Impact of Emerging Scientific Methods on Food Safety Policy: Issues and Examples

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The food supply chain



Adulteration (Relevant Clauses), 21 U.S.C. §342

- Food that contains any poisonous or deleterious (injurious to health; harmful) substance,
 - Exception: "but in case the substance is not an added substance, such food shall not be considered adulterated ... if the quantity of such substance in such food does not ordinarily render it injurious to health."
 - Zero tolerance (presence/absence) vs. tolerance (allowable amount)
- Food that has been prepared, packed, or held under insanitary conditions whereby it **may have become** contaminated with filth, or whereby it may have been rendered injurious to health
 - Note, the food does not have to be unsafe in order for it to be adulterated; even food that is safe to consume will be considered adulterated if it passed through an area that is insanitary and that **could** have contaminated the food.
- Additives, microbes, and conditions that could lead to contamination; 21 CFR 110.5; must not have conditions that can lead to contamination
 - Note that this prohibition does not address only the food product, but the conditions under which the food product is manufactured; thus this prohibition extends the reach of the regulatory agency.
- The prohibitions against adulterated foods under U.S. federal law primarily apply to processing. State law also generally prohibits adulterated and misbranded foods; these laws usually apply to the processing and retail/food service sectors
- Food processors are required to establish that their food product meets legal requirements/standards; that is, establish that the food is not adulterated or misbranded. This is not the government's responsibility

How is Adulterated Food Identified?

- Pathogens enter the food chain mostly unintentionally
- Identification by:
 - Epidemiological investigation (illnesses, i.e., outbreak)
 - Routine microbiological testing
 - Industry
 - Regulatory
 - Both?
- What is the general source of contamination?
 - Environmental (e.g., Listeria monocytogenes)
 - Animal feces (e.g., Salmonella, Campylobacter)
 - Human feces (e.g., Shigella, norovirus, hepatitis A virus)
- Where does the contamination occur?
 - Farm, processing plant, restaurant, etc.
- What are the extenuating factors?

Emerging Scientific Methods and Implications

- Epidemiological surveillance (FoodNet, PulseNet, Genometrakr)
- Molecular-based detection methods—Polymerase chain reaction (PCR)**
- Next generation sequencing (NGS), metagenomics, and bioinformatics**
- Mathematical modeling and risk assessment**
- Social media and crowd sourcing (e.g., iwaspoisoned.com)**
- Gene editing (CRISPR-Cas9)/genetic engineering

Example #1: Non-Cultivable Foodborne Pathogens

EMEL FOOD & CONSUMER PRODUCTS TESTING **Professional Laboratory Services Since 1981 FOODBORNE ILLNESSES**



sofication - The most common ood home illness caused by many pecies of lancteria. It causes acute set of headache, fever, bdominal pain, diarrhea, nausea h occasional vomiting. ehydration in infants and the erly can be severe. Incubation od is 6-72 hours usually tween 12-36 hours. onvoir - Exists in domestic and

wild animals including poultry, pigs, cattle, rodents, and pets such as baby chicks and ducklings,

turtles, iguanas, dogs and cats. ion - ingestion of the organism in food obtained Tr parter from infected animals or contaminated by feces from infected animals or people. Epidemics are traced to contaminated vegetables and fruit, eggs, processed meat, undercooked poultry products, raw milk and dairy products and foods prepared by infected food personne



coli 0157:H tification - Causes acute diarrhea with no fever. Incubation period is 2 to 10 days, most commonly 3-4 days. Diarrhea may

be mild to severe with no blood or almost entirely blood. About 8% of people having diarrhea caused by this organism progress to hemolytic uraemic syndrome (HUS). infectious dose is very low. Children under 5 are at greatest risk for developing HUS

reoir - Cattle are the primary reservoir although it is also found in deer. Humans can serve as the reservoir for person to person transmission

Transmission - Fecal/oral and the ingestion of food contaminated with ruminant feces. Serious outbreaks have been associated with petting zoos, beef, hamburger, melons, spinach, lettuce, scallions, apple cider, alfalfa sprouts, and unpasteurized milk. Person to person transmission occurs in families, custodial care facilities, and day care centers. Water borne transmission comes from drinking and recreational water



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impylobacte

iner An enteric disease aused by Campylobacter jejuni or coll accompanied by malaise. thea, bloody stools, abdomina sain, fever, nausea, and vomiting imptoms may occur 2-5 days after sure and persist for a week. ervoir - Poultry, cattle and ther animals such as pupples, kittens, other pets, swine, sheep, rodents and birds. Most raw

poultry is contaminated with Campylobacter. Transmission - Ingestion of the organisms in undercooked meat, contaminated water and food, raw milk, farm animals, pets. Infective dose is low. Person to person transmission is possible but not common



Contification - A disease which causes meningoencephalitis and/or septicemia in new-borns and adults that is caused by L. monocytogenes In prognant women it causes fever and miscarriage or stillbirths. An asymptomatic woman can transmit the disease to the fetus. High risk populations include neonat elderly, immunocompromised pregnant women, alcoholics, maberics.

Reservoir - Soil, silage, forage, and water. Animal reservoirs include infected wild and domestic animals. Up to 10% of the healthy people have L. monocytogenes in their feces but do not have symptoms

ion - Ingestion of contaminated foods such as soft Tran cheeses, raw milk, vegetables, ready to eat meats and pates, in neonatal infections, the bacteria is transmitted by the mother in utero or from passage through the birth canal.

> Norovirus Identification - A viral infection

hylococcus aureus. The disease characterized by abrupt (30 inutes to 4 hours) and violent net of vomiting, severe nauses ramps, and prostration. Illness ists a day or two. These iterotoxins are resistant to boiling or thermal processing.

refection but is caused by the

interntoxint produced by

on - It is not an

ir - Humans, About 25 % of the population carries this bacteria. Occasionally cows with infected udders, dogs and fowl. Transmission - Ingestion of a food containing the enterotoxin The food becomes contaminated first with the bacteria via the food handlers' hands. At room temperature, the bacteria multiply and produce the enterotoxin. Can be found in improperly handled or stored salad dressings, custards, sliced meat, meat products, meat sandwiches, unprocessed cheese,



Aflatoxin ntoxication

Identification - Liver cancer caused by foods contaminated with certain species of Aspengillus fungi. As the fungi grow, they produce aflatoxins and other mycotoxins hat contaminate the food. incubation period for fungal prowth may be 2 days to 3 months. ervoir - Aspergillus fungal species are ubiguitous and exist worldwide particularly in decaying

plant material, compost piles, mulch, and leaf piles. Affatoxin and mycotoxin production is variable and depends upon the type of Aspergillus species and environmental conditions mission - Airborne transmission of spores. Ingestion and possibly inhalation of mycotoxins.



alf-limiting diarrhea, or chronic, requent diarrhea with oramps, ploating and incomplete absorption of fats and vitamins eventually leading to fatigue and weight loss. In severe glardiasis there may be eactive arthritis and damage to the fuodenal and jejunal mucosal cells. Median incubation is 7-10 days.

Reservoir - Humans and possibly beavers and other wild and domesticated animals nission - Localized outbreaks occur from the ingestion of

food and water contaminated with protozoan cysts. Typical chlorine treatment of drinking water is not enough to destroy the cysts. Unfiltered, contaminated recreational water can be a source. Person to person transmission occurs from transfer of cysts from infected people particularly in day care centers and institutions

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that causes mild to moderate gastrointestinal illness with nausea, vomiting, diarrhea, odominal pain, headache, mataise, and low grade fever Usually lasts for 1-3 days. Reservoir - Humans are the only known reservoir. Paramission - Fecal/oral through ingestion of contaminated food. water or shell fish. Also contact



with infected for

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Conventional Culture Methods--GOLD STANDARD



Non-Cultivable Pathogens--Enteric Viruses



Hepatitis A virus

-Picornaviridae

- Self-limiting hepatitis syndrome
- Most severe of the foodborne viral diseases
- Reportable diseas dic state

- Simple structure
 - Protein coat (capsid)
 - Nucleic acid core (RNA)
- Very small (20-50 nm diameter)
- Fecal-oral transmission: *Human* fecal material
- RTE foods (restaurants) and produce





Human Norovirus

-Caliciviridae

- Self-limiting vomiting and diarrhea in adults and children
- Leading cause of viral gastroenteritis and foodborne disease
- Not a reportable disease

Non-Cultivable Pathogens--Parasitic Protozoa





- Much larger than bacteria (eukaryotes)
- Complex life cycle
- Of greatest foodborne significance *Cyclospora cayetanensis*
- Gastrointestinal illness
- Fecal-oral transmission (*humans*)
 - Water
 - Feces
 - Soil
 - Other sources?
- Fresh produce

Detection of Non-Cultivable Pathogens in Foods



End product is an amplified piece of DNA Is/was it ALIVE????



PCR Exponential Amplification

For Viruses, Preceded by Reverse Transcription Step (RT), RNA ----> cDNA



- Detects nucleic acid (DNA or RNA), not live virus or protozoa
- Nucleic acid can have be very stable, even after the microorganism is no longer infectious
- Detection of nucleic acid by RT-qPCR or PCR is not assurance that there is a "live" pathogen present— INFECTIVITY DILEMMA
- We don't have a culture in-hand by which we can "prove" infectivity or do further characterization
- There is a need to confirm (sequence)

Microbiological Surveillance Sampling: FY18-21 Fresh Herbs (Cilantro, Basil & Parsley) and Processed Avocado and Guacamole Assignments



Available at: https://www.fda.gov/food/sampling-protect-foodsupply/microbiological-surveillance-sampling-fy18-21-fresh-herbs-cilantro-basilparsley-and-processed#Results

Microbiological Surveillance Sampling: FY 19-20 Frozen Berries (Strawberries, Raspberries and Blackberries)





Available at: https://www.fda.gov/food/sampling-protect-food-supply/microbiological-surveillance-sampling-fy-19-20-frozen-berries-strawberries-raspberries-and#sampling

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

Kroger Recalls Select Frozen Private Selection Berries for Possible Health Risk

Shenandoah Growers, Inc Issues a Limited, Voluntary Recall of Specific Imported Organic Basil Because of Potential Health Risk

But there are are identifiable cases of illness

- What is the public health significance of a positive finding in the case of no associated illness?
- Interpretive criteria for RT-qPCR
 - Small proportion of the genome sequenced (<250 bp vs. 7.5 kb)
 - Interpretation of high Ct values (what constitutes a positive?)
 - Criteria for successful amplification, sequencing, sample positivity
 - Absence of a live culture upon which additional characterization can be done
- Expense to producers and processors
- Balance of economic vs. public health risks
- Surveillance studies for the pathogens will only be increasing

PCR Positivity Criteria used Internationally

- Move toward a Ct cut-off value
 - Ct<40 considered positive
 - Supported by clinical diagnostics (COVID-19, norovirus)
- Establishment of genome copy "tolerance"
 - Molluscan shellfish in Europe, in negotiation
 - 100-1,000 GEC (38-40, supported by clinical medicine, shellfish sanitation in UK/Europe
- Establish criteria for number of replicates positive and/or repeat testing (Eastern Europe)
- Risk-based (Canadian approach)

Use of PCR-Positive as an Indicator of the Potential for Product Adulteration

- Microbiological indicator: an organism, metabolite, or molecular signature whose presence and/or concentration in a sample is used as proxy for the potential presence of a pathogen or other harmful substance
- Examples
 - Shellfish sanitation (generic *E. coli*)
 - ATP bioluminescence to monitor sanitation
- Is the presence of a positive PCR signal for enteric viruses be an indicator of potential human fecal contamination?
 - Infectivity dilemma
 - Persistence of nucleic acids in the environment
 - Needs to be scientifically vetted

Example #2: Managing SARS CoV-2 Transmission in the Essential Workforce

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Fig. 5. Transmission routes involving direct contact, indirect contact by contaminated surfaces and fomites, as well as by droplets (short range) and droplet nuclei (long range) spreading [on the basis of (Tang et al., 2006)].

Understanding Transmission, the Food Industry is Applying Risk-Based Approaches to Protect Workers from SARS-CoV-2

- Temperature, Symptom Monitoring & Furlough
- Close Contact Documentation
- 🕤 Universal Mask Usage
 - Handwashing or Sanitizer Stations
 and Education
- Surface Disinfection: Increased frequency and rigor

- Physical Distancing Controls
 - Plexiglass Shields
 - Slower line speeds
 - Worker Shifts
 - No contact between Proc **6** ft Workers and Visitors/Administrative Staff
 - Smaller Cohorts for breaks
 - Uni-directional traffic
 - Smaller cohorts for breaks



Controlling risk of SARS-CoV-2 infection in essential workers of enclosed food manufacturing facilities

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^a Rollins School of Public Health, Emory University, Atlanta, GA, 30322, USA ^b Food, Bioprocessing and Nutrition Sciences, North Carolina State University, Raleigh, NC, 27695, USA CONTROL CONTROL

Among essential food workers in an enclosed facility,

- 1. Which transmission pathway is most important?
 - Resiratory—Aerosol/Droplets
 - Fomites (Surfaces)
- 2. Are worker protection strategies enough?

Worker Protection Strategies

- Physical Distance
- Mask Use
- Air Exchange
- Hand-Hygiene
- Surface Disinfection



Parameter	Units	Description	Input Values (a, b) *	Distribution
VIRUS				
Log ₁₀ (C _{virus})	PFU/mL	Concentration of virus in saliva	6.1 (5.2, 7.0)	Uniform
d _{p,c}	cm	Diameter of respiratory particles for coughing event	6E-4 (2E-4, 4.9E-3)	Triangular
V _{F,c}	mL/Cough	Fraction of volume associated with droplet diameters 100µm–750µm	6.8E-3 (4.0E-3, 7.6E-3)	Triangular
$\lambda_{ m virus}$	hr	Viral decay of SARS-CoV-2 per relative humidity environment	HH: (0.0466, 0.0911) LH: (0.0676, 0.1527)	Uniform
STRATEGY				
S _{mask}	Log reduction	Surgical mask efficacy	0.1549 (0.140, 0.222)	Triangular
C_{mask}	Log reduction	Cloth mask efficacy	(0.0458, 0.7100)	Uniform
SC _{eff}	Log reduction	Surface cleaner percent reduction in virus	(2.0, 6.0)	Uniform
HW_{freq}	Washes / hr	Frequency of handwashing per hour	1	Point
RISK				
F _{sa}	m²	Surface area of fomite	(0.74, 2.20)	Uniform
F ₁₂	Proportion	Proportion of virus transferred from fomite to hand per relative humidity	HH: 0.374 (0.160) LH: 0.069 (0, 0.158)	Normal Triangular
L_{dep}	Proportion	Deposition fraction of infectious virus into the lungs	0.210 (0.006, 0.320)	Triangular
k _{risk}	Unitless	Dose-response parameter	2.46E-3 (1.35E-3, 4.59E-3)	Triangular

Table 3

Impact of bundled interventions (mask use, ventilation, hourly handwashing and surface disinfection twice per shift [4 h and 8 h]) on median infection risk (5th - 95th percentile) and percent risk reduction (%) following 8 h cumulative exposure to an infected worker (cough event as a function of distance). Colors indicate risk level from each bundled package. Dark purple indicates a high relative level of risk (>0.25-1.0), medium purple indicates a moderate relative level of risk (<0.01-0.25), and light purple indicates a low relative level of risk (<0.01).

	Relative level of risk:		High (>0.25-1.0)	Moderate (0.01-0.25)	Low (<0.01)	
			1m	2m	3m	Aerosols
No ACH	No mask	Risk $(5^{th} - 95^{th})$	0.98 (0.76–0.99)	0.15 (0.07–0.32)	0.09 (0.04–0.18)	0.05 (0.01–0.13)
2 ACH CI	Cloth mask	Risk (5 th – 95 th)	0.22 (0.06–0.61)	0.005 (0.002–0.01)	0.004 (0.001–0.01)	0.002 (0.0005–0.009)
		% Reduction	77.6%	96.6%	95.9%	95.5%
	Surgical mas	Risk $(5^{th} - 95^{th})$	0.14 (0.02–0.47)	0.003 (0.0009–0.01)	0.002 (0.0005–0.007)	0.001 (0.0001–0.006)
		% Reduction	86.0%	97.8%	97.4%	97.1%
	Double mask	Risk $(5^{th} - 95^{th})$	0.04 (0.005–0.30)	0.001 (0.0002–0.005)	0.0007 (0.0001–0.004)	0.0003 (0.00003-0.003
		% Reduction	96.2%	99.3%	99.2%	99.3%
6 ACH C	Cloth mask	Risk $(5^{th} - 95^{th})$	0.10 (0.02–0.33)	0.002 (0.0007–0.006)	0.001 (0.0005–0.004)	0.001 (0.0002–0.003)
		% Reduction	89.8%	98.6%	98.3%	98.2%
	Surgical mas	Risk $(5^{th} - 95^{th})$	0.06 (0.009–0.24)	0.001 (0.0004–0.004)	0.001 (0.0002–0.003)	0.001 (0.00005–0.002)
		% Reduction	93.8%	99.1%	98.9%	98.8%
	Double mask	Risk $(5^{th} - 95^{th})$	0.02 (0.002–0.14)	0.0004 (0.00007-0.002)	0.0003 (0.00004–0.002)	0.0001 (0.00001–0.001
		% Reduction	98.4%	99.7%	99.7%	99.7%



в

Outbreak probability is most reduced by daily testing or high vaccination coverage combined with masking or distancing.



SCHOOL OF PUBLIC HEALTH

FROZEN FOOD

INSTITUTE

Vaccine Coverage 0 0 0.25 0.5 0.75 1

Title: Low risk of SARS-CoV-2 transmission via fomite, even in cold-chain

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Findings: In a representative facility with no specific interventions, SARS-CoV-2 infection risk to a susceptible worker from contact with contaminated packaging was 2.8×10^{-3} per 1h-period (95%CI: 6.9 x 10^{-6} , 2.4×10^{-2}). Implementation of standard infection control measures, handwashing and masks (9.4 x 10^{-6} risk per 1h-period, 95%CI: 2.3×10^{-8} , 8.1×10^{-5}), substantially reduced risk (99.7%). Vaccination of the susceptible worker (two doses Pfizer/Moderna, vaccine effectiveness: 86-99%) combined with handwashing and masking reduced risk to less than 1.0×10^{-6} . Simulating increased infectiousness/transmissibility of new variants (2-, 10-fold viral shedding) among a fully vaccinated workforce, handwashing and masks continued to mitigate risk (2.0×10^{-6} - 1.1×10^{-5} risk per 1h-period). Decontamination of packaging in addition to these interventions reduced infection risks to below the 1.0×10^{-6} risk threshold.

Interpretation: Fomite-mediated SARS-CoV-2 infection risks were very low under cold-chain conditions. Handwashing and masking provide significant protection to workers, especially when paired with vaccination.

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Example #3: Next Generation Sequencing, Metagenomics, and Bioinformatics

Novel opportunities for NGS-based one health surveillance of foodborne viruses

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January 24, 2020

Petition Asks FSIS to Declare 31 Salmonella Strains as Adulterants

Marler Clark LLP filed a petition on behalf of several individuals and consumer groups on January 19, asking USDA's Food Safety and Inspection Service (FSIS) to issue an interpretive rule declaring 31 salmonella strains as per se adulterants in meat and poultry products. These strains, which the petition refers to as the *"Salmonella* Outbreak Serotypes," include four antibiotic-resistant strains—*Salmonella hadar*, *heidelberg*, *newport*, and *typhimurium*—as well as *Salmonella dublin*, *enteritidis*, and *infantis*. The petition seeks expedited review of its request on the grounds that these strains have been shown to be linked to foodborne illness outbreaks and/or product recalls and, as such, constitute an imminent threat to public health.

According to the petition, declaring these 31 strains as adulterants would promote the goals of the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act to protect public health by encouraging the meat and poultry industry to implement more effective safeguards and oversight measures. The petition relies heavily on its interpretation of precedent established following the 1993 *Escherichia coli*, when USDA declared *Escherichia coli* O157:H7 a per se adulterant in raw ground beef through interpretive rulemaking.

https://www.jdsupra.com/lega lnews/petition-asks-fsis-todeclare-31-35558/ **CONFIDENTIAL INTERNAL USE ONLY - NOT FOR REDISTRIBUTION**

Example #4: Crowd Sourcing



Online reporting platform allows consumers to easily search, find the site, and file reports **2.** Manage Data



Data analytics team curates and moderates the data and extracts usable intelligence. **3.** Provide Services



Early warning signals are provided to subscribers, including the public health community, industry and consumers



Sample Report

Local Restaurant a New Jersey Town

Reported: Jan 14th 2019 Symptoms: Diarrhea, Nausea

I ate the meal on Sunday January 13th, at around 12:00. At 1:00am, approximately 11 hours subsequent, I had violent diharreah and stomach pain. This is the point I'm at rn, writing this.

I ate:

-lobster bisque

-house salad with iceberg lettuce and the champagne vinegarette

-the platter with lobster, crab legs, and two types of shrimp. I barely ate shrimp or lobster though (besides in the bisque), mostly just the crab, so that is my suspect

I just had tap water to drink, and haven't eaten anything else all day.





Outbreak Case Study

Calgary, CA December 2019

We first began receiving reports relating to ******** in Calgary on Dec 5th, 2019. By Dec 19th, we had received reports of over 100 sick, and local news coverage commenced. By the 23rd: 123 sickened, and Alberta Health Services confirmed a Norovirus outbreak linked to the local chain. We found out about this over 3 weeks in advance. This is the type of outcome we specialize in preventing.

⊙ ▼ NEWS



Click <u>here</u> to watch the news story



Conclusions

- As scientific and analytical methods become more sophisticated and sensitive, there will be downstream management and regulatory actions that have policy and legal implications
- For example:
 - Identification of outbreaks in near real-time
 - Identification of new or emerging pathogens (e.g., STEC, Cyclospora cayetanensis)
 - Detection advances-"chasing zero" and finding "needles in haystacks"
 - Regulatory actions in food production (e.g., FSMA Water Rule in fresh produce)
- It is important to carefully consider the strengths and weaknesses of these techniques to prevent unintended consequences that can manifest as overprotection of public health and have financial implications, among other consequences