Fortification of Staple Commodities and Microbial Safety Requirements for Human Food Production: Distant USAID F2F Program in Haiti

Trip Report (April 8, 2021)

Aliyar Fouladkhah, PhD, MPH, CFS

Faculty Director, Public Health Microbiology Laboratory

Tennessee State University, Nashville, TN

Summary:

I was privileged and honored to serve as a volunteer for this assignment in Haiti. Due to an ongoing global respiratory pandemic/endemic and consequently local and global travel restrictions, this assignment was completed solely via Zoom and distantly. Nevertheless, thanks to the support and cooperation of F2F colleagues from Washington and Haiti offices, and the enthusiastic participation of the host, this assignment was very impactful for capacity building and progress. The assignment was originally designed for only two weeks in July, however, due to requests from the host institution, the meeting was extended until December 2020.

During the first three months of the assignment, through various Zoom/Team calls and email conversations, the public health microbiology program was able to share and discuss resources and best practices about micronutrient malnutrition with the host institution including information from USAID Micronutrient Program and the World Health Organization. Specifically, methods and best practices were discussed for fortification of flour with iron including Qualitative Test (Spot Test), Semi-Quantitative Test (Spot Test), Semi-Quantitative Test (Colorimetric method), Quantitative Test (Spectrophotometric method), and Quantitative Test (Atomic absorption spectrophotometric [AAS]) method. These assays could be incorporated as part of regulatory affairs in the field as well as during laboratory analyses to assure effectiveness and compliance of the intervention.

In the next phase of the assignment, a list of reagents and consumables was developed to assure the host institutions are capable of conducting these endeavors. The list was tailored to the need of the host institution by assuring assays and laboratory procedures could be completed domestically after acquiring the supplies. Cost-saving recommendations as well as suggestions to purchase service contract for parts and labor were made to assure sensitive instrumentation could remain functional for an extended time.

In November of 2020, some participants of the host program in Haiti joined a multiday food safety certification workshop hosted by the public health microbiology laboratory. While receiving the certifications, members of the host also shared valuable and insightful information about great progress in the food industry and fortification programs in Haiti that benefited the

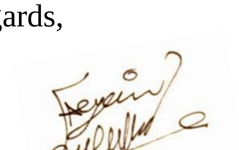
participants of the workshop. Excerpts of the workshop presentations are provided in this trip report.

One of the most impactful parts of this assignment was a fortification workshop held in December of 2020 where detailed best laboratory practices, nutrition information, and food safety procedures were discussed with 13 senior-level participants of the workshop including members from governmental and non-governmental organizations and the food industry (specifically participants were from Ministry of Health; Oil Industry: Carribex & HUHSA; Salt Industry: Bon Sel D'Haiti; Wheat Flour Industry: LMH & Caribbean Milling; and RANFOSE).

Not only am very pleased about the great progress and deliverables of this extended assignment, but as well I would like to sincerely thank great colleagues from RANFOSE for their outstanding work and progress for food security and public health in their country. Specifically, am grateful for friendship and collaboration with Mr. Regis Yves-Laurent and Dr. Ruth Climat who inspired me by their outstanding progress, professionalism, and dedication to the fortification program in their home country.

Finally, I would like to thank all colleagues in the Washington and Haiti F2F office, specially Ms. Susanna Meyer, for the outstanding work they are doing and for harmonizing the events of this program. With their help and support and with assistance from the members of the public health microbiology laboratory, we were able to conduct this impactful and important training event during the unknown and stressful global respiratory pandemic/endemic times. Am pleased and excited about the capacity-building endeavors in this assignment and hope that the host company and the F2F office in Haiti continue to flourish in future years to come.

Sincere regards,



Aliyar Fouladkhah, PhD, MPH, CFS

Assistant Professor, Tennessee State University

Faculty Director, Public Health Microbiology Laboratory

Yale School of Public Health Alumnus

Consumables and Methods

Hello, Mr. Regis,

I put together the testing methods for iron in flour to seek your input. I just would want to make sure that I am on right track and if these are the tests that you have in mind.

If you would like to schedule a phone call I would complete some other tests by then and could report to you all more on these. For Iron testing I divided the tests in three categories (1) **Qualitative/spot test**. This would be helpful for inspection purposes and shows presence or absence of the micronutrient in the food vehicle, relatively inexpensive and easy to conduct. The second category (2), called them **semi-quantitative test** that are wet chemistry-based and do not need major instrumentations, 2.A. is similar to the spot test and 2.B is a spectrophotometric methods. Both 2.A. and 2.B. could be used in regional labs and also in the manufacturing facilities. Third categories are **quantitative methods**, those are obviously more labor intensive and more difficult to conduct as they require iron standards, 3.A. is spectrophometric tests and 3.B is Atomic absorption spectrophotometric methods. I just would want to make sure that I am on right track and if these are the tests that you have in mind. Once we schedule the next phone call, I will report on remaining of progress as well.

Testing Iron in Flour:

1. Qualitative Test (Spot Test):

Method: Iron qualitative method, AACC Method 40-40

Reagents:

Thiocyanate reagent (Dissolve 10 g KSCN in 100 ml water).

2N HCl,

Hydrogen peroxide, 3%.

Equipment: none

2.A. Semi-Quantitative Test: (Spot Test):

Method: Semi-quantitative spot test for iron INCAP method IV.

Reagents:

Hydrochloric acid, HCl

Hydrogen peroxide, H2O2

Potassium thiocyanate, KSCN

H2O2

2. B. Semi-Quantitative Test (Colorimetric method):

Method: Semi-quantitative colorimetric determination of iron in flour INCAP method V

Sodium acetate ($CH_3COONa.3H_2O$), 99%

Hydrochloric acid (HCl), 37%

a,a-dipyridyl (2,2' bipyridine)

Bathophenanthroline, 4,7-diphenyl-1,10-phenanthroline-disulfonic acid ($C_{24}H_{16}N_2O_6S_2$)

Hydroxylamine hydrochloride ($NH_2OH.HCl$)

Iron standards: Electrolytic iron, Merck 3810 or Baker 2234

3.A. Quantitative Test (Spectrophotometric method):

Method: Iron spectrophotometric method AACC method 40-41B

Reagents:

Orthophenanthroline solution (0. l g o-phenanthroline in about 80 ml water).

Iron standard solution, (10 µg Fe/ml)

Hydroxylamine hydrochloride solution (10 g $NH_2OH.HCl$ in water and dilute to 100 ml)

Acetate buffer solution (8.3 g anhydrous sodium acetate in water)

3.B. Quantitative Test Atomic absorption spectrophotometric (AAS) method:

Method: Spectrophotometric analysis for quantitative, INCAP method VI

Reagents:

Sodium acetate ($CH_3COONa.3H_2O$), 99%

Hydrochloric acid (HCl), 37%, 1.19 g/mL

a,a-dipyridyl (2,2' bipyridine) ($C_{10}H_8N_2$)

Bathophenanthroline, 4,7-diphenyl-1,10-phenanthroline-disulfonic acid ($C_{24}H_{16}N_2O_6S_2$)

Hydroxylamine hydrochloride ($NH_2OH.HCl$)

Iron standards: Electrolytic iron, Merck 3810

Spot Test for Iron in Flour

AACC Method 40-40: Iron Qualitative Method

References:

Schlesinger, H. I., and Van Valkenburgh, H. B. 1931. The structure of ferric thiocyanate and the thiocyanate test for iron. J. Am. Chem. Soc. 53:1212.

Johnson, Q., Mannar, V. and Ranum, P., 2004. Fortification handbook: Vitamin and mineral fortification of wheat flour and maize meal. Ottawa: Micronutrient Initiative.

Reagents:

	Suggested catalog number VWR	Suggested catalog number Fischer
Acetonitrile, HPLC grade	BDH83642.050	A998-1
Ascorbic acid, Analytical reagent grade	BDH9242-250G	LC115309
Deionized (DI), water Nanopure, 18.2 megaohm	BDH1168-4LP	9180-32
Flour Unenriched	n/a	n/a
Folic acid, 98% pure analytical reagent grade	AAJ60833-22	AC216630100
Glacial acetic acid, Analytical reagent grade	BDH3093-2.2LP	02-002-123
Hexane, HPLC grade	BDH1129-4LP	H303-1
Methanol, HPLC grade	BDH7941-1	A454-1
pH buffers, 4.00 and 7.00	BDH5046-500ML; BDH0196-55GL	13-301-133
Phosphoric acid, Analytical reagent grade	BDH7347-1	RABP0030500
Potassium hydroxide, Analytical reagent grade	BDH7548-4	P246-3
Potassium phosphate, dibasic Analytical reagent grade	BDH153184U	P285-500
Reference flour	n/a	n/a
Sodium acetate, anhydrous Analytical reagent grade	BDH9278-500G	ICN19549601
Sodium chloride Analytical reagent grade	BDH7466-1	S271-500

Iron—Spectrophotometric Method

Inorganic Constituents AACC Method 40-41B

References:

AOAC International. 1995. Official Methods of Analysis of AOAC International, 16th ed. Method 965.09. The Association, Arlington, VA.

Gatehouse, B. M., and Willis, J. B. 1961. Performance of a simple atomic absorption spectrophotometer.
Spectrochim. Acta 17:710.

Johnson, Q., Mannar, V. and Ranum, P., 2004. Fortification handbook: Vitamin and mineral fortification of wheat flour and maize meal. Ottawa: Micronutrient Initiative.

Reagents:

	Suggested catalog number VWR	Suggested catalog number Fischer
Ortho phenanthroline solution	RC5522-32	NC0646077
Iron standard solution (from analytical grade Fe)	AA11381-GH	US-ICP-126
Fe $(NH_4)_2(SO_4)_2 \cdot 6H_2O$	700001-550	US-ICP-126
HCL	BT224145-4L	A508-P500
Hydroxylamine hydrochloride (from $NH_2OH \cdot HCl$)	EM1.04616.1000	NC1020874
Anhydrous sodium acetate	BDH9278-500G	S210-500
Mg $(NO_3)_2 \cdot 6H_2O$	AAH52101-MD	n/a
Redistilled HNO_3	34126-320	A198C-212

B-Vitamins Tests by HPLC

Vitamins AACC Method 86-90

References:

Johnson, Q., Mannar, V. and Ranum, P., 2004. Fortification handbook: Vitamin and mineral fortification of wheat flour and maize meal. Ottawa: Micronutrient Initiative.

Reagents:

	Suggested catalog number VWR	Suggested catalog number Fischer
Pentanesulfonic acid	BDH152813W	02-002-049
Acetic acid	87003-239	SA36-1
Calcium carbonate, HPLC grade	JT1301-5	LC126901
Methanol	BDH7941-1	NC0446254
Niacin	10791-832	18-604-780
Niacinamide	10791-810	AAJ19480A1
Pyridoxine hydrochloride	103510-526	18-605-992
Riboflavin	97062-304	AC132350250
Niacin	10791-832	18-604-780
Niacinamide	10791-810	AAJ19480A1
CaCO3	95032-222	18-609-528

Elements by Atomic Absorption Spectrophotometry

Inorganic Constituents AACC Method 40-70

References:

Johnson, Q., Mannar, V. and Ranum, P., 2004. Fortification handbook: Vitamin and mineral fortification of wheat flour and maize meal. Ottawa: Micronutrient Initiative.

AOAC International. 1995. Official Methods of Analysis of AOAC International, 16th ed. Method 965.09. The Association, Arlington, VA.

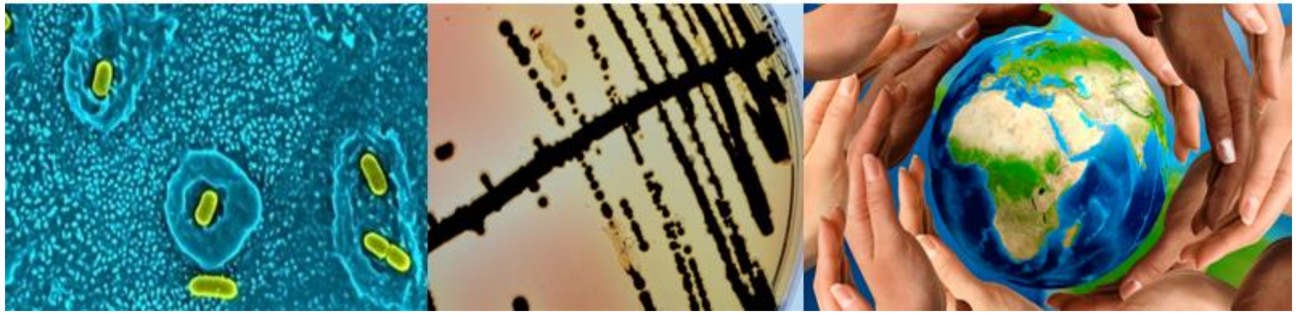
Gatehouse, B. M., and Willis, J. B. 1961. Performance of a simple atomic absorption spectrophotometer. Spectrochim. Acta 17:710.

Zook, E. G., Greene, F. E., and Morris, E. R. 1970. Nutrient composition of selected wheats and wheat products. VI. Distribution of manganese, copper, nickel, zinc, magnesium, lead, tin, cadmium, chromium, and selenium as determined by atomic absorption spectroscopy and colorimetry. Cereal Chem. 47:720.

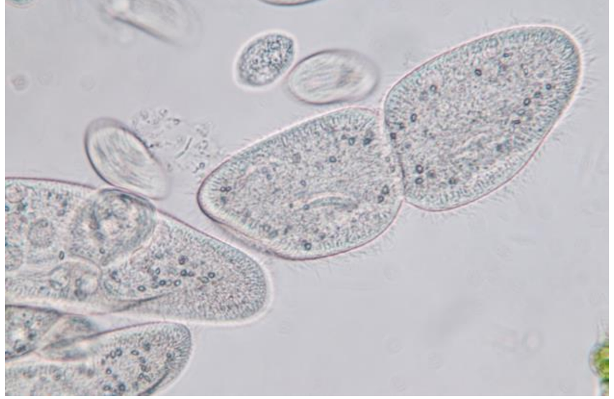
Reagents:

	Suggested catalog number VWR	Suggested catalog number Fischer
Distilled-deionized water	MKH45309	9180-32
CaCO3	103514-732	LC127007
3N HCl	BDH7375-1	R3720000120
Copper (pure Cu)	JT1720-1	AC206330050
HNO3	BT127005-1LB	60-010-99
Iron (pure Fe)	JT4348-22	AC169430050
6N HCl	BDH7204-4	18-610-924
Magnesium (pure Mg)	AAL08120-0E	AA1023322
Manganese (pure MnO2)	AA10236-A7	AA3631514
Zinc (pure Zn metal)	103524-180	Z5-500
La2O3	AA11264-30	AC193291000
1% HCl	470301-230	n/a

Excerpts of Food Safety Workshop Presentations and Certificants



Foodborne Diseases of Public Health Importance



Bacteria

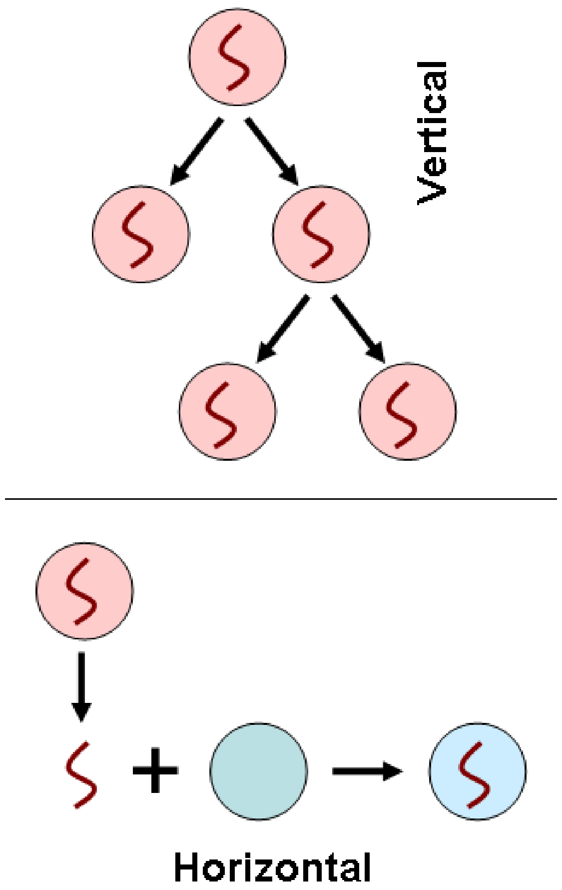
- If **conditions are ideal**, bacteria can multiply once every 20 minutes
- It is unlikely you'll ever start with just ONE bacterium
- Some pathogens can make people sick with a dose of **10 cells or less**
- What conditions are **optimal**?
  - **Food source**
  - **Moisture**
  - **Right temperature**

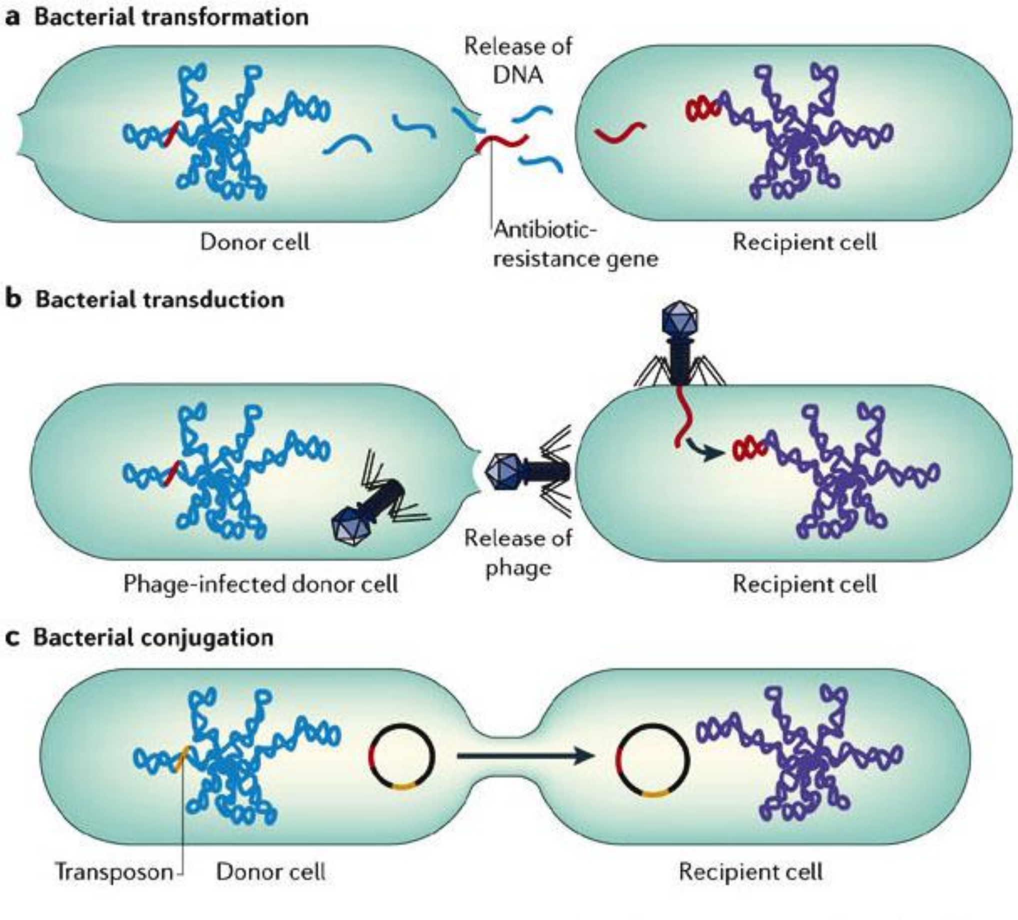
Time	# of Bacteria
20 min	2
40 min	4
1 hour	8
80 min	16
100 min	32
2 hours	64
4 hours	4096
6 hours	262,144
8 hours	16,777,216

Emerging pathogens

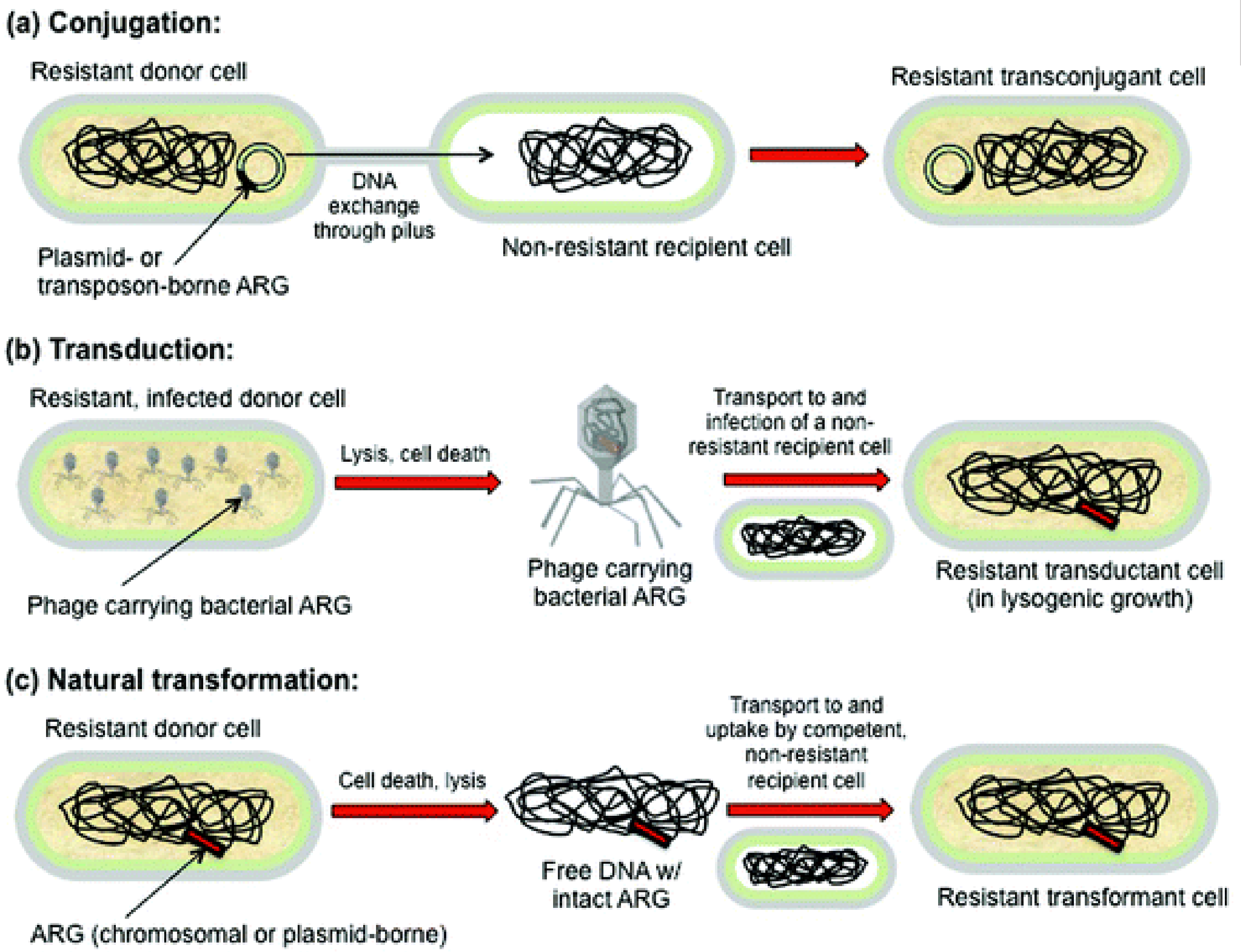
Diversity, moving towards *"fitness" and Emerging Pathogens*

Photo Courtesy:
http://www.daviddarling.info/encyclopedia/B/binary_fission.html





Horizontal Gene Transfer



Donn, 2012

Planktonic cells and Biofilm Communities

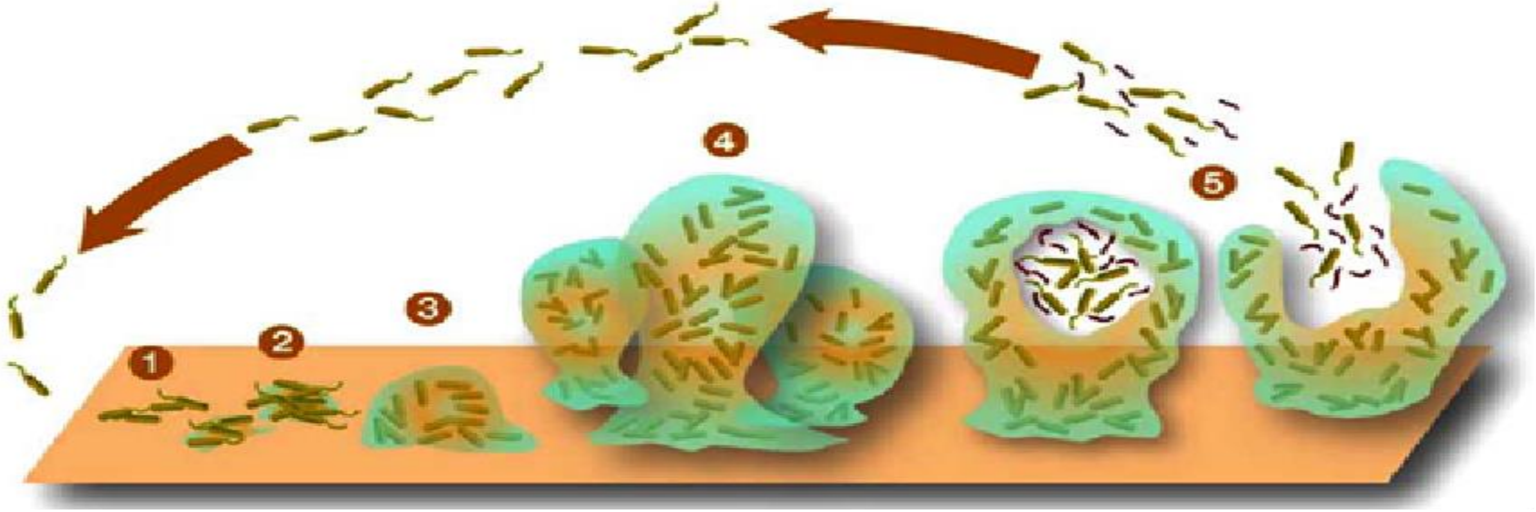


Photo Courtesy: http://prometheus.matse.illinois.edu/glossary/biofilms/

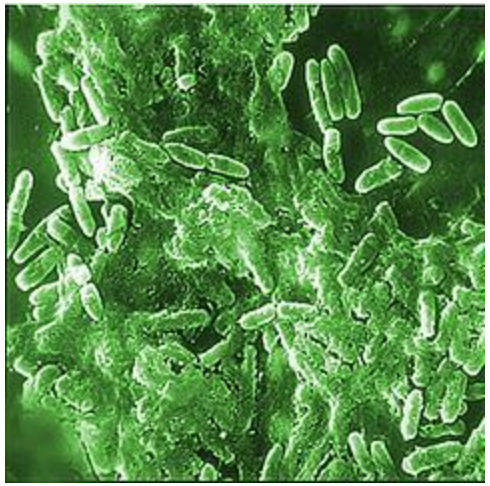


Photo Courtesy: http://micro-writers.egybio.net/blog/?tag=antibiotic-resistance

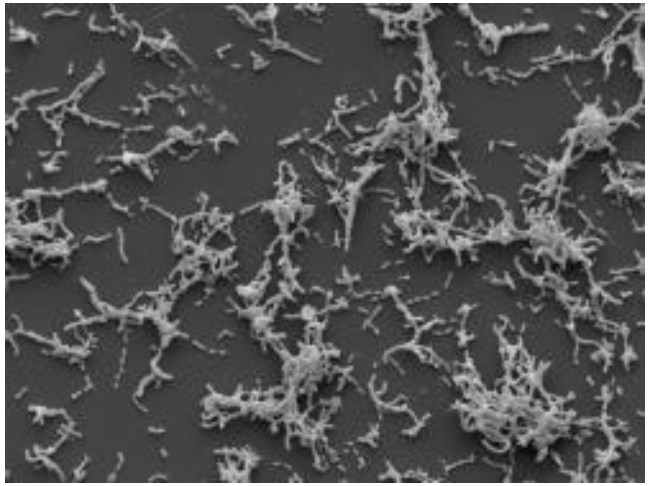


Photo Courtesy: http://www.ifenergy.com/50226711/boosting_microbial_fuel_cells_with_biofilm.php

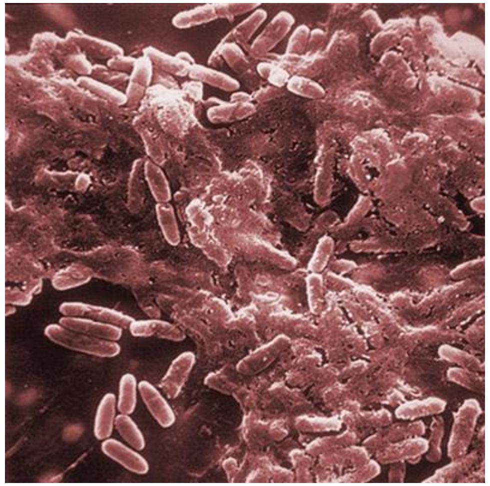
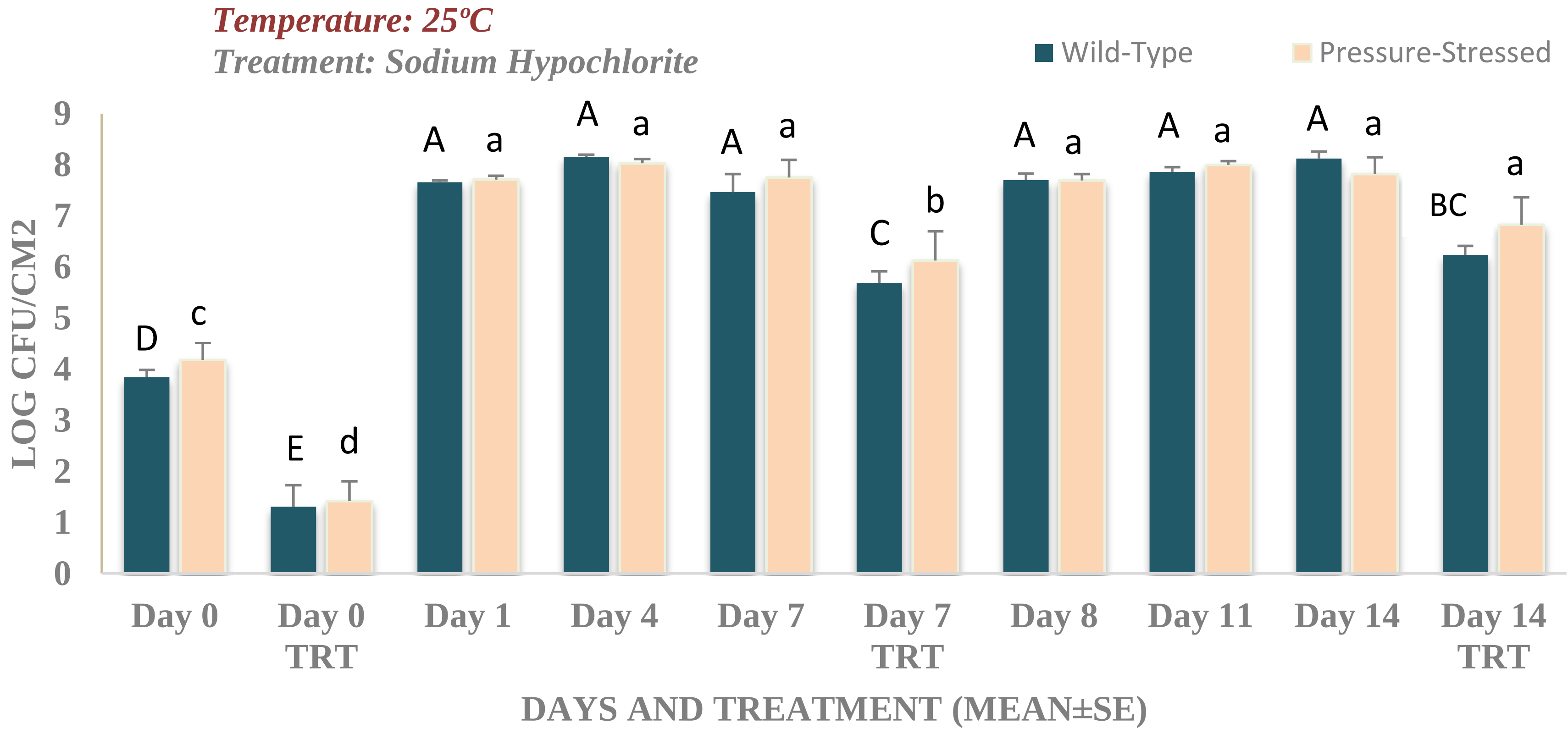


Photo Courtesy: http://www.microbiologybytes.com/blog/category/biofilms/

Cronobacter sakazakii
Two outbreaks in Tennessee (1998, Memphis; 2001 Knoxville)

Biofilm Formation and Decontamination of Wild-Type and Pressure-Stressed *Cronobacter Sakazakii*



Allison et al., 2020

Quorum Sensing and Biofilm formation

Shiga toxin-Producing E. coli and antibiotics treatment

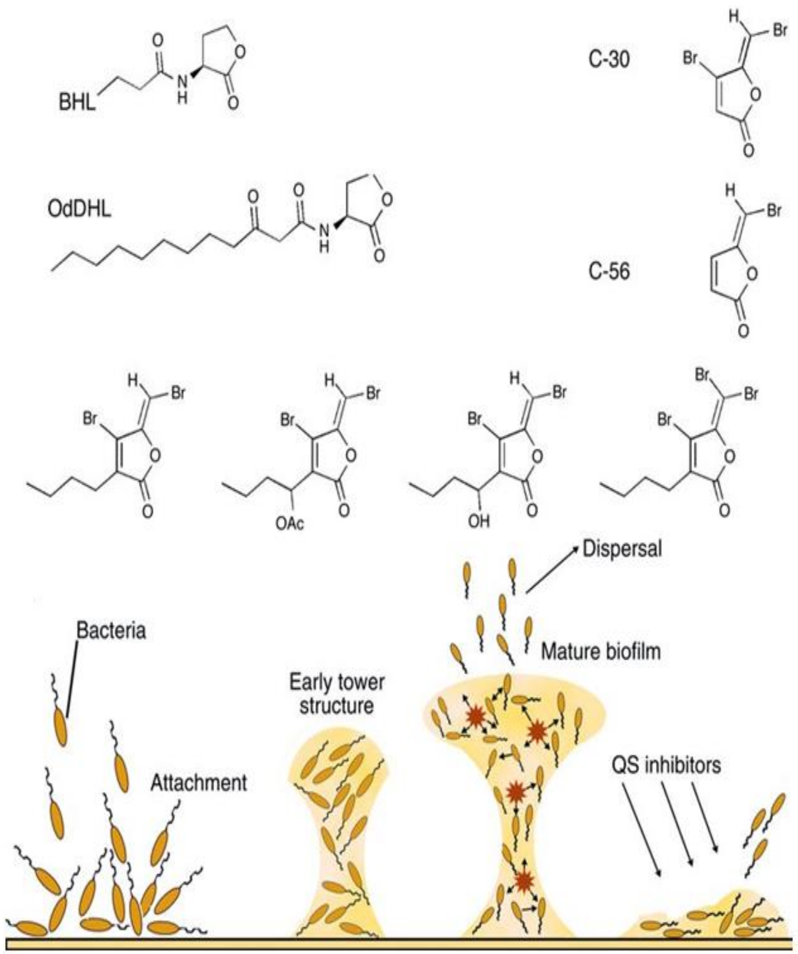


Photo Courtesy: http://www.jci.org/articles/view/20074/figure/2

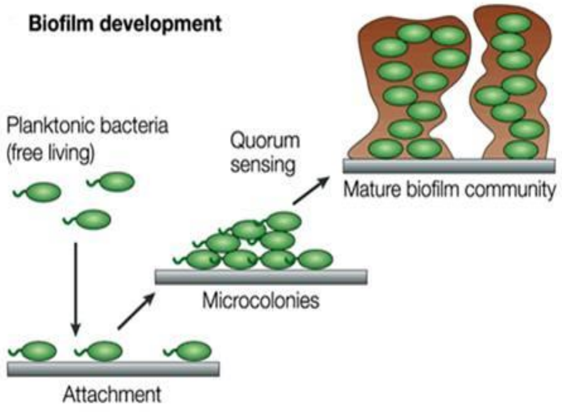


Photo Courtesy: http://labrat.fieldofscience.com/2010/07/quorum-sensing-and-biofilms.html

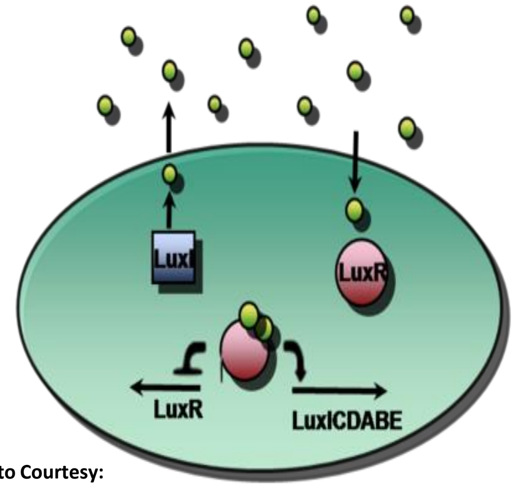


Photo Courtesy: http://2009.igem.org/Team:Aberdeen_Scotland/WetLab/quorumsensing

Infectious Diseases in Animals and Human is a Moving Target…

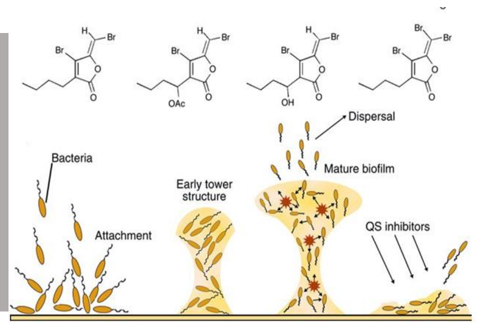
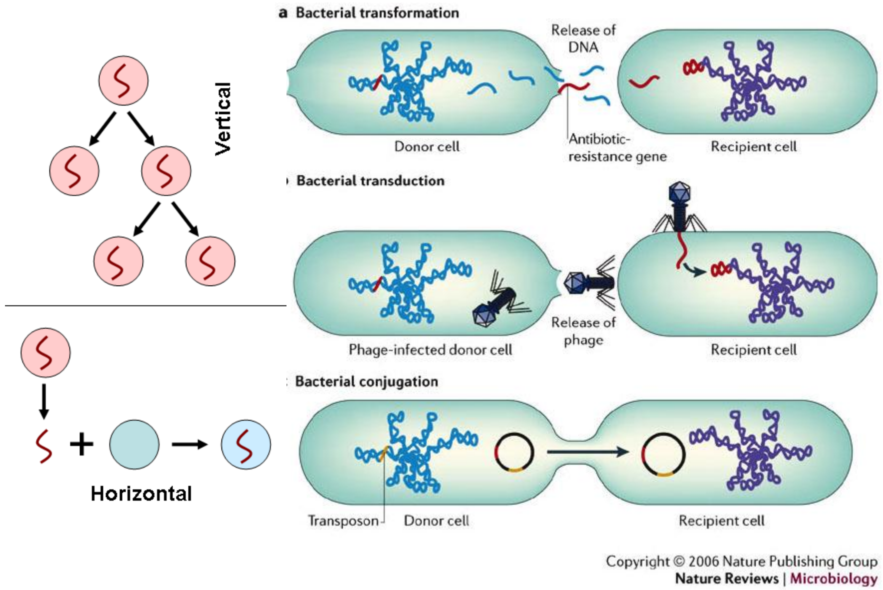


Photo Courtesy: http://www.jci.org/articles/view/20074/figure/2

- It is estimated only 1% of microbial community has been identified.
- Currently **etiological agent** of 80.3% of foodborne illnesses, **56.2% of hospitalization**, and 55.5% of deaths remain unknown.



"Emerging" Pathogens:

- Vertical and horizontal gene transfer spores and biofilm formation
- Quorum sensing and cell to cell communication

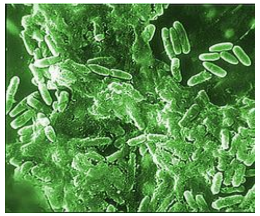
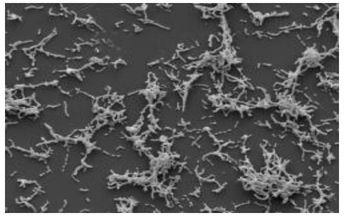
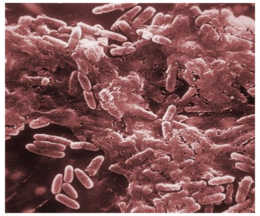




Photo Courtesy: http://www.microbiologybytes.com/blog/category/biofilms/
http://www.ifenergy.com/50226711/boosting_microbial_fuel_cells_with_biofilm.php
http://micro-writers.egybio.net/blog/?tag=antibiotic-resistance

"It is the microbes who will have the last word."

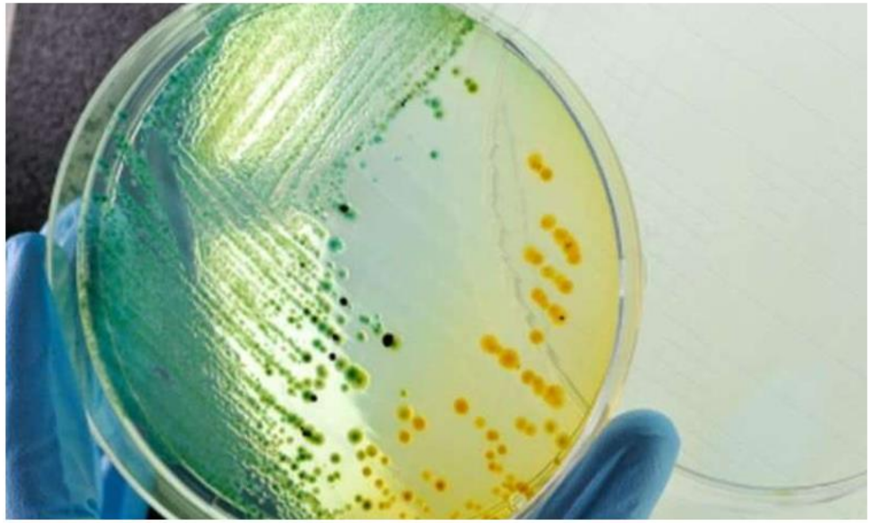
-Louis Pasteur

A superbug resistant to every available antibiotic in the U.S. kills Nevada woman

BY HELEN BRANSWELL, STAT *January 13, 2017 at 10:01 AM EST*

AUGUST 23, 2019

Multidrug-resistant salmonella outbreak characterized



(HealthDay)—A recent multidrug-resistant (MDR) *Salmonella enterica* serotype Newport outbreak, affecting patients in 32 states, was associated with soft cheese and beef consumption, according to a report published in the Aug. 23 issue of the U.S. Centers for Disease Control and Prevention *Morbidity and Mortality Weekly Report*.

Rare strain of E. coli strikes across Canada: source unknown

BY NEWS DESK | JANUARY 14, 2017

A dozen cases of E. coli O121 have been confirmed in three Canadian provinces, according to matching genetic fingerprint data, but the source of the outbreak has not yet been identified.

The Public Health Agency of Canada reports four of the rare O121 cases were confirmed in British Columbia, four in Saskatchewan and four in Newfoundland and Labrador. The illness onset dates were in November and December of 2016.

Four of the v
Those indivi
the process o
determine th
coli O121 cor

The Public H
improper ha
eating raw g
common sou
common sou

Photo illustration

CDC says outbreak traced to raw clover sprouts has come to an end

By News Desk on April 23, 2020

The Food and Drug Administration's investigation of an outbreak of E. coli 0103 in clover sprouts has been completed, and the Centers for Disease Control and Prevention has declared that the outbreak is over.

The FDA, along with CDC and state and local partners, investigated 51 illnesses

Epidemiology of Foodborne Diseases

- **Based on data from 1990s:** *(Mead et al., 1999)*

76 million illnesses, 323,000 hospitalizations, **5,200 deaths** in the United States.

- **More recent estimates show:** *(Scallan et al., 2011)*

47.8 million illnesses, 127,839 hospitalizations, and more than **3,037** deaths in the United States.

- 9.4 million illnesses, 55,961 hospitalizations, and 1,351 deaths are cause by 31 known foodborne agents.
- In addition to consumer insecurity, foodborne diseases cause around $**77.7 billion** for losses in productivity and economical losses.
- Approximately 30% of population are especially "at risk" for foodborne diseases (The **YOPI**'s: The young, the old, Pregnant, and Immunocompromised)

Significant foodborne pathogens…
based on Mead et al., 1999 and Scallan et al., 2011 studies

- **Leading etiological agents for illnesses**: *Norovirus* (58%), Nontyphoidal *Salmonella* serovars (11%), *Clostridium perfringens* (10%), and *Campylobacter* spp (9%).
- **Leading etiological agents for hospitalization:** Nontyphoidal *Salmonella* serovars (35%), *Norovirus (26%),* *Campylobacter* spp (15%), and *Toxoplasma gondii* (8%).
- **Leading etiological agents for death:** Nontyphoidal *Salmonella* serovars (28%), *T. gondii* (24%), *Listeria monocytogenes* (19%), and *Norovirus (11%).*

Signs and Symptoms of Foodborne Diseases

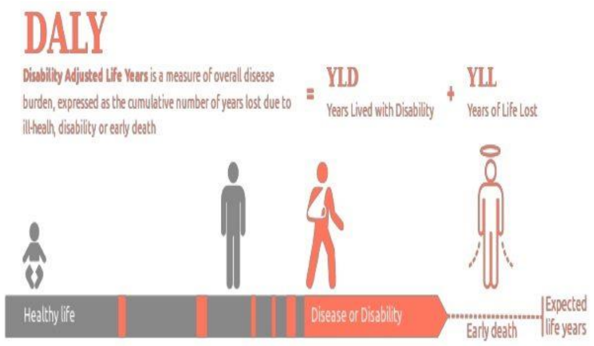
- Mild illness (no medical care sought)
- **Guillain–Barré syndrome** (*Campylobacter* and *Salmonella*)
- **Post-infectious irritable bowel syndrome** (*Campylobacter* and *Salmonella*)
- **Reactive arthritis** (*Campylobacter* and *Salmonella*)
- **Haemolytic uraemic syndrome** (*E. coli* O157)
- **End-stage renal disease** (*E. coli* O157)
- Death

Significant Foodborne Pathogens of Public Health Concern: Considering DALY and QALY *(Scallan et al., 2015)*

- **Disability Adjusted Life Year (*DALY*).** *Loss of life and health due to illness compared with 'perfect' health*

- Non-typhoidal *Salmonella* (329000)
- Toxoplasma (32700)
- *Campylobacter* (22500)
- Norovirus (9900)
- *Listeria monocytogenes* (8800)
- *Clostridium perfringens* (4000)
- *Escherichia coli* O157 (1200)

62% bacterial agents; 29% parasitic agents; 9% viral agents



- Mild illness (no medical care sought)
- **Guillain–Barré syndrome** (*Campylobacter* and *Salmonella*)
- **Post-infectious irritable bowel syndrome** (*Campylobacter* and *Salmonella*)
- **Reactive arthritis** (*Campylobacter* and *Salmonella*)
- **Haemolytic uraemic syndrome** (*E. coli* O157)
- **End-stage renal disease** (*E. coli* O157)
- Death

CDC Estimates of Food Safety Burden

http://www.cdc.gov/foodborneburden/attribution-image.html#foodborne-illnesses

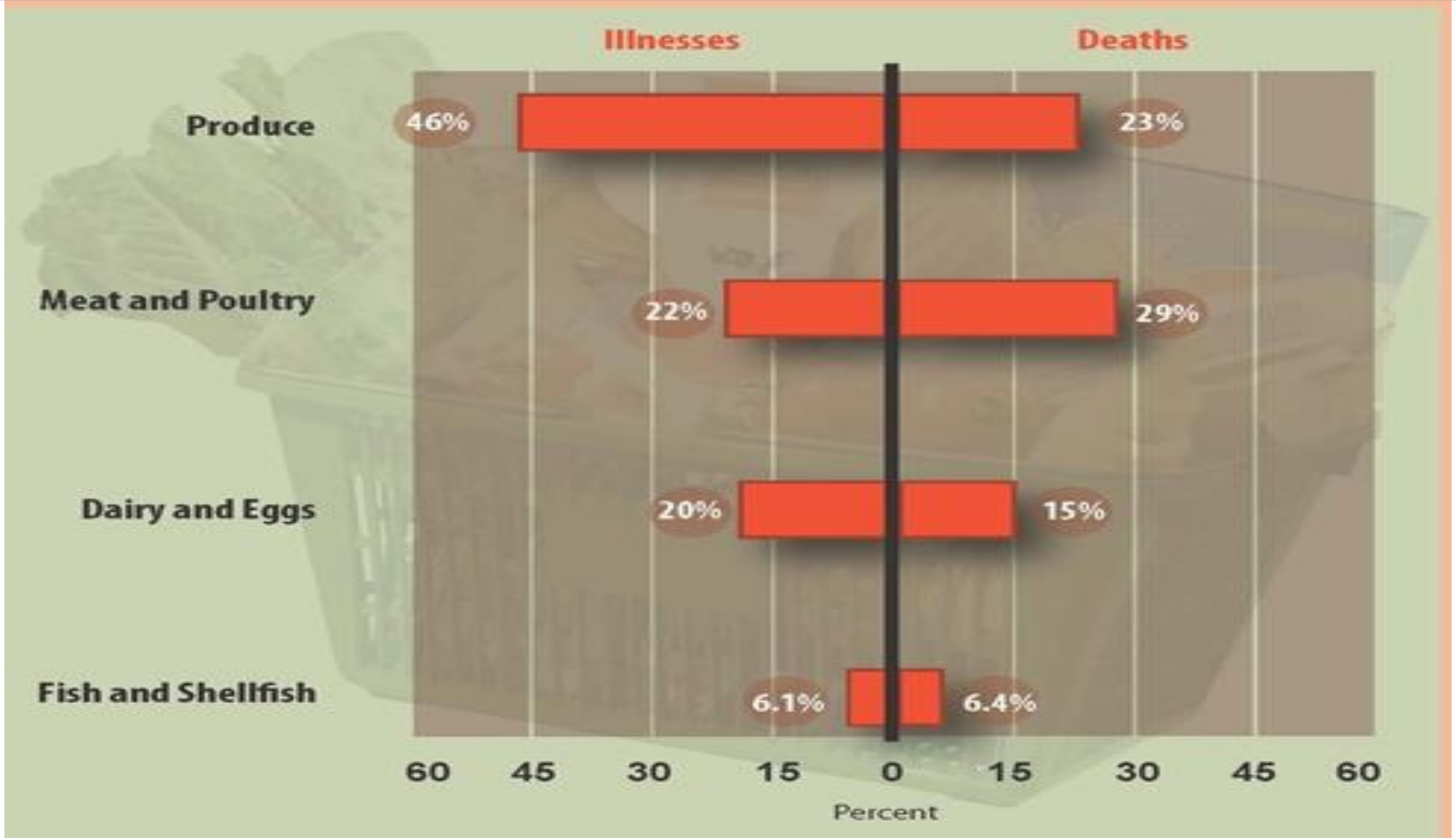


*Chart does not show 5% of illnesses and 2% of deaths attributed to other commodities. In addition, 1% of illnesses and 25% of deaths were not attributed to commodities; these were caused by pathogens not in the outbreak database, mainly *Toxoplasma* and *Vibrio vulnificus*.

Are these outbreaks associated with corporates and lager manufactures?

Prevalence of Pathogens in Medium-sized Poultry Operations

- 200–300 ft houses, 3000 to 5000 birds, conventional operation

  (Alali et al., 2010)

	Salmonella serovars
Fecal samples (n=420)	38.8%
Feed (n=140)	27.5%

- Total of 135 sample from commercial free-range chicken producers
  (Bailey et al., 2005)

	Salmonella serovars
Chicken Carcasses in Operation 1	64%
Chicken Carcasses in Operation 2	31%

Alali et al., 2010, J Foodborne Pathogens and Diseases; Bailey et al., 2005, J Food Protection

Prevalence of Pathogens in Small Poultry Farms

- Study of 60 Small poultry slaughterhouses (fewer than 200 birds slaughtered per day)

Sampling sites	***Salmonella* serovars** (*Albany, Hadar, Indiana, and Enteritidis sub-species*)
Carcasses after slaughter	42%
Utensils	23.1%
Storage freezers and refrigerators	71.4%

- The Study concluded "*The widespread occurrence of Salmonella in small slaughterhouses reinforces the need for implementation of effective control measures…*"

Terumi et al., 2000, Journal of Food Protection

Climate Change and Public Health Microbiology

Non-typhoidal *Salmonella enterica* serovars

- **Global death:** 50,000 global death in 2010 (WHO, 2020)
- **Public Health Burden in the U.S.:** >1 million annual cases in 2011 (CDC, 2011)

Climate Change:

- **1 °C increase : 5 to 10% increases in Salmonellosis (WHO, 2010)**
- 2500 to 5000 additional global death
- 50,000 to 100,000 U.S. morbidity

At our current rate:

- >1.5 °C by 2040
- >4.8 °C by 2100

microorganisms

MDPI

Editorial

Safety of Food and Water Supplies in the Landscape of Changing Climate

Aliyar Cyrus Fouladkhah [1,*], Brian Thompson [2] and Janey Smith Camp [3]

[1] Public Health Microbiology Laboratory, Tennessee State University, Nashville, TN 37209, USA
[2] School of Public Health, Yale University, 60 College St, New Haven, CT 06510, USA; brian.thompson@yale.edu
[3] Department of Civil and Environmental Engineering, Vanderbilt University, Nashville, TN 37235, USA; janey.camp@vanderbilt.edu
* Correspondence: afouladk@tnstate.edu or aliyar.fouladkhah@aya.yale.edu; Tel.: +1-970-690-7392

Received: 15 September 2019; Accepted: 16 October 2019; Published: 18 October 2019

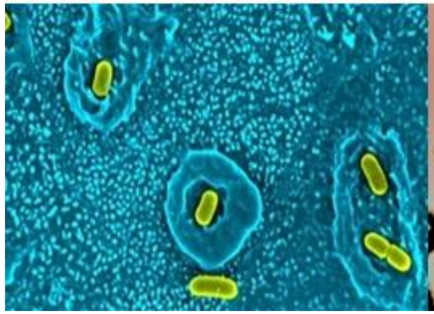
check for updates

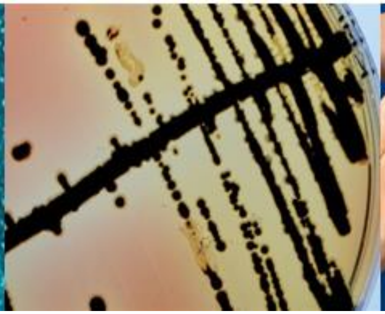
In response to evolving environmental, production, and processing conditions, microbial communities have tremendous abilities to move toward increased diversity and fitness by various pathways such as vertical and horizontal gene transfer mechanisms, biofilm formation, and quorum sensing [1,2]. As such, assuring the safety of water and food supplies from various natural and anthropogenic microbial pathogens is a daunting task and a moving target. Recent outbreaks of *Listeria monocytogenes* in South Africa associated with a ready-to-eat product (affecting close to 1000 individuals) and the 2018 outbreak of Shiga toxin-producing *Escherichia coli* O26 associated with ground meat in the United States (leading to the recall of more than 132,000 pounds of products) are bitter reminders of the devastating influences of foodborne diseases on the public health and food manufacturing [3,4].

Recent epidemiological studies of world populations indicate that 420,000 people lose their lives every year due to foodborne diseases, with around one-third of those being 5 years of age or younger. It is further estimated that every year, 1 in 10 individuals experience foodborne diseases around the globe, leading to an annual loss of 33 million healthy life years [5]. These episodes of food and water

Main Bacterial Pathogens Associated with Animal and Human Health Diseases

Foodborne Pathogens of Public Health Concerns *>200 foodborne diseases*





- *Salmonella* serovars
- *Staphylococcus aureus*
- *Campylobacter* spp.
- *Bacillus cereus*
- Shiga Toxin-Producing *Escherichia coli* (STEC)
- *Vibrio* spp.
- *Yersinia enterocolitica*
- *Streptococcus* spp.
- *Shigella* spp.
- *Listeria monocytogenes*
- *Mycobacterium bovis*
- *Cronobacter sakazakii*

Salmonella serovars

- **Annual illness (death): 1,027,561 (378) in American adults and children**
- **Infection** causes nausea, vomiting, diarrhea, fever, headache
- **Primary sources**: Intestinal tract of people and animals
- **Transmitted by** meat, poultry, eggs, raw milk, unpasteurized juice, many other foods (nuts, spices, produce, chocolate, flour) [Low-moisture environment]
- **Contributing factors**: cross-contamination, undercooked food, poor agricultural practices

Growth parameters	Minimum	Optimum	Maximum
Temperature	41°F (5.2°C)	95-109°F (35-43°C)	115°F (46.2°C)
pH	3.7	7-7.5	9.5
a_W	0.94	0.99	>0.99
Other	Non-spore former		
Atmosphere	Facultative - grows with or without oxygen		

Sources: ICMSF 1995 and Bad Bug Book 2nd edition, Scallan et al., 2011, and FSPCA

Salmonella serovars

- **Carriers**: **Reptiles** (turtles, lizards, and snakes); **Amphibians** (frogs and toads); **Poultry** (chicks, chickens, ducklings, ducks, geese, and turkeys); **Other birds** (parakeets, parrots, and wild birds); **Rodents** (mice, rats, hamsters, and guinea pigs); Other **small mammals** (hedgehogs); **Farm animals** (goats, calves, cows, sheep, and pigs); **Dogs; Cats; Horses. [Pretty much ubiquitous!]**
- **Dogs and cats** that become ill from *Salmonella* infection generally will have **diarrhea** that may contain blood or mucus
- Some cats do not have diarrhea, but will have a **decreased appetite, fever, and excess salivation**.

Prevention:

- **Minimizing direct contact**, **washing hands**, and **cleaning up after the pets** could minimize the risk of transmission from infected animals to human.

Staphylococcus aureus

Foodborne Diseases

- Infection
- Intoxication
- Toxico-infection

- **Annual illness (death): 241,148 (6) Americans every year**
- Both causes infection and toxico-infection
- Produces **heat stable toxins** after extensive growth
- **Primary sources**: Boils, nasal passages and skin (around 20% positive on nasal passage, >10% hands)
- **Transmitted** by recontaminated **cooked foods**, and foods with high salt or high sugar (**Gram-positive, poor competitor**)
- **Contributing factors**: Recontamination and **time/temperature abuse**

Growth parameters	Minimum		Optimum		Maximum	
	Growth	Toxin	Growth	Toxin	Growth	Toxin
Temperature	45°F (7°C)	50°F (10°C)	99°F (37°C)	104-113°F (40-45°C)	122°F (50°C)	118°F (48°C)
pH	4	4	6-7	7-8	10	9.8
a_W	0.83	0.85	0.98		>0.99	
Other	Poor competitor, non-sporeformer					
Atmosphere	Facultative – grows with or without oxygen, but slower without					

Sources: ICMSF 1995 and Bad Bug Book 2nd edition, Scallan et al. 2011, and FSPCA

Staphylococcus aureus

- **Methicillin-resistant *Staphylococcus aureus* (MRSA**) a major concern for animal and human health.
- Humans working closely in **animal feeding operations** are in elevated risk of exposure to this pathogen particularly the antibiotic resistant phenotypes
- A **contagious bacterium** responsible for vast majority of environmental **Mastitis in dairy** operations.
- Cause of “bumblefoot” in chickens
- A major pathogen of farm rabbits

Campylobacter spp.

- **Annual illness (death): 845,024(76)**
- Infection causes diarrhea, and potential nerve damage
- **Primary sources**: Intestinal tract of animals
- **Transmitted** by raw poultry, raw milk products, contaminated water, poultry (dump tank, nearly 80%). Relatively high infective dose
- **Contributing factor**: cross contamination and undercooking

Growth parameters	Minimum	Optimum	Maximum
Temperature	86°F (30°C)	108-109°F (42-43°C)	113°F (45°C)
pH	4.9	6.5-7.5	9.5
a_W	>0.987	0.997	-
Other	Non-spore former		
Atmosphere	3-5% oxygen optimum		

Sources: ICMSF 1995 and Bad Bug Book 2nd edition and FSPCA

Campylobacter spp.

- Bacterium exist in GI track of **many healthy farm and companion** animals.
- **Dogs six week and younger** are prone to Campylobacteriosis with symptoms:

  -Fever

  -Vomiting

  -Loss of appetite

  -Enlarged lymph nodes

- **Staying in kennels** that increases the **exposure to fecal matter** and contact with contaminated food and water are main sources of disease in dogs.

Bacillus cereus

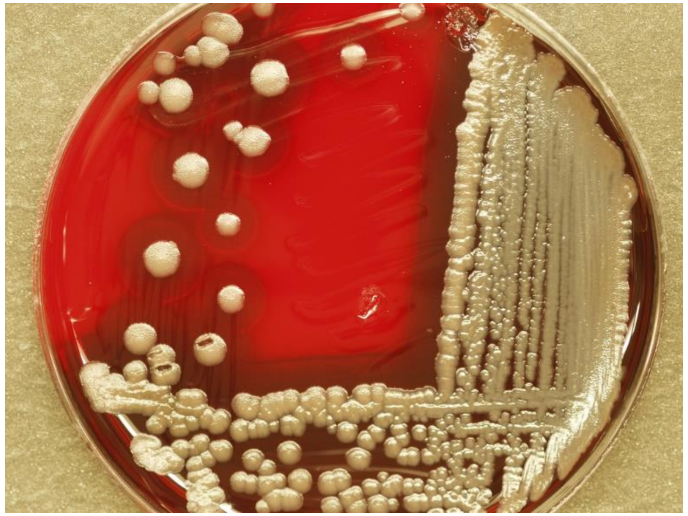
- **Annual illness (death): 63,400 (0)**
- Produces toxins and extensive growth is required for illness
- **Primary source**: soil and GI track
- **Transmitted** by: rice and starchy foods, meats, vegetables, milk products, sauces
- Contributing factors: **temperature abuse**

Growth parameters	Minimum	Optimum	Maximum
Temperature	39°F (4°C)	82-95° F (28-35°C)	131°F (55°C)
pH	4.3	6.0-7.0	9.3
a_w	0.92	-	-
Other	Spore former; one toxin is heat stable		
Atmosphere	Facultative – grows with or without oxygen		

Sources: Seafood Hazards Guide, ICMSF 1995, Bad Bug Book, Scallan et al. 2011, and FSOCA

Bacillus cereus

- Some studies indicate the bacterium could behave as an agent of mammary gland **infection in cows** and goats thus causing **mastitis.**
- Cases of **food poisoning in dogs and cats** had also been reported, although not very frequent in nature.
- Many agricultural animals carry the **bacterium in their intestinal area** without symptoms.



Shiga Toxin-Producing *Escherichia coli* (STEC)

- **Annual illness (death): 176,152 (20)**
- **Notable outbreak:** 1992-1993 outbreak in pacific northwest- Very important regulatory status (adulterant)
- **Infection causes** bloody diarrhea, and sometimes kidney failure and death [HUS in kids]
- **Primary sources**: Intestinal tract of ruminant animals (e.g., cows, sheep)
- **Transmitted** by raw and undercooked beef, poultry, leafy greens, and unpasteurized milk and juices
- **Contributing factors**: poor GAP, inadequate heating, and person-to-person

Growth parameters	Minimum	Optimum	Maximum
Temperature	**44°F (6.5°C**)	95-104°F (35-40°C)	121°F (49.4°C)
pH	4	6-7	10
a_W	0.95	0.995	-
Other	Non-spore forming		
Atmosphere	Facultative - grows with or without oxygen		

Sources: ICMSF 1995 and Bad Bug Book 2nd edition,Scallan et al. 2011, and FSPCA

Shiga Toxin-Producing *Escherichia coli* (STEC)

- **Animals that can spread *E. coli* O157 to humans include**:

    -cows, especially calves

    -goats

    -sheep

    -deer

- *E. coli* infection very common in **cats and puppies younger than one week**.
- **Colostrum**, plays a pivotal role in protecting a newborn the animal's undeveloped immune system against *E. coli* infection.
- As high as **80% of agricultural animals** **could carry various serogroups of shiga-toxigenic *E. coli*** without having symptoms

Vibrio spp.

- Causing about **80,000 illness and 100 death** annually in the United States.
- **Infection symptoms** vary depending on strain, ranging from diarrhea to high fever
- Vibrio is a **halophilic bacterium** and is a major concern in aquaculture industry
- **Primary sources**: Salt water environments and seafood
- Requires salt to reproduce (halophile)

Growth parameters	Minimum	Optimum	Maximum
Temperature	41°F (5°C)	99°F (37°C)	114°F (45.3°C)
pH	4.8	7.8-8.6	11
a_W	0.94	0.98	0.996 (10% NaCl)
Other	Non-sporeformer, requires salt		
Atmosphere	Facultative - grows with or without oxygen		

Sources: Seafood Hazards Guide 2011, ICMSF 1995 and Bad Bug Book 2nd edition

Yersinia enterocolitica

- *Not a reportable disease, no statistics available*
- **Infection causes** abdominal pain, fever and diarrhea. May mimic appendicitis.
- **Primary sources**: Raw pork, raw milk
- **Contributing factors**: Cross-contamination between raw pork products and RTE foods

Growth parameters	Minimum	Optimum	Maximum
Temperature	30°F (-1.3°C)	77-99°F (25-37°C)	108°F (42°C)
pH	4.2	7.2	10
a_W	0.945	-	-
Other	Non-spore former, raw milk in fridge?		
Atmosphere	Facultative - grows with or without oxygen		

Sources: Seafood Hazards Guide, ICMSF 1995, and Bad Bug Book

Foodborne Streptococcus spp.

- *Not a reportable disease, no statistics available (not part of active surveillance data of CDC)*
- **Infection causes** sore throat, tonsillitis and fever
- **Primary sources**: **Infected sites of humans and animals**, **raw milk**
- **Contributing factors**: Infected **workers handling food** and **consumption of raw milk** or **meat products**.
- **Symptoms**: meningitis, sepsis, and pneumonia (>200,000 sepsis cases per year, not foodborne)
- **Found in**: cattle, horses, dogs, rabbits, guinea pigs and mice
- Important cause of mastitis in cows.

Growth parameters	Minimum	Optimum	Maximum
Temperature	50°F (10°C)	99°F (37°C)	<113°F (<45°C)
pH	4.8-5.3	7	>9.3
%NaCl (salt)	-	-	<6.5
Other	Non-sporeformer		
Atmosphere	Facultative - grows with or without oxygen		

Sources: Seafood Hazards Guide, ICMSF 1995, and Bad Bug Book

Shigella spp.

- **Infection in humans causes** diarrhea, which may be watery to bloody. The infection is also known as dysentery [Taxonomy similar to *Salmonella* serovars]
- **Primary sources**: Human and Animal intestinal tract
- **Transmitted** by **fecal contamination** from contaminated **water** or **infected food**.
- **Clinical signs are rare in dogs and cats**, mostly mild diarrhea.
- Many species such dogs, cats, rodents and nonhuman primates could **carry the pathogen asymptomatically.**

Growth parameters	Minimum	Optimum	Maximum
Temperature	43°F (**6.1°C**)	-	117°F (47.1°C)
pH	4.8	-	9.3
a_W	0.96	-	-
Other	Non-spore former		
Atmosphere	Facultative - grows with or without oxygen		

Sources: Seafood Hazards Guide 2011, ICMSF 1995 and Bad Bug Book 2nd edition

Mycobacterium bovis

- **Infection** causing respiratory symptoms and **tuberculosis**
- **Primary sources**: Cattle and raw milk
- **Other source**: bison, elk, and deer.
- **Contributing factors**: Lack of milk **pasteurization** and exposure to aerosols from infected animals
- **Grows very slowly and under reduced oxygen (microaerophilic)**
- The **US has nearly eliminated** *M. bovis* infection from cattle, over **one million animal is tested** for the bacterium by inspectors. [USDA FSIS]
- *M. bovis* can be found in **wild animals** such as bison, elk, and deer; uninfected cattle that come into contact with these wild animals can become infected.

Source: CDC at https://www.cdc.gov/tb/publications/factsheets/general/mbovis.pdf

Listeria monocytogenes

- **Infection causes** severe illness in susceptible people – mortality 15-30%
- **Primary sources**: Occurs widely in agriculture (soil, plants and water) –(Important during pregnancy)
- **Transmitted by**: Refrigerated RTE foods that support growth (South Africa, Largest in History in 2018)
- **Contributing factors**: Environmental pathogen spread by environmental contamination, equipment, people, incoming raw ingredients (ubiquitous in nature)
- **Common in domesticated ruminates particularly** sheep, poultry, and birds.
- **Could cause sporadic and farm outbreaks in ruminants**
- **Could cause: Encephalitis, late abortion, and GI problems in ruminants**.

Growth parameters	Minimum	Optimum	Maximum
Temperature	31°F (-0.4°C)	99°F (37°C)	113°F (45°C)
pH	4.4	7.0	9.4
a_W	0.92	-	-
Other	Non-sporeformer		
Atmosphere	Facultative - grows with or without oxygen		

Sources: ICMSF 1995 and Bad Bug Book 2nd edition

Cronobacter Sakazakii

- **Recently reclassified** bacteria (2006-07), formerly known as ***Enterobacter sakazakii***
- The **Genus *Cronobacter*** was derived from the Greek term "Cronos," a Titans of ancient mythology who swallowed each of his infants as soon as they were born (he was afraid to be replaced by his infants).
- The **species name, *sakazakii***, is named in honor of the Japanese microbiologist, Riichi Sakazaki, when the bacterium was first explained in 1980.
- Gram-negative, rod-shaped bacteria.
- Facultative anaerobic
- The growing temperature range is 6°C-45°C
- Primarily associated with **Powered Infant Formula**
- There has been several outbreaks associated with the bacterium and neonatal meningitis and death including two outbreaks in **Tennessee** (**1998 and 2001**).

APHA Compendium of Methods, Salfinger and Lou Tortorello, Fifth Edition

Cronobacter Sakazakii

Prevention (CDC & WHO guidelines)

- Breastfeed
- Practice careful hygiene
- Clean and sanitize properly
- Prepare Powered Infant Formula as recommended

Symptoms:

- poor feeding response,
- irritability,
- jaundice,
- grunting **respirations**,
- **instability of body temperature**,
- Could lead to: **seizures, brain abscess**, hydrocephalus, and developmental delay, or **death**

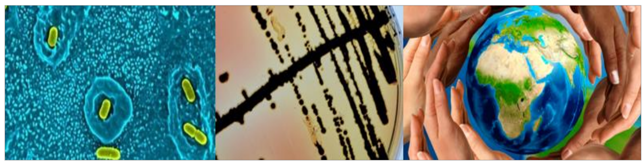
One of the student from class published a great article about this pathogen:

https://www.mdpi.com/2076-2607/7/3/77

APHA Compendium of Methods, Salfinger and Lou Tortorello, Fifth Edition

Thank you

Food Safety Modernization Act Certification



Aliyar Cyrus Fouladkhah

Public Health Microbiology Laboratory

Cooperative Extension Program

Tennessee State University

1

Food Safety Modernization Act (FSMA)

- Signed to law in January of 2011, FSMA is the largest expansion of U.S. food safety authorities since the 1930s.
- Many sectors of agriculture and manufacturing will undergo strict regulations for the **first time in the history of the country**.
- Shifting responses from food safety problems to **proactively prevent** the episodes
- FSMA, a large and comprehensive legislation **broaden FDA's ability** to:
  - **Mandatory recall** of contaminated food products
  - **Enhanced surveillance** to investigate foodborne illness outbreaks
  - Established **new preventive controls** and food safety plans at some food processing facilities and farms
  - Enhanced FDA's **traceability capacity**
  - **Increased inspection** frequencies of high-risk food facilities (both domestic and foreign facilities)
  - Expanded authority and oversight capabilities with regard to **foreign companies**

2

Regulatory Landscape of Food Industry Before FSMA

Very small companies:

Exemption from federal requirements, need to follow state policies

Restaurant operations:

Exemption from federal requirements, need to follow state policies (food code)

Food Safety Inspection Service (FSIS) of USDA:

Meat, Poultry and Egg products, HACCP requirements

Food and Drug Administration of DHHS:

High Risk Foods: Juices, seafood, and shell egg, *HACCP requirements*

Farmers and other food products:

No federal regulation

3

Mandated by FSMA

- Food manufacturing (processors)
- Farmers and growers (producers)
- Transportation, retailers
- Imported foods
- Third party laboratories
- Local, state, and federal agencies
- Foreign governments

Not mandated by FSMA

- FSMA does not directly address sectors under **pre-existing** jurisdictions. HACCP will remain the dominant regulation for:
- Meat, poultry, and egg products (USDA-FSIS)
- Juices, seafood, and shell eggs (DHHA-FDA)
- Very small producers and processors could receive exception from FSMA requirements (**cottage industry**).
- FSMA does not mandate **GM products, antibiotic resistant organisms, organic production, and pesticide and fertilizer** use.

4

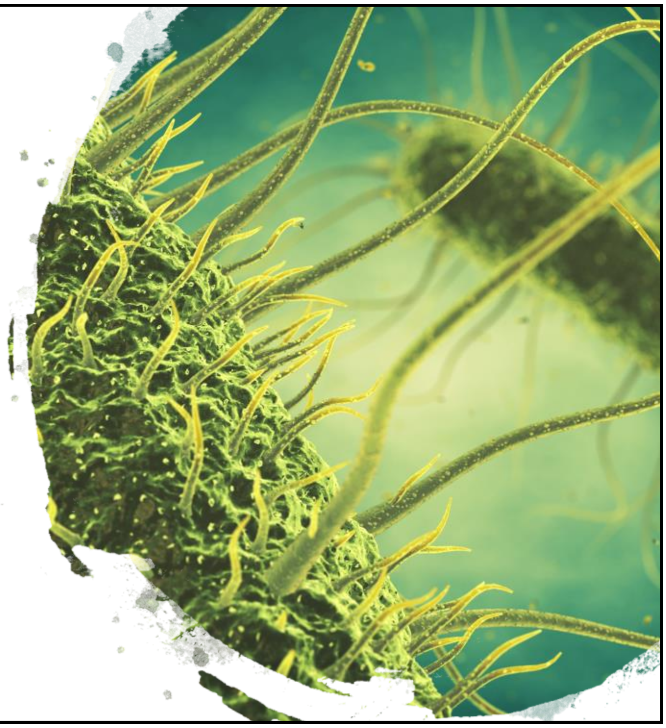
FSMA Implementation Schedule

FSMA was signed into law on **January, 2011**

Regulations were supposed to be finalized within one to two years of enactment (roughly **January 2012 and January 2013**)

Revised implementation dates: (all drafts are currently publically available)

- **Preventative controls**: FSMA §103(a) and(c): August 30, 2015
- **Foreign supplier verification program**: FSMA §301(a): October 31, 2015
- **Accreditation of third party auditors**: FSMA §307): October 31, 2015
- **Produce safety Rule:** FSMA §105(a): October 31, 2015 [Week 11+ Survey]
- **Sanitary transportation practices for food and feed**: FSMA §111: March 31, 2016
- **Intentional adulteration of food**: FSMA §106(b): May 31, 2016.



5

Produce and Preventive Rules and Land-grant Institutions

- Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (**Produce Rule**): **Producers**
- Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (**Preventive Rule**): **Processors**

- Large producers and processors
- Small and medium size producers and processors
- Very small (hobbyists) producers and processors (local and cottage industry)

- Many of small and medium size entrepreneur will require assistance from the nations 75 land-grant institution for **safe and economical access to market**.

6

Preventive Control for Human Food Rule: Overview (PC QI)

- Regulate "**processors**"
- Under the regulation all "**facilities**" have to be registered with FDA
- The rule has **two sections**: **Hazard Analysis (HARPc) and GMP**, facilities obligated to have one or both.
- **Exemptions:** Juice, seafood, and shell egg sectors and businesses that store agricultural comities. (differs with preventive rule)

Modified Requirements:

- Three-year average sales less than $500K, AND
  - Direct sales to restaurants and consumers within 275 mile radius, or
  - Within states sales in 275 mile radius.

7

Requirements of Preventive Rule
cGMP-*Current Good Manufacturing Practices*

- Similar to prerequisite program in HACCP
- **Nearly all facilities are required** to follow this section of the rule

Exemption:

(1) Businesses that store agricultural commodities

(2) Businesses that selling directly to a manufacturing facility like canning operation (vertically integrated farms)

Main Principles:

- Sanitation
- Employee training
- Environmental control and training
- Recall contingency plan
- Allergen control
- Supplier verifications
- Sanitary transportation

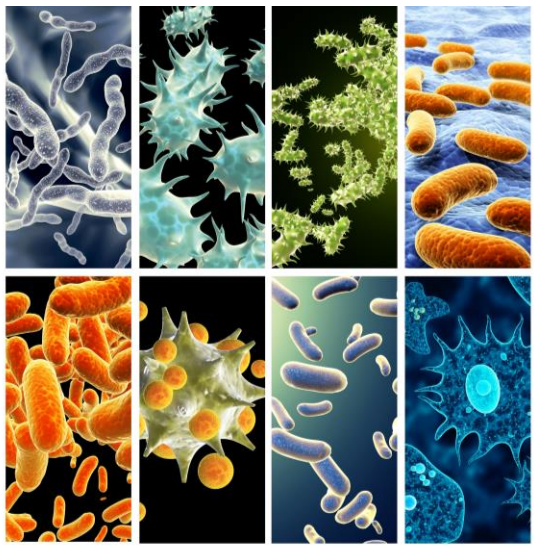
8

Requirements of Preventive Rule
Hazard Analysis and Risk-Based Preventative Controls (HARPC)

- Previous a 7-step plan for FSIS HACCP, 12-step plan for Codex HACCP, and currently 5-step plan for HARPC:

- **Hazard analysis**
- Identification and implementation **preventive controls**.
- **Monitoring** the performance of controls.
- Developing **corrective actions** for preventative deviation.
- **Verification and recordkeeping** of preventative controls effectiveness

- 2.5 day workshop Preventive Control Qualified Individuals (PC QI)



9

Preventive Rule: Implementation and compliance dates

- **Implementation date:** August 30, 2015
- **Compliance date:**
  - **Very small** facility ($2.5*m and below): 3 year
  - **Small** facility (less than 500 employee and does not qualified for exception): 2 years
  - **"Other" facilities**: 1 years

Modified Requirements:

- Three-year average sales less than $500K, AND
  - Direct sales to restaurants and consumers within 275 mile radius, or
  - Within states sales in 275 mile radius.

*Total annual sale; the categories differ in preventive and produce rules.

10

COURSE TYPE	LEAD INSTRUCTOR	COURSE START	WEB ADDRESS TO REGISTER	COST	CONTACT EMAIL	ADDRESS	LANGUAGE	FORMAT
Human Food	Esmeralda Paz Lemus	Dec 3, 2020	Register	USD 615	Contact	Alcaldía Cuauhtemoc Ciudad de México Mexico	Spanish	In Person - Live
Human Food	Derrick Payne	Dec 1, 2020	Register	USD 400	Contact	Decatur IL United States	English	Virtual - Online, Web Based Live
Human Food	Satoshi IMANARI	Oct 6, 2020	Register	JPY 108,000	Contact	Live-Virtual Live-Virtual Japan	Japanese	Virtual - Online, Web Based Live
Human Food	Donna F. Schaffner	Sep 30, 2020	Register	USD 845	Contact	Bridgeton NJ United States	English	Virtual - Online, Web Based Live
Human Food	Donna F. Schaffner	Dec 8, 2020	Register	USD 895	Contact	Bridgeton NJ United States	English	Virtual - Online, Web Based Live
Human Food	Sonia Akbarzadeh	Dec 16, 2020	Register	USD 695	Contact	Live-Virtual Interactive Live-Virtual Interactive United States	English	Virtual - Online, Web Based Live
Human Food	Heidi Kassenborg	Dec 2, 2020	Register	USD 750	Contact	No Travel No Travel United States	English	Virtual - Online, Web Based Live
Human Food	Heidi Kassenborg	Nov 4, 2020	Register	USD 750	Contact	No Travel No Travel United States	English	Virtual - Online, Web Based Live
Human Food	Heidi Kassenborg	Oct 7, 2020	Register	USD 750	Contact	No Travel No Travel United States	English	Virtual - Online, Web Based Live
Human Food	Bartosz Dobek	Nov 4, 2020	Register	USD 699	Contact	Naperville Illinois United States	English	Virtual - Online, Web Based Live
Human Food	Bartosz Dobek	Oct 14, 2020	Register	USD 699	Contact	Marietta Georgia United States	English	In Person - Live
Human Food	Bartosz Dobek	Sep 23, 2020	Register	USD 699	Contact	Naperville IL United States	English	In Person - Live

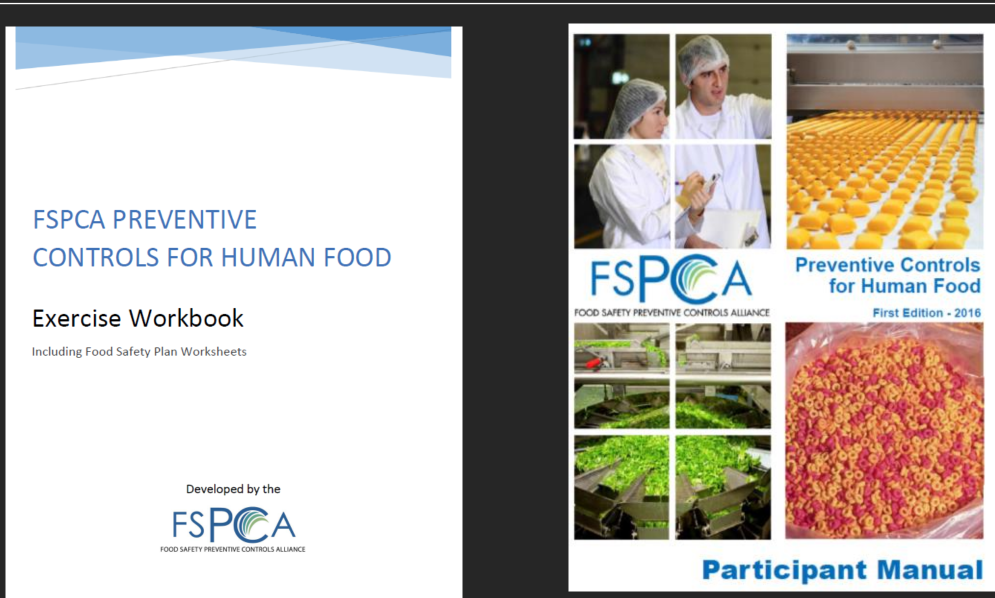
Preventive Control for Human Food: PC QI

- Our course 10-08-20202 to 10-29-2020
- Funded by USDA

- Animal Food PC QI:

https://fspca.force.com/FSPCA/s/courselist?language=en_US

USDA NIFA
United States Department of Agriculture
National Institute of Food and Agriculture


FSPCA PREVENTIVE
CONTROLS FOR HUMAN FOOD
Exercise Workbook
Including Food Safety Plan Worksheets
Developed by the
FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE
FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE
Preventive Controls
for Human Food
First Edition - 2016
Participant Manual

12

COURSE TYPE	LEAD INSTRUCTOR	COURSE START	WEB ADDRESS TO REGISTER	COST	CONTACT EMAIL	ADDRESS	LANGUAGE	FORMAT
Animal Food	Kimberly Baker	Apr 13, 2021	Register	USD 495	Contact	Pendleton SC United States	English	In Person - Live
Animal Food	RACHEL MONTGOMERY	Dec 7, 2020	Register	USD 850	Contact	COST INCLUDES CERT., CONVENIENT PARTIAL DAYS NO TRAVEL, EARLY-BIRD & GROUP DISCOUNTS United States	English	Virtual - Online, Web Based Live
Animal Food	Dr. Jayne Stratton	May 24, 2021	Register	USD 599	Contact	Lincoln NE United States	English	Virtual - Online, Web Based Live
Animal Food	Bita Saidi	Feb 16, 2021	Register	USD 695	Contact	Live-Virtual Interactive Live-Virtual Interactive Canada	English	Virtual - Online, Web Based Live
Animal Food	Dr. Tamla Blunt	Dec 16, 2020	Register	USD 795	Contact	Fresno CA United States	English	In Person - Live
Animal Food	RACHEL MONTGOMERY	Nov 2, 2020	Register	USD 850	Contact	COST INCLUDES CERT., CONVENIENT PARTIAL DAYS, NO TRAVEL, EARLY-BIRD & GROUP DISCOUNTS United States	English	Virtual - Online, Web Based Live
Animal Food	Bita Saidi	Nov 18, 2020	Register	USD 695	Contact	Live-Virtual Interactive Live-Virtual Interactive Canada	English	Virtual - Online, Web Based Live
Animal Food	Charles Mike Nolan	Nov 4, 2020	Register	USD 850	Contact	Virtual Virtual Virtual	English	Virtual - Online, Web Based Live
Animal Food	Leslie Smith	Nov 16, 2020	Register	USD 600	Contact	Self-Study Flexible Schedule United States	English	Virtual - Online, Web Based Live

Animal Food PC QI:
https://fspca.force.com/FSPCA/s/courselist?language=en_US

13

Photos courtesy: Adobe Stock, royalty (standard license) purchased by public health microbiology laboratory

14

FSPCA

FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

Dr. Ruth Climat

in recognition for having successfully completed
the Food Safety Preventive Controls Alliance course:

FSPCA Preventive Controls for Human Food

delivered by Lead Instructor

Dr. Aliyar Cyrus Fouladkhah

completed on

11/27/2020

Robert Brackett, VP and Director
Institute for Food Safety and Health

Gerald Wojtala, Executive Director
International Food Protection Training Institute

Steve Mandernach, Executive Director
Association of Food and Drug Officials

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH
ILLINOIS INSTITUTE OF TECHNOLOGY

ifpti

AFDO

Certificate # c6db1b28

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

Yves-Laurent Regis

in recognition for having successfully completed
the Food Safety Preventive Controls Alliance course:

FSPCA Preventive Controls for Human Food

delivered by Lead Instructor

Dr. Aliyar Cyrus Fouladkhah

completed on

11/27/2020

Robert Brackett, VP and Director
Institute for Food Safety and Health

Gerald Wojtala, Executive Director
International Food Protection Training Institute

Steve Mandernach, Executive Director
Association of Food and Drug Officials

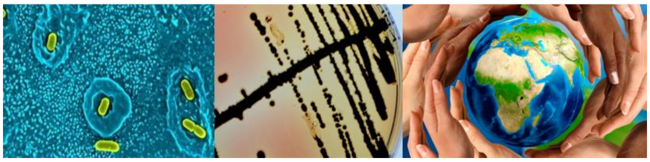
IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH
ILLINOIS INSTITUTE OF TECHNOLOGY

ifpti

AFDO

Certificate # ff3d55c5

Food Fortification Workshop



Fortification of Staple Commodities and Microbial Safety Requirements for Human Food Production

USAID F2F assignment: Haiti, Nashville, TN

12-7-2020

Tennessee State University, Nashville, TN

A. Fouladkhah: Faculty Director, Public Health Microbiology Laboratory

USAID FROM THE AMERICAN PEOPLE

USDA NIFA United States Department of Agriculture National Institute of Food and Agriculture

1

Presentation Content

Part I: *Brief Introduction to my Program*

Part II: *Recent Food Safety Requirements*

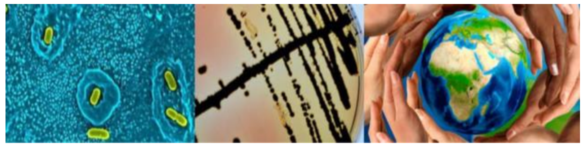
Part III: *Dietary Guidelines and Fortifications*

USAID FROM THE AMERICAN PEOPLE

USDA NIFA United States Department of Agriculture National Institute of Food and Agriculture

PBI Pressure BioSciences Inc.

2



Part I: *Brief Introduction to my Program*

3

Colorado State University

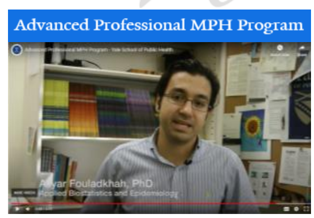
- Microbiology and Food Safety, PhD
- Applied Statistics and Data Analysis, Graduate Certificate
- Food Science & Human Nutrition, MS

Microbac

RODELLE established 1936

Yale SCHOOL OF PUBLIC HEALTH

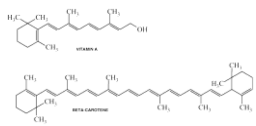
- Biostatistics and Epidemiology, Advanced Professional MPH
- Food and Drug Regulatory Affairs, Graduate Certificate
- Climate Change and Health, Graduate Certificate

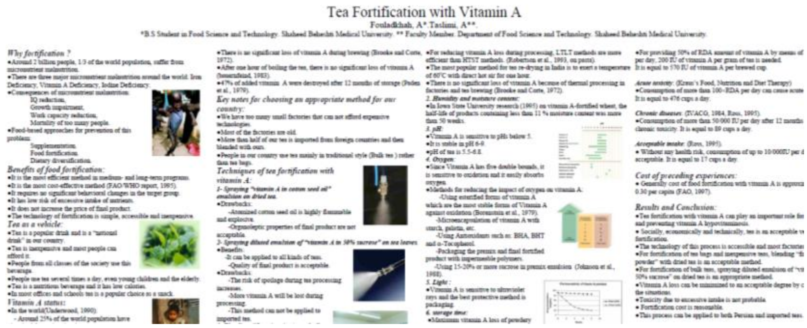


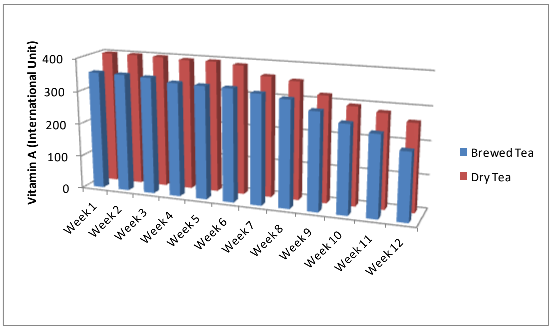
Website: https://publichealth.yale.edu/advanced/
Video: https://www.youtube.com/watch?v=IGVN9JfoIt8

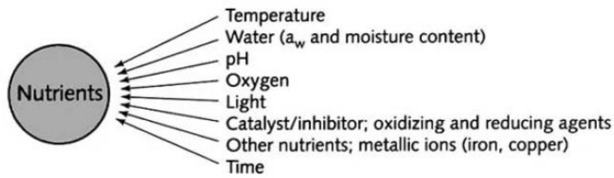
CPH Certified in Public Health · sas Certified Base Programmer for SAS 9 · CFS Certified Food Scientist

4




Tea Fortification with Vitamin A
Fouladkhah, A* Taslimi, A**



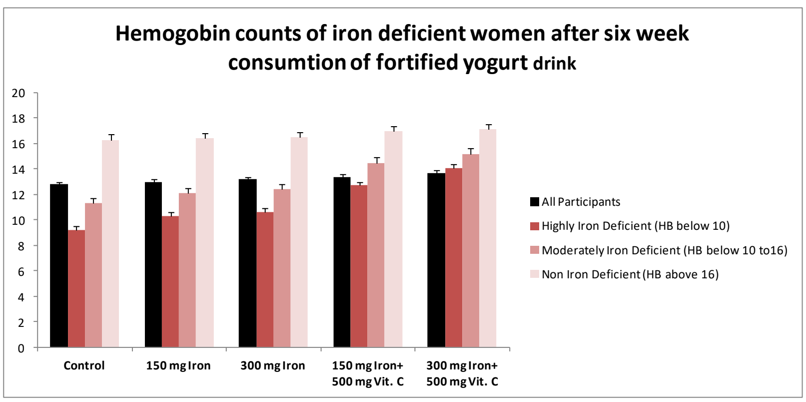


Fouladkhah and Taslimi, 2006

5

Fortification of Yogurt Drinks with Iron and vitamin C

- >53 increase in HB counts in 6 weeks



Fouladkhah et al., 2007

6

Public Health Microbiology Laboratory Tennessee State University

MPH Curriculum Food Safety and Applied Epidemiology

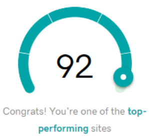
United States Department of Agriculture
National Institute of Food and Agriculture

Pressure BioSciences Inc.

- ❖ **Stablished in 2015:**
- ❖ Currently $7,000/year from Cooperative Extension Program

Website: https://publichealthmicrobiology.education/

- ❖ **Extramural Funding**
- ❖ National Institute of Health: $**33,680** (PD of Sub-award, 2020-21)*
- ❖ Pressure BioScience Inc.: **$35,000** (Role: PD, 2019-2024)
- ❖ USDA-NIFA CBG: **$350,000** (Role: PD, 2018-2022)
- ❖ USDA-NIFA HEC: **$50,000** (Role: PD, 2018-2021)
- ❖ USDA-NIFA FSOP: **$165,000** (Role: PD, 2018-2021)
- ❖ Pressure BioScience Inc.: **$23,500** (Role: PD, 2017-2019)
- ❖ USDA-NIFA FSOP: **$59,750** (Role: PD, 2016-2019)
- ❖ Pressure BioScience Inc.: **$9,400** (Role: PD, 2017-2019)
- ❖ USDA-NIFA FSOP.: **$880,000** (Role: CO-PD, 2019-2023)**
- ❖ USDA-NIFA FSOP.: **$1,197,751** (Role: CO-PD, 2015-2020)**
- ❖ USDA-NIFA CBG.: **$300,000** (Role: CO-PD, 2018-2022)



Website performance: 4/22/2020

**Pending account setting and internal administrative approval.*
*** Sub-awardee of Southern Center Main Awards.*

7

Public Health Microbiology Laboratory Current Members

- **Current Graduate Students** (Primary Advisor/Degree Chair: A. Fouladkhah):
- *Sadiye Aras (2018-),* Graduate Research Assistant, (PhD candidate, Biological Sciences c. Food Microbiology)
- *Jyothi George (2019-),* Graduate Research Assistant (PhD student, Biological Sciences c. Food Microbiology)
- *Sabrina Wadood (2020-),* Graduate Research Assistant (MS student, c. Food Microbiology)

- **Current Research Technician, Associates, and Interns** (Primary Supervisor: A. Fouladkhah):
- *Shahid Chowdhury*, BS. Research Technician (2016-present)
- *Niamul Kabir*, PhD. Post-doctoral Research Associate (2018-present).
- Amir Kashipazha, MS. Data Visualization Intern and Web Editor (2018-present).
- Dr. Bagheri, PhD, MSPH, Visiting Scholar (2020-present).

- **Current Graduate Student Committee:**
- *-Shreya Singh Hamal, PhD candidate*, Biological Sciences con. Food Microbiology (Committee member).
- *Yun Tian, PhD student*, Biological Sciences con. Genomics & Immunology (Committee member).
- *Zedonia Williams, MS student*. M.S. degree in Food and Animal Sciences (Committee member).

Fall 2019 Graduates

Abimbola Allison, PhD

Tyler Keene, MS

Monica Henry-Smith, MS

8

Public Health Microbiology Laboratory
Success Story- FSOP Funded Student

- **Fall 2019 Graduates**
- Abimbola Allison, PhD
- Tyler Keene, MS
- Monica Henry-Smith, MS

TN Department of Human Resources | Tennessee Leaders of Tomorrow Internship

9/12/2019

Monica Smith
1282 Vantage Pointe Rd – Apt. 304
Ashland City, TN 37015

Dear Monica,

Congratulations! You have been selected for an internship with Tennessee State Government. Being selected for this internship is very competitive and is a great honor. So, be proud of your accomplishment! We are excited to have you as a member of our customer focused team. We hope that this opportunity provides you with the professional development experience that you are seeking.

Below are the details of your internship offer

Job Title: Tennessee Department of Agriculture - Intern

9

Students Awards
Adviser: A. Fouladkhah

Students Success Available at:
https://publichealthmicrobiology.education/students-awards

Public Health Microbiology Laboratory

- *-1st Place, Oral Competitions, Health and Medical Sciences section.* 2019 Tennessee Academy of Sciences. The 129th annual meeting, Columbia State Community College. Columbia, TN. Student: A. Allison.
- *-2nd Place, Oral Competitions, Health and Medical Sciences section.* 2019 Tennessee Academy of Sciences. The 129th annual meeting, Columbia State Community College. Columbia, TN. Student: S. Aras.
- *-1st Place (tied), Poster Competitions, Health and Medical Sciences section,* 2019 Tennessee Academy of Sciences. The 129th annual meeting, Columbia State Community College. Columbia, TN. 2019 Summer Intern: A. Chowdhury
- *-2nd Place, Poster Competitions, Health and Medical Sciences section.* 2019 Tennessee Academy of Sciences. The 129th annual meeting, Columbia State Community College. Columbia, TN. Student: S. Aras.
- *-2nd Place, Oral Graduate Competitions*, 2019 Annual State-wide Competition for Food Safety Modernization Act, Food Safety, and Food Science Students. Tennessee (Volunteer) section Institute of Food Technologists. Student: A. Allison
- *-1st Place, Oral Graduate Competitions*, 2019 Annual State-wide Competition for Food Safety Modernization Act, Food Safety, and Food Science Students. Tennessee (Volunteer) section Institute of Food Technologists. Student: M. Henry
- *-1st Place, Oral Competitions, Health and Medical Sciences section.* 2018 Tennessee Academy of Sciences. The 128th annual meeting, Austin Peay State University, Clarksville, TN. Student: M. Henry
- *-2nd Place, Oral Competitions, Health and Medical Sciences section.* 2018 Tennessee Academy of Sciences. The 128th annual meeting, Austin Peay State University, Clarksville, TN. Student: A. Allison
- *-1st Place (tied), Graduate Poster Competitions*, 2018 Annual State-wide Poster Competition for Food Safety Modernization Act, Food Safety, and Food Science Students. Tennessee (Volunteer) section Institute of Food Technologists. Student: M. Henry
- *-1st Place, Undergraduate Poster Competitions*, 2018 Annual State-wide Poster Competition for Food Safety Modernization Act, Food Safety, and Food Science Students. Tennessee (Volunteer) section Institute of Food Technologists. Student: B. Simpson.
- *-2nd Place, Undergraduate Poster Competitions*, 2018 Annual State-wide Poster Competition for Food Safety Modernization Act, Food Safety, and Food Science Students. Tennessee (Volunteer) section Institute of Food Technologists. Student: A. Sumlin.
- *-2nd Place, Oral Competitions*, Graduate Life and Physical Sciences Oral Division, 40th Annual University-Wide Research Symposium, Tennessee State University, Nashville, TN, 2018. Student: M. Henry
- *-2nd Place, Oral Competitions*, Graduate Life and Physical Sciences Division, 40th Annual University-Wide Research Symposium, Tennessee State University, Nashville, TN, 2018. Student: A. Allison.
- -*1st Place, 2017 Tennessee Academy of Science*, Health and Medical Sciences Student Oral Competition (Student: K. Sampson), Presentation: Sampson, K., Day, K., Allison, A., Chowdhury, S., Fouladkhah, A. 2017. Fate and Biofilm formation of Wild-type and rifampicin-resistant Cronobacter sakazakii in biotic and abiotic environments. Health and Medical Sciences section, 127th Meeting of Tennessee Academy of Science, November 17, 2017, University of Tennessee at Martin, Martin, Tennessee.
- *-2nd Place, Oral Competitions*, Graduate Biological Sciences Division, 39th Annual University-Wide Research Symposium, Tennessee State University, Nashville, TN, 2017. Student: A. Allison, PhD Student

2019 Tennessee Academy of Science
Health and Medical Sciences Division
1st (A. Allison);2nd (S. Aras); 3rd (M. Henry)
Adviser: A. Fouladkhah

2018 Tennessee Academy of Science
Health and Medical Sciences Division
1st (M. Henry);2nd (A. Allison); 3rd (J. Adhikari)
Adviser: A. Fouladkhah

A. Allison, Outstanding PhD Student in College of Agriculture, Receiving an Award from Dean Reddy.

10

Teaching in Tennessee and Internationally

2019 Evaluation:

- *"Dr. Fouladkhah is an excellent professor. He does the absolute best job of making students feel comfortable making discussion in class and is exceptionally knowledgeable in the area of food sciences. The in class exercises are definitely helpful to make sure the lectures are being retained and assists in requiring little to no studying outside of the class meetings."*
- *"This course is top notch, one of the best courses I have ever taken, Much gratitude to the lead instructor Dr. Fouladkhah. I learned so much in the class and my knowledge on food policies and regulation has increased a thousandfold."*

2018 Evaluation:

- *"This man is so amazing. Learned so much in his class thank you Dr. Fouladkhah."*
- *"He is very helpful and always very encouraging. He helped me planned my studies and even future goals."*

International Travel Reports Available at:
https://publichealthmicrobiology.education/international-programs

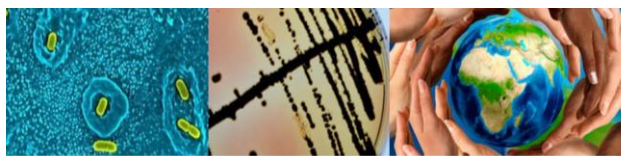
Public Health Microbiology Laboratory

Celebration of UN 1st Food Safety Day

2019, Philippi Township, Cape Town, South Africa:
HIV Prevention Training

2018 and 2020, Antigua, Guatemala
Food Safety Training for Food Industry Leadership

2017, Santiago, Dominican Republic
USAID Public Health and Microbiology Training
Faculty and Staff of ISA University



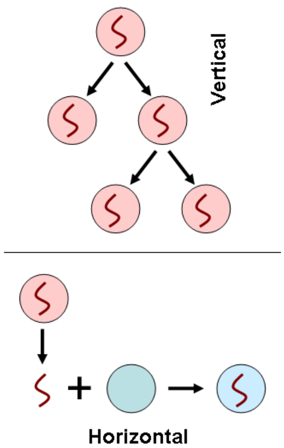
Part II: Recent Food Safety Requirements

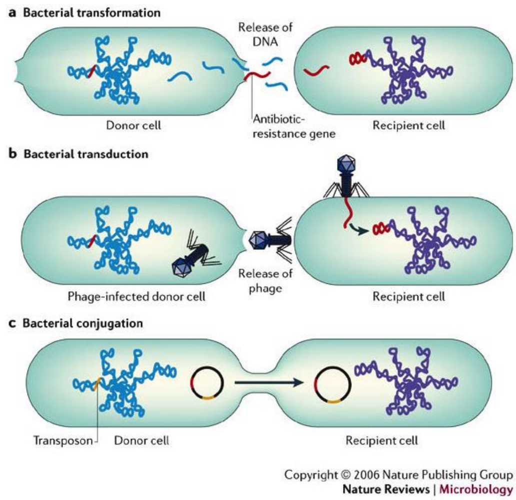
PUBLIC HEALTH MICROBIOLOGY LABORATORY

Emerging pathogens

Vertical and Horizontal Gene Transfer and Emerging Pathogens

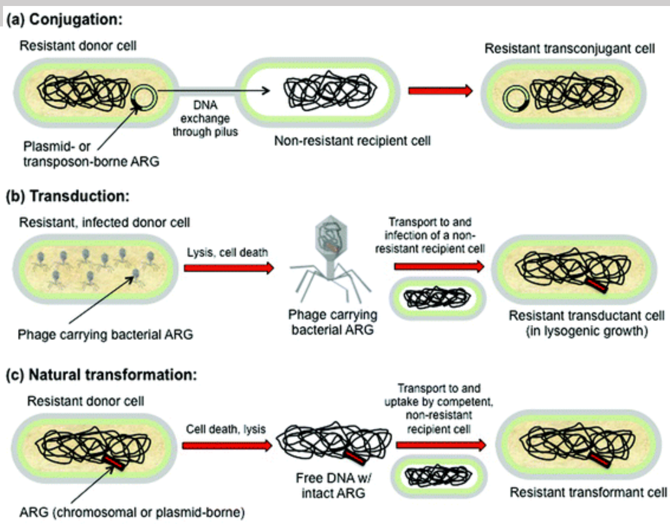
Photo Courtesy: http://www.daviddarling.info/encyclopedia/B/binary_fission.html





13

Horizontal Gene Transfer



Donn, 2012

14

Planktonic cells and Biofilm Communities

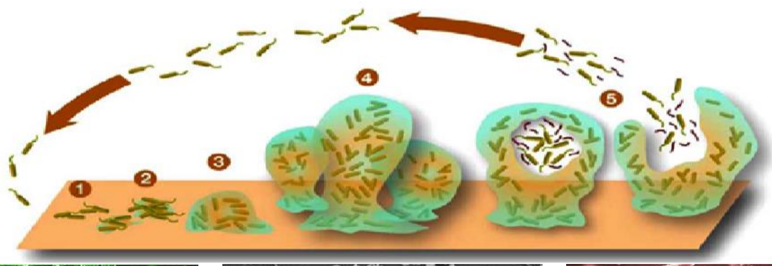


Photo Courtesy: http://prometheus. matse.illinois.edu/ glossary/biofilms/

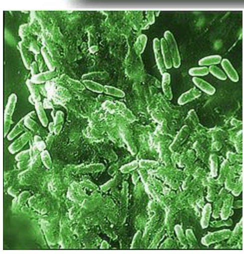


Photo Courtesy: http://micro-writers.egybio.net/blog/?tag=antibiotic-resistance

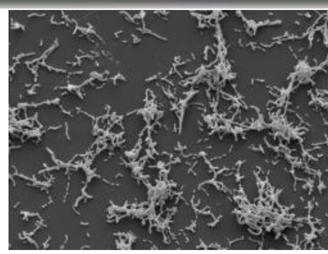


Photo Courtesy: http://www.ifenergy.com/50226711/boosting_microbial_fuel_cells_with_biofilm.php

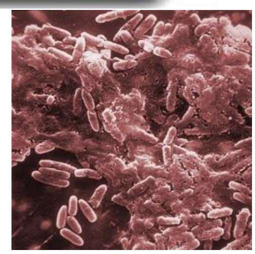
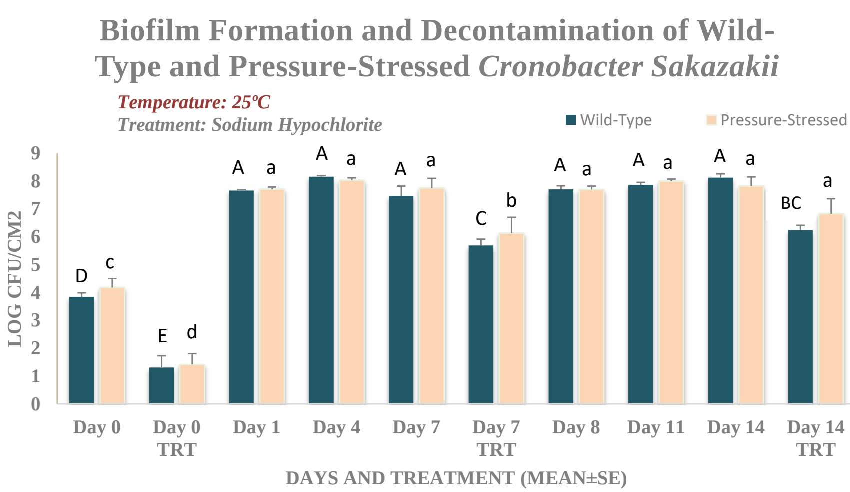


Photo Courtesy: http://www.microbiologybytes.com/blog/category/biofilms/

15

Cronobacter sakazakii
Two outbreaks in Tennessee (1998, Memphis; 2001 Knoxville)



Allison et al., 2020

16

Quorum Sensing and Biofilm formation

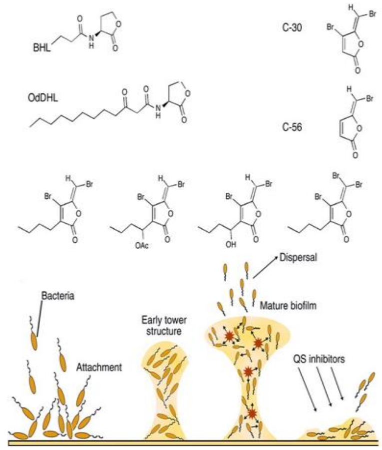


Photo Courtesy: http://www.jci.org/articles/view/20074/figure/2

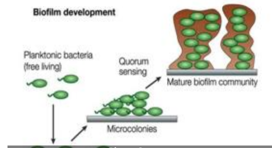


Photo Courtesy: http://labrat.fieldofscience.com/2010/07/quorum-sensing-and-biofilms.html

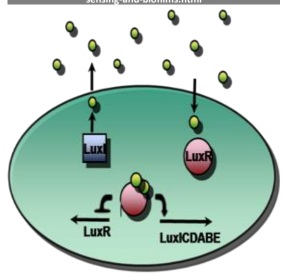


Photo Courtesy: http://2009.igem.org/Team:Aberdeen_Scotland/WetLab/quorumsensing

17

Infectious Diseases in Animals and Human is a Moving Target…

- It is estimated only 1% of microbial community has been identified.
- Currently etiological agent of 80.3% of foodborne illnesses, 56.2% of hospitalization, and 55.5% of deaths remain unknown.

“Emerging” Pathogens:

- Vertical and horizontal gene transfer spores and biofilm formation
- Quorum sensing and cell to cell communication

“It is the microbes who will have the last word.”

-Louis Pasteur

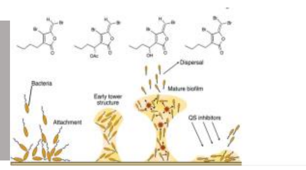
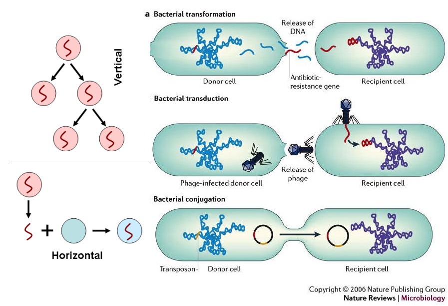


Photo Courtesy: http://www.jci.org/articles/view/20074/figure/2



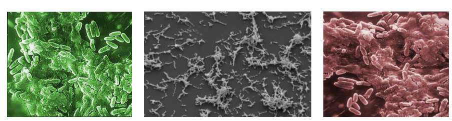


Photo Courtesy: http://www.microbiologybytes.com/blog/category/biofilms/
http://www.ifenergy.com/50226711/boosting_microbial_fuel_cells_with_biofilm.php
http://micro-writers.egybio.net/blog/?tag=antibiotic-resistance

18

Burden of Food Safety in the United States

- **Based on data from 1990s:** *(Mead et al., 1999)*

76 million illnesses, 323,000 hospitalizations, 5,200 deaths in the United States.

- **More recent estimates show:** *(Scallan et al., 2011)*

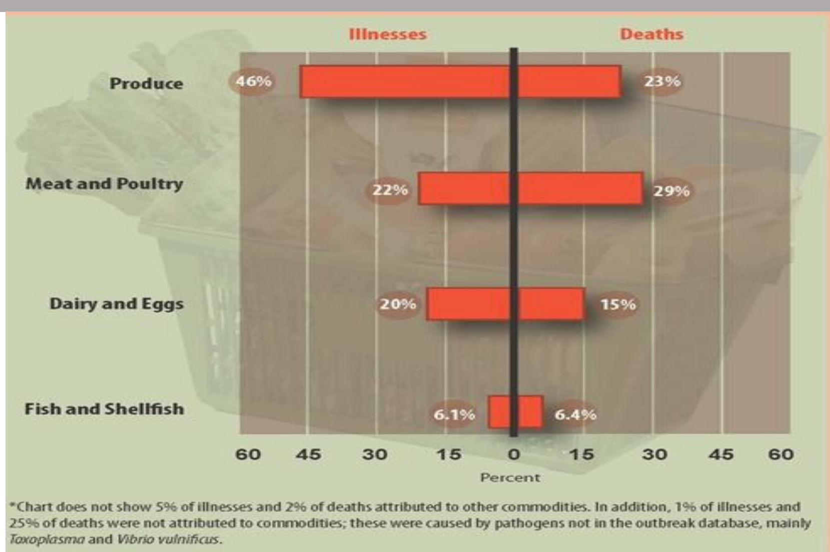
47.8 million illnesses, 127,839 hospitalizations, and more than **3,037** deaths in the United States.

- 9.4 million illnesses, 55,961 hospitalizations, and 1,351 deaths are cause by 31 known foodborne agents.
- In addition to consumer insecurity, foodborne diseases cause around $**77.7 billion** for losses in productivity and economical losses.
- Approximately **30% of population** are especially "at risk" for foodborne diseases (The **YOPI**'s: The young, the old, Pregnant, and Immunocompromised)

19

CDC Estimates of Food Safety Burden

http://www.cdc.gov/foodborneburden/attribution-image.html#foodborne-illnesses



20

Food Safety Modernization Act (FSMA)

- Signed to law in January of 2011, FSMA is the largest expansion of U.S. food safety authorities since the 1930s.
- Many sectors of agriculture and manufacturing will undergo strict regulations for the **first time in the history of the country**.
- Shifting responses from food safety problems to **proactively prevent** the episodes
- FSMA, a large and comprehensive legislation **broaden FDA's ability** to:
  - **Mandatory recall** of contaminated food products
  - **Enhanced surveillance** to investigate foodborne illness outbreaks
  - Established **new preventive controls** and food safety plans at some food processing facilities and farms
  - Enhanced FDA's **traceability capacity**
  - **Increased inspection** frequencies of high-risk food facilities (both domestic and foreign facilities)
  - Expanded authority and oversight capabilities with regard to **foreign companies**

21

Regulatory Landscape of Food Industry Before FSMA

Very small companies:

Exemption from federal requirements, need to follow state policies

Restaurant operations:

Exemption from federal requirements, need to follow state policies (food code)

Food Safety Inspection Service (FSIS) of USDA:

Meat, Poultry and Egg products, HACCP requirements

Food and Drug Administration of DHHS:

High Risk Foods: Juices, seafood, and shell egg, *HACCP requirements*

Farmers and other food products:

No federal regulation

22

Mandated by FSMA

- Food manufacturing (processors)
- Farmers and growers (producers)
- Transportation, retailers
- Imported foods
- Third party laboratories
- Local, state, and federal agencies
- Foreign governments

Not mandated by FSMA

- FSMA does not directly address sectors under **pre-existing** jurisdictions. HACCP will remain the dominant regulation for:
- Meat, poultry, and egg products (USDA-FSIS)
- Juices, seafood, and shell eggs (DHHA-FDA)
- Very small producers and processors could receive exception from FSMA requirements (**cottage industry**).
- FSMA does not mandate **GM products, antibiotic resistant organisms, organic production, and pesticide and fertilizer** use.

23

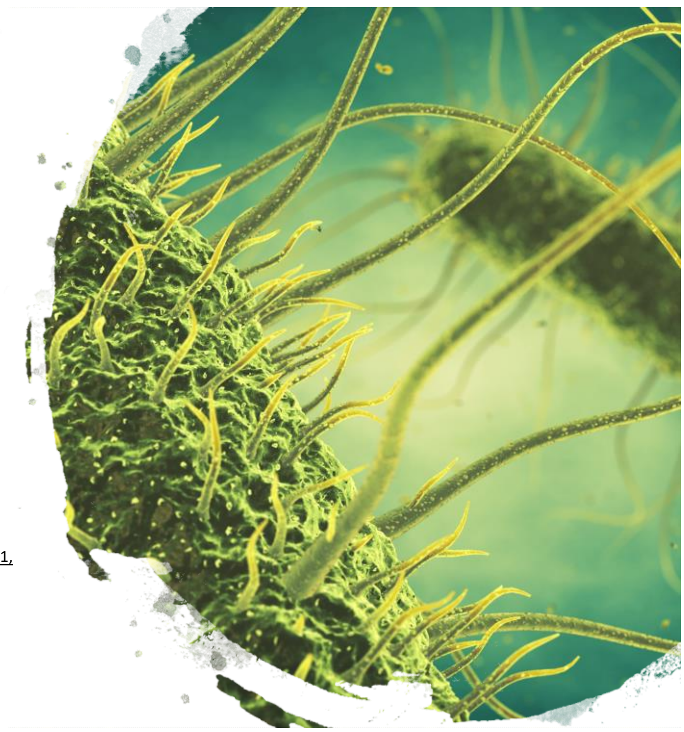
FSMA Implementation Schedule

FSMA was signed into law on **January, 2011**

Regulations were supposed to be finalized within one to two years of enactment (roughly **January 2012 and January 2013**)

Revised implementation dates: (all drafts are currently publically available)

- **Preventative controls**: FSMA §103(a) and(c): August 30, 2015
- **Foreign supplier verification program**: FSMA §301(a): October 31, 2015
- **Accreditation of third party auditors**: FSMA §307): October 31, 2015
- **Produce safety Rule:** FSMA §105(a): October 31, 2015 [Week 11+ Survey]
- **Sanitary transportation practices for food and feed**: FSMA §111: March 31, 2016
- **Intentional adulteration of food**: FSMA §106(b): May 31, 2016.



24

Produce and Preventive Rules and Land-grant Institutions

- Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (**Produce Rule**): **Producers**
- Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (**Preventive Rule**): **Processors**

- Large producers and processors
- Small and medium size producers and processors
- Very small (hobbyists) producers and processors (local and cottage industry)

- Many of small and medium size entrepreneur will require assistance from the nations 75 land-grant institution for **safe and economical access to market**.

25

Preventive Control for Human Food Rule: Overview (PC QI)

- Regulate “**processors**”
- Under the regulation all “**facilities**” have to be registered with FDA
- The rule has two sections**: Hazard Analysis (HARPc) and GMP**, facilities obligated to have one or both.
- **Exemptions:** Juice, seafood, and shell egg sectors and businesses that store agricultural comities. (differs with preventive rule)

Modified Requirements:

- Three-year average sales less than $500K, AND
    - Direct sales to restaurants and consumers within 275 mile radius, or
    - Within states sales in 275 mile radius.

26

Requirements of Preventive Rule
cGMP-*Current Good Manufacturing Practices*

- Similar to prerequisite program in HACCP
- **Nearly all facilities are required** to follow this section of the rule

Exemption:

(1) Businesses that store agricultural commodities

(2) Businesses that selling directly to a manufacturing facility like canning operation (vertically integrated farms)

Main Principles:

- Sanitation
- Employee training
- Environmental control and training
- Recall contingency plan
- Allergen control
- Supplier verifications
- Sanitary transportation

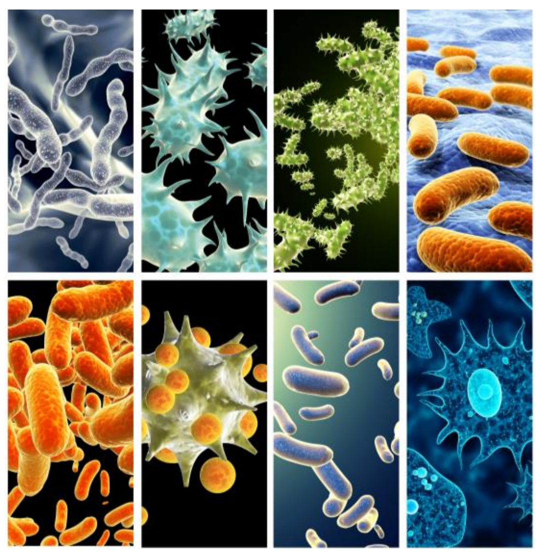
27

Requirements of Preventive Rule
Hazard Analysis and Risk-Based Preventative Controls (HARPC)

- Previous a 7-step plan for FSIS HACCP, 12-step plan for Codex HACCP, and currently 5-step plan for HARPC:

- **Hazard analysis**
- Identification and implementation **preventive controls**.
- **Monitoring** the performance of controls.
- Developing **corrective actions** for preventative deviation.
- **Verification and recordkeeping** of preventative controls effectiveness

- 2.5 day workshop Preventive Control Qualified Individuals (PC QI)



28

Preventive Rule: Implementation and compliance dates

- **Implementation date:** August 30, 2015
- **Compliance date:**
    - **Very small** facility ($2.5*m and below): 3 year
    - **Small** facility (less than 500 employee and does not qualified for exception): 2 years
    - **"Other" facilities**: 1 years

Modified Requirements:

- Three-year average sales less than $500K, AND
    - Direct sales to restaurants and consumers within 275 mile radius, or
    - Within states sales in 275 mile radius.

*Total annual sale; the categories differ in preventive and produce rules.

29

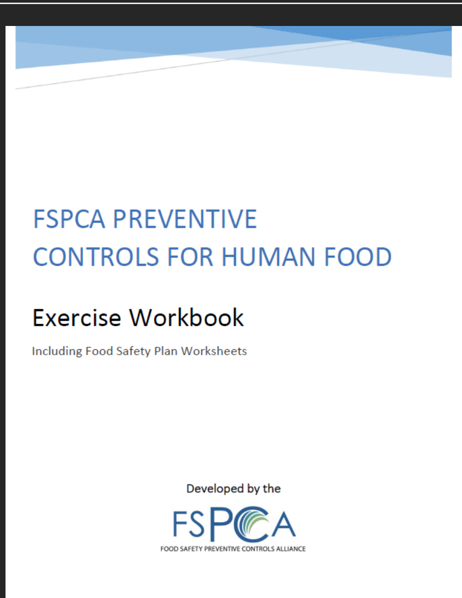
COURSE TYPE	LEAD INSTRUCTOR	COURSE START	WEB ADDRESS TO REGISTER	COST	CONTACT EMAIL	ADDRESS	LANGUAGE	FORMAT
Human Food	Esmeralda Paz Lemus	Dec 3, 2020	Register	USD 615	Contact	Alcaldía Cuauhtemoc Ciudad de México Mexico	Spanish	In Person - Live
Human Food	Derrick Payne	Dec 1, 2020	Register	USD 400	Contact	Decatur IL United States	English	Virtual - Online, Web Based Live
Human Food	Satoshi IMANARI	Oct 6, 2020	Register	JPY 108,000	Contact	Live-Virtual Live-Virtual Japan	Japanese	Virtual - Online, Web Based Live
Human Food	Donna F. Schaffner	Sep 30, 2020	Register	USD 845	Contact	Bridgeton NJ United States	English	Virtual - Online, Web Based Live
Human Food	Donna F. Schaffner	Dec 8, 2020	Register	USD 895	Contact	Bridgeton NJ United States	English	Virtual - Online, Web Based Live
Human Food	Sonia Akbarzadeh	Dec 16, 2020	Register	USD 695	Contact	Live-Virtual Interactive Live-Virtual Interactive United States	English	Virtual - Online, Web Based Live
Human Food	Heidi Kassenborg	Dec 2, 2020	Register	USD 750	Contact	No Travel No Travel United States	English	Virtual - Online, Web Based Live
Human Food	Heidi Kassenborg	Nov 4, 2020	Register	USD 750	Contact	No Travel No Travel United States	English	Virtual - Online, Web Based Live
Human Food	Heidi Kassenborg	Oct 7, 2020	Register	USD 750	Contact	No Travel No Travel United States	English	Virtual - Online, Web Based Live
Human Food	Bartosz Dobek	Nov 4, 2020	Register	USD 699	Contact	Naperville Illinois United States	English	Virtual - Online, Web Based Live
Human Food	Bartosz Dobek	Oct 14, 2020	Register	USD 699	Contact	Marietta Georgia United States	English	In Person - Live
Human Food	Bartosz Dobek	Sep 23, 2020	Register	USD 699	Contact	Naperville IL United States	English	In Person - Live

Preventive Control for Human Food: PC QI

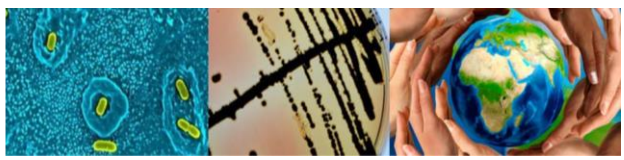
- 2020 Workshops:
- Workshop 1: 10-08-20202 to 10-29-2020
- Workshop 2: 11-23- to 25-2020
- Funded by USDA

United States Department of Agriculture
National Institute of Food and Agriculture

30



31



<u>Part III:</u> Dietary Guidelines and Fortifications

PUBLIC HEALTH MICROBIOLOGY LABORATORY

32

National Nutrition Monitoring and Related Research Act of 1990

An evidence-based legislation

Dietary Guidelines for Americans

National Health and Nutrition Examination Survey

conducted in 1971, and in 1999 the surveys became an annual even

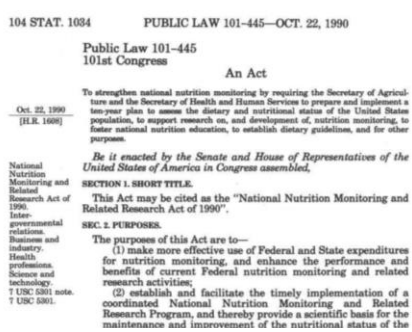
33

National Nutrition Monitoring and Related Research Act of 1990

- Poor diet and physical inactivity
- Epidemic of overweigh and obesity
  - Men, women and children
  - All segments of the society
- **Poor diet and physical inactivity**: a leading cause of premature morbidity and mortality
- Absence of harmonized national policy and guidelines for food, nutrition and health
- Lead to enactment of:

National Nutrition Monitoring and Related Research Act of 1990

(Public Law 101-445, Title III, 7 U.S.C. 5301 et seq.)



104 STAT. 1034 PUBLIC LAW 101-445—OCT. 22, 1990

Public Law 101-445
101st Congress

An Act

Oct. 22, 1990
[H.R. 1608]

To strengthen national nutrition monitoring by requiring the Secretary of Agriculture and the Secretary of Health and Human Services to prepare and implement a ten-year plan to assess the dietary and nutritional status of the United States population, to support research on, and development of, nutrition monitoring, to foster national nutrition education, to establish dietary guidelines, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

National Nutrition Monitoring and Related Research Act of 1990.
Intergovernmental relations.
Business and industry.
Health professions.
Science and technology.
7 USC 5301 note.
7 USC 5301.

SECTION 1. SHORT TITLE.

This Act may be cited as the "National Nutrition Monitoring and Related Research Act of 1990".

SEC. 2. PURPOSES.

The purposes of this Act are to—

(1) make more effective use of Federal and State expenditures for nutrition monitoring, and enhance the performance and benefits of current Federal nutrition monitoring and related research activities;

(2) establish and facilitate the timely implementation of a coordinated National Nutrition Monitoring and Related Research Program, and thereby provide a scientific basis for the maintenance and improvement of the nutritional status of the

https://www.gpo.gov/fdsys/pkg/STATUTE-104/pdf/STATUTE-104-Pg1034.pdf

34

Oral Comment Meeting

On August 11, 2020, USDA and HHS hosted a virtual meeting to hear comments from the public on the Scientific Report of the 2020 Dietary Guidelines Advisory Committee. USDA and HHS will consider the Committee's Scientific Report, along with public and agency comments, as the Departments develop the next edition of the Dietary Guidelines.

Meeting Materials

View the agenda and list of oral commenters. The archived webcast is available below. The meeting transcript will be posted to this page once available.

View Archived Webcast

Advisory Committee Meetings

The 2020 Dietary Guidelines Advisory Committee's work is now complete. The Advisory Committee held 6 public meetings. Information from these meetings, including meeting materials and archived webcasts, can be found here.

35

DGA *main concepts*

- **(1) Maintain calorie balance over time to achieve and sustain a healthy weight** (quantity of diet)
  - *Decrease the calories consumption*
  - *Increase the calories expenditure through physical activity*
- **(2) Consuming nutrient-dense foods and beverages** (quality of diet)
  - *Reduction in consumption of:*
    - *Sodium,*
    - *Calories from solid fats, **(Trans fatty acids, another great topic for the paper)***
    - *Added sugars,*
    - *Refined grains.*
  - *Increase in consumption of:*
    - *Vegetables, fruits, and whole grains,*
    - *Fat-free or low-fat milk and milk products,*
    - *Seafood, lean meats and poultry, eggs,*
    - *Beans and peas, and nuts and seeds.*

36

Foods and Nutrients to Increase Recommendations Specific Age Groups

Women capable of becoming pregnant

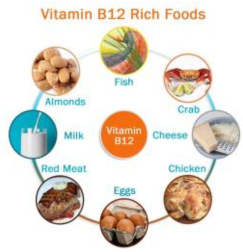
- Choose foods that supply heme iron, which is more readily absorbed by the body, additional **iron sources**, and **enhancers of iron absorption** such as vitamin C-rich foods.
- Consume **400 micrograms (mcg) per day of synthetic folic acid** (from fortified foods and/or supplements) in addition to food forms of folate from a varied diet.
- *[Low childhood mortality in the United States]*
- *[Since 1998, folic acid (B9) required breads, cereals, pasta, flour, rice, cornmeal and other processed grain products] Whole Grain Cereals Vs. Processed Cereals ... Pizza Crust?*

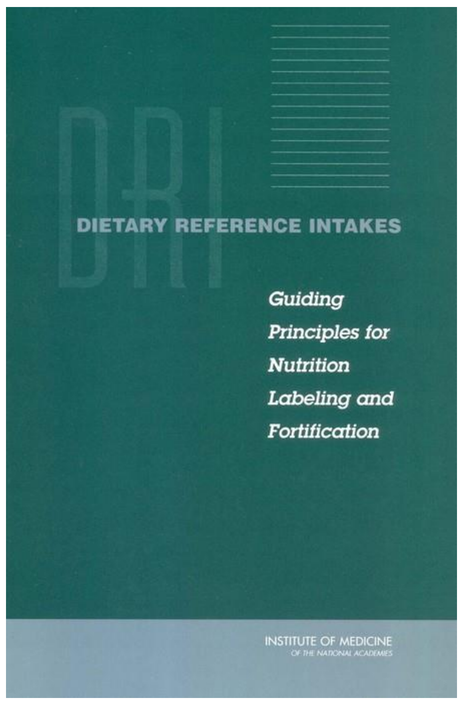
Women who are pregnant or breastfeeding

- Consume 8 to 12 ounces of seafood per week from a variety of seafood types.
- Due to their **methyl mercury content**, limit white (albacore) tuna to 6 ounces per week and do not eat the following four types of fish: tilefish, shark, swordfish, and king mackerel.
- If **pregnant, take an iron supplement as recommended** by an obstetrician or other health care provider.

Individuals ages 50 years and older

- Consume foods **fortified with vitamin B12**, such as fortified cereals, or dietary supplements.



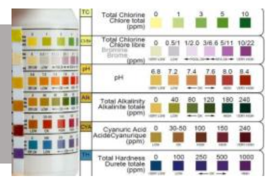


Iron Fortifications

- **Substantial numbers of women** who are capable of becoming pregnant, including adolescent girls, are **deficient in iron**.
- They can **improve their iron** status by choosing foods that supply **heme iron**, which is more readily absorbed by the body, as well as additional **iron sources and enhancers** of iron absorption such as vitamin **C-rich foods**.
- **Sources of heme iron** include lean meat and poultry and seafood.
- **Sources of non-heme iron include:** beans, lentils, and spinach, as well as foods enriched with iron, such as most breads and cereals.
- Non-heme iron is **not as readily absorbed** by the body.
- **Women who are pregnant** are advised to take an **iron supplement** as recommended by an obstetrician or other health care provider.

39

Testing Iron in Flour:



- 1. Qualitative Test (Spot Test):
- **Method:** Iron qualitative method, AACC Method 40-40
- **Reagents**: Thiocyanate reagent (Dissolve 10 g KSCN in 100 ml water); 2N HCl, Hydrogen peroxide, 3%.
- **Equipment:** none
- 2.A. Semi-Quantitative Test: (Spot Test):
- **Method:** Semi-quantitative spot test for iron INCAP method IV.
- **Reagents:** Hydrochloric acid, HCl; Hydrogen peroxide, H_2O_2; Potassium thiocyanate, KSCN; H_2O_2
- 2. B. Semi-Quantitative Test (Colorimetric method):
- **Method:** Semi-quantitative colorimetric determination of iron in flour INCAP method V
- Sodium acetate ($CH_3COONa.3H_2O$), 99%
- Hydrochloric acid (HCl), 37%
- a,a-dipyridyl (2,2' bipyridine)
- Bathophenanthroline, 4,7-diphenyl-1,10-phenanthroline-disulfonic acid ($C_{24}H_{16}N_2O_6S$
- Hydroxylamine hydrochloride ($NH_2OH.HCl$)
- Iron standards: Electrolytic iron, Merck 3810 or Baker 2234

40

Testing Iron in Flour:

3.A. Quantitative Test (Spectrophotometric method):

- **Method:** Iron spectrophotometric method AACC method 40-41B
- **Reagents:**
- Orthophenanthroline solution (0. l g o-phenanthroline in about 80 ml water).
- Iron standard solution, (10 µg Fe/ml)
- Hydroxylamine hydrochloride solution (10 g NH2OH.HCl in water and dilute to 100 ml)
- Acetate buffer solution (8.3 g anhydrous sodium acetate in water)

3.B. Quantitative Test Atomic absorption spectrophotometric (AAS) method:

- **Method:** Spectrophotometric analysis for quantitative, INCAP method VI
- **Reagents:**
- Sodium acetate (CH3COONa.3H2O), 99%
- Hydrochloric acid (HCl), 37%, 1.19 g/mL
- a,a-dipyridyl (2,2' bipyridine) (C10H8N2)
- Bathophenanthroline, 4,7-diphenyl-1,10-phenanthroline-disulfonic acid (C24H16N2O6S2)
- Hydroxylamine hydrochloride (NH2OH.HCl)
- Iron standards: Electrolytic iron, Merck 3810

41

General Requirements for Records

- **Form**
  - Could be **true copies** or **electronic**
- **Content**
  - **Actual values or observations**
  - **Accurate, permanent** (e.g., in ink) and **legible**
  - **Real time recording**
  - **Adequate detail**

FSPCA FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

42

Computerized Records

- **Must be equivalent to paper records** and **hand written signatures**
- An electronic record-keep system must:
  - Be **authentic, accurate and protected**
  - Provide **accurate and complete copies of records**
  - **Protect records for later retrieval**
  - **Limit access** to **authorized individuals**
  - Provide a **secure record for audit trail**
  - Be **reviewed by a trained individual or PC QI**

FSPCA FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

43

Basic Information on Records

- **Name of record**
- **Name and location of facility**
- **Date** and, when appropriate, **time** of activity documented
- **Actual measurement** or observation taken, as applicable
- **Product identification**, if applicable
- **Signature or initials** of the person **performing** the monitoring activity
- **Signature or initials** of the person **reviewing** the record, and date of the review

FSPCA FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

44

5 Implementation Records

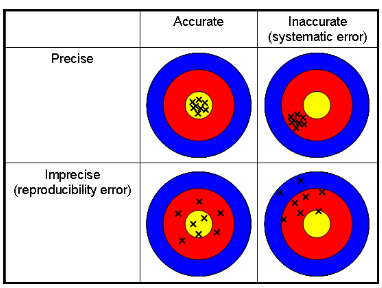
- (1) **Monitoring records** for preventive controls
- (2) **Corrective action** records
- (**3) Verification records**, when required
  - Validation
  - Verification of monitoring and corrective action
  - Calibration of monitoring and verification instruments
  - Product testing
  - Environmental monitoring
  - Records reviews
  - Reanalysis
- **(4) Supply-chain program** and supporting documentation
- **(5) Training records**, as appropriate

FSPCA FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

45

Testing Considerations

- **Considerations for calibration:**
  - Design of the **monitoring device**
  - **Reliability and sensitivity of the device** **(precision and accuracy)**
  - **Environment or conditions** in which it is used

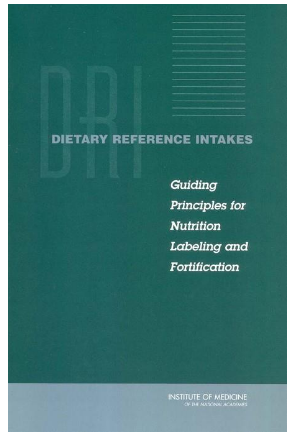


FSPCA FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

46

Product Testing Procedures Must…

- Must be **scientifically valid** **(AOAC, AOCS, BAM, USDA microbiology and chemistry guidebooks)**
- Must identify:
  - The **microorganism or analyte**
  - **Relationship to lots** **(e.g. from geometrical center)**
  - The **number of samples, frequency**, and analytical unit
  - **Analytical test method**
  - **Laboratory**
  - **Corrective action procedures**



FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

47

PUBLIC HEALTH MICROBIOLOGY LABORATORY

Photos courtesy: Adobe Stock, royalty (standard license) purchased by public health microbiology laboratory

48

Recommendations

FARMER TO FARMER
The USAID John Ogonowski and Doug Bereuter Farmer-to-Farmer Program

PARTNERS *of the* AMERICAS
Connect • Serve • Change Lives

John Ogonowski and Doug Bereuter Farmer-to-Farmer Program

Volunteer Recommendations Form

Name of Volunteer: ______Aliyar Cyrus Fouladkhah, PhD, MPH________________________

Country of Service: _______Haiti______ Dates of Trip:_July 14 to December 7, 2020_______

# of Persons *Formally* Trained[1] – male:	6	
# of Persons *Formally* Trained – female:	7	
# of Persons *Formally* Trained – Non-Binary:		
# of Persons *Formally* Trained who are Youth:		
# of Persons *Formally* Trained – total:	13	

*****Please review footnotes for definitions of "persons trained" and "persons directly assisted"*****

Recommendations Made by the Volunteer:[2]

Please summarize the recommendations you made to the people/groups/organizations you assisted. Details of the recommendations should be included in the trip report – this is a summary table only.

Recommendation	Category*	Host	Time frame to implement change
Development, validation, and implementation of spot test for measuring iron content of the fortified product based on provided information.	1,3	RANFOSE and F2F Office in Haiti	Within two years
Incorporating food safety best practices based on information discussed in the workshops to assure regulatory compliance and safety of fortified products.	2	RANFOSE and F2F Office in Haiti	Within two years
Dissemination of the information discussed in the fortification workshop to relevant stakeholders.	2, 3	RANFOSE and F2F Office in Haiti	Within one year
Development of semi-quantitative and quantitative testing methodologies for measuring iron in flour-based commodities.	1,4	RANFOSE and F2F Office in Haiti	Within two years
Determining the stability of the fortificant during the shelf-life of flour-based products.	2, 4	RANFOSE and F2F Office in Haiti	Within two years

[1] **Persons Formally Trained:** number of persons who received technical/instructional training *in a "formal" setting:* classroom, workshop, institute/university or on-the-job setting with specific learning objectives and outcomes

[2] **Recommendations Made by the Volunteer:** The definition of "recommendation" is quite subjective, but might include an improved procedure, a technological or management innovation, a useful product or marketing tool, etc. Volunteers might make numerous detailed recommendations to a variety of hosts. Recommendations should be written in a way that is clear and measurable. *Please try to limit recommendations to no more than six per host.*

Development, optimization, and validation of laboratory best practices for ensuring effectiveness of testing based on provided information.	1,3	RANFOSE and F2F Office in Haiti	Within two years
Utilization of developed methods and consumables list for implementing new testing programs at field and laboratory levels.	3,4	RANFOSE and F2F Office in Haiti	Within two years
Dissemination of information about food quality control and food safety plan to relevant stakeholders to assure success of fortification programs.	2,3	RANFOSE and F2F Office in Haiti	Within one year
Expanding the currently in place fortification program to other staple commodities such as rice, table salt, and pasta.	1,2	RANFOSE and F2F Office in Haiti	Within five years

***** All recommendations should fall under one of four categories:

1. <u>Economic:</u> improvement of profitability of the farm, business, or enterprise
2. <u>Organizational:</u> improvement to organizational effectiveness, management, and sustainability
3. <u>Environmental:</u> improvement of environmental management and natural resource conservation
4. <u>Financial:</u> improvement in the provision of financial services