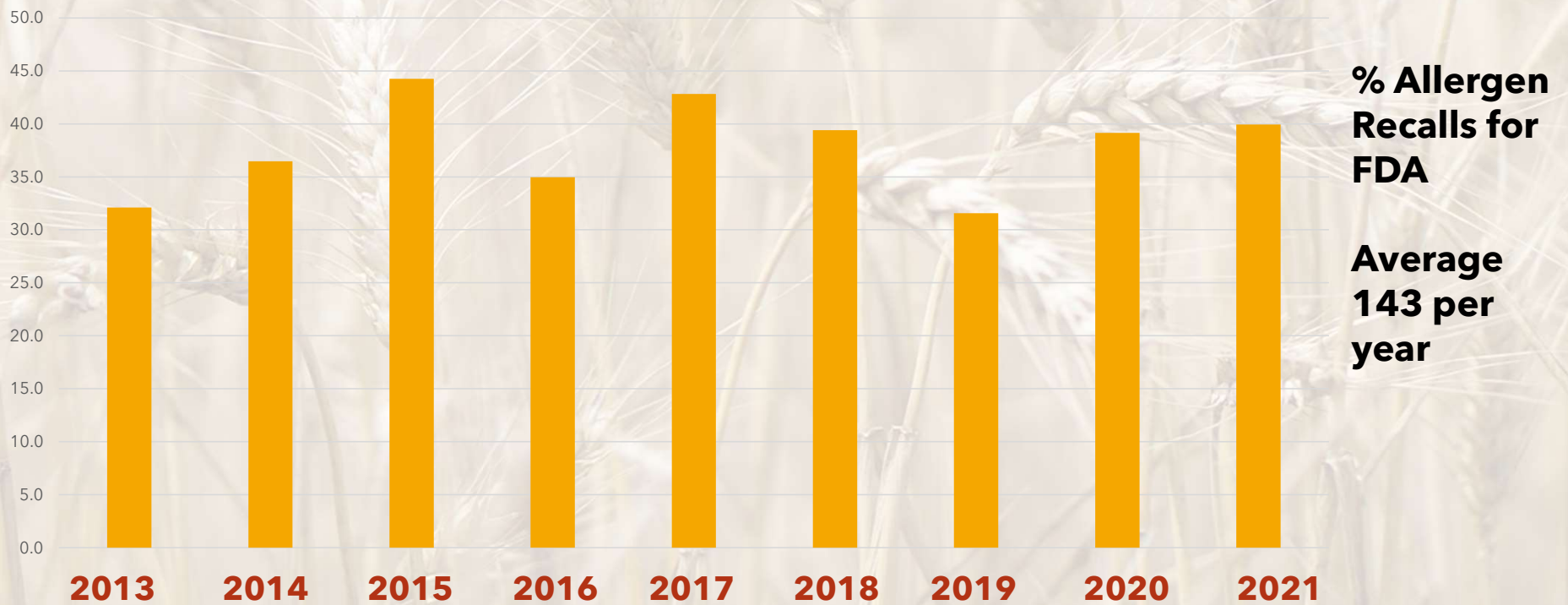
Unlike all the other hazards discussed today:

- **Food allergens are healthy and nutritious for most consumers**
- **Communication is the risk management tool**
 - **Assuming accurate and complete labeling**

The problem

- **Undeclared allergens remain the leading cause of food recalls in the US and around the world**
- **Sensitive consumers are still at risk 16 years after FALCPA became effective**
- **Under the PCHF rule manufacturers should have effective allergen controls but many do not**

The shape of the problem



Examples of the problem

- **October 2022**
- **The recall was initiated because the Gluten Free claim on the side of the packaging did not match with the product's ingredient label and allergen information.**

Examples of the problem

- **November 2022**
- **It was discovered at a retail location by staff that cases labeled [X] contained [X], but were labeled with the [Y] sleeves, resulting in the undeclared allergen**

Examples of the problem

- **December 2022**
- **The recall was initiated after it was discovered that the [H] product was mislabeled as [J] and peanut was not declared on finished product label.**

Other Examples of the problem - FDA Warning Letters

- **Your allergen control program did not adequately address the monitoring of labels**
- **Your hazard analysis did not identify and evaluate known or reasonably foreseeable hazards ...
Specifically, you did not identify and evaluate ...
allergen hazards to determine whether they require a preventive control**

What can we learn from all this?

- **Labels are a vital part of your safety program**
 - **Control**
 - **What they are supposed to say**
 - **What they do say**
 - **Where/when they are used**

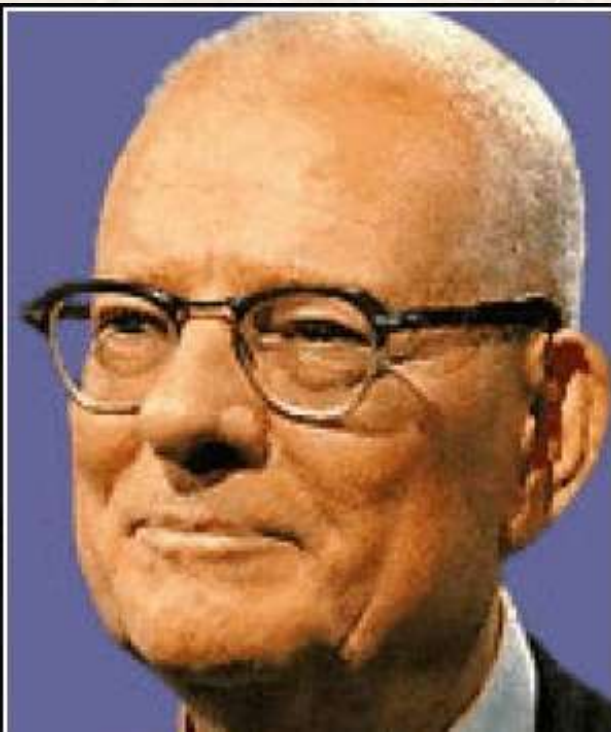
What can we learn from all this?

- **Allergen sanitation is not enough**
 - **Neither is testing**
- **Supply chain controls are critical**

Why does this problem persist?

- You can't prevent problems if you don't know why they happen
 - Why is as important as what
 - Need to identify “known and reasonably foreseeable” failures
 - AKA Vulnerabilities

A final thought



Manage the cause, not the result.

— *W. Edwards Deming* —

**For support and help
steve@gendelfoodsafety.com**





Better Food. Better Health. Better World.

Allergens

360° Solutions



Allergen Program

Enhancing your Allergen program to keep your facility safety under control & prevent food recalls

Chemical Hazards - Allergens

- A food allergy is a medical condition in which exposure to a food triggers a harmful immune response. The immune response, called an allergic reaction, occurs because the immune system attacks proteins in the food that are normally harmless. The proteins that trigger the reaction are called allergens.
- The symptoms of an allergic reaction to food can range from mild (itchy mouth, a few hives) to severe (throat tightening, difficulty breathing).
- Anaphylaxis is a serious allergic reaction that is sudden in onset and can cause death.

**Researchers estimate that up to
15 million Americans have food allergies,
including 5.9 million children under age 18,
1 in 13 children**

Factors to consider when identifying allergens as a hazard:

- Incoming ingredients with 'pass-through', unexpected allergens
- Different processing types: Peanuts are an allergen but is the oil?
- Processing Aids/Lubricants with incidental allergens: Soy Lecithin
- Are there multiple allergens handled in the same facility, same area, same line?
- Is their potential for cross contamination or cross contact from occurring during processing or sanitation activities (environment, tools)

Best Practices for Proactively Managing Allergens

- ID of ingredients that are allergens (inbound id)
- Warehouse storage control
- Controls in formulation (utensils, scoops, labeling, bins)
- Scheduling of processes
- ID and control of WIP and rework (like into like)
- Change over (allergen to a non-allergen) – validation
 - Wet sanitation
 - Dry sanitation
 - Product flush
- Label approval and labeling (“May contain” statements)

360° Solutions

Providing food safety, quality & sustainability **solutions**
by combining a complete suite of **services**
at every stage of the **food value chain**, from farm to fork.



CHEMISTRY

- ELISA Kit
- Real-time PCR

MICROBIOLOGY

- Incorporation with your environmental monitoring program

RESEARCH

- Allergen Product Formulation & Substitution
- Process Validation for Allergens

CONSULTANCY & LABELING

- Allergen Sanitation Validation
- Allergen Label Check

DIGITAL TOOLS

- EnviroMap—Allergen testing mapping
- Regulatory Update—new allergen regulations
- Safety HUD—Allergen recalls

AUDITING & TRAINING

- Allergen Verification Audit
- Allergen Training (online & in person)



360 Solutions

Allergen Program

Free Allergen Program Kit

Read & download

Resource Kit: Allergen Program

- ❑ Guide: Allergen Management
- ❑ Allergen Test Method Comparison
- ❑ Environmental Allergen Swab Guide
- ❑ Keys to preventing Undeclared Allergen Blog
- ❑ Webinar on Allergens - An Evolving Health Issue Challenging Food Manufacturers
- ❑ And More



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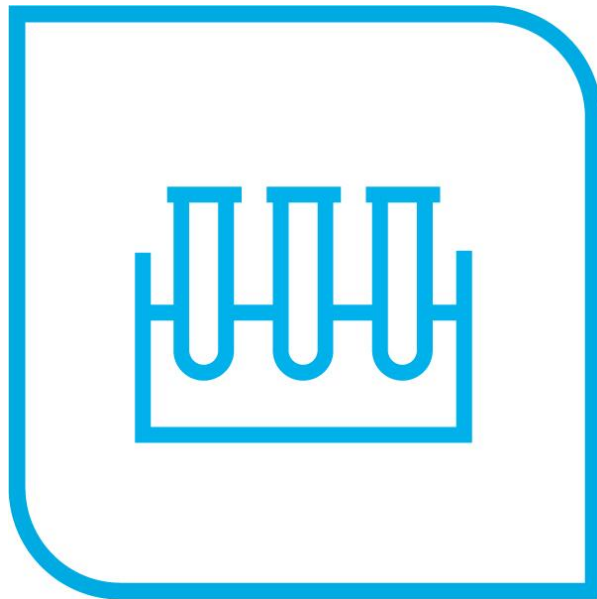
Thank you

www.merieuxnutrisciences.com/na

Allergen Chemistry



Mérieux NutriSciences helps you preventing product recalls due to unintentional product contamination and inefficient cleaning procedures by testing your finished product or swabs for a number of known Allergens by ELISA Kit or by Real-time PCR.



- Allergen Validation Studies
- Analytical Allergen Consultation
- Allergen Swab testing
- Allergen Product Testing
 - ➔ By ELISA Kit: *Gluten, Almond, Coconut, Crustacean, Egg, Hazelnut, Macadamia Nut, Milk, Mustard, Pecan, Peanut, Sesame, Soy, Tree nut, Walnut*
 - ➔ By Real-time PCR: *Mustard, further offerings in validation*
 - ➔ X-Map technology

Allergen Microbiology



Mérieux NutriSciences is the industry's leading food microbiology testing partner with 9 out of the top 10 food manufacturers using our trusted services.



- Allergen Environmental Monitoring Program (EMP)
- Sanitation Validation
- Sampling & Courier

Allergen Digital Tools



Let's face it, in today's high-tech world you need software to record and manage your procedure. Manually searching through spreadsheets for data causes more frustration than it is worth. Elevate your digital landscape with these digital tools.



- **EnviroMap**

- ➔ A secure, cloud-based system that allows you to automate your allergen environmental monitoring program and assists with the entire sampling lifecycle.

- **SafetyHud**

- ➔ Discover allergen recalls from ingredient suppliers in real-time with data from 73 countries to safeguard your supplier programs.

- **Regulatory Update**

- ➔ Understand allergen regulations and compliance policies in XX countries to help you reach new markets

Allergen Auditing & Training



Auditing your facility ensure your facility is meeting allergen standards every day. We offer our Allergen Training courses in a variety of different formats.



Audits

- Allergen Audit
- BRCGS - Gluten Free Certification Audit

Training Courses

- Controlling Food Allergens in the Plant (streaming video)
- Allergens & Their Controls (eLearning)
- Advanced Allergen Management (eLearning)
- Allergen Management Beyond Preventive Controls (Live Instructor Led)

Allergen Consultancy & Labeling



We start by understanding and responding to your needs, from risk assessment to crisis management. Drawing on decades of industry and regulatory expertise, our experts help you safeguard your product, fortify security protocols and protect your brand.



At the onset of each new project, we assess your needs and partner you with our most experienced and industry-specific consultants.

- Allergen Crisis Management Support
- Allergen Program Development
- Allergen Risk Assessment
- Allergen Label Check
- Allergen Ingredient Assessments

Allergen Research & Sensory



Our services give you the ability to evaluate the quality of your food and beverage products, discover new consumer attitudes, compare products against competitors and generate new product ideas all in one place.



Mérieux NutriSciences offers an innovative portfolio of research and sensory services to the food industry to guarantee product stability, quality, and safety from concept development to retail shelf.

Research Services

- Reformulation support and consumer insights
- Process Validation for Allergens
- Troubleshooting
 - ➔ Identification
 - ➔ Whole Genome Sequencing

DHS S&T CSAC Food Adulteration Events and Chemical Toxicity



Science and
Technology

Jessica Cox, Carol Brevett
Chemical Security Analysis Center
Office of National Laboratories
Innovation & Collaboration

December 13, 2022

DHS Science and Technology

Responding to the Needs of the Homeland Security Enterprise



Science and Technology

Prevent
Terrorism and
Enhance
Security

Secure and
Manage Our
Borders

Ensure
Resilience to
Disasters

Safeguard and
Secure
Cyberspace

Enforce and
Administer Our
Immigration
Laws

S&T's Role: To deliver effective and innovative insight, methods, and solutions for the critical needs of the Homeland Security Enterprise

Mission

S&T CSAC is the nation's only federal studies, analysis, and knowledge management center for assessing the threat and hazard associated with an accidental or intentional large-scale chemical event or chemical terrorism event in the United States.

S&T CSAC is built on an Integrated Capability platform with a foundation in Modeling & Simulation and Core Subject Matter Expertise

Hazard Analysis

Hazard
Characterization

Surveillance / Detection

• Chemical Hazard Analysis

- S&T-based Technical Assistance 24/7
- Quick Reaction Bulletins (e.g., Aqaba Jordan)
- Daily Reports / Weekly Reports
- Chemical Agents Reactions Database (CARD)
- ChemInformatics, including interagency Non-Traditional Agents (NTA) Library

• Chemical Hazard Characterization

- Chemical Assessment – tailored assessments
- Chemical Characterization – assessing the threat posed by the intentional use of high-consequence chemicals

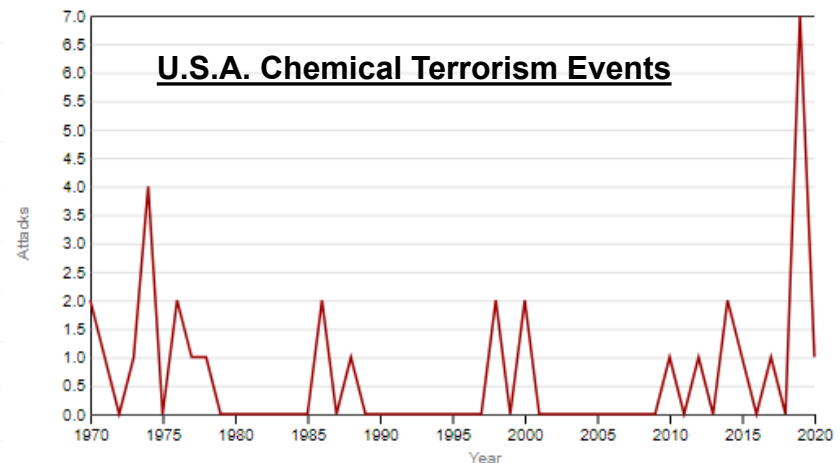
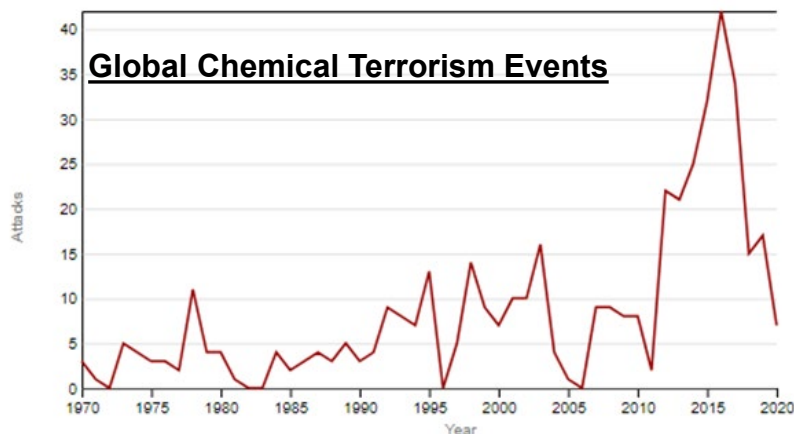
• Chemical Surveillance / Detection

- Chemical detection subject matter expertise and knowledge products

Chemical Hazard Landscape

According to the Global Terrorism Database:

- 425 Incidents of Chemical Terrorism occurred globally from 1970 to 2020
- Majority occurred in South Asia (121), Middle East (99) and Western Europe (52)
- **38 Chemical Terrorism Incidents occurred in North America, 33 in the U.S.A.**
- Worldwide private citizens, police, educational institutes and the military/government were the targets attacked most



START. (2022). Global Terrorism Database 19 July 2022.
Retrieved from <http://www.start.umd.edu/gtd>



Chemical Hazard and Threat Characterization Landscape

- In September 2022, the Chemical Abstracts Service Registry had **200 million** unique organic and inorganic chemical substances of which **350,000** are produced commercially and **86,000** are regulated by the U.S. Environmental Protection Agency (EPA) under the Toxic Substances Control Act.
- Large number of these chemical compounds are **highly toxic** and used in a number of industries throughout the country. They are **transported, stored, processed, sold and disposed of in large quantities.**
- Each of these points provides potential for access or diversion of the material to become a “**weapon of opportunity.**”
- There are **billions of possible scenarios** that involve these chemicals of opportunity.



Food Defense Incidents



- Accidental, intentional and criminal food adulteration incidents occur routinely
- These incidents provide case scenarios for future intentional adulteration events and draw attention to the impacts and toxicities of the compounds for bad actors/terrorists

Chemicals of Concern for Food & Water Targets that are Modeled by DHS

Chemicals of Concern for Food & Water Targets from S&T CSAC Threat Assessments

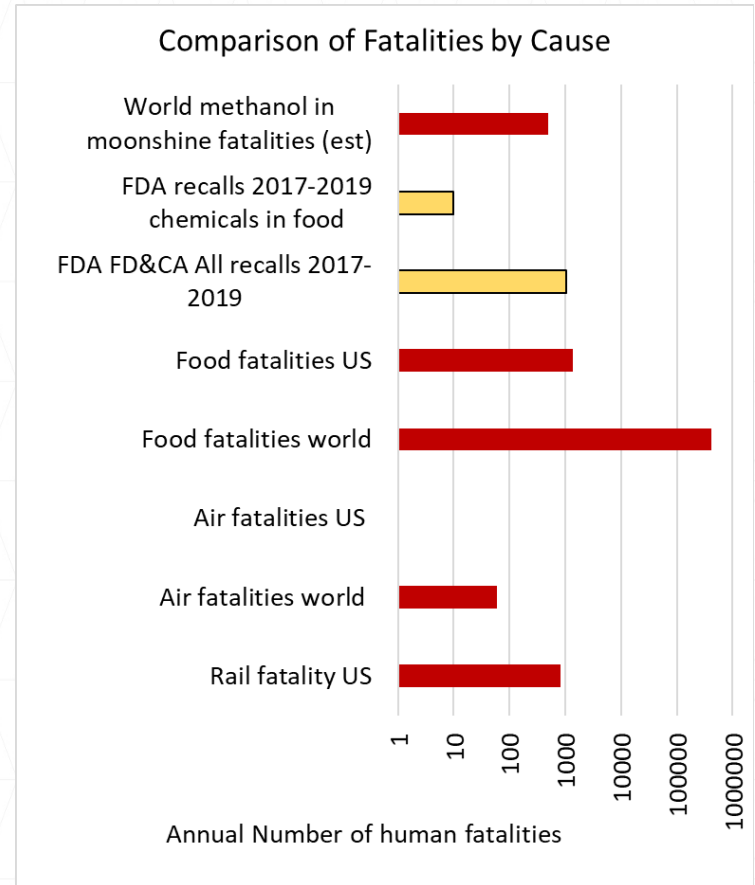
<u>Opioids</u> Fentanyl Carfentanil	<u>Stimulants</u> Caffeine Nicotine 2,4-Dinitrophenol	<u>Carbamate Pesticides</u> Aldicarb Methomyl
<u>Metallic compounds</u> Arsenic Trioxide Dimethyl Mercury Mercuric Chloride Osmium Tetroxide Thallium Sulfate Vanadium Pentoxide	<u>Other</u> 4-Aminopyridine Brodifacoum Cyanides Methacrylonitrile Sodium Fluoroacetate (1080) Sodium Azide Strychnine Tetramine (TETS)	<u>Organophosphorus Pesticides</u> Chloropyrifos Disulfoton Methamidophos Parathion Phorate Phosphamidon Tetraethylpyrophosphate (TEPP)
<u>Acids & Alkalis</u> Aqueous Ammonia Nitric Acid Hydrofluoric Acid	<u>Toxins</u> Anatoxin A Picrotoxin	<u>Nerve Agents</u> GB GD VX

Criteria: Solid or Liquid, Stable, High Toxicity

Red, bold = chemical has been used in a food adulteration event

Comparison of 2017 Fatalities by Cause

- Food fatalities greatly outrank air and rail fatalities
- Most food fatalities are caused by microbes, but chemical adulterants, and poor manufacturing (e.g., wood alcohol in ethanol) do occur.
- Sub-lethal Food Economically Motivated Adulteration (EMA) can become very widespread and persistent, such as di(2-ethylhexyl) phthalate in Taiwan (2011).
- The melamine in milk EMA (2008) incident in China was very widespread, and there were fatalities.



Food Adulteration Events: Common

• Multiple Events - Common Occurrences

- Methanol in home brewing – worldwide occurrence
- Methanol in bottled beverages from commercial establishments (Manning & Kowalska, 2021)
- Suicide, homicide, and family murders with pesticides; especially common in South East (SE) Asia (Bonvoisin, 2020)
- Tetramine poisonings in China that occurred from ~2000 to ~2006 (Li, 2014). 148 events, 3526 victim, 225 fatalities.
- Melamine in milk in China (Huang, Quartz, 2018)

NEWS
Tainted alcohol killed 19 people in Costa Rica last month
By Tania Lopez
July 21, 2019 | 7:20am



Li et al. BMC Public Health 2014, 14:842
<http://www.biomedcentral.com/1471-2458/14/842>

BMC
Public Health

Open Access

RESEARCH ARTICLE

Tetramine poisoning in China: changes over a decade viewed through the media's eye

Yi Li¹, Yanxia Gao², Xuezhong Yu^{3*}, Jingmin Peng⁴, Fei Ma¹ and Lewis Nelson⁴



Science and
Technology

Food Adulteration Events: Occasional

- Non-familial food preparation, such as in restaurants or at schools
- On-farm, manufacturing, wholesale, and any pre-purchase contamination
- Workplace and social event poisonings
- Select EMA events - on rare occasions the adulterant gives noticeable negative health effects
- Select Accidents – on rare occasions these are not caught or recalled, and the adulterant causes noticeable negative health effects



Data Collection

Sources:

- DHS S&T CSAC's daily publication '*DHS S&T CSAC Chemical Current News Report*' on chemical-related news events, including food adulteration
- Relevant events from the daily electronic publication *Food Safety News*
- Journals and Academic publications

Required Information:

- Location of the poisoning
- Chemical used
- Number of people affected (illnesses and deaths)

Desired Information:

- Location of adulteration
- Intent (often inferred from the article)
- Perpetrator, if arrested

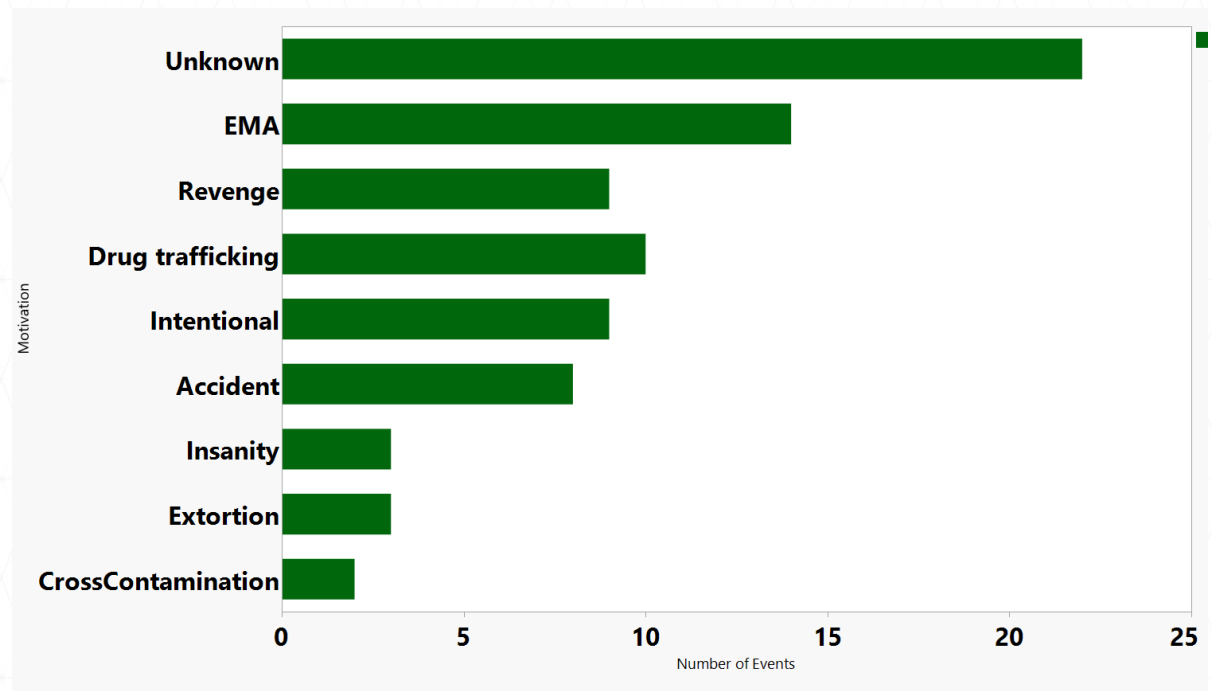


Science &
Technology

Chemical Security Analysis Center
Chemical Current News Report
21 July 2020

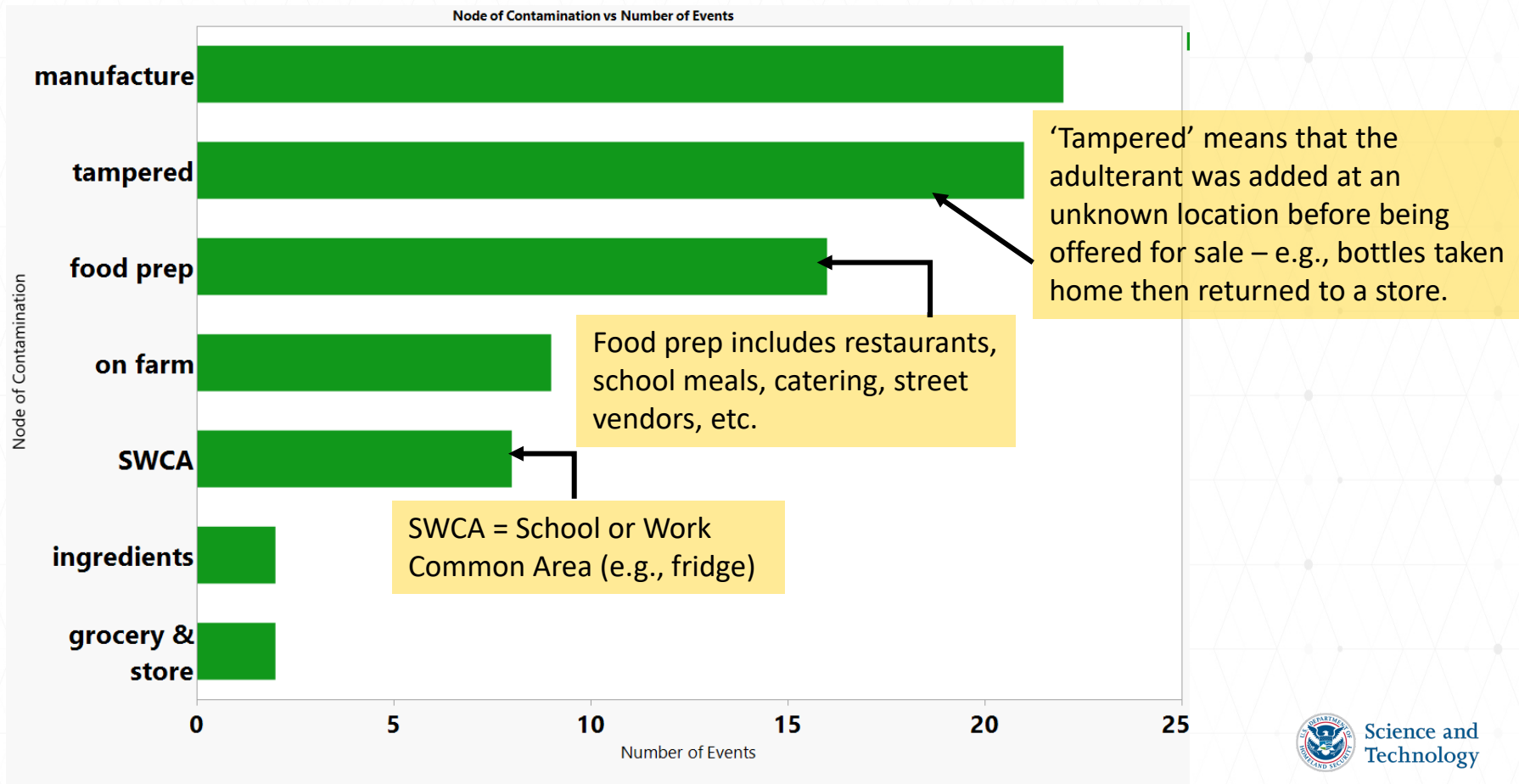
Motivations for Food Adulteration with Chemicals

- Total of 80 events from 2009 to August 2022 were identified
- In many instances the motivation was inferred from the news reports, but in 28% of the cases it was simply unknown.
- Although cross-contamination and accidents occur during manufacturing, these instances are generally caught before the product is shipped.
- Cross-contamination, EMA, and accident events illustrate how an intentional adulteration could be enacted.



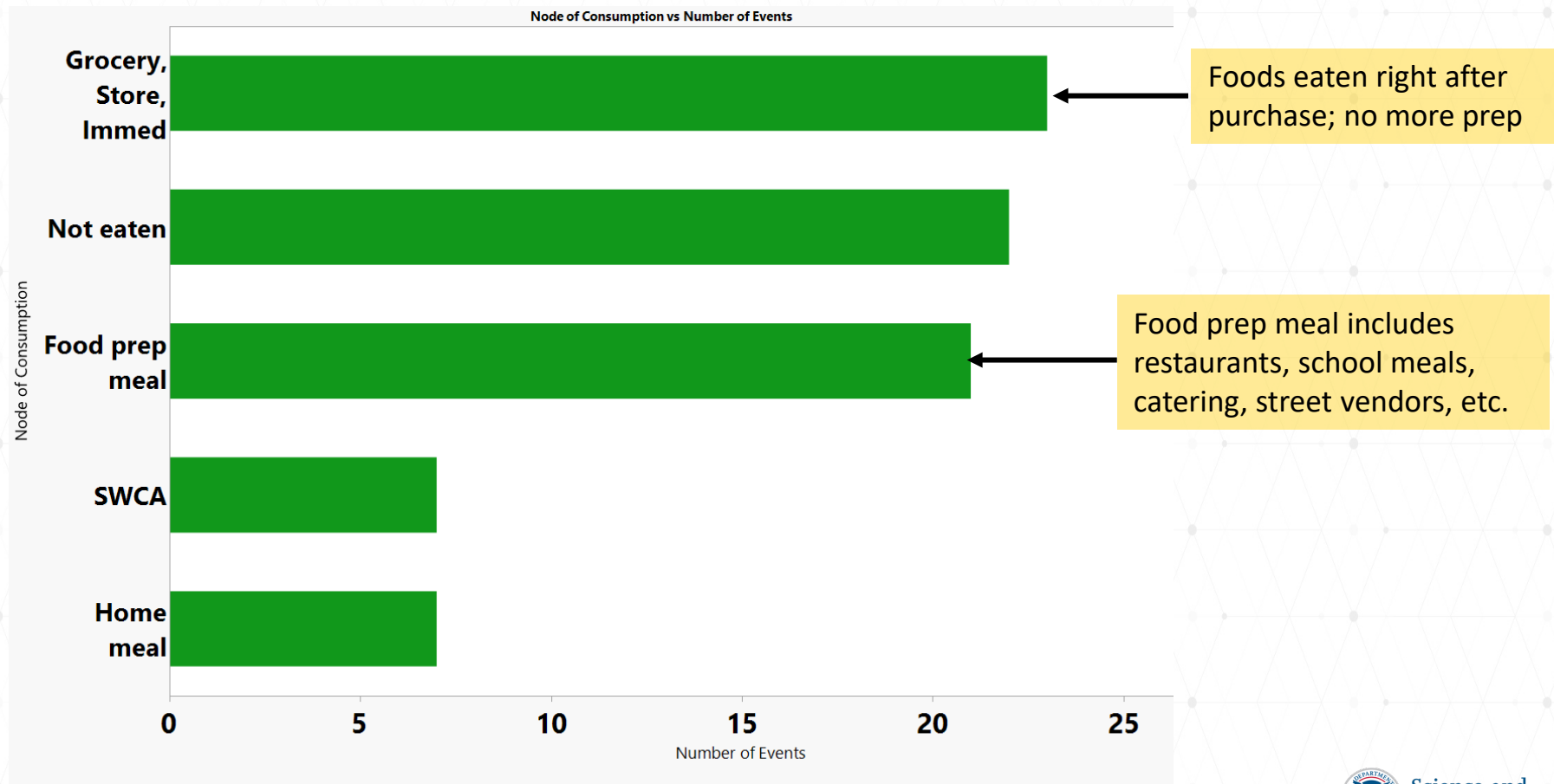
Node of Contamination vs. Number of Events

The node of contamination was inferred from the news article, although in tampering cases the exact node was hard decipher.



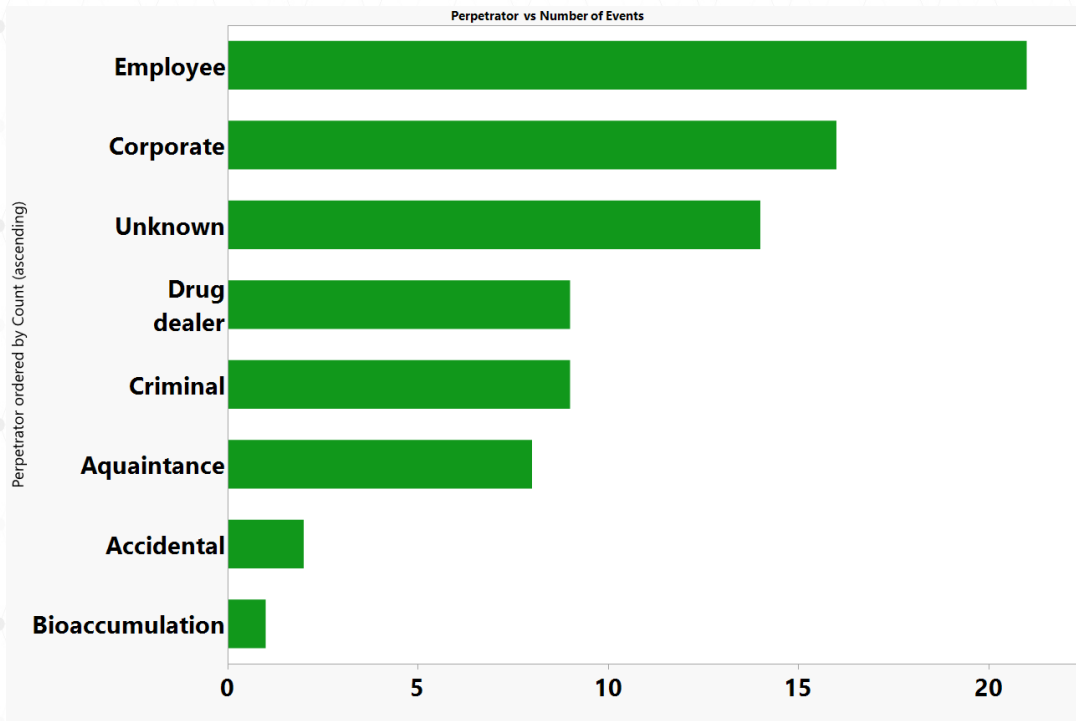
Node of Consumption vs Number of Events

The node of consumption was generally available from the news articles.

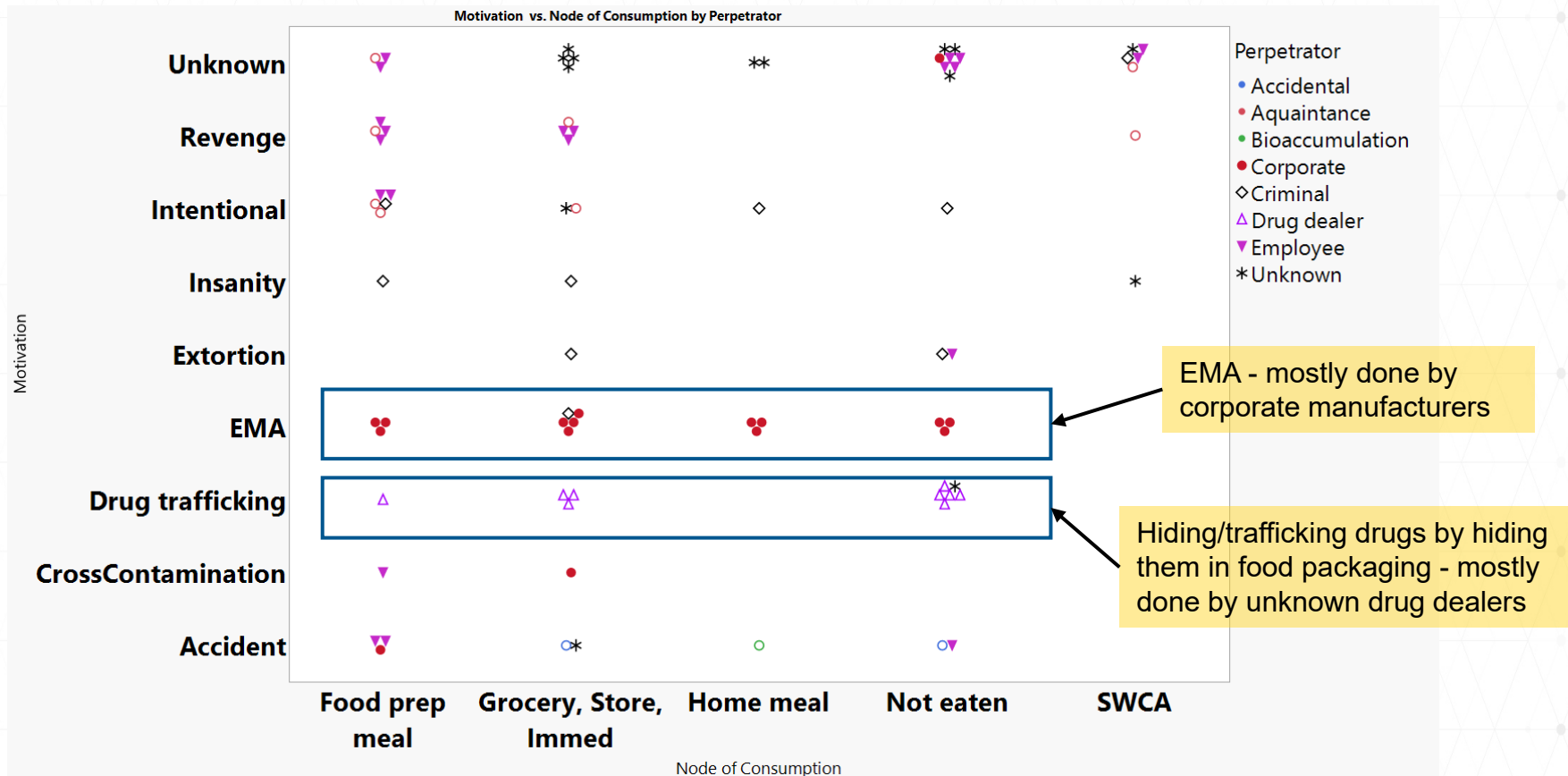


Perpetrators for Food Adulteration

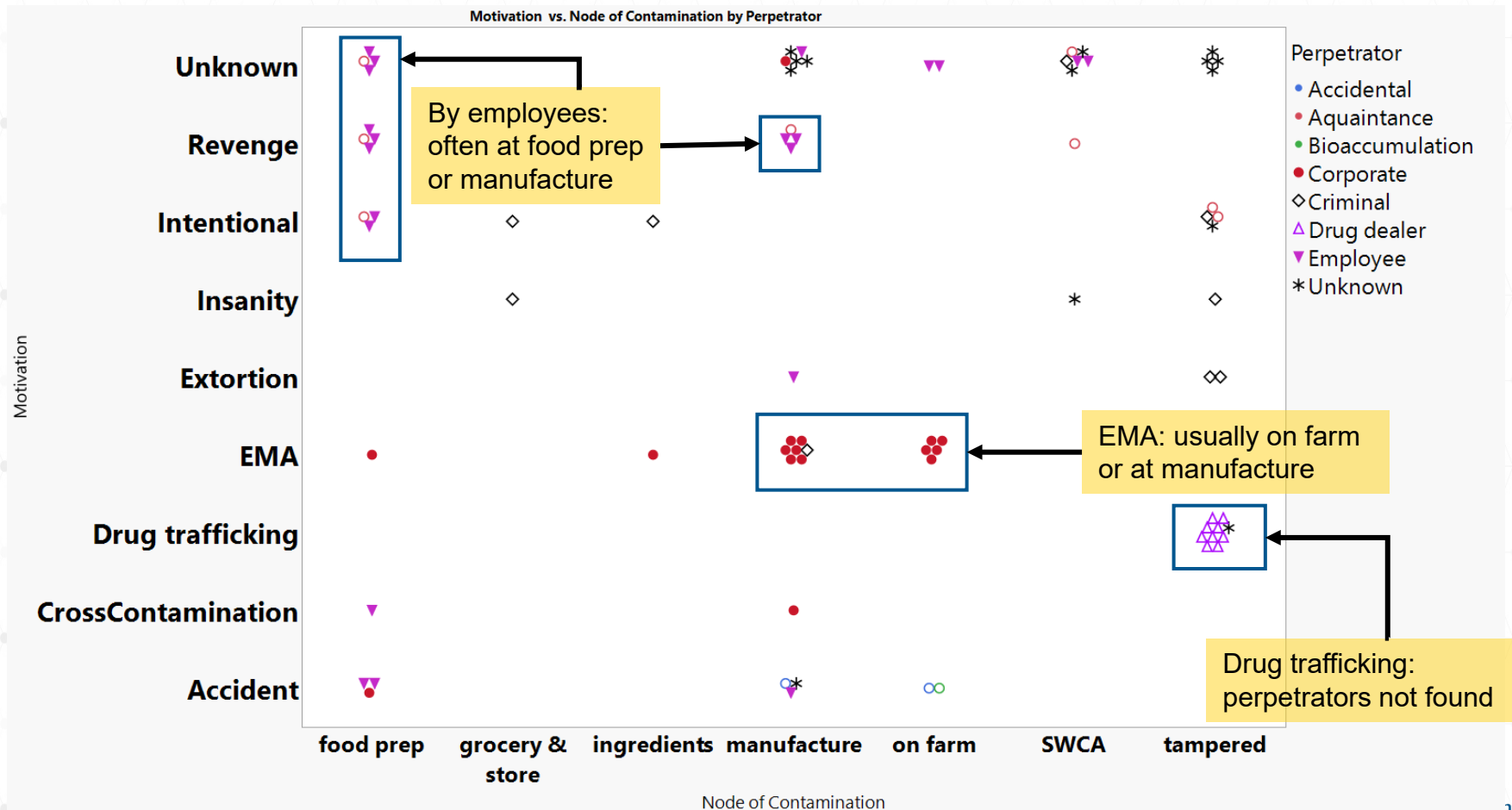
- The perpetrator was sometimes identified in the news article.
- In 58.8% of the cases no-one was arrested.
- In 25.0% of the cases one person was arrested.



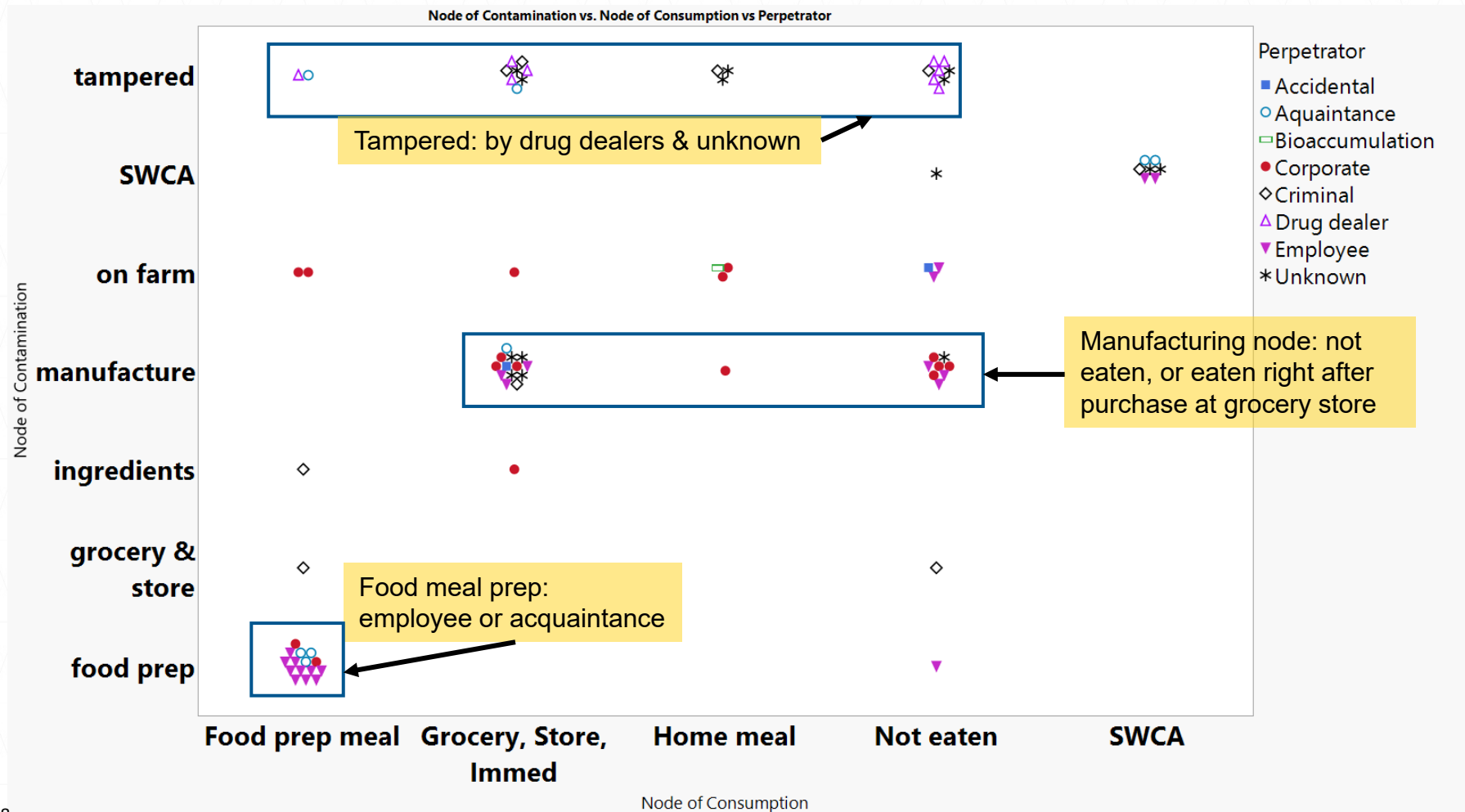
Motivation vs Node of Consumption by Perpetrator



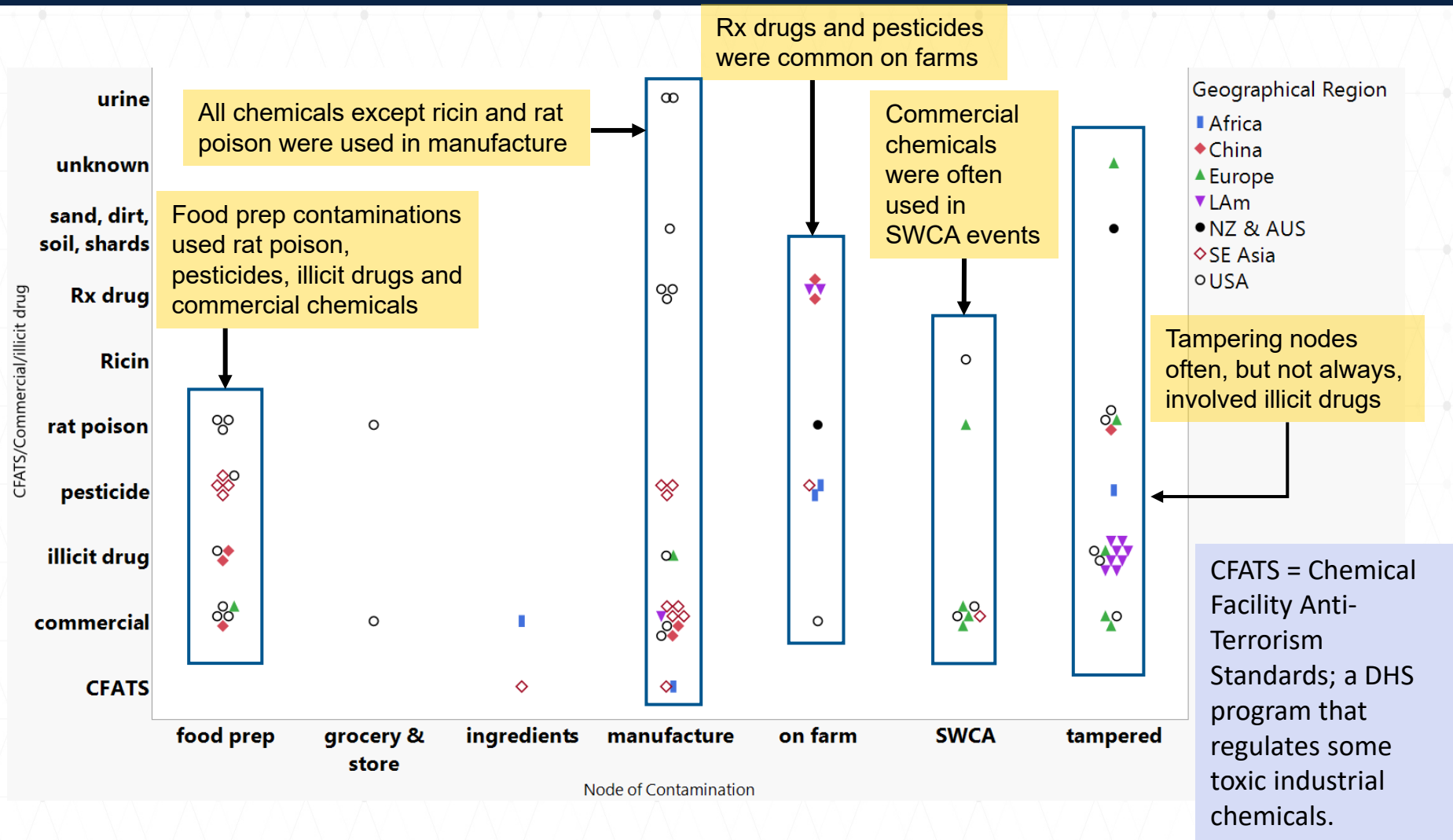
Motivation vs Node of Contamination by Perpetrator



Node of Contamination vs Node of Consumption by Perpetrator

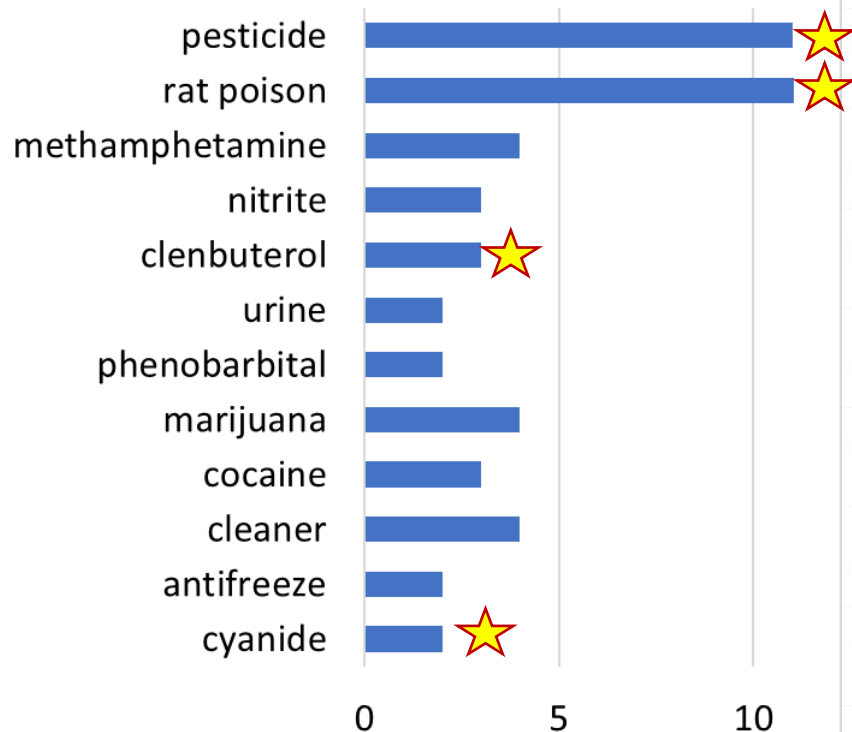


Class of Adulterant vs Node of Contamination by Geographical Region



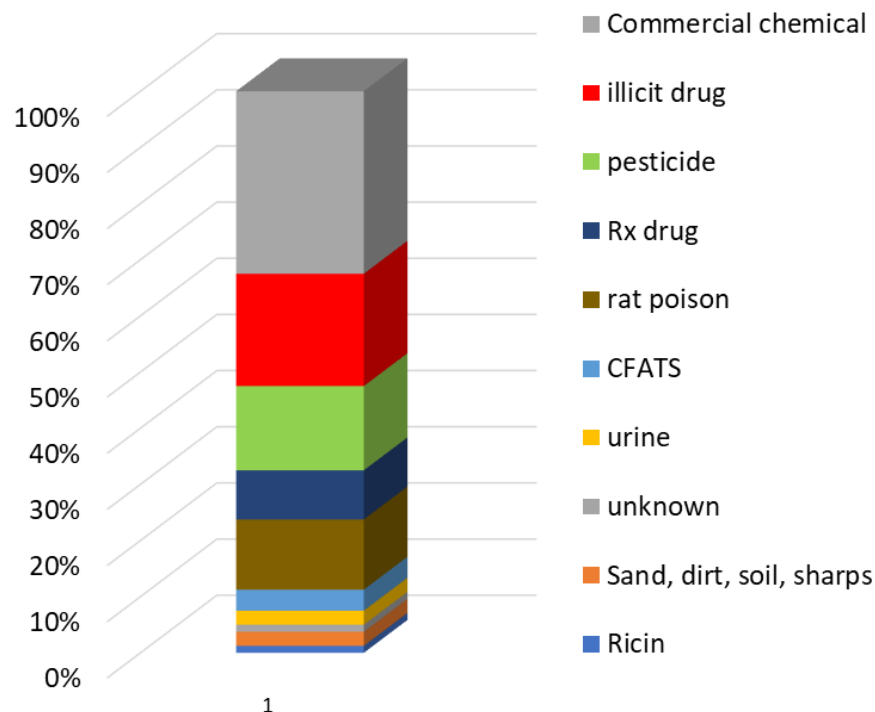
Types of Adulterants Used

Most Commonly Used Adulterants

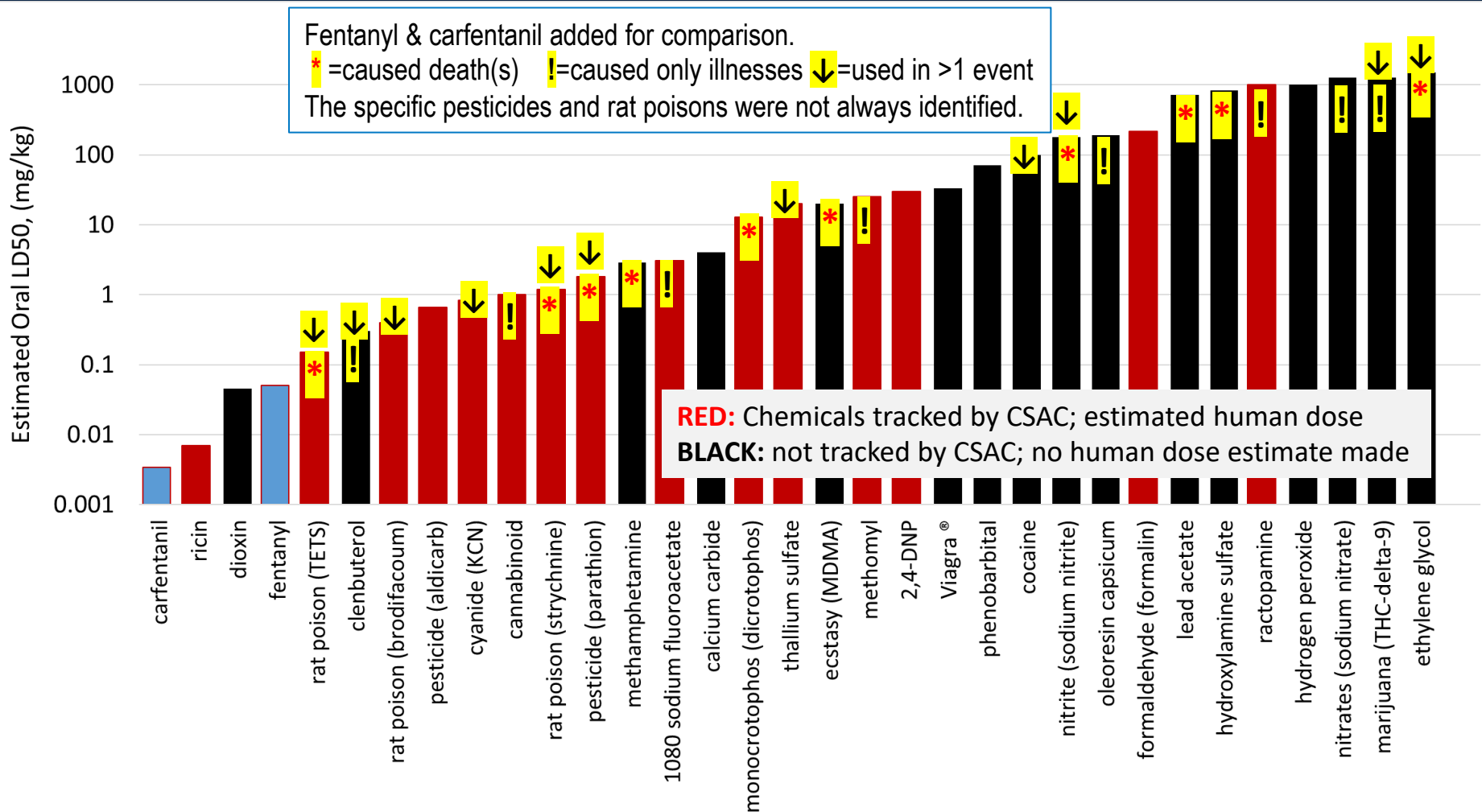


★ = LD50 < 1 mg/kg

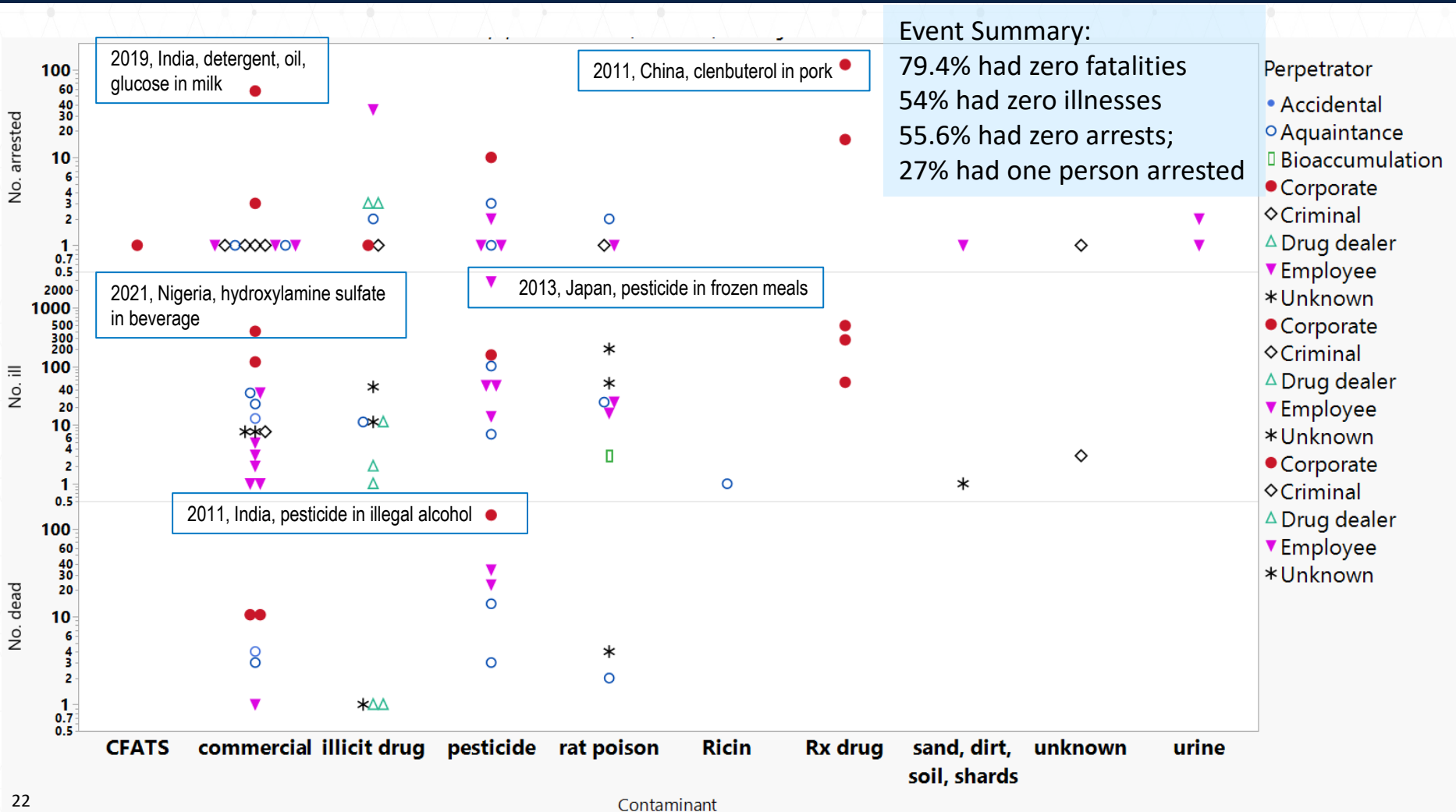
Types of Adulterants



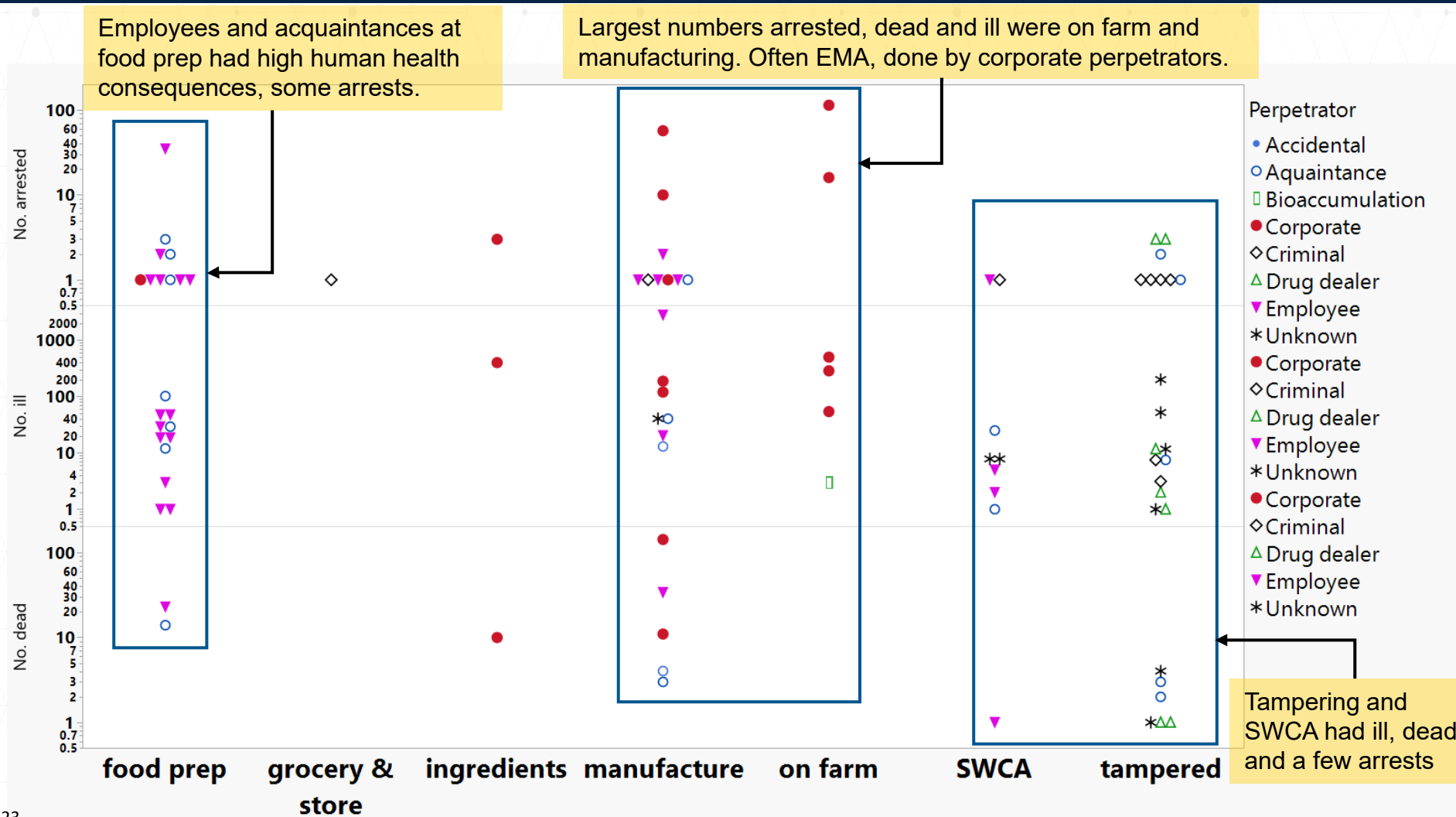
Oral Toxicity of Compounds Used



Human Consequences vs. Adulterant Used

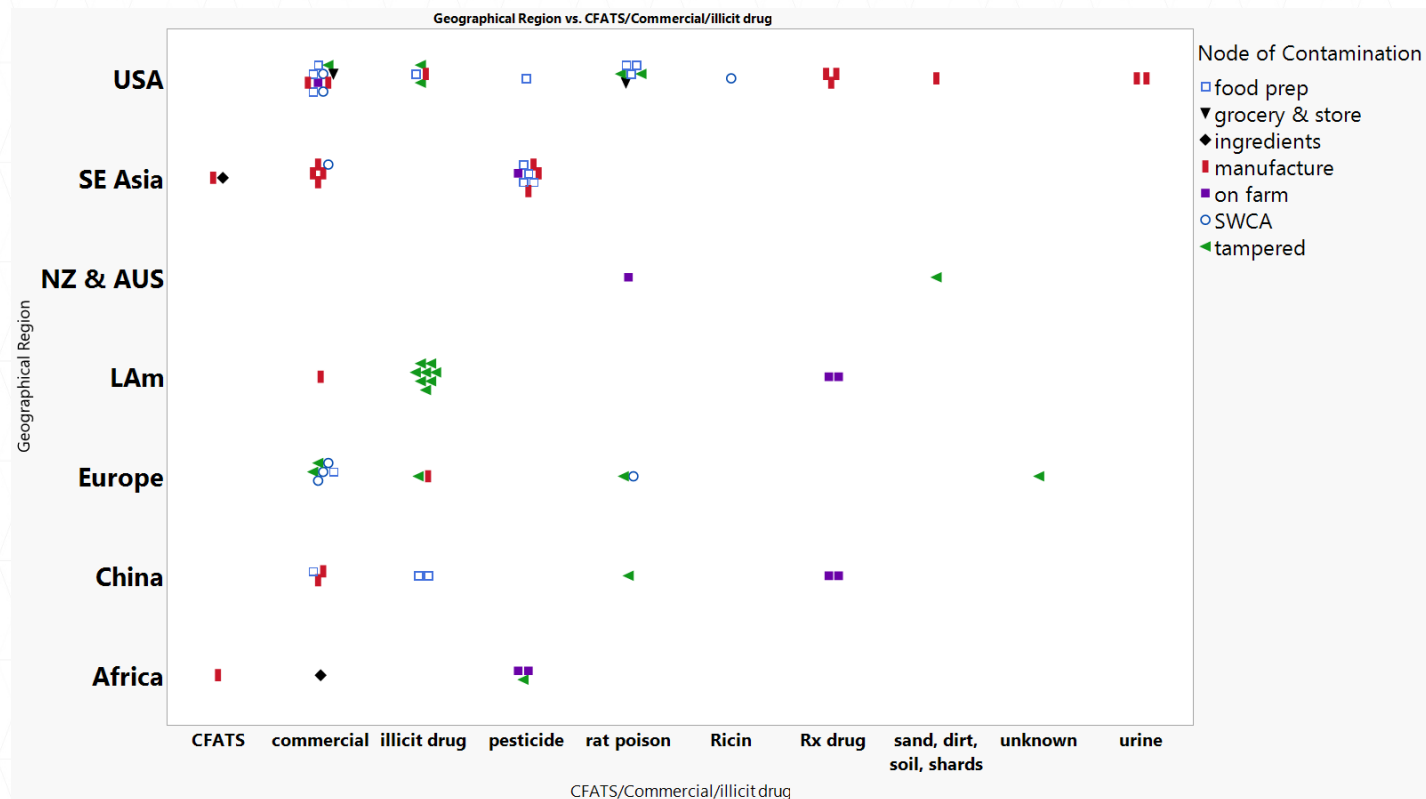


Human Consequences by Node of Contamination



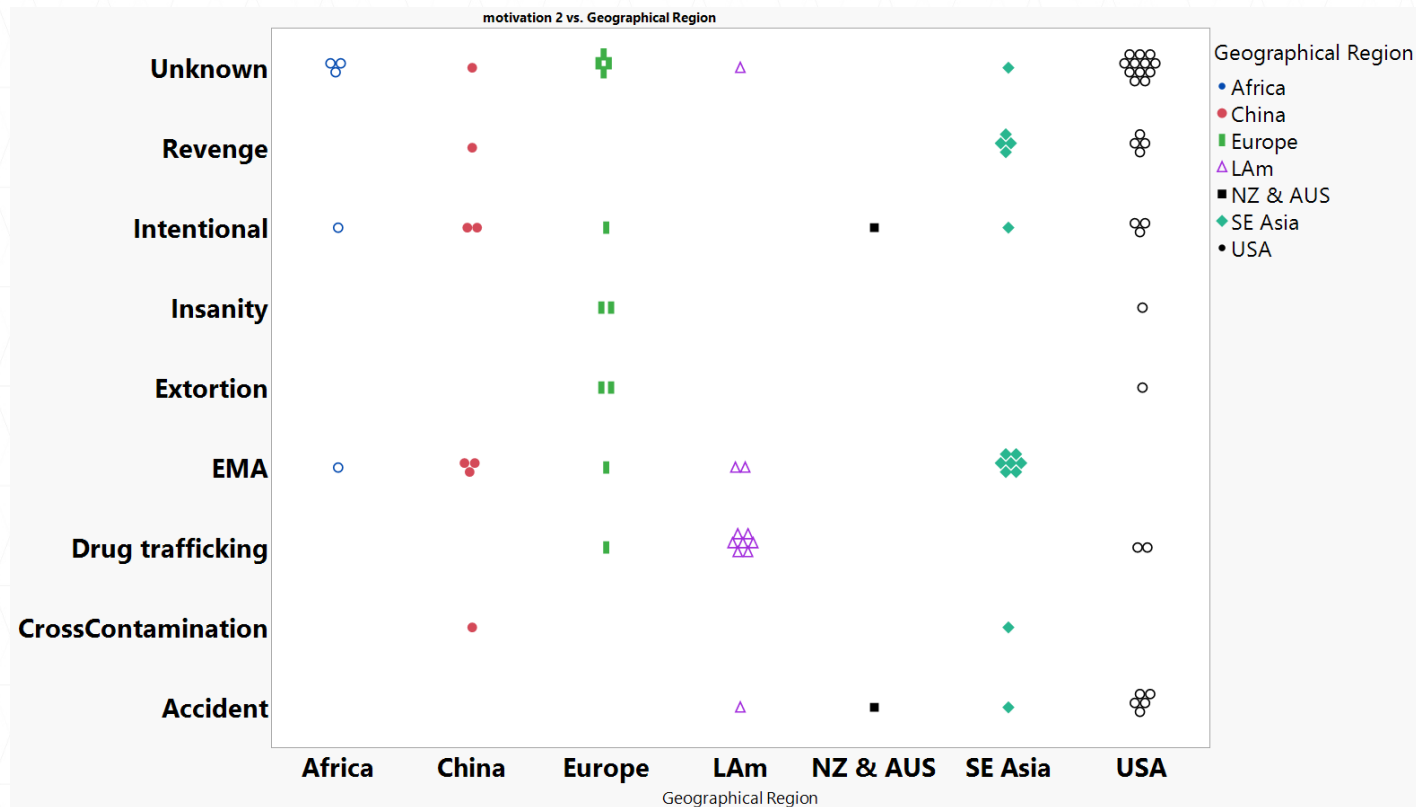
Geographical Trends in Chemicals Used

- Pesticides – seen mostly in SE Asia and Africa
- Illicit Drugs concealed with food – most were in Latin America
- Commercial chemical are used in all locales
- The US has the widest variety of chemicals used



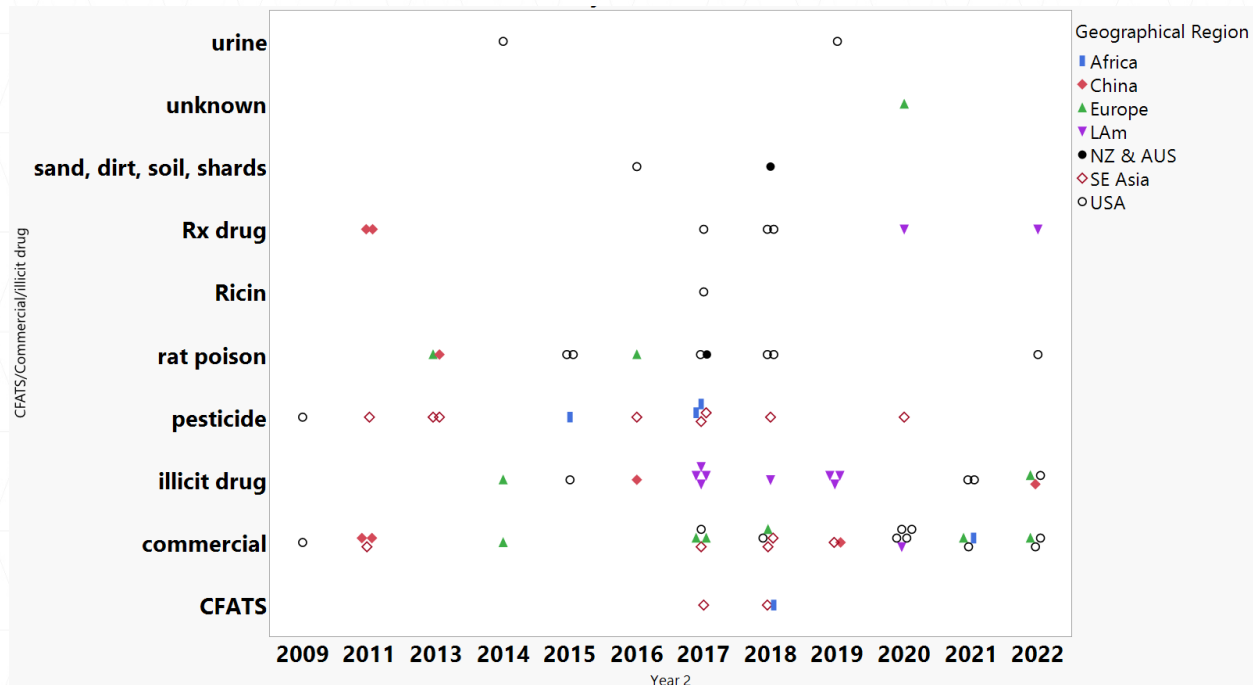
Geographical Trends in Motivation

- EMA was very common in SE Asia
- Revenge common in US and SE Asia
- Unknown motivation in 28% of cases



Annual Trends

- Few trends with type of chemical and year of event
- Illicit drug concealment as food was first noted in 2017
- Multiple food fraud incidents were found in China over the years, but the incidents did not have the information needed for this study
 - Many of these events involved ingredients (salt, oil, milk) or animal husbandry, and arrests of perpetrators occurred



Summary

- Food defense events happen routinely, providing **case examples** for the terrorists.
- Our routine use and dependency upon a large number of highly toxic compounds make them a **“weapon of opportunity.”**
 - All of the chemicals chosen were readily available; none were Chemical Warfare agents.
 - The chemicals chosen spanned a range of toxicity values.
- Some food adulteration scenarios have the potential to produce hundreds of thousands of injured people.
- DHS S&T CSAC can model scenarios to help the food sector **focus food defense planning, preparedness and mitigation efforts on the most likely, most catastrophic and highest risk compounds and toxidromes** to secure our food supply and save lives.

List of the Top Fatality and Illness Events

Year	Country	Agent used	Type of chemical	Food	Motivation	Node of Consumption	Node of Contamination	Perpetrator	No. dead	No. Ill	No. arrested
2011	India	pesticide	Commercial	local illegal alcohol 'desi daroo'	EMA	Retail direct	manufacture	Corporate	143	144	10
2016	Pakistan	pesticide	pesticide	Candy	Revenge	Retail direct	manufacture	Employee	34	14	0
2013	India	monocrotophos	pesticide	school lunch	CrossContamination	Food prep meal	food prep	Employee	23	47	1
2018	India	monocrotophos	pesticide	tomato rice	Revenge	Food prep meal	food prep	aquaintance	14	102	3
2011	China	antifreeze	Commercial	vinegar	CrossContamination	Retail direct	manufacture	Corporate	11	120	0
2021	Nigeria	hydroxylamine sulfate	Commercial	Dan Tsami beverage	EMA	Retail direct	ingredients	Corporate	10	400	3
2018	USA	rat poison	rat poison	Synthetic marijuana	Unknown	Home meal	tampered	Unknown	4	200	0
2011	China	nitrite	Commercial	milk	Revenge	Retail direct	manufacture	aquaintance	3	36	1
2013	Japan	pesticide	pesticide	Frozen Products	Revenge	Retail direct	manufacture	Employee	0	2800	1
2022	Mexico	clenbuterol	Rx drug	pork (cochinita)	EMA	Food prep meal	on farm	Corporate	0	500	0
2011	China	ractopamine	Rx drug	pork	EMA	Retail direct	on farm	Corporate	0	286	16
2009	USA	methomyl	pesticide	Salsa	Revenge	Food prep meal	food prep	Employee	0	48	2
2015	USA	cannabinoid	illicit drug	Bread (King cake)	Unknown	Retail direct	manufacture	Unknown	0	45	0
2011	China	clenbuterol	Rx drug	pork	EMA	Retail direct	on farm	Corporate	0	0	114
2022	China	opium	illicit drug	chili oil	EMA*	Food prep meal	food prep	Corporate	0	0	1
2019	India	liquid detergent, refined oil, glucose powder	Commercial	Milk	EMA	Retail direct	manufacture	Corporate	0	0	57

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Questions?



Science and
Technology

FDA Update on Closer to Zero and PFAS Activities

12/13/2022

Food Safety Tech Meeting

Paul South, Ph.D.

Center for Food Safety and Applied Nutrition

U.S. Food and Drug Administration

Discussion Outline

- FDA Statutory Authority
- FDA Enforcement Options
- FDA's Monitoring and Compliance Programs
- Two Examples
 - Toxic Elements/Closer to Zero Action Plan
 - Per- and Polyfluoroalkyl Substances

Federal Food, Drug and Cosmetic Act

- Provides FDA with regulatory authority with regard to adulterated foods that are in interstate commerce or delivered for introduction into interstate commerce
- Defines when a food is adulterated [Section 402 Federal Food, Drug, and Cosmetic Act]

Adulteration under § 402(a)(1)

- 1) Food bears or contains any poisonous or deleterious substance ***and...***

- 2) If the substance is ***added***, FDA must show that the quantity of the substance in the food ***may render*** the food injurious to health

or

If the substance is ***not added***, FDA must show that the quantity of the substance in the food ***ordinarily renders*** it injurious to health

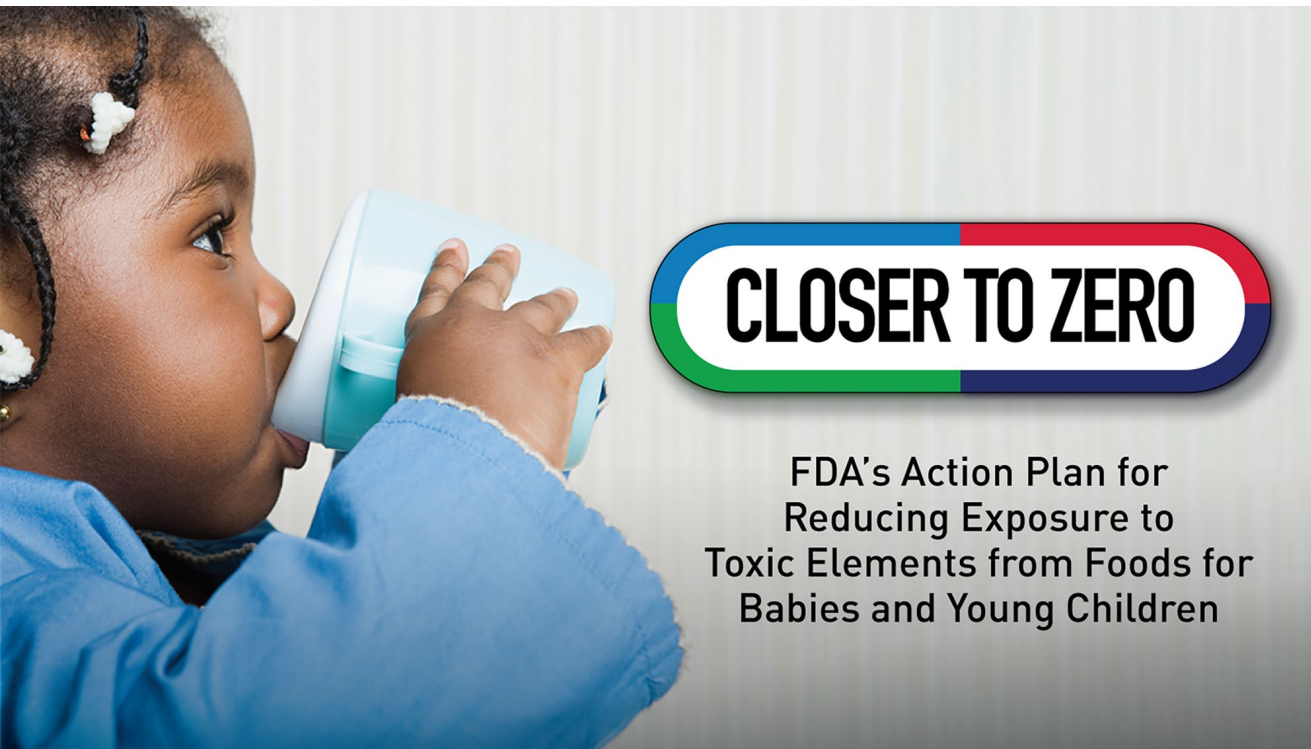
Enforcement Options for 402(a)(1)

- Tolerances, regulatory limits, action levels under 21 CFR part 109
- Case-by-case, using safety assessments
 - Level of contaminant
 - Type of food and consumption of that food
 - Available toxicological information
- If a food is adulterated under FFDCA
 - Seizure/recall of domestic food
 - Detention or refusal of entry of imported foods

FDA Monitoring and Compliance Programs for Chemical Contaminants in Food

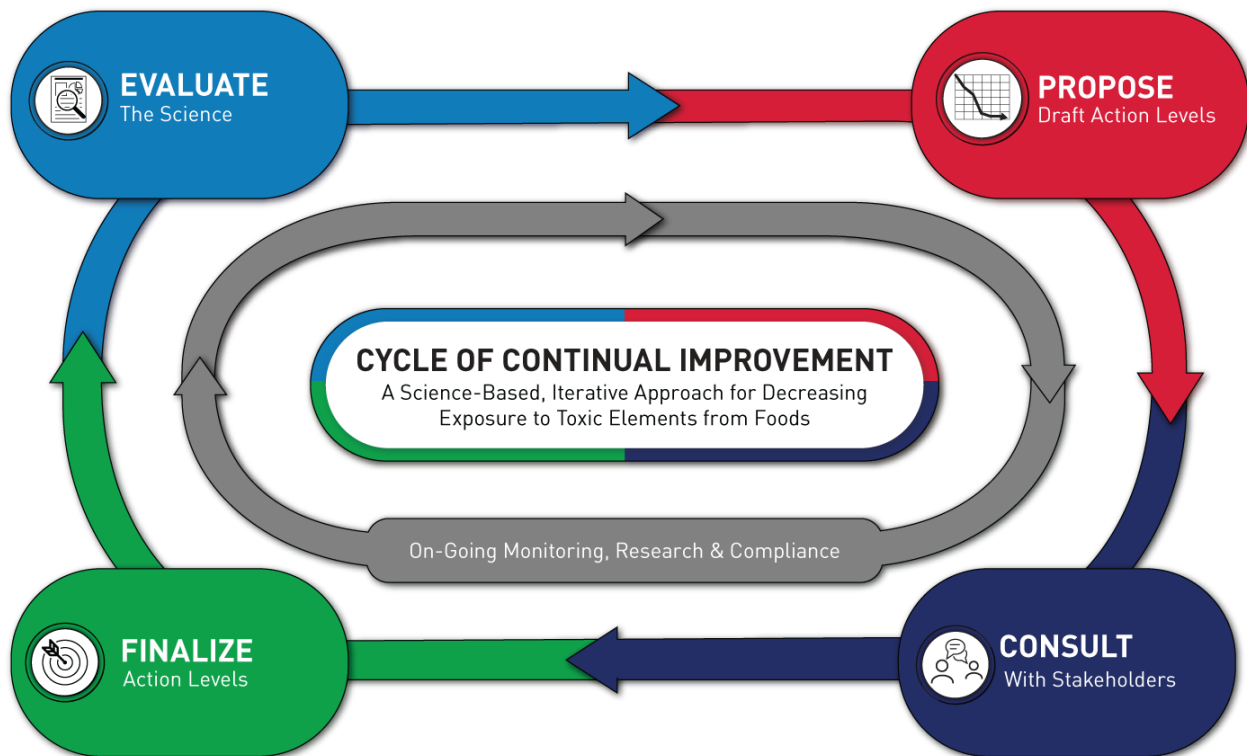
- FDA Monitoring and Compliance Programs
 - Total Diet Study
 - Toxic Elements in Food and Foodware, and Radionuclides in Food - Import and Domestic
 - Pesticides and Industrial Chemicals – Import and Domestic
 - Mycotoxins in Food – Import and Domestic
 - Laboratory Flexible Funding Model

Toxic Elements



CLOSER TO ZERO

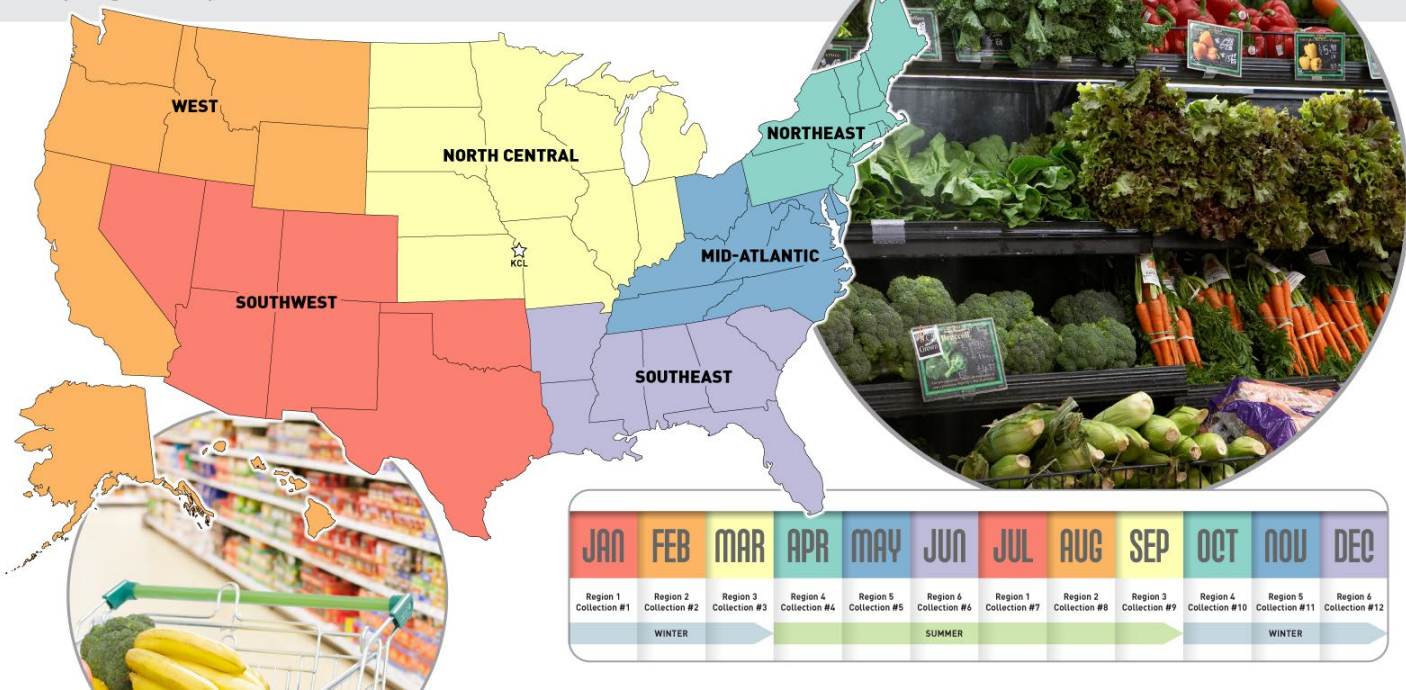
FDA's Action Plan for
Reducing Exposure to
Toxic Elements from Foods for
Babies and Young Children



FDA's Total Diet Study

FDA'S TOTAL DIET STUDY

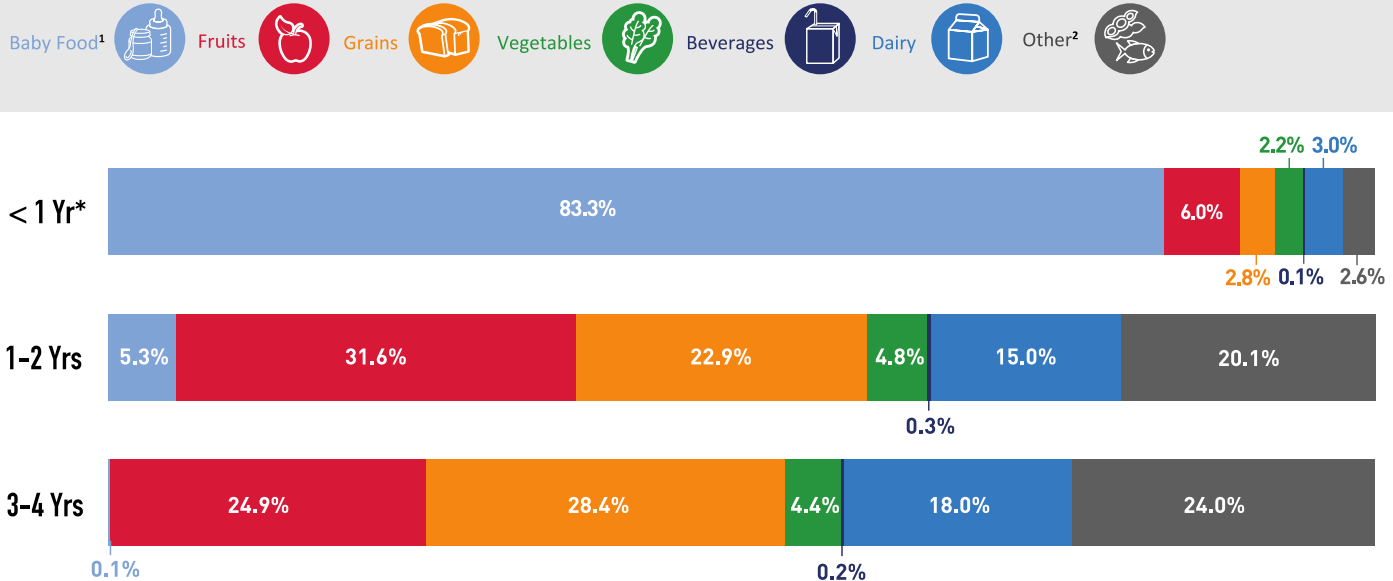
Sampling Plan by Calendar Year



JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
Region 1 Collection #1	Region 2 Collection #2	Region 3 Collection #3	Region 4 Collection #4	Region 5 Collection #5	Region 6 Collection #6	Region 1 Collection #7	Region 2 Collection #8	Region 3 Collection #9	Region 4 Collection #10	Region 5 Collection #11	Region 6 Collection #12
	WINTER				SUMMER					WINTER	

LEAD EXPOSURE IN FOOD CONSUMED BY BABIES AND YOUNG CHILDREN

Total Percentage of Exposure by Food Groups



1. Includes infant formula.

2. Includes eggs, fats/oils, legumes, nuts, seeds, meat, poultry, fish, mixtures, and sweets.

* Excludes children who consumed human milk in the 2-day period.

Data Source: 2014-2016 TDS and 2009-2014 NHANES/WWEIA

Action Levels for Lead in Juice: Guidance for Industry

Draft Guidance

This guidance is being distributed for comment purposes only.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition**

April 2022



THE KEY TO A WELL-BALANCED DIET IS EATING A VARIETY OF HEALTHY FOODS

This is important for the growth and development of babies and young children ages 6 months and older.

Per- and Polyfluoroalkyl Substances (PFAS)

- PFAS are water and oil repellent and thermally and chemically stable.
- Used in stain- and water-resistant fabrics and carpeting, cleaning products, paints, fire-fighting foams, cookware, and food packaging.
- Thousands of PFAS chemicals; PFOA and PFOS, 8-chain carbon compounds, have been the most extensively produced and studied.

PFAS Attributes and Potential Health Effects

- PFAS are persistent in the environment.
- Certain PFAS have been shown to accumulate in plants and animals and in the human body.
- Exposure pathways: oral, inhalation, dermal; via food, water, indoor dust, and a variety of consumer products.
- Health effects associated with certain PFAS exposure in humans and animals include:
 - Increased cholesterol levels
 - immunotoxicity; reproductive and developmental toxicity;
 - evidence of carcinogenic activity for some PFAS.

Overview of FDA's Role

- Measuring PFAS concentrations in food and estimating dietary exposure to help inform efforts to identify and prioritize activities to reduce PFAS in human and animal food.
- Developing new and more precise testing methods to measure PFAS concentrations in various foods and working with states to build capacity for local testing laboratories.
- Supporting state and local governments in responding to known and possible contamination events that may impact human food or animal food, including as an exposure source for food-producing animals.
- Assessment and regulatory authority over food contact substances containing PFAS.

Ongoing PFAS Activities

- **Continue to expand testing and analysis of U.S. food supply**
 - Additional TDS foods, seafood survey, other foods
- **PFAS method development/method transfe**
 - Analyte extension (additional PFAS)
 - Transfer methods to FDA field laboratories, state laboratories, other laboratories
 - Standard Reference Material
- **Work with states**
 - Technical assistance, including analyzing human and animal food
 - Method transfer

Ongoing PFAS Activities

- **Work with other federal agencies**
 - Interagency meetings for information sharing and collaboration
- **PFAS in food contact applications**
 - Monitoring the phase-out of certain short-chain PFAS
 - Fluorinated polyethylene
- **Communications and outreach**
 - Post PFAS methods and testing results on FDA webpage: <https://www.fda.gov/food/chemical-contaminants-food/and-polyfluoroalkyl-substances-pfas>

