Public Health and Food Safety Certification Workshop and Process Authority Consultation for Low Water Activity Human Food Production Using Freeze Drying

Trip Report (January 2022)

USAID Assignment on December 5 to 19, Guatemala City, Guatemala

Dr. Aliyar Fouladkhah, PhD, MPH, CFS, CPH

Faculty Director, Public Health Microbiology Laboratory, Tennessee State University

Dr. Minoo Bagheri, PhD, MSPH

Postdoctoral Fellow, Department of Medicine Vanderbilt University Medical Center

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

It was wonderful to return to Guatemala for another USAID assignment. Guatemala is a beautiful country in Central America and approximately 50% of the GDP of the country is associated with Agriculture. Although we are experiencing an unprecedented global pandemic/endemic, we were able to make great progress on this two-week assignment thanks to the great help and support from USAID F2F offices in Washington and Guatemala and outstanding safety precautions. As such, special and sincere appreciation is needed for Ms. Susanna Meyer for her outstanding support and help in harmonizing the events of the program from Washington and to Mr. Jose Eduardo Cano Ozaeta and Mr. Otto Rivera from the Guatemala USAID office. Additionally, technical help and translation from Ms. Crista Rosenberg are sincerely appreciated during the course of this assignment.

We visited an entrepreneur in Guatemala that has asked for help from the USAID F2F office for his operations in the Guatemala City suburbs. The entrepreneur's companies are collectively employing around 150 Guatemalans. The founder and original owner of the operations had sadly passed away recently and his son is tasked to continue the operations. The entrepreneur has recently purchased a freeze dryer and is in process of business development for value-added food products using agricultural commodities of the country. Dr. Minoo Bagheri and I spend two weeks providing technical assistance and training to this entrepreneur. The freeze drying business at this point is pre-sale and is in the R&D stage so this assignment was very timely and of great need for the entrepreneur.

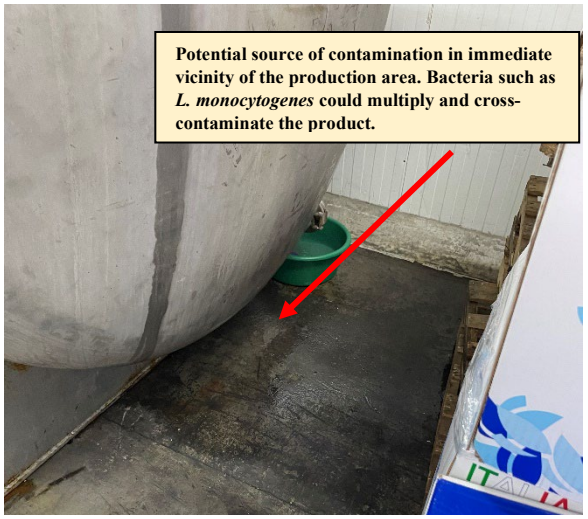
The first week of the assignment we delivered a public health and food safety workshop for 15 individuals from the regional industries and USAID office of Guatemala. As further detailed in the accompanying evaluations, the three-day workshop was received very well by the stakeholders and the event was supplemented with group discussions associated with the stakeholders' product to provide evidence-based information and regulatory advice to ensure the safety and compliance of the products. The workshop curriculum is developed by FSPCA in Chicago and is currently the only curriculum recognized as adequate by the U.S. Food and Drug Administration for Food Safety Modernization Act (FSMA) Preventive Control Qualified Individual for Human Food production. In addition to this curriculum, several lectures were added from the Public Health Microbiology Laboratory about the Food Safety Modernization Act, safe use of ingredients using FDA GRAS list, information on Nutrition Facts Label, and array of topics associated with foodborne and waterborne infectious diseases and epidemiology of transboundary diseases. Excerpts of the slides are provided as an addendum to this report. Participants received a certificate of competition for this FSMA Preventive Control Qualified Individual (PC QI) Workshop, and all received the legal designation of PC QI and a textbook of the course in Spanish.

As a process authority, I provided time to all participants to have one-by-one discussions about their products, these consultation sessions are priced at $135 per stakeholder that we provided at no-cost to the participants. A similar certification program are scheduled in Mexico on December 6, 2021, and in California on January 26, 2022, and were costing $779 and $775 per participant, respectively. This workshop was funded by the Food Processing Support Center of the Public Health Microbiology Laboratory and thus participants received the certification at no

cost. Thus, the cost-saving for the host for the workshop and consultation is conservatively estimated at 12,000 USD (c. 92,000 Quetzal).

In the second week of the assignment, we visited the freeze drying operation and these areas for improvement were identified and discussed with the entrepreneur.

1. **Control of environmental pathogens such as *Listeria monocytogenes*, for reducing the risk of cross-contamination of the freeze-dried products, and implementing a sanitation procedure.** Currently, the freeze-drying unit is located in a high traffic area and there were evidence of potential contamination and standing water in the immediate surrounding of the unit. There is no implemented sanitation procedure and products are prone to cross-contamination after processing. It is recommended to identify a new location for the unit that is away from the high traffic area. During the short visit to the unit, we observed more than five forklifts passing the area, which could very well be a route for the introduction of the potential pathogens. It is noteworthy that reducing the water activity of the product may inhibit the proliferation of bacteria but in case of cross-contamination, bacterial pathogens could survive the low-moisture environment for extended periods. It is also noteworthy that bacteria such as *L. monocytogenes* could even survive the refrigeration temperatures. Additionally, implementation of a validated Sanitation Standard Operating Procedures for food contact and non-food contact surfaces are strongly recommended, supplemented with an environmental monitoring program. Additionally, the unit is located inside a warehouse with several allergen-containing products in the immediate vicinity. It is further recommended to establish practices to eliminate the risk of cross-contact with the allergens and implement proper sanitation and labeling for the product. The solutions to these challenges were discussed in detail with the entrepreneur during the above-mentioned certification workshop.


Potential source of contamination in immediate vicinity of the production area. Bacteria such as *L. monocytogenes* could multiply and cross-contaminate the product.

Spanish textbook provided to workshop participant

2. **Determining the endpoint of the freeze-drying based on validated water activity measurements.** Currently, the products are processed until they are visually dried, and no validated testing is undertaken to ensure the product meets the regulatory requirements for a shelf-stable product. Interaction of pH and water activity determine whether a commodity is a potentially hazardous or Time-Temperature Control for Safety (TCS) product or if the product is shelf-stable and non-TCS. Testing and validation procedures for each

product would need to be conducted to ensure the end-point of drying is evidence-based and to ensure the safety of the product during the shelf-life. Extensive information on this was discussed during the workshop.

3. **Proper packing to ensure elimination of cross-contamination, cross-contact, and ensuring the safety of the products.** Freeze-dried products are prone to re-absorption of the water during the shelf-life and thus require careful packaging and proper handling after processing. As illustrated earlier, currently the product is at a very high risk of cross-contamination with environmental pathogens and cross-contact with allergens. Additionally, the current packaging does not protect the product from re-absorption of water during shelf-life. In addition to the need for a major improvement in sanitation and allergen cross-contact, the entrepreneur would need to utilize a packing procedure to ensure the safety and quality of the product. Freeze-dried products could additionally be easily oxidized during the shelf-life due to increased surface area so the conduct of shelf-life studies and using oxygen absorbers could assist the entrepreneurs in meeting the food safety requirement for local, national, and international food commerce. It is noteworthy that this product is considered a ready-to-eat product and consumers will not have any additional "kill" step to eliminate microbial hazards thus implementation of discussed food safety practices and environmental monitoring is of great concern and importance.

Proper packaging, sanitation procedure, validated end-point for drying, environmental monitoring for mitigating the risk of cross-contamination with pathogens and cross-contact with allergens are recommended.

With these being said, I would like to thank the great colleagues in Washington and Guatemala F2F offices for their help harmonizing the events of this program. I would also need to thank Dr. Minoo Bagheri for accompanying me on this trip and for help valuable suggestions and advice for the entrepreneur during this assignment. I commend the host institution for their willingness to learn and encourage them to implement these public health and food safety practices to ensure the safety of their product and their consumers.

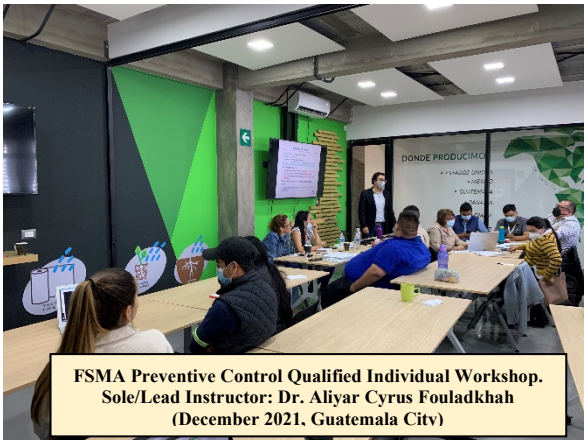
With best wishes,

Aliyar Fouladkhah, PhD, MS, MPH, MACE, CFS, CPH

Associate Professor, Tennessee State University

Faculty Director, Public Health Microbiology Laboratory

Yale School of Public Health Alumnus



FSMA Preventive Control Qualified Individual Workshop. Sole/Lead Instructor: Dr. Aliyar Cyrus Fouladkhah (December 2021, Guatemala City)

FSMA Preventive Control for Qualified Individuals Workshop Invitation

Public Health Microbiology Laboratory:
https://publichealthmicrobiology.education/

Public Health Microbiology Laboratory
Tennessee State University
Aliyar Cyrus Fouladkhah, Faculty Director
CARP Research Complex Laboratories 112 & 114,
3500 John A. Merritt Boulevard, Nashville, TN 37209
Office: (615)963-7471; Lab: (615)963-1578; Mobile: (970)690-7392
Email: afouladk@tnstate.edu or aliyar.fouladkhah@aya.yale.edu
Webpage: https://publichealthmicrobiology.education/

2021 FSMA PC QI Workshop (12-6 to 8-2021)*: *November 30, 2021*
Lead Instructor: Dr. Aliyar Cyrus Fouladkhah

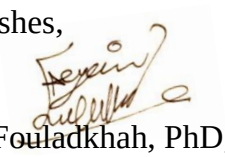
Dear participants,

It is my pleasure to welcome you to our 2021 food safety and public health certification workshop. During this multiday event, in addition to information from the public health microbiology program in Nashville, I will cover the FSPCA curriculum, currently recognized as adequate by one of the leading food safety regulatory institutions in the United States. This workshop will be held in person with safety precautions due to the ongoing national and global respiratory pandemic/endemic.

Participants are expected to be present and actively engaged in-class activities on December 6, 7, and 8 from 9:00 am to 4:00 pm (CDT). We will additionally hold/schedule optional meetings for further specific discussions about food safety and public health practices for each entrepreneur. Below please find the tentative agenda for the meeting. You could also access the survey web link and a QR code that you could use for providing feedback to the instructor at the end of the workshop.

I hope you find this important and timely workshop of assistance for further improving the safety of your operation and meeting and exceeding the regulatory requirements for food commerce. Special recognition is necessary for Partners of the Americas Guatemala Farmer-to-Farmer Program and the Public Health Microbiology Laboratory for co-sponsoring this event.

Best wishes,



Aliyar Fouladkhah, PhD, MS, MPH, MACE, CFS, CPS
Associate Professor, Tennessee State University
Faculty Director, Public Health Microbiology Laboratory
Yale School of Public Health Alumnus

Public Health Microbiology Laboratory
Tennessee State University
Aliyar Cyrus Fouladkhah, Faculty Director
CARP Research Complex Laboratories 112 & 114,
3500 John A. Merritt Boulevard, Nashville, TN 37209
Office: (615)963-7471; Lab: (615)963-1578; Mobile: (970)690-7392
Email: afouladk@tnstate.edu or aliyar.fouladkhah@aya.yale.edu
Webpage: https://publichealthmicrobiology.education/

** Funding support from the National Institute of Food and Agriculture and Public Health Microbiology program is gratefully acknowledged.*

Monday, December 6, 2021 (required): 9:00 am to 4:00 pm
- Introductions from instructor and participants
- Chapters 1 to 8

Tuesday, December 7, 2021 (required): 9:00 am to 4:00 pm
- Chapters 8 to 12
- Individual discussions with entrepreneurs

Wednesday, December 8, 2021 (required): 9:00 am to 4:00 pm
- Individual consultation with a process authority about product safety
- Chapters 12 to 16

For completion of the workshop evaluation survey, you could use the below weblink or Scan this QR code with your cellphone:
https://tnstateu.az1.qualtrics.com/jfe/form/SV_38YWAmCW4VPdqt0

FSMA Preventive Control for Qualified Individuals Workshop Attendees

Public Health Microbiology Laboratory:
https://publichealthmicrobiology.education/

FSPCA®

FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

Edna Beatriz Landaverde Alonzo

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

12/08/2021

Jason Wan, Interim Director
Institute for Food Safety and Health

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH
ILLINOIS INSTITUTE OF TECHNOLOGY

Gerald Wojtala, Executive Director
International Food Protection Training Institute

ifpti

Steve Mandernach, Executive Director
Association of Food and Drug Officials

AFDO

Certificate # 5b4d8169

FSPCA®

FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

Crista Rosenberg Carrera

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

12/08/2021

Jason Wan, Interim Director
Institute for Food Safety and Health

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH
ILLINOIS INSTITUTE OF TECHNOLOGY

Gerald Wojtala, Executive Director
International Food Protection Training Institute

ifpti

Steve Mandernach, Executive Director
Association of Food and Drug Officials

AFDO

Certificate # bd816f39

FSPCA®

FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

Diego Alejandro Mayorga Súchite

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

12/08/2021

Jason Wan, Interim Director
Institute for Food Safety and Health

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH
ILLINOIS INSTITUTE OF TECHNOLOGY

Gerald Wojtala, Executive Director
International Food Protection Training Institute

ifpti

Steve Mandernach, Executive Director
Association of Food and Drug Officials

AFDO

Certificate # 98904649

FSPCA®

FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

Elías Raúl Lopez de Leon

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

12/08/2021

Jason Wan, Interim Director
Institute for Food Safety and Health

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH
ILLINOIS INSTITUTE OF TECHNOLOGY

Gerald Wojtala, Executive Director
International Food Protection Training Institute

ifpti

Steve Mandernach, Executive Director
Association of Food and Drug Officials

AFDO

Certificate # 5ba8bb6a

FSPCA®

FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

Elieser Sánchez

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

12/08/2021

Jason Wan, Interim Director
Institute for Food Safety and Health

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH
ILLINOIS INSTITUTE OF TECHNOLOGY

Gerald Wojtala, Executive Director
International Food Protection Training Institute

ifpti

Steve Mandernach, Executive Director
Association of Food and Drug Officials

AFDO

Certificate # 6f079d0c

FSPCA®

FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

Elsa Zulema Chet Saban

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

12/08/2021

Jason Wan, Interim Director
Institute for Food Safety and Health

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH
ILLINOIS INSTITUTE OF TECHNOLOGY

Gerald Wojtala, Executive Director
International Food Protection Training Institute

ifpti

Steve Mandernach, Executive Director
Association of Food and Drug Officials

AFDO

Certificate # 17d21460

FSPCA®

FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

Felix Azumanche Xia Quiej

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

12/08/2021

Jason Wan, Interim Director
Institute for Food Safety and Health

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH
ILLINOIS INSTITUTE OF TECHNOLOGY

Gerald Wojtala, Executive Director
International Food Protection Training Institute

ifpti

Steve Mandernach, Executive Director
Association of Food and Drug Officials

AFDO

Certificate # 6b65fd67

FSPCA®

FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

Gabriela Calderón

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

12/08/2021

Jason Wan, Interim Director
Institute for Food Safety and Health

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH
ILLINOIS INSTITUTE OF TECHNOLOGY

Gerald Wojtala, Executive Director
International Food Protection Training Institute

ifpti

Steve Mandernach, Executive Director
Association of Food and Drug Officials

AFDO

Certificate # 43d08dcc

FSPCA®

FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

Gilda Graciela Delgado de Chinchilla

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

12/08/2021

Jason Wan, Interim Director
Institute for Food Safety and Health

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH
ILLINOIS INSTITUTE OF TECHNOLOGY

Gerald Wojtala, Executive Director
International Food Protection Training Institute

ifpti

Steve Mandernach, Executive Director
Association of Food and Drug Officials

AFDO

Certificate # f433882e

FSPCA®

FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

Hans Jefferson Mejia de León

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

12/08/2021

Jason Wan, Interim Director
Institute for Food Safety and Health

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH
ILLINOIS INSTITUTE OF TECHNOLOGY

Gerald Wojtala, Executive Director
International Food Protection Training Institute

ifpti

Steve Mandernach, Executive Director
Association of Food and Drug Officials

AFDO

Certificate # 27869ee0

FSPCA®

FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

Lucia Fernanda Tuch Yanes

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

12/08/2021

Jason Wan, Interim Director
Institute for Food Safety and Health

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH
ILLINOIS INSTITUTE OF TECHNOLOGY

Gerald Wojtala, Executive Director
International Food Protection Training Institute

ifpti

Steve Mandernach, Executive Director
Association of Food and Drug Officials

AFDO

Certificate # b31e2568

FSPCA®

FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

Naidil Matos Oliva

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

12/08/2021

Jason Wan, Interim Director
Institute for Food Safety and Health

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH
ILLINOIS INSTITUTE OF TECHNOLOGY

Gerald Wojtala, Executive Director
International Food Protection Training Institute

ifpti

Steve Mandernach, Executive Director
Association of Food and Drug Officials

AFDO

Certificate # 85397bac

FSPCA®

FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

Nery Fernández

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

12/08/2021

Jason Wan, Interim Director
Institute for Food Safety and Health

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH
ILLINOIS INSTITUTE OF TECHNOLOGY

Gerald Wojtala, Executive Director
International Food Protection Training Institute

ifpti

Steve Mandernach, Executive Director
Association of Food and Drug Officials

AFDO

Certificate # 592e08a2

FSPCA®

FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

Oscar Saldaña

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

12/08/2021

Jason Wan, Interim Director
Institute for Food Safety and Health

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH
ILLINOIS INSTITUTE OF TECHNOLOGY

Gerald Wojtala, Executive Director
International Food Protection Training Institute

ifpti

Steve Mandernach, Executive Director
Association of Food and Drug Officials

AFDO

Certificate # a3fa9cd6

FSPCA®

FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

Vivían Ordóñez

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

12/08/2021

Jason Wan, Interim Director
Institute for Food Safety and Health

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH
ILLINOIS INSTITUTE OF TECHNOLOGY

Gerald Wojtala, Executive Director
International Food Protection Training Institute

ifpti

Steve Mandernach, Executive Director
Association of Food and Drug Officials

AFDO

Certificate # b3fc7c38

Workshop Evaluation

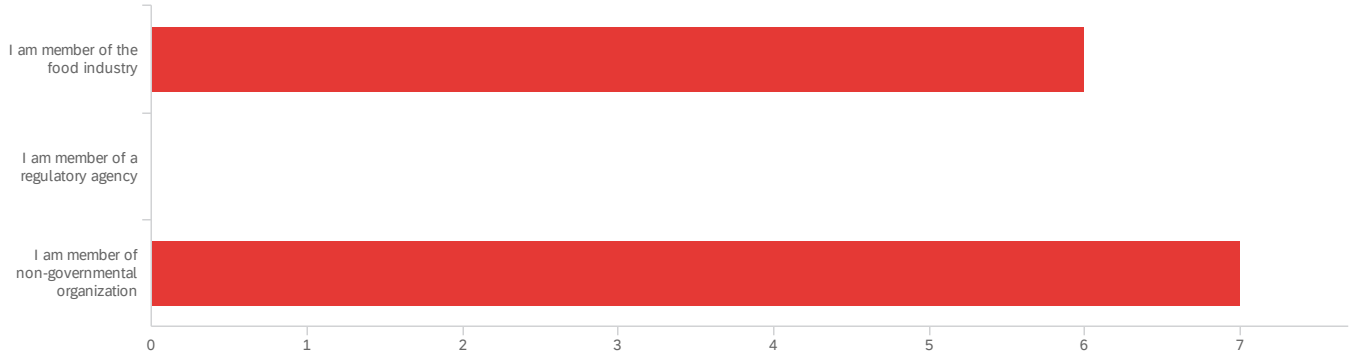
Public Health Microbiology Laboratory:
https://publichealthmicrobiology.education/

Default Report

2021 FSMA PC QI Workshop (12-5 to 8-2021): Lead Instructor: Dr. Aliyar Cyrus Fouladkhah - Copy

January 19, 2022 12:08 PM MST

Q1 - What is your primary career association?

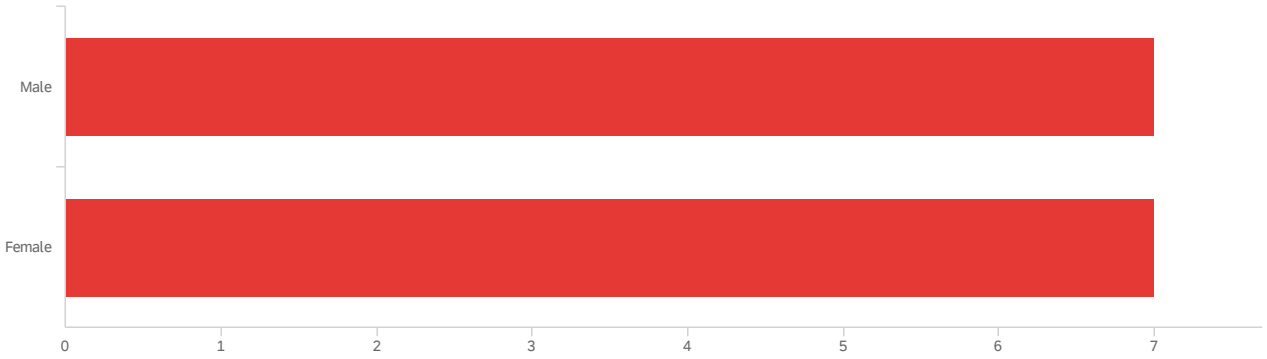


#	Field	Minimum	Maximum	Mean	Std Deviation	Variance	Count
1	What is your primary career association?	1.00	3.00	2.08	1.00	0.99	13

#	Field		Choice Count
1	I am member of the food industry	46.15%	6
2	I am member of a regulatory agency	0.00%	0
3	I am member of non-governmental organization	53.85%	7
			13

Showing rows 1 - 4 of 4

Q2 - What is your gender?



#	Field	Minimum	Maximum	Mean	Std Deviation	Variance	Count
1	What is your gender?	1.00	2.00	1.50	0.50	0.25	14

#	Field		Choice Count
1	Male	50.00%	7
2	Female	50.00%	7
			14

Showing rows 1 - 3 of 3

Q3 - How satisfied are you for attending this workshop: 0=Not satisfied at all;

100=extremely satisfied

#	Field	Minimum	Maximum	Mean	Std Deviation	Variance	Count
1	My instructor is knowledgeable of the subject matter.	94.00	100.00	99.43	1.59	2.53	14
2	My instructor communicated effectively.	90.00	100.00	97.57	3.85	14.82	14
3	My instructor stimulated my interest in the subject.	85.00	100.00	98.36	4.24	17.94	14
4	My instructor answered questions thoroughly.	100.00	100.00	100.00	0.00	0.00	14
5	My instructor treated all students with respect.	100.00	100.00	100.00	0.00	0.00	14
6	I would recommend this instructor to my friends.	93.00	100.00	99.50	1.80	3.25	14
7	My knowledge of the subject increased as a result of this workshop.	77.00	100.00	96.21	7.69	59.17	14
8	This workshop made a significant contribution to my career.	80.00	100.00	98.21	5.21	27.17	14

Q4 - Please share any information or feedback you would like with the instructor about your experience in this workshop:

Please share any information or feedback you would like with the instructor...
Very good
Muy bonito el curso, e aprendido mucho sobre procesos y acciones que conlleva realizar productos y que pueda realizarse en mi area trabajo
Se nota que tiene un amplio conocimiento sobre el tema
I would be delighted to have had the material in Spanish so that I could take advantage of the course much more, the translation at the end of each topic helped us a lot, it was also a lot to have received the different topics of this course.
Good job! More examples maybe or videos for practical cases or examples
Información muy completa y resolución de dudas
Es muy interesan pero seria genial que se impartirá en español para personas que no sabemos ingles
Wonderful workshop, excellent information, thanks for share with us!
The doctor was great, he is very capable to share his knowledge
excellent information and very good exhibitor

End of Report

Partners Farmer-to-Farmer (F2F) Program – Assignment Report Template

Public Health Microbiology Laboratory:
https://publichealthmicrobiology.education/

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

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

Partners Farmer-to-Farmer (F2F) Program – Assignment Report Template

Remote Farmer-to-Farmer volunteers are required to submit (1) recommendations for the host organization and (2) an overall assignment report at the conclusion of their assignment. This template includes both components. Reports are shared with hosts and field staff and are translated as needed.

INSTRUCTIONS

- Topics and Format: Your report should answer all questions below in the text boxes and be within the paragraph range recommended in the prompt. You may include any additional content as annexes attached to your submission email.
- Submission: Please email an electronic copy of your report before the end of your assignment to Bo Maher (rmaher@partners.net) and Susie Meyer (farmertofarmer@partners.net) once you and your field officer have agreed it is finalized.

ASSIGNMENT TITLE (found on Scope of Work):	USAID649_GT_Fouladkhah,A_Quality and Shelf Life

EXECUTIVE SUMMARY

It was wonderful to return to Guatemala for another USAID assignment. Guatemala is a beautiful country in Central America and approximately 50% of the GDP of the country is associated with Agriculture. Although we are experiencing an unprecedented global pandemic/endemic, we were able to make great progress on this two-week assignment thanks to the great help and support from USAID F2F offices in Washington and Guatemala and outstanding safety precautions. As such, special and sincere appreciation is needed for Ms. Susanna Meyer for her outstanding support and help in harmonizing the events of the program from Washington and to Mr. Jose Eduardo Cano Ozaeta and Mr. Otto Rivera from the Guatemala USAID office. Additionally, technical help and translation from Ms. Crista Rosenberg are sincerely appreciated during the course of this assignment. I would also need to thank Dr. Minoo Bagheri for accompanying me on this trip and for help valuable suggestions and advice for the entrepreneur during this assignment. I commend the host institution for their willingness to learn and encourage them to implement these public health and food safety practices to ensure the safety of their product and their consumers.

BACKGROUND and OBSERVATIONS

The products are processed until they are visually dried, and no validated testing is undertaken to ensure the product meets the regulatory requirements for a shelf-stable product. Interaction of pH and water activity determine whether a commodity is a potentially hazardous or Time-Temperature Control for Safety (TCS) product or if the product is shelf-stable and non-TCS. Testing and validation procedures for each product would need to be conducted to ensure the end-point of drying is evidence-based and to ensure the safety of the product during the shelf-life. Extensive information on this was discussed during the workshop. Freeze-dried products are prone to re-absorption of the water during the shelf-life and thus require careful packaging and proper handling after processing. As illustrated earlier, currently the product is at a very high risk of cross-contamination with environmental pathogens and cross-contact with allergens. Additionally, the current packaging does not protect the product from re-absorption of water during shelf-life. In addition to the need for a major improvement in sanitation and allergen cross-contact, the entrepreneur would need to utilize a packing procedure to ensure the safety and quality of the product. Freeze-dried products could additionally be easily oxidized during the shelf-life due to increased surface area so the conduct of shelf-life studies and using oxygen absorbers could assist the entrepreneurs in meeting the food safety requirement for local, national, and international food commerce. It is noteworthy that this product is considered a ready-to-eat product and consumers will not have any additional “kill” step to eliminate microbial hazards thus implementation of discussed food safety practices and environmental monitoring is of great concern and importance.

ACTIVITIES

The first week of the assignment we delivered a public health and food safety workshop for 15 individuals from the regional industries and USAID office of Guatemala. As further detailed in the accompanying evaluations, the three-day workshop was received very well by the stakeholders and the event was supplemented with group discussions associated with the stakeholders' product to provide evidence-based information and regulatory advice to ensure the safety and compliance of the products. The workshop curriculum is developed by FSPCA in Chicago and is currently the only curriculum recognized as adequate by the U.S. Food and Drug Administration for Food Safety Modernization Act Preventive Control Qualified Individual for Human Food production. In addition to this curriculum, several lectures were added from the Public Health Microbiology Laboratory about the Food Safety Modernization Act, safe use of ingredients using FDA GRAS list, information on Nutrition Facts Label, and array of topics associated with foodborne and waterborne infectious diseases and epidemiology of transboundary diseases. Excerpts of the slides are provided as an addendum to this report. Participants received a certification of competition for this FSMA Preventive Control Qualified Individual (PC QI) Workshop and all received the legal designation of PC QI and a textbook of the course in Spanish. In the second week of the assignment, we visited the freeze-drying operation and these areas for improvement were identified and discussed with the entrepreneur.

HOSTS

The first week of the assignment we delivered a public health and food safety workshop for 15 individuals from the regional industries and USAID office of Guatemala. As a process authority, I provided time to all participants to have a one-by-one discussion about their products, these consultation sessions are priced at $135 per stakeholder that we provided at no-cost to the participants. A similar certification program was conducted in Mexico on December 6, 2021, and in California on January 26, 2022, and were costing $779 and $775 per participant, respectively. This workshop was funded by the Food Processing Support Center of the Public Health Microbiology Laboratory and thus participants received the certification at no cost. Thus, the cost-saving for the host for the workshop and consultation is conservatively estimated at 12,000 USD (c. 92,000 Quetzal).

List groups and people with whom you met or worked. The field staff can help you with the specific names of groups, farmers, and other hosts with whom you collaborated.

RESULTS

1. Control of environmental pathogens such as *Listeria monocytogenes*, for reducing the risk of cross-contamination of the freeze-dried products, and implementing a sanitation procedure.
2. Determining the endpoint of the freeze-drying based on validated water activity measurements.
3. Proper packing to ensure elimination of cross-contamination, cross-contact, and ensuring the safety of the products.

NEXT STEPS and FUTURE VOLUNTEER NEEDS

Currently, the freeze-drying unit is located in a high traffic area and there was evidence of potential contamination and standing water in the immediate surrounding of the unit. There is no implemented sanitation procedure and products are prone to cross-contamination after processing. It is recommended to identify a new location for the unit that is away from the high traffic area. Additionally, implementation of a validated Sanitation Standard Operating Procedures for food contact and non-food contact surfaces are strongly recommended, supplemented with an environmental monitoring program. Future help from a food microbiologist is strongly recommended for the company to ensure the public's health.

PERSONAL REFLECTION

I would like to thank the great colleagues in Washington and Guatemala F2F offices for their help in harmonizing the events of this program. I would also need to thank Dr. Minoo Bagheri for accompanying me on this trip and for help valuable suggestions and advice for the entrepreneur during this assignment. I commend the host institution for their willingness to learn and encourage them to implement these public health and food safety practices to ensure the safety of their product and their consumers.

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: Drs. Aliyar Fouladkhah Minoo Bagheri
Country of Service: Guatemala Dates of Trip: December 5 to 19, 2021

# of Persons *Formally* Trained[1] – male:	7	
# of Persons *Formally* Trained – female:	8	
# of Persons *Formally* Trained – Non-Binary:	0	
# of Persons *Formally* Trained who are Youth:	0	
# of Persons *Formally* Trained – total:	15	

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	Host	Time frame to implement change
Control of environmental pathogens such as *Listeria monocytogenes*, for reducing the risk of cross-contamination of the freeze-dried products, and implementing a sanitation procedure	**Agroindustrias SUCCESSO**	**One year**
Determining the endpoint of the freeze-drying based on validated water activity measurements	**Agroindustrias SUCCESSO**	**One year**
Proper packing to ensure elimination of cross-contamination, cross-contact, and ensuring the safety of the products.	**Agroindustrias SUCCESSO**	**One year**

[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.*

The Assignment

Public Health Microbiology Laboratory:
https://publichealthmicrobiology.education/

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

To Whom It May Concern,

My name is Susie Meyer and I am the recruiter for the USAID-funded Farmer-to-Farmer program at Partners of the Americas. F2F is a program that promotes economic development and food security abroad by sending volunteer technical specialists from the U.S. to Latin America to provide technical assistance to producers, cooperatives, agribusinesses, NGO's, and educational institutions (referred to as "hosts"). Our program covers all volunteer costs including airfare, lodging, meals, insurance, and any other assignment-related expenses.

The F2F Guatemala office is pleased to invite Dr. Minoo Bagheri and Dr. Aliyar Fouladkhah to support the *Agroindustrias SUCCESSO* as Experts in Quality and Shelf Life from December 5 – 19, 2021.

Please find a description of the needs that Dr. Minoo Bagheri and Dr. Fouladkhah will address during their 15-day stay in Guatemala:

- SUCCESSO has developed an interest on improving quality of their production processes and standards to manage shelf-life during production and the commercialization of their microorganisms. Dr. Minoo Bagheri and Dr. Aliyar Fouladkhah will support SUCCESO develop an analysis of current processes, determine improvement opportunities, and provide recommendations to improve their protocols, specifically for quality and shelf life of the products. It is expected that at the end of the assignment, they will have effective and practical quality control methods on their production line, better practices to extend shelf life of their products, and part of the staff trained on how to maintain effective control of the recommendations. This assignment contributes to the broader goals and objectives of the Rural Enterprise Development strategy by strengthening the capacities of production and commercialization of Guatemalan bio inputs, adapting strategies to increase shelf life and quality of the microorganisms.

Partners of the Americas is following safety protocols in relation to the COVID 19 pandemic and will provide Personal Protective Equipment and maintain social distancing throughout the assignment. All assignments are assessed for risk prior to travel, taking into account the varying levels of COVID-19 throughout the region. Our local Guatemala team and headquarters in Washington, DC are committed and prepared to support Dr. Santamaria throughout the assignment.

Please reach out to our F2F recruitment office at farmertofarmer@partners.net should you have any questions.

Sincerely,
Susie Meyer

Recruitment Office
Farmer-to-Farmer
Economic Development & Health

Partners of the Americas
1424 K Street NW, Suite 700 | Washington, DC 20005
farmertofarmer@partners.net | Partners.net/farmer-to-farmer
LinkedIn | Facebook | Twitter | Instagram

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

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

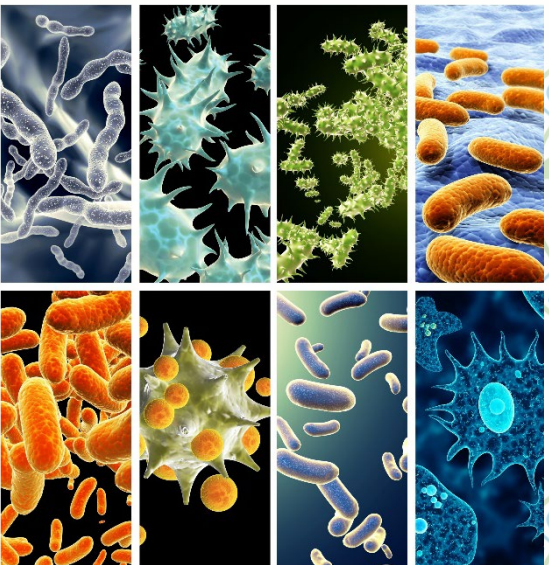
We envision a world where communities and individuals are empowered and sustained through volunteerism and partnerships.
Our Mission is to connect people and organizations across and within borders to serve and change lives.
Partners inspires through our values of Service, Partnership, Impact, Resilience, Respect, Empowerment and Sustainability

Excerpts of Teaching Material

Public Health Microbiology Laboratory:
https://publichealthmicrobiology.education/

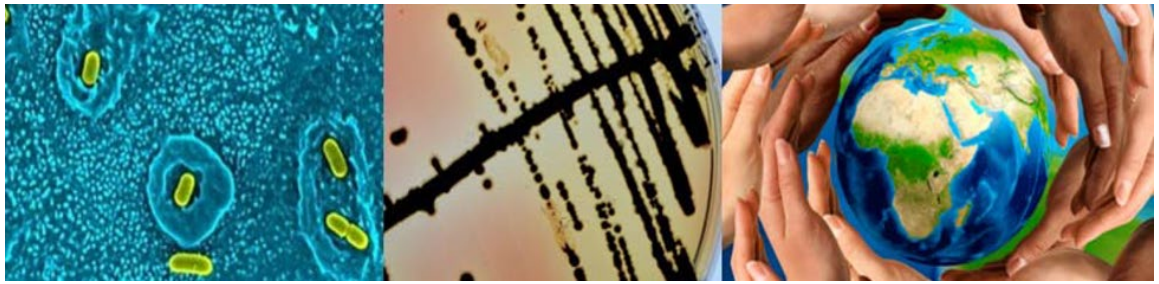
Public Health Microbiology in Guatemala: *Food Safety Under the Landscape of Climate Change*

Aliyar Cyrus Fouladkhah, PhD, MPH, MACE, CFS, CPH
Faculty Director, Public Health Microbiology Laboratory
Tennessee State University



F2F USAID Program
December 5-19, 2021, Via Zoom

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



Brief Introduction to my Program

Colorado State University

- Microbiology and Food Safety, PhD (CSU Animal Science Dept.)
- Applied Statistics and Data Analysis, Graduate Certificate (CSU Statistics Dept.)
- Food Science & Human Nutrition, MS (CSU Food Science Dept.)
- Food Science and Technology, BS, National University of Iran.

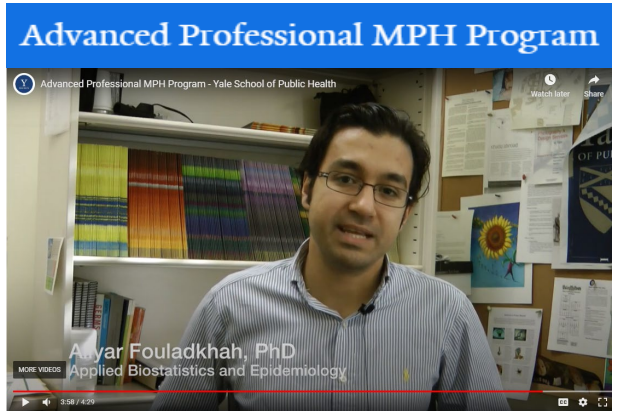
Microbac

BOULDER BRANDS

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



CPH Certified in Public Health

sas® Certified Base Programmer for SAS®9

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

Public Health Microbiology Laboratory
Tennessee State University

MPH Curriculum Food Safety and Applied Epidemiology (now under CEPH certification)

United States Department of Agriculture
National Institute of Food and Agriculture

- Secured extramural support >$3.4M as PD or Co-PD since 2015
- **T&P** applications both approved, will be effective July 31, 2021.
- **Funding sources**

(1) Dean's Office: $7,000/year and a Research Technician

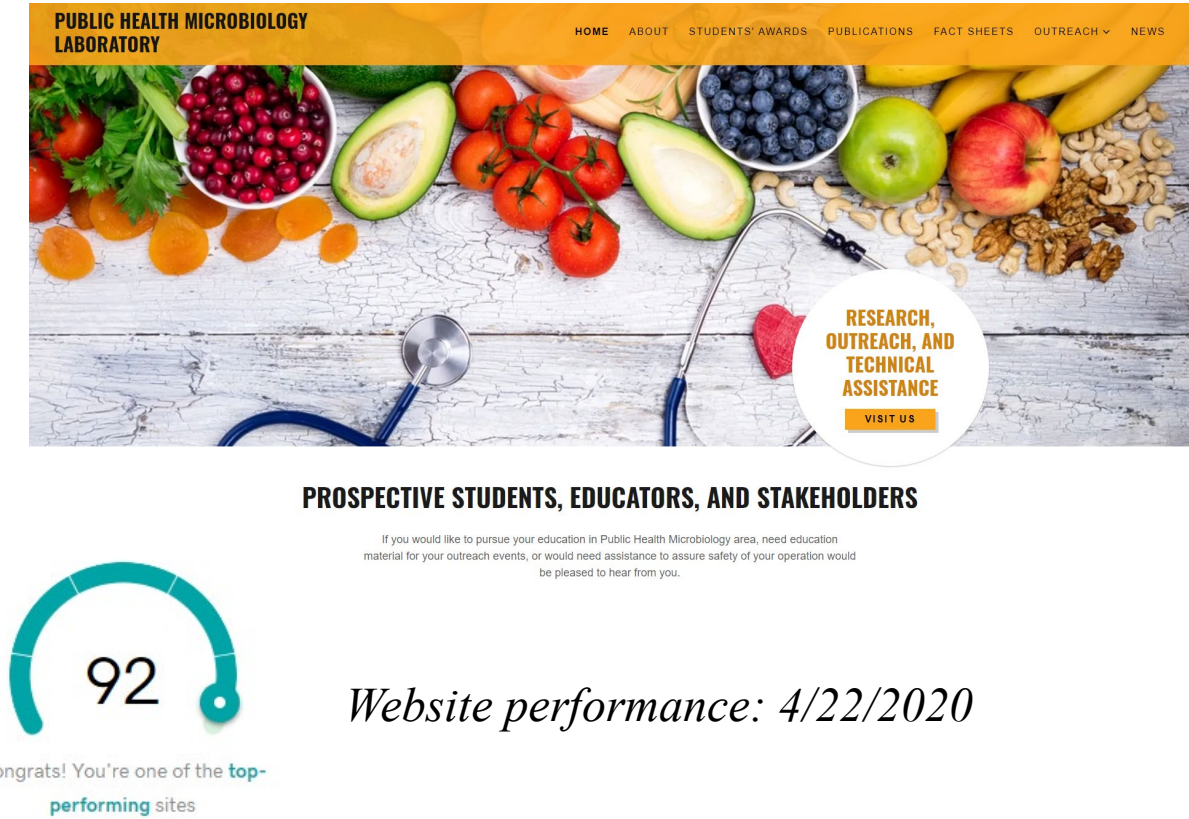
(2) Association of Food and Drug Officials (AFDO) Process Authority: $15-50K per year depending on the projects

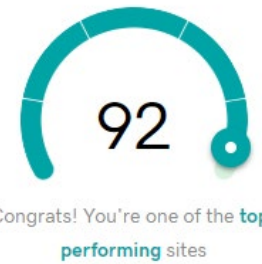
(3) Extramural Funding: >$3.4M since 2015

- 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)
- NIFA FSOP.: **$880,000** (Role: CO-PD, 2019-2023)**
- USDA-NIFA FSOP.: **$1,197,751** (Role: CO-PD, 2015-2020)**
- NIFA CBG.: **$300,000** (Role: CO-PD, 2018-2022)

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

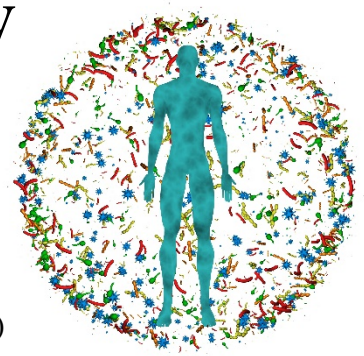
Website: https://publichealthmicrobiology.education/

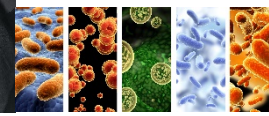




Website performance: 4/22/2020

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 Dean Scholar/Undergraduate Students:

- *Akiliyah Sumlin* (2018-), Dean Scholar/Undergraduate Research Assistant.*
- *Simen Asefaw (2019-), Undergraduate student (adviser for senior project)*
- *Kennedye Miller (2020-), Undergraduate student (adviser for senior project)*

Current Research Technician, Associates, and Interns (Primary Supervisor: A. Fouladkhah):

- *Mr. Shahid Chowdhury**, Research Technician (2016-present)
- *Dr. Niamul Kabir, PhD.* Post-doctoral Research Associate (2018-2021).
- Ms. Amir Kashipazha, MS. Data Visualization Intern and Web Editor (2018-present).
- Dr. Naraghi, 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).

Recent Graduates

Abimbola Allison, PhD

Tyler Keene, MS

Monica Henry-Smith, MS

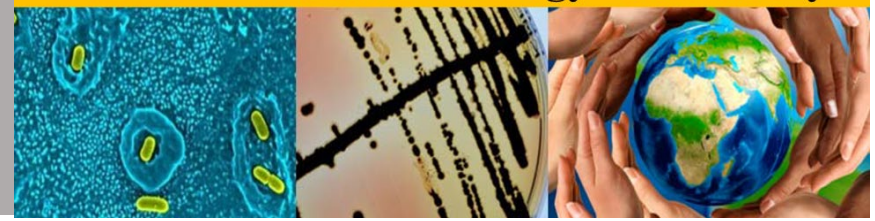
** Supported by office of the Dean*

Students Awards
Adviser: A. Fouladkhah

> 45 awards and Scholarships (2017-2020)

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

Public Health Microbiology Laboratory



- -1st Place, Health & Medical Sciences Section, Oral Competitions. 130th Meeting of the Tennessee Academy of Science. Virtual meeting (due to ongoing respiratory pandemic/endemic) hosted by East Tennessee State University. November 21, 2020. Student: S. Wadood.
- -2nd Place, Health & Medical Sciences Section, Oral Competitions. 130th Meeting of the Tennessee Academy of Science. Virtual meeting (due to ongoing respiratory pandemic/endemic) hosted by East Tennessee State University. November 21, 2020. Student: S. Aras
- -3rd Place, Health & Medical Sciences Section, Oral Competitions. 130th Meeting of the Tennessee Academy of Science. Virtual meeting (due to ongoing respiratory pandemic/endemic) hosted by East Tennessee State University. November 21, 2020. Student: N. Kabir.
- -3rd Place, Health & Medical Sciences Section, Poster Competitions. 130th Meeting of the Tennessee Academy of Science. Virtual meeting (due to ongoing respiratory pandemic/endemic) hosted by East Tennessee State University. November 21, 2020. Student: J. George.
- -1st Place, Graduate Students Oral Competitions. 4th Annual State-wide Competition for Food Safety Modernization Act, Food Safety, and Food Science. Tennessee (Volunteer) section Institute of Food Technologists/Public Health Microbiology laboratory. September 8, 2020. Student: S. Wadood.
- -2nd Place, Graduate Students Oral Competitions. 4th Annual State-wide Competition for Food Safety Modernization Act, Food Safety, and Food Science. Tennessee (Volunteer) section Institute of Food Technologists/Public Health Microbiology laboratory. September 8, 2020. Student: J. George.
- -3rd Place, Graduate Students Oral Competitions. 4th Annual State-wide Competition for Food Safety Modernization Act, Food Safety, and Food Science. Tennessee (Volunteer) section Institute of Food Technologists/Public Health Microbiology laboratory. September 8, 2020. Student: S. Aras.
- -1st Place (tied), Oral Emerging Leader Competitions. 4th Annual State-wide Competition for Food Safety Modernization Act, Food Safety, and Food Science. Tennessee (Volunteer) section Institute of Food Technologists/Public Health Microbiology laboratory. September 8, 2020. Scholar: Dr. M.S.B. Naraghi (part-time visiting scholar of the PHM lab).
- -2nd Place, Oral Emerging Leader Competitions. 4th Annual State-wide Competition for Food Safety Modernization Act, Food Safety, and Food Science. Tennessee (Volunteer) section Institute of Food Technologists/Public Health Microbiology laboratory. September 8, 2020. Scholar: Dr. Niamul Kabir (Post doc of PHM lab).
- -3rd Place, Poster Student Competitions. 4th Annual State-wide Competition for Food Safety Modernization Act, Food Safety, and Food Science. Tennessee (Volunteer) section Institute of Food Technologists/Public Health Microbiology laboratory. September 8, 2020.Student: A. Sumlin.
- -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
- -3rd Place, Oral Competitions, Health and Medical Sciences section. 2019 Tennessee Academy of Sciences. The 129th annual meeting, Columbia State Community College. Columbia, TN. Student: M. Henry
- -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: J. George
- -3rd Place, Poster Competitions, Health and Medical Sciences section. 2019 Tennessee Academy of Sciences. The 129th annual meeting, Columbia State Community College. Columbia, TN. Student: T. Keene
- -3rd Place, Poster 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: J. Adhikari.
- -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

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

M. Henry (2nd from left), Outstanding MS Student in College of Agriculture, Received an Award from Dean Reddy.

2020 Tennessee Academy of Science
Virtual Health and Medical Sciences Division
1st (S. Wadood);2nd (S. Aras); 3rd (N. Kabir): Adviser: A. Fouladkhah

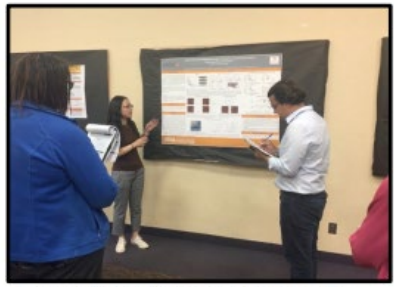
2019 Tennessee Academy of Science
Health and Medical Sciences Division
1st (A. Allison);2nd (S. Aras); 3rd (M. Henry)
Adviser: A. Fouladkhah

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

Available at: https://publichealthmicrobiology.education/annual-competitions

Annual State-Wide Competitions For Food Safety Modernization Act, Food Safety and Infectious Disease Students

- **Networking and Stakeholder Engagement**
- **Competition**
- **Regulatory Compliance Booth**
- **Tour of HPP Facilities**
- **Categories:**
- *Graduate Poster and Oral*
- *Undergraduate Poster*
- *Emerging Leader (Post Doc and recent graduates) [Added in 2020]*
- **2017-2020: 31 funded award (extramural grants of A. Fouladkhah)**
- **Current AFRI Application Pending**



Nan Li, PhD student at UT, presenting her research poster during the Poster Competition session at the IFT Volunteer Section Nashville Meeting

4th Annual State-Wide Competition for Food Safety Modernization Act, Food Safety, and Food Science Students

Revised Agenda due to COVID-19 Pandemic

New Date and Time:
Tuesday Sep. 8, 2020- 2:00 to 7:30 pm (central time)

Tentative Agenda:
2:00 to 3:30 pm: Taco Tuesday networking in Nashville Downtown for students, faculty, and food industry members (optional)
3:30 to 4:00 pm: Networking, tour of TSU high pressure processing facility and Food Safety Modernization Act booth (optional)
4:00 to 4:45 pm: Students arrival, registration, poster/power point presentations set-up, and networking
5:00 to 6:00 pm: Graduate students' oral competitions
6:00 to 7:00 pm: Graduate students' poster competitions
7:00 to 7:30 pm: Judges discussions
7:30 pm: Announcement of awardees

In case physical distancing is still preferred by finalists and is recommended by public health agencies on competition date, the competition will be held electronically via Zoom.

Question:
Competition Organizer, A. Fouladkhah,
Phone: (970) 690-7392 Email: afouladk@msutate.edu

3rd Annual State-Wide Competition for Food Safety Modernization Act, Food Safety, and Food Science Students Winners	
Poster Division 1st: Kaleh Karim (TSU) (tied), Jennifer Vuia-Riser (UT) (tied) 2nd: Shreya Singh Hamal (TSU) (tied), Purni Wickramasinghe (UT) (tied) 3rd: Jayashan Adhikari (TSU)	**Oral Division** 1st: Monica Henry (TSU) (tied), Trent Kerley (UT) (tied) 2nd: Abimbola Allison (TSU) 3rd: Shan Hong (UT)
Co-Chairs and Judges Dr. Aliyar Fouladkhah Dr. Niamul Kabir Mr. Shahid Chowdhury Dr. Monique McCallister	

A. Fouladkhah: Competition Founder and Director

4th (2020) Annual State-Wide Competition for Food Safety Modernization Act, Food Safety, and Food Science Students

Emerging Leaders Category:
First Place (tied): Dr. M. Naraghi, Vanderbilt University of Medical Sciences (Award: $350)
First Place (tied): Dr. Tylor-Bowden, Tennessee State University (Award: $350)
Second Place: Dr. Md Niamul Kabir, Tennessee State University (Award: $200)
Third Place: Not awarded this year.

Finalists in Oral Competitions for Students:
First Place: Sabrina Wadood, Tennessee State University (Award: $400)
Second Place: Jyothi George, Tennessee State University (Award: $300)
Third Place: Sadiye Aras, Tennessee State University (Award: $200)

Finalists in Poster Competitions for Students:
First Place: Andrea Nieto Veloza, University of Tennessee (Award: $350)
Second Place: Anika Chowdhury, Middle Tennessee State University (Award: $250)
Third Place (tied): Shreya Hamal, Tennessee State University (Award: $150)
Third Place (tied): Akiliyah Sumlin, Tennessee State University (Award: $150)

3rd (2019) Annual State-Wide Competition for Food Safety Modernization Act, Food Safety, and Food Science Students

2019 Graduate Oral Competition Winners
1st Place (tied): Monica Henry, TSU
1st Place (tied): Trent Kerley, UT
2nd Place: Abimbola Allison, TSU
3rd Place: Shan Hong, UT

2019 Graduate Oral Competition Winners
1st Place (tied): Jennifer Vuia-Riser, UT
1st Place (tied): Kaleh Karim, TSU
2nd Place (tied): Shreya Singh Hamal, TSU
2nd Place (tied): Purni Wickramasinghe, UT
3rd: Place Jayashan Adhikari, TSU

2nd (2018) Annual State-Wide Competition for Food Safety Modernization Act, Food Safety, and Food Science Students

2018 Graduate Competition Winners
1st Place (tied) Monica Henry: Graduate Competition, TSU
1st Place (tied) Grace Shupe: Graduate Competition, UT
2nd Place Devendra Bhandari: Graduate Competition, TSU
3rd Place Michelle Heatherly: Graduate Competition, UT

Public Health Microbiology Laboratory

Also Available at: https://www.ift.org/events/event-listing/2020/sep/4th-annual-statewide-competition-for-food-safety-modernization-act-food-safety-and-food-science-stud

December 16:
Keynote Speaker: Current IFT President with 34 years of Experience in NASA

IFT Volunteer Section
Institute of Food Technologists

Public Health Microbiology Laboratory

Holiday Appreciation Day for Students and 5th Annual State-Wide Competition for Food Safety Modernization Act, Food Safety, and Food Science Students

Meeting to be Held via Zoom due to Ongoing Respiratory Pandemic/Endemic

Date and Time
Thursday, Dec. 16, 2021, from 4:00 to 7:30 pm (central time)

Tentative Agenda:
Zoom link: https://tennessee.zoom.us/j/92315846388
Passcode: PHMLab *(Case sensitive passcode: first four letters are Uppercase)*

Teaching in Tennessee and Internationally

Graduate Course in Food Policy and Regulations

2020 Student Evaluation:

- *"…Dr. Fouladkhah is easily the nicest professor I have ever had the pleasure of meeting. He seriously cares about you and how you're doing."*
- *""I loved this class it was so interactive and different from any other class I have taken here at TSU!"*

2019 Student 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."*
- *"Everything was well organised, I think it is perfect. Nothing else is needed."*

2018 Student Evaluation:

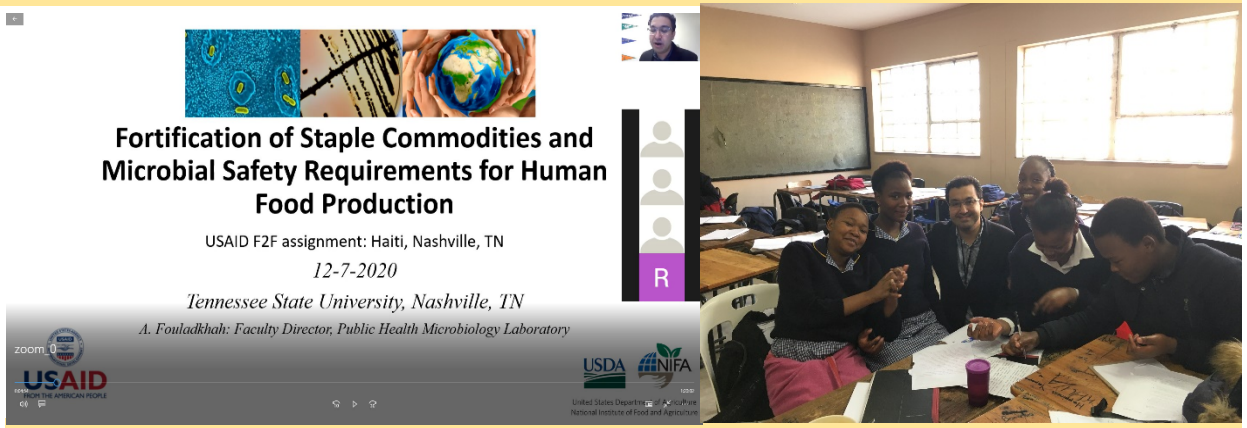
- *"This man is so amazing. Learned so much in his class thank you Dr. Fouladkhah."*
- *"He is very helpful and always very encouraging. He helped me planned my studies and even future goals."*

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

2021, Jamaica
November 2021

2020, Haiti (Distant Appointment)
Haiti Government, Fortification with iron, vitamin b12, and zinc

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



2018 & 2020 Guatemala
Food Safety Training for Food Industry Leadership

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

Process Authority, Variance Committee, PC QI Certifications

(1) **Process Authority**, for state of Tennessee

- List of current 63 process authorities: https://www.afdo.org/directories/fpa/

(2) Additionally, Serve on State **Variance**

"Variance" *means a written document issued by the REGUL AUTHORITY that authorizes a modification or waiver of on requirements of this Code if, in the opinion of the REGULAT AUTHORITY, a health HAZARD or nuisance will not result modification or waiver.*

Serving as FSPCA Lead Instructor since 2016:

(3) **Preventive Control Qualified Indivi QI) Certifications**. Meeting requirements drug administration.

FSPCA

FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

Gloria Andrade-Feraud

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

10/29/2020

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

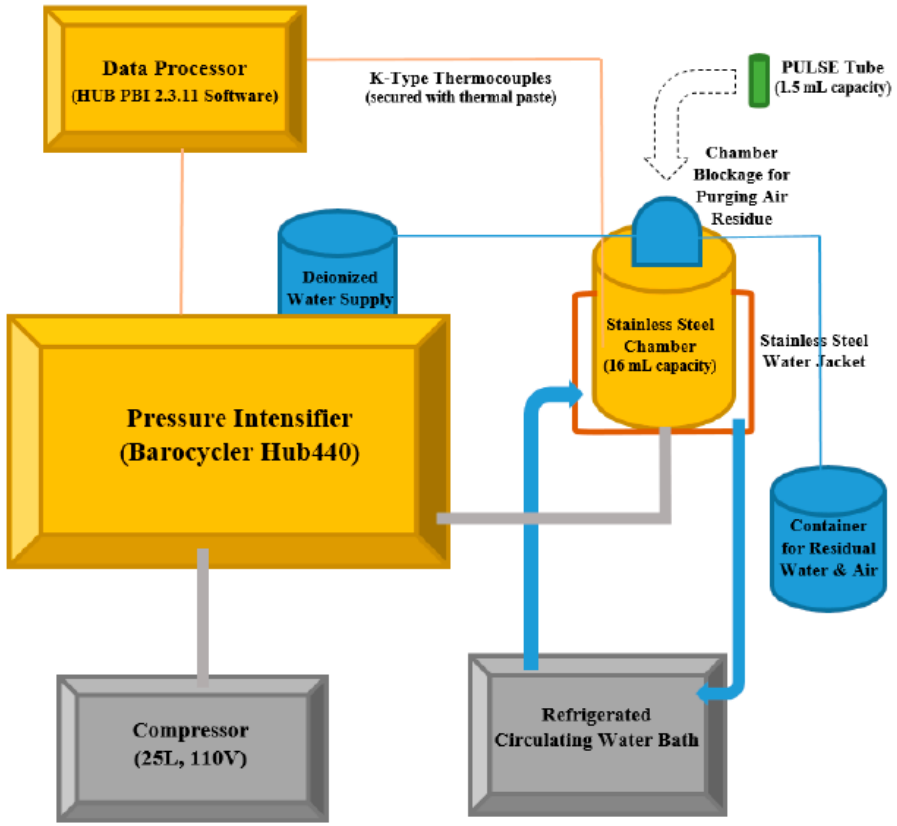
IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH
ILLINOIS INSTITUTE OF TECHNOLOGY

ifpti

Certificate # ee0111fd

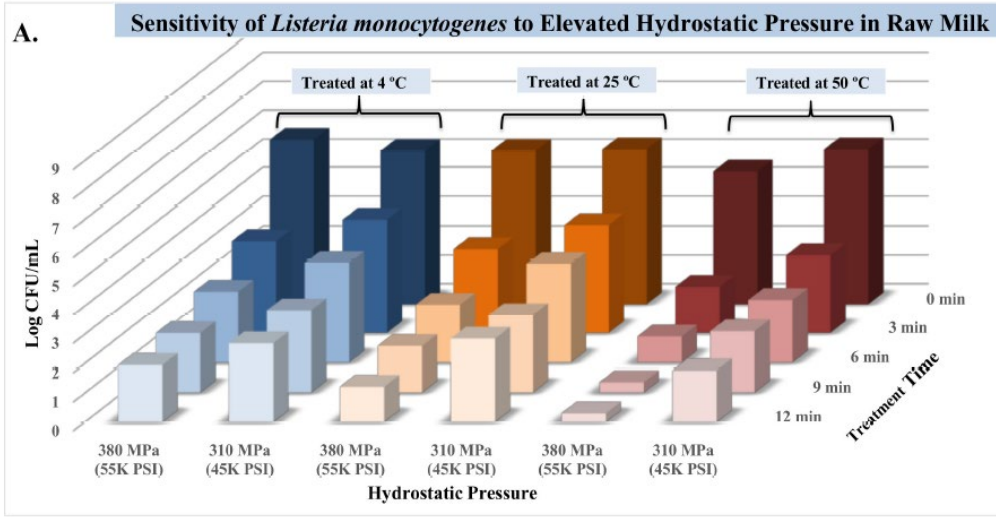
Research Responsibility:
1. Elevated Hydrostatic Pressure
2. Bacterial Biofilm
3. Effects of Climate Change on infectious disease

- Elevated Hydrostatics Pressure:
- Hub880, up to **650 MPa**
- Deepest part of Oceans (Mariana Trench): c. **110 MPa**
- Programable unit Hub 440, 380 MPa
- Controlling the temperature
- Synergism with bacteriocin and bactericidal compounds



High Pressure Processing, Public Health Microbiology Laboratory

Information about the units: https://ir.pressurebiosciences.com/press-releases/detail/284/pressure-biosciences-announces-commercial-release-of-the



Allison et al., 2018

High Pressure Processing, Public Health Microbiology Laboratory

Coming Soon …

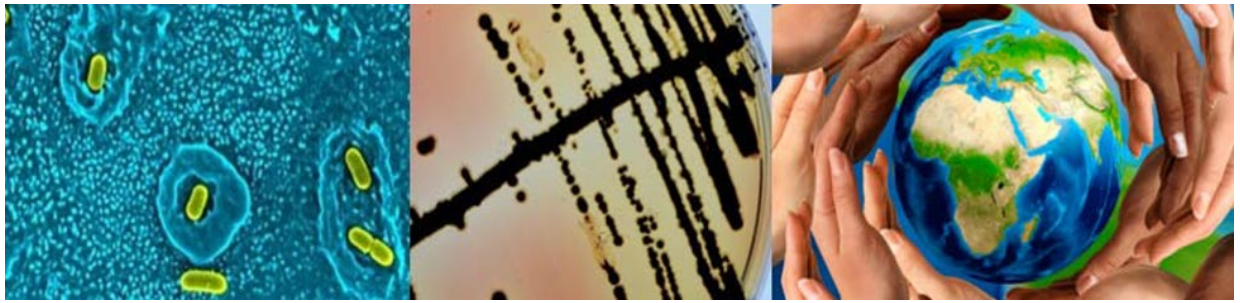
Ask Cyrus!?

Answering Your Public Health Microbiology, Infectious Diseases, and Food Safety Questions

https://publichealthmicrobiology.education/ask-cyrus

Limitation:

- No medical or emergency advice
- No regulatory advice
- No assistance to students' exams/HW



Epidemiology of Foodborne Diseases

Emerging pathogens

Vertical and Horizontal Gene Transfer and Emerging Pathogens

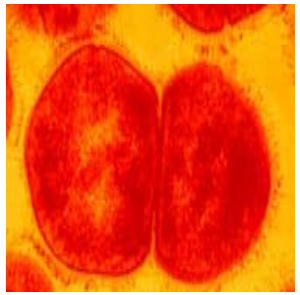
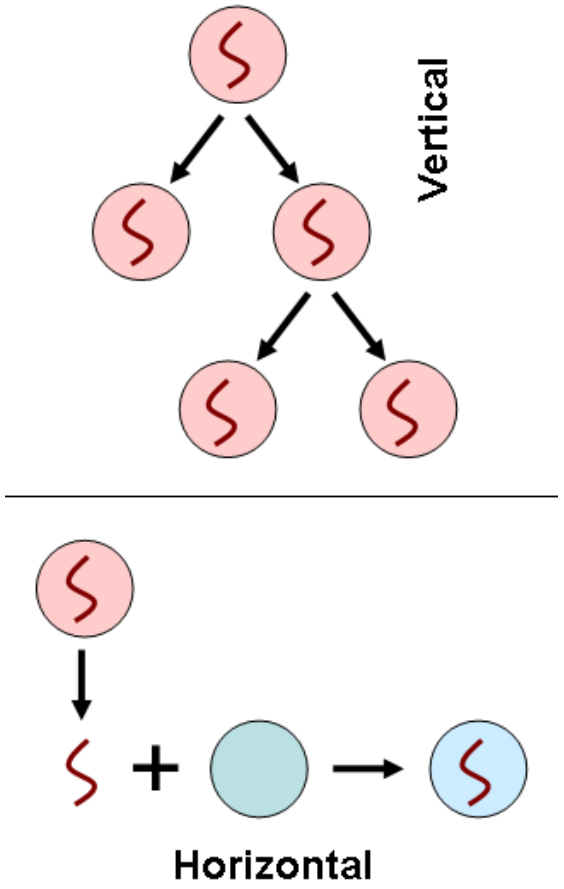
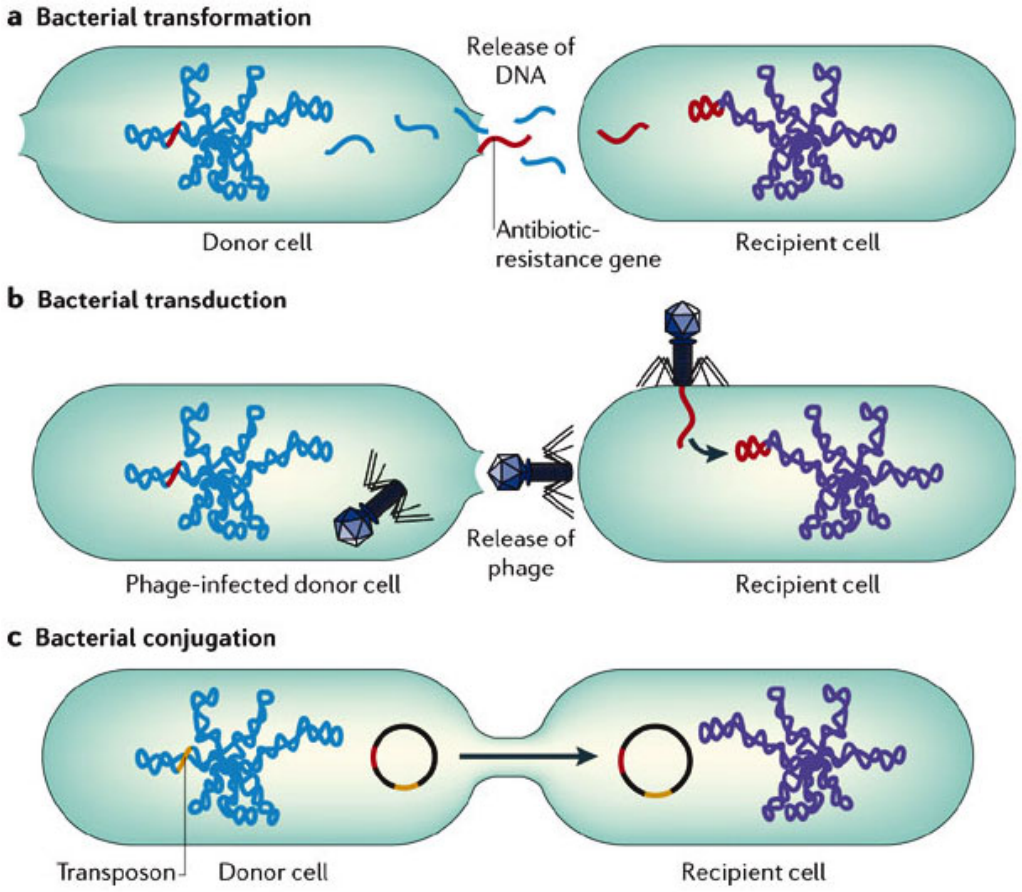
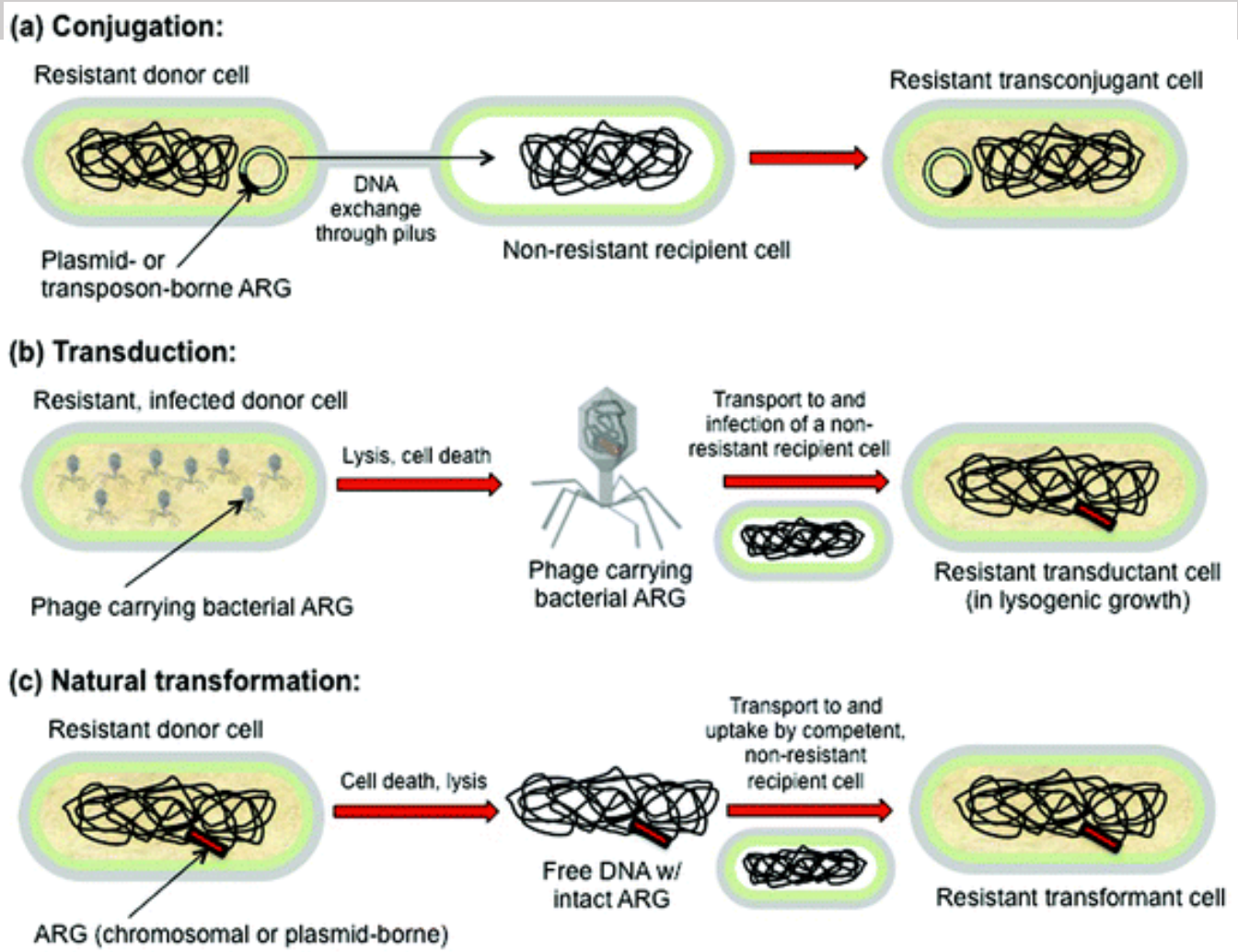


Photo Courtesy:
http://www.daviddarling.info/encyclopedia/B/binary_fission.html





Horizontal Gene Transfer



Donn, 2012

Planktonic cells and Biofilm Communities

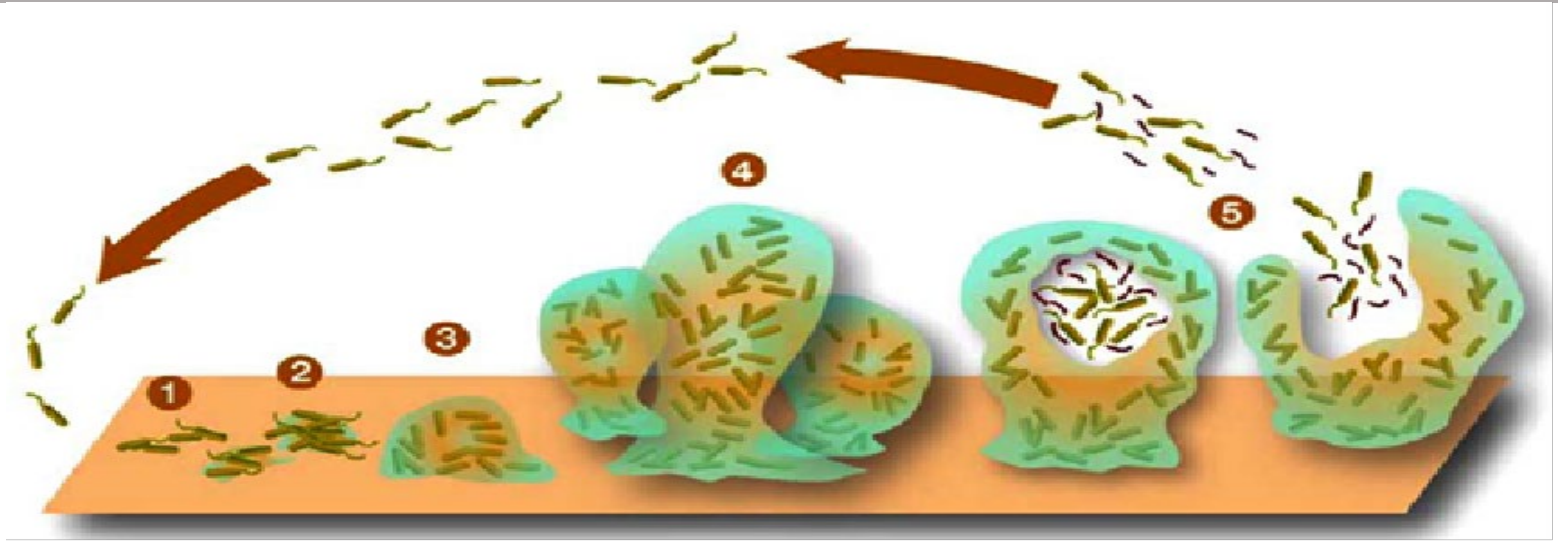


Photo Courtesy: http://prometheus.matse.illinois.edu/glossary/biofilms/

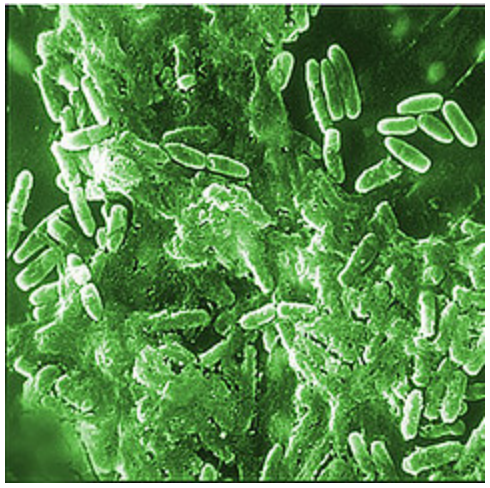


Photo Courtesy: http://micro-writers.egybio.net/blog/?tag=antibiotic-resistance

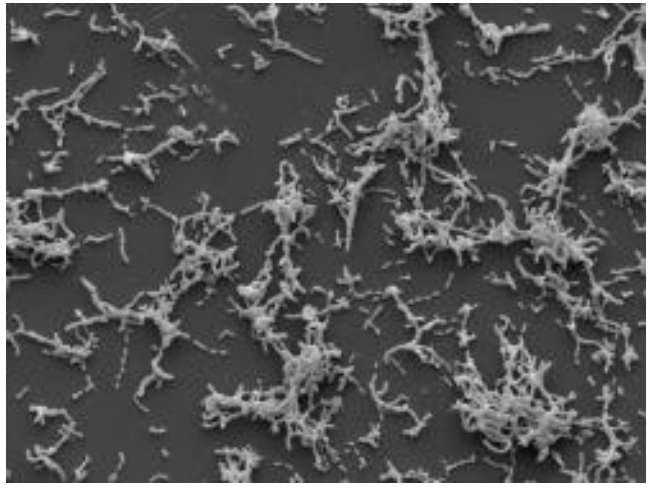


Photo Courtesy: http://www.ifenergy.com/50226711/boosting_microbial_fuel_cells_with_biofilm.php

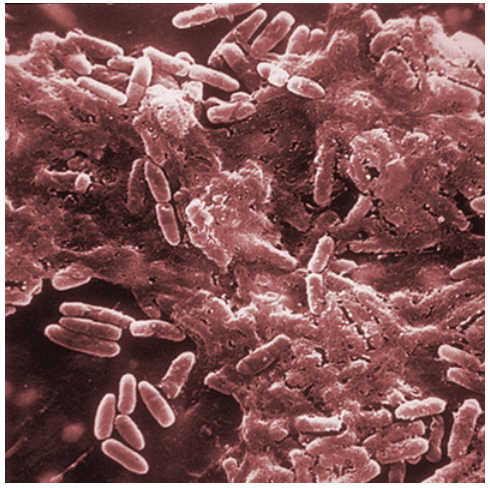
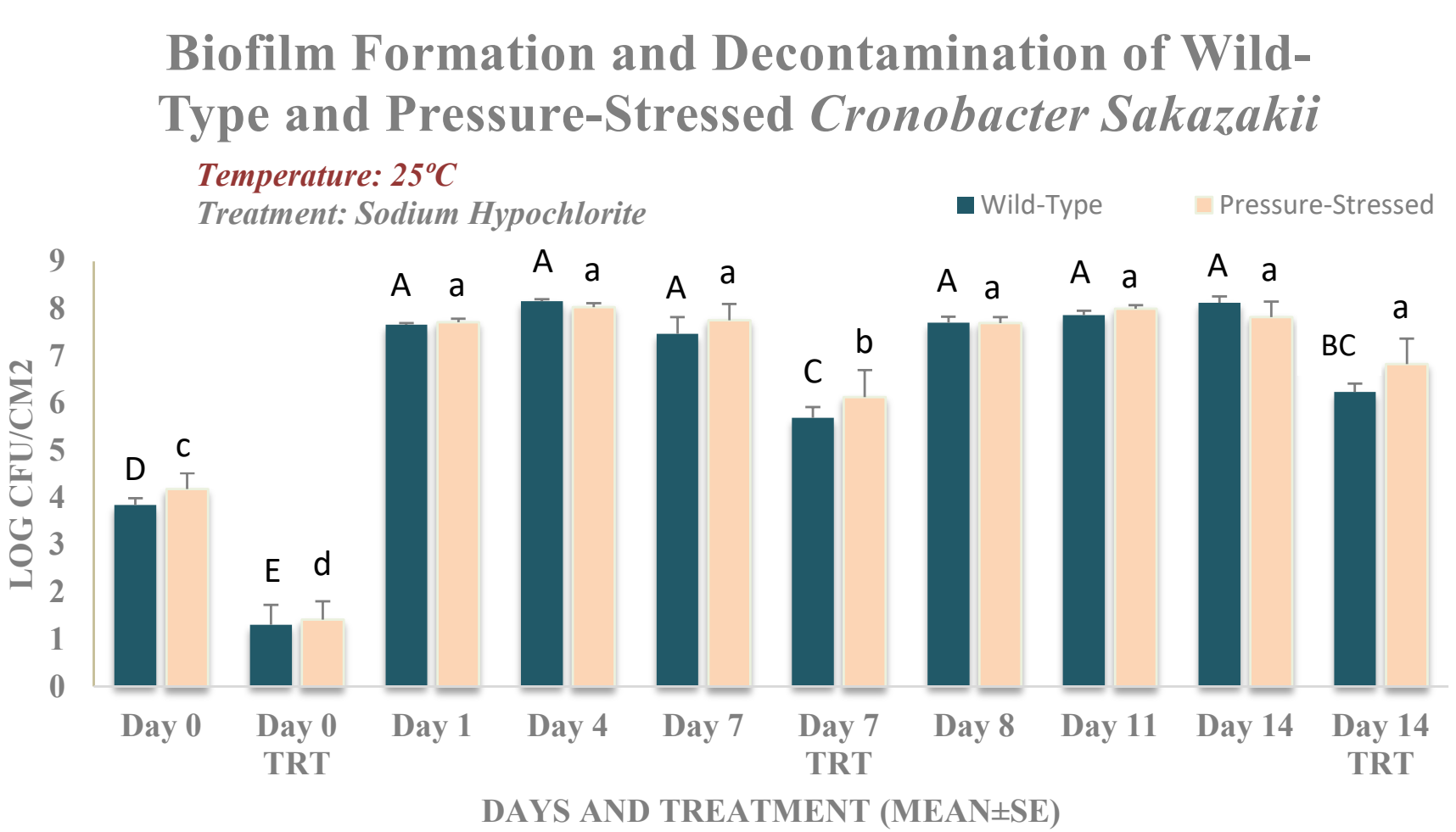
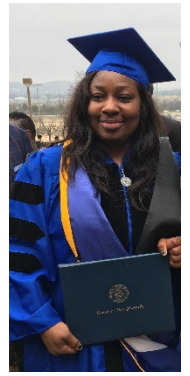


Photo Courtesy: http://www.microbiologybytes.com/blog/category/biofilms/

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





Allison et al., 2020

Quorum Sensing and Biofilm formation

Shiga toxin producing *E. coli*, not antibiotic treatment due to Quorum Sensing Concerns

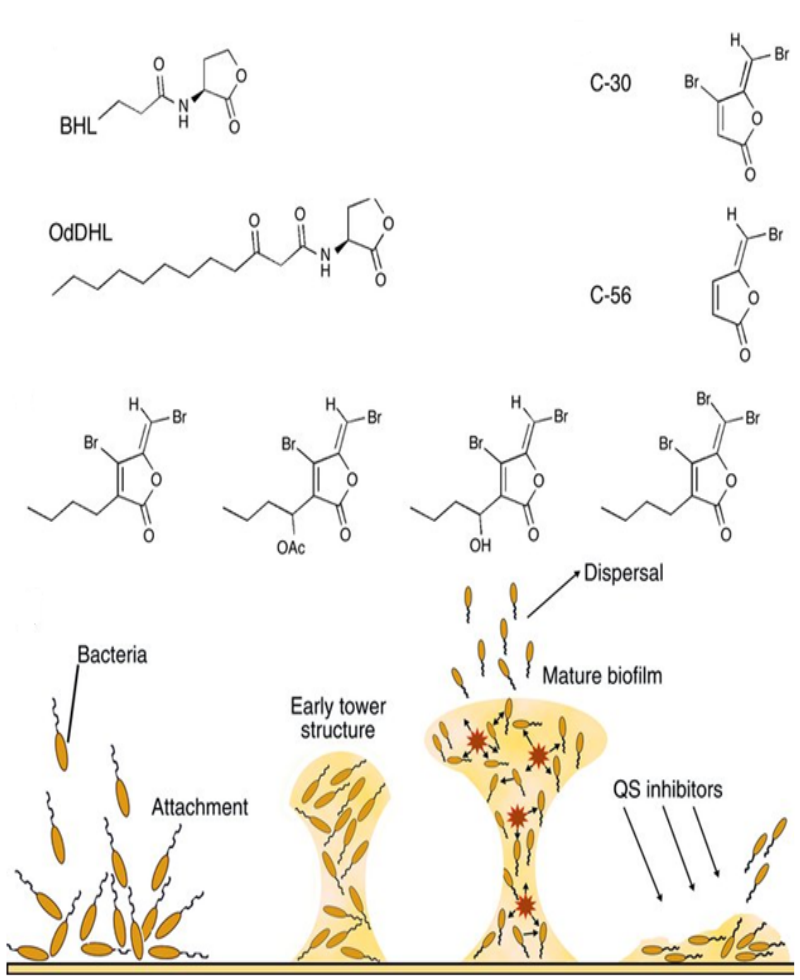


Photo Courtesy: http://www.jci.org/articles/view/20074/figure/2

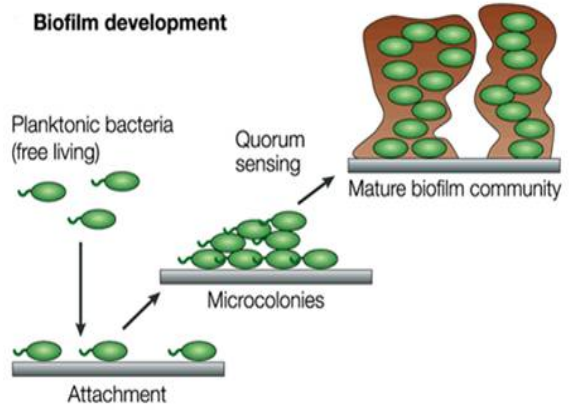


Photo Courtesy: http://labrat.fieldofscience.com/2010/07/quorum-sensing-and-biofilms.html

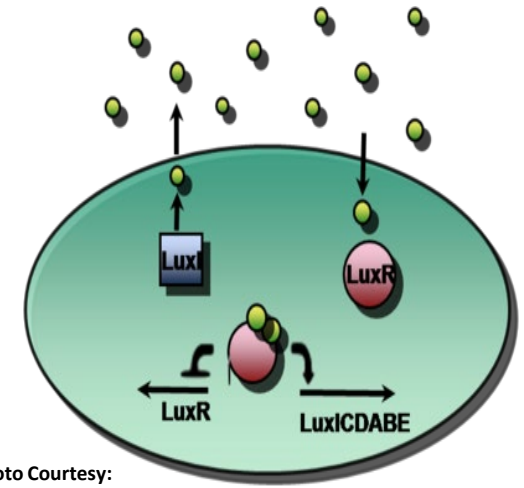


Photo Courtesy: http://2009.igem.org/Team:Aberdeen_Scotland/WetLab/quorumsensing

Infectious Diseases is a Moving Target…

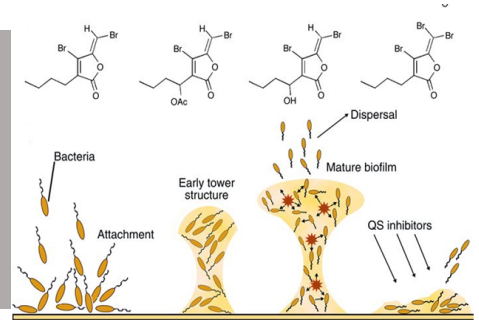


Photo Courtesy: http://www.jci.org/articles/view/20074/figure/2

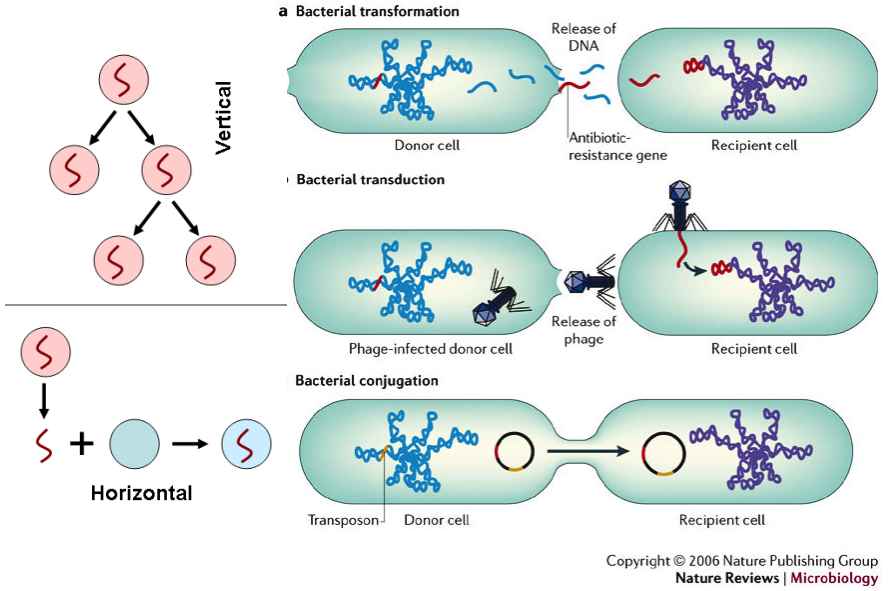
- It is estimated only 1% of microbial community has been identified.
- Currently etiological agent of 80.3% of foodborne illnesses, 56.2% of hospitalization, and 55.5% of deaths remain unknown.

"Emerging" Pathogens:

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

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

-Louis Pasteur



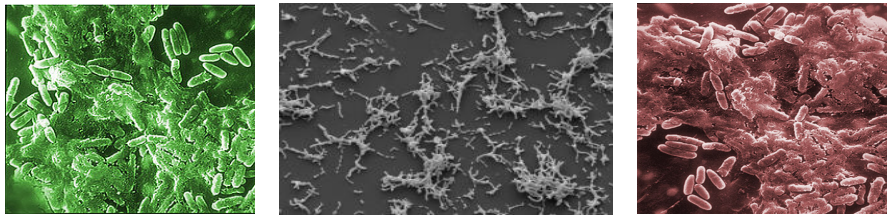


Photo Courtesy: http://www.microbiologybytes.com/blog/category/biofilms/
http://www.ifenergy.com/50226711/boosting_microbial_fuel_cells_with_biofilm.php
http://micro-writers.egybio.net/blog/?tag=antibiotic-resistance

Epidemiology of Foodborne Diseases

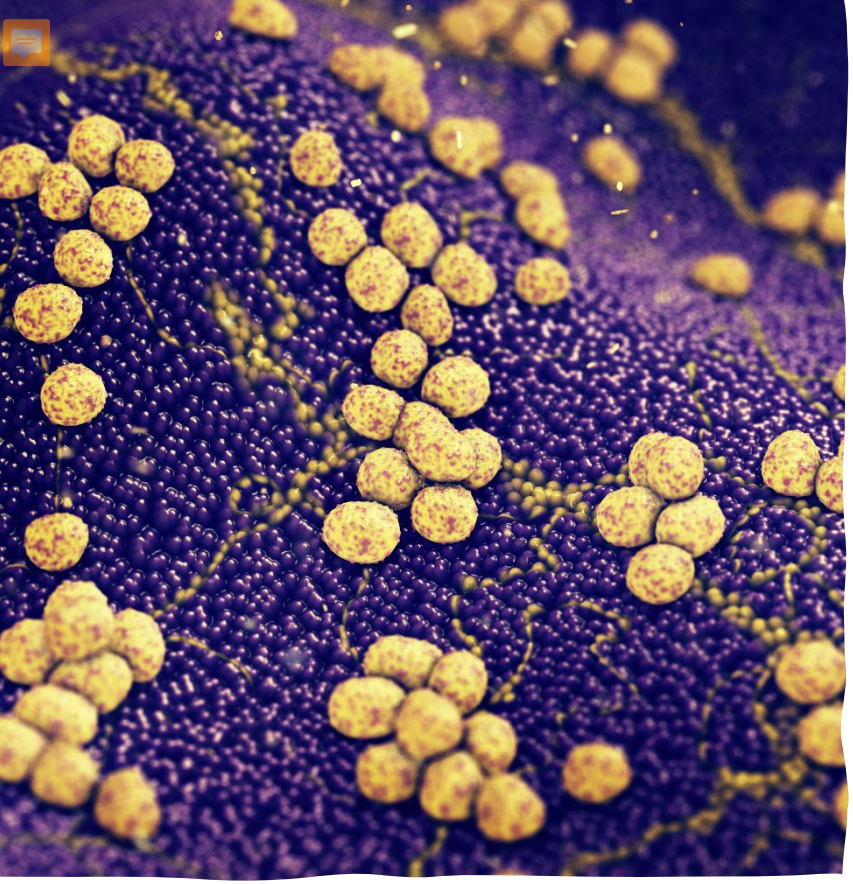
- **Based on data from 1990s:** *(Mead et al., 1999)*

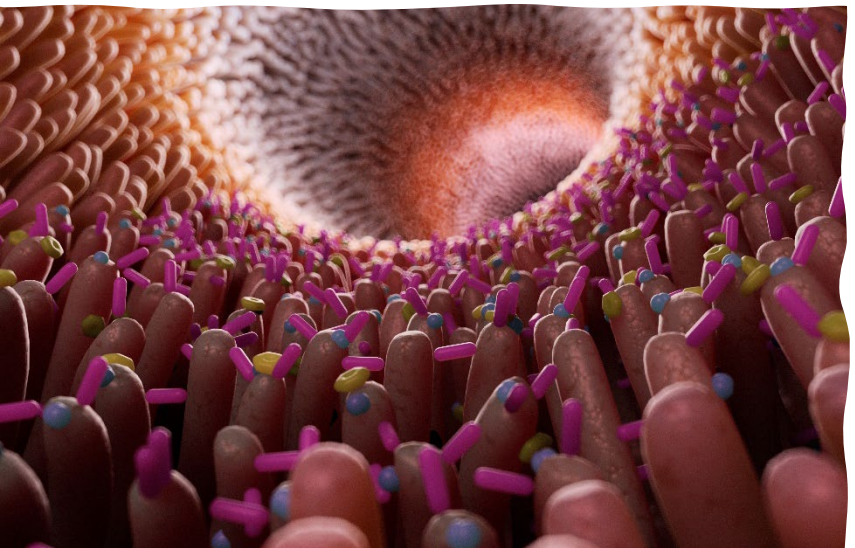
76 million illnesses, 323,000 hospitalizations, 5,200 deaths in the United States.

- **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…
based on Scallan et al., 2015 study

- **Disability adjusted life year** (DALY). *DALY: Loss of life and health due to illness*
- Non-typhoidal *Salmonella* (329000)
- Toxoplasma (32700)
- *Campylobacte*r (22500)
- Norovirus (9900)
- *Listeria monocytogenes* (8800)
- *Clostridium perfringens* (4000)
- *Escherichia coli* O157 (1200)

One DALY can be thought of as one **lost year of "healthy" life**.

DALY= YLL+YLD

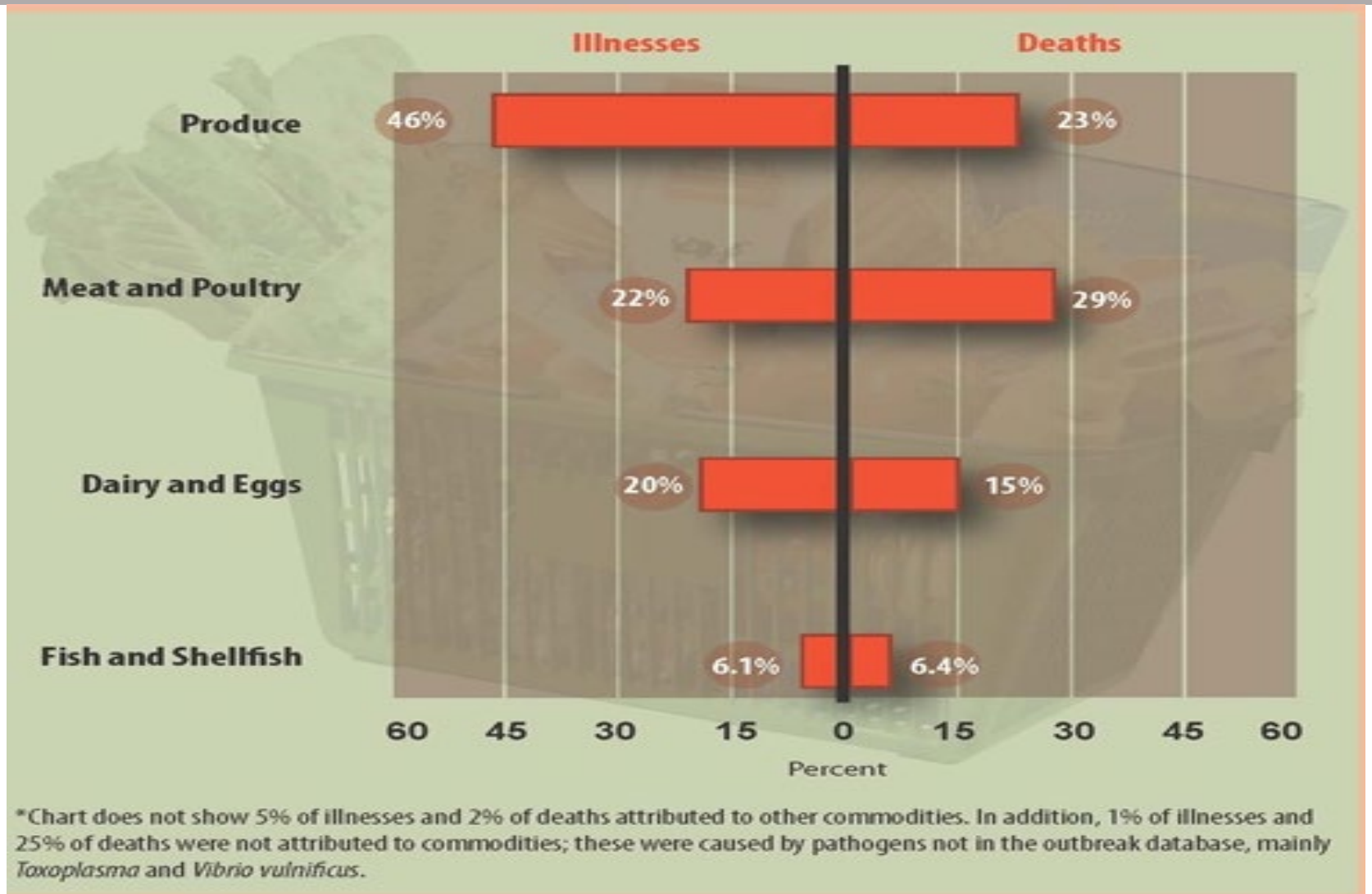
YLL: Years of Life Lost (YLL) due to **premature mortality** in the population
YLD: Years Lost due to Disability (YLD) for **people living with the health condition**

Source: WHO, 2019

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

CDC Estimates of Food Safety Burden

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



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

Water Safety Study

microorganisms

MDPI

Article

Fate and Biofilm Formation of Wild-Type and Pressure-Stressed Pathogens of Public Health Concern in Surface Water and on Abiotic Surfaces

Md Niamul Kabir [1], Sadiye Aras [1], Sabrina Wadood [1], Shahid Chowdhury [1] and Aliyar Cyrus Fouladkhah [1,2,*]

[1] Public Health Microbiology Laboratory, Tennessee State University, Nashville, TN 37209, USA; mkabir@my.tnstate.edu (M.N.K.); saras@my.tnstate.edu (S.A.); swadood@tnstate.edu (S.W.); schowdh1@tnstate.edu (S.C.)

[2] Cooperative Extension Program, Tennessee State University, Nashville, TN 37209, USA

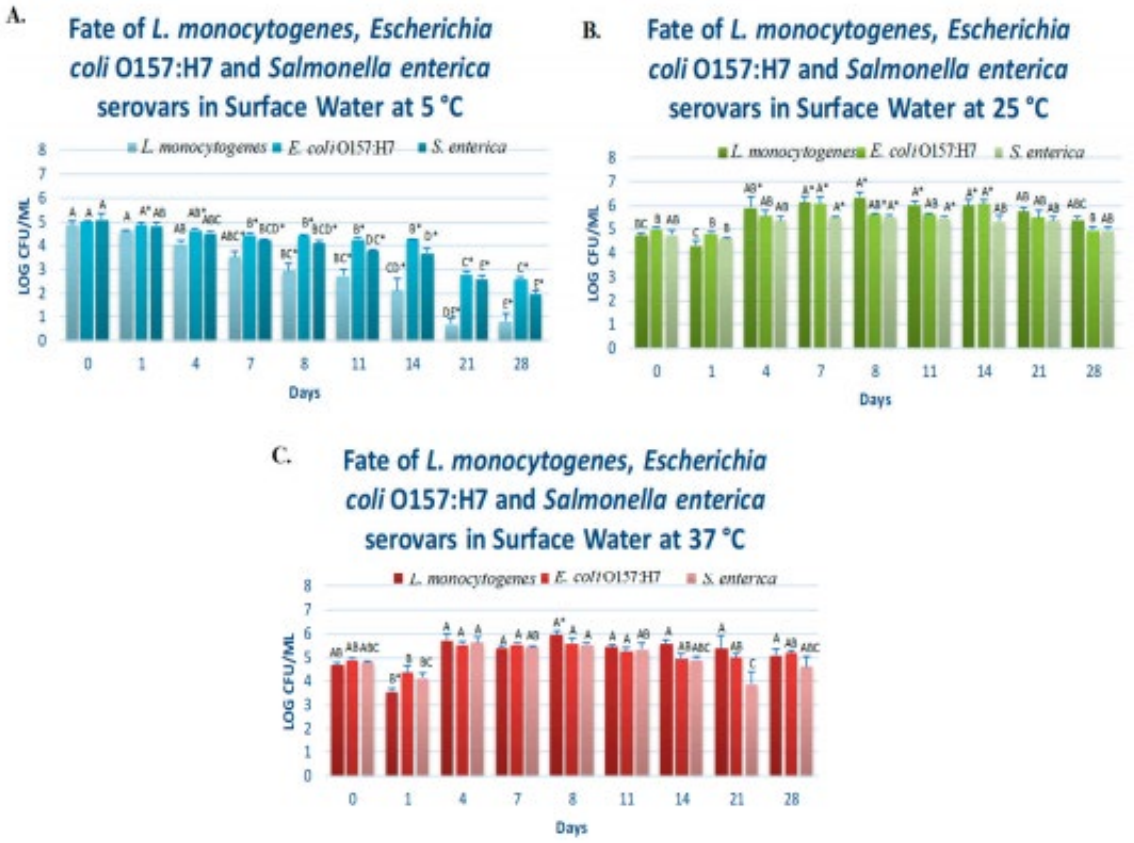
* Correspondence: aliyar.fouladkhah@aya.yale.edu; Tel.: +1-970-690-7392

Received: 18 February 2020; Accepted: 11 March 2020; Published: 13 March 2020

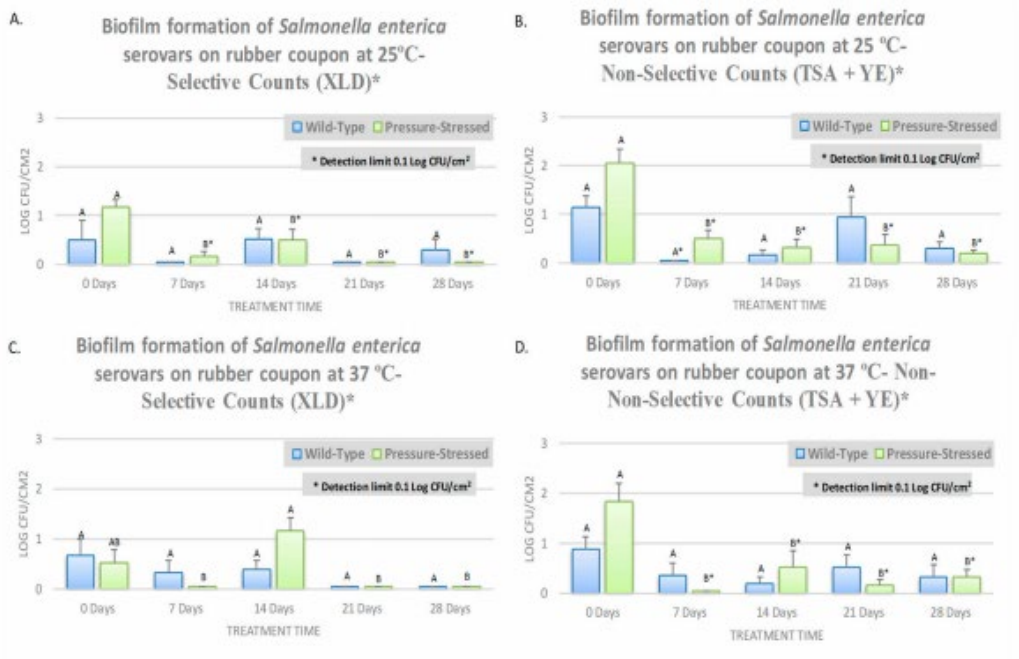
Public Health Burden of Waterborne Disease

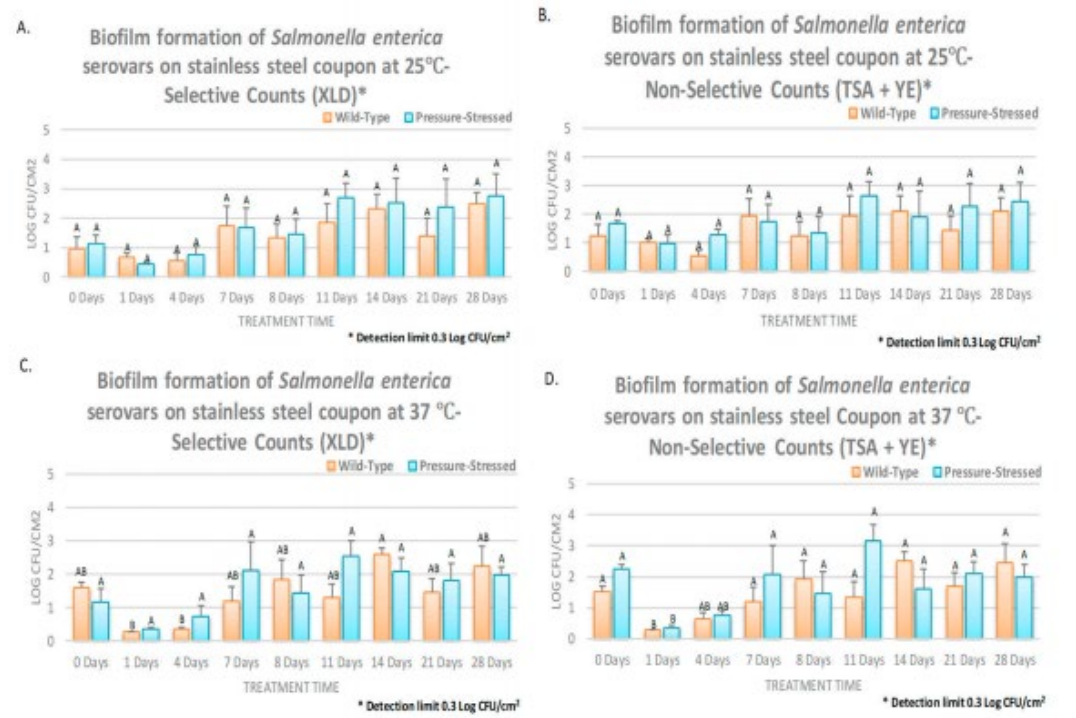
17 waterborne pathogens cause estimated: (Collier et al., 2021)

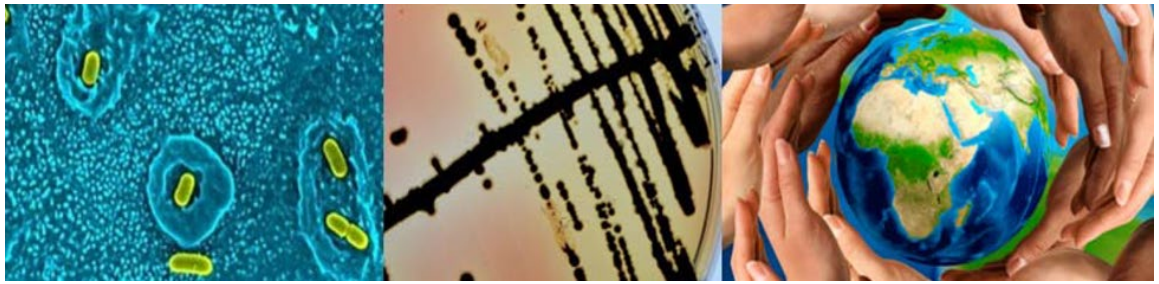
601,000 **illness**; 118,000 **hospitalization**; 6,630 **deaths**, and cost the economy up to $ 8.77 **billions.**



Water Safety Study-
Biofilm Formation on Abiotic Surfaces







Impact of Climate Change on Foodborne and Waterborne Infectious Diseases

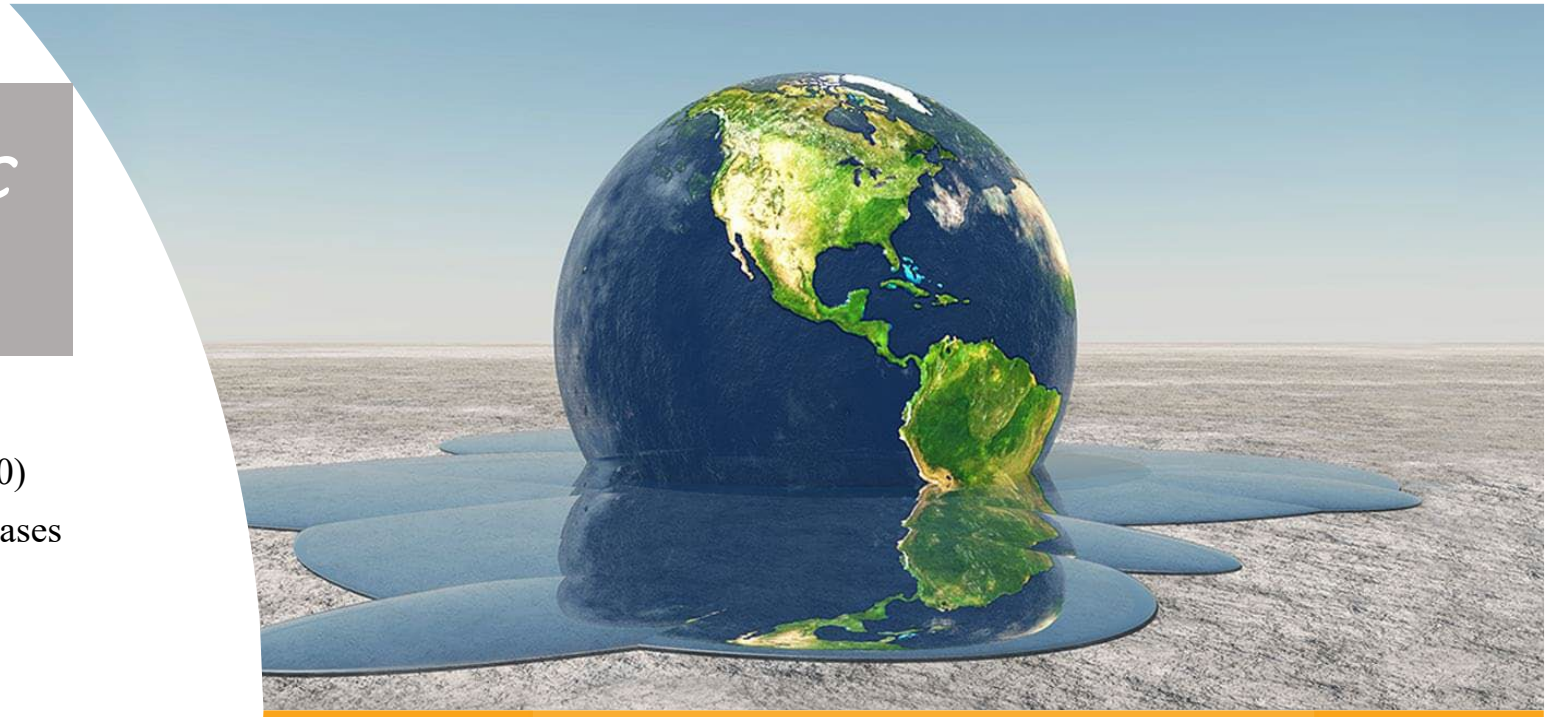
Salmonella serovars (Non-typhoidal)

- **Annual illness (death): 1,027,561 (378) in humans**
- **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)
- **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

Climate Change and Public Health Microbiology



Non-typhoidal *Salmonella enterica* serovars

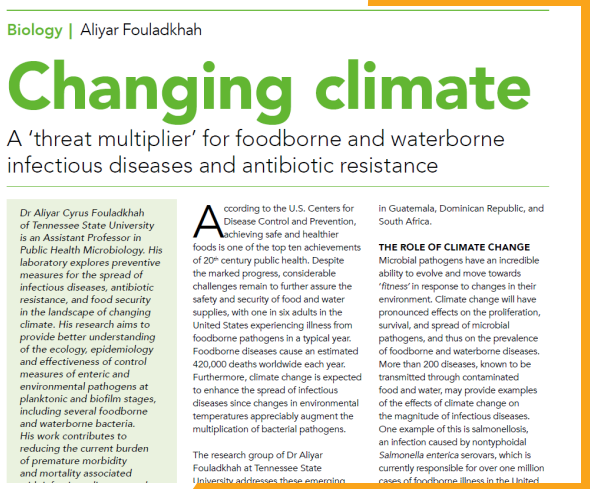
- **Global death:** 50,000 global death in 2010 (WHO, 2020)
- **Public Health Burden in the U.S.:** >1 million annual cases in 2011 (CDC, 2011)

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 (2021 IPCC report)

- >1.5 °C by 2040
- >4.8 °C by 2100



Biology | Aliyar Fouladkhah

Changing climate

A 'threat multiplier' for foodborne and waterborne infectious diseases and antibiotic resistance

Dr Aliyar Cyrus Fouladkhah of Tennessee State University is an Assistant Professor in Public Health Microbiology. His laboratory explores preventive measures for the spread of infectious diseases, antibiotic resistance, and food security in the landscape of changing climate. His research aims to provide better understanding of the ecology, epidemiology and effectiveness of control measures of enteric and environmental pathogens at planktonic and biofilm stages, including several foodborne and waterborne bacteria. His work contributes to reducing the current burden of premature morbidity and mortality associated

According to the U.S. Centers for Disease Control and Prevention, achieving safe and healthier foods is one of the top ten achievements of 20th century public health. Despite the marked progress, considerable challenges remain to further assure the safety and security of food and water supplies, with one in six adults in the United States experiencing illness from foodborne pathogens in a typical year. Foodborne diseases cause an estimated 420,000 deaths worldwide each year. Furthermore, climate change is expected to enhance the spread of infectious diseases since changes in environmental temperatures appreciably augment the multiplication of bacterial pathogens.

The research group of Dr Aliyar Fouladkhah at Tennessee State University addresses these emerging

in Guatemala, Dominican Republic, and South Africa.

THE ROLE OF CLIMATE CHANGE

Microbial pathogens have an incredible ability to evolve and move towards 'fitness' in response to changes in their environment. Climate change will have pronounced effects on the proliferation, survival, and spread of microbial pathogens, and thus on the prevalence of foodborne and waterborne diseases. More than 200 diseases, known to be transmitted through contaminated food and water, may provide examples of the effects of climate change on the magnitude of infectious diseases. One example of this is salmonellosis, an infection caused by nontyphoidal *Salmonella enterica* serovars, which is currently responsible for over one million cases of foodborne illness in the United

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

Vibrio spp.

Currently 760,000 global illness/24,000 death per year.

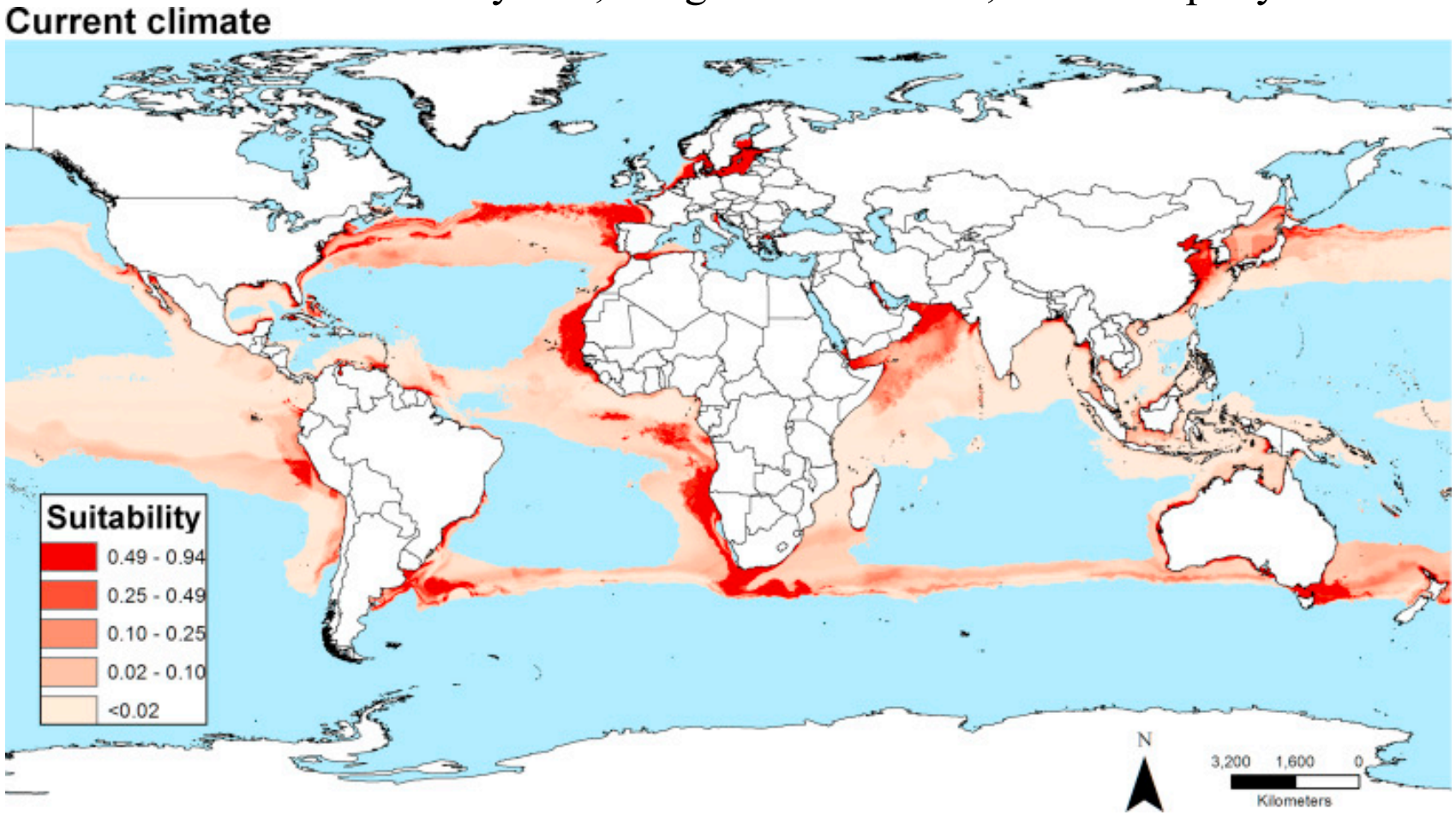
- Causing about **80,000 illness and 100 death** annually in the United States.
- **Infection symptoms** vary depending on strain, ranging from diarrhea to high fever
- Vibrio is a **halophilic bacterium** and is a major concern in aquaculture industry
- **Primary sources**: Salt water environments and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

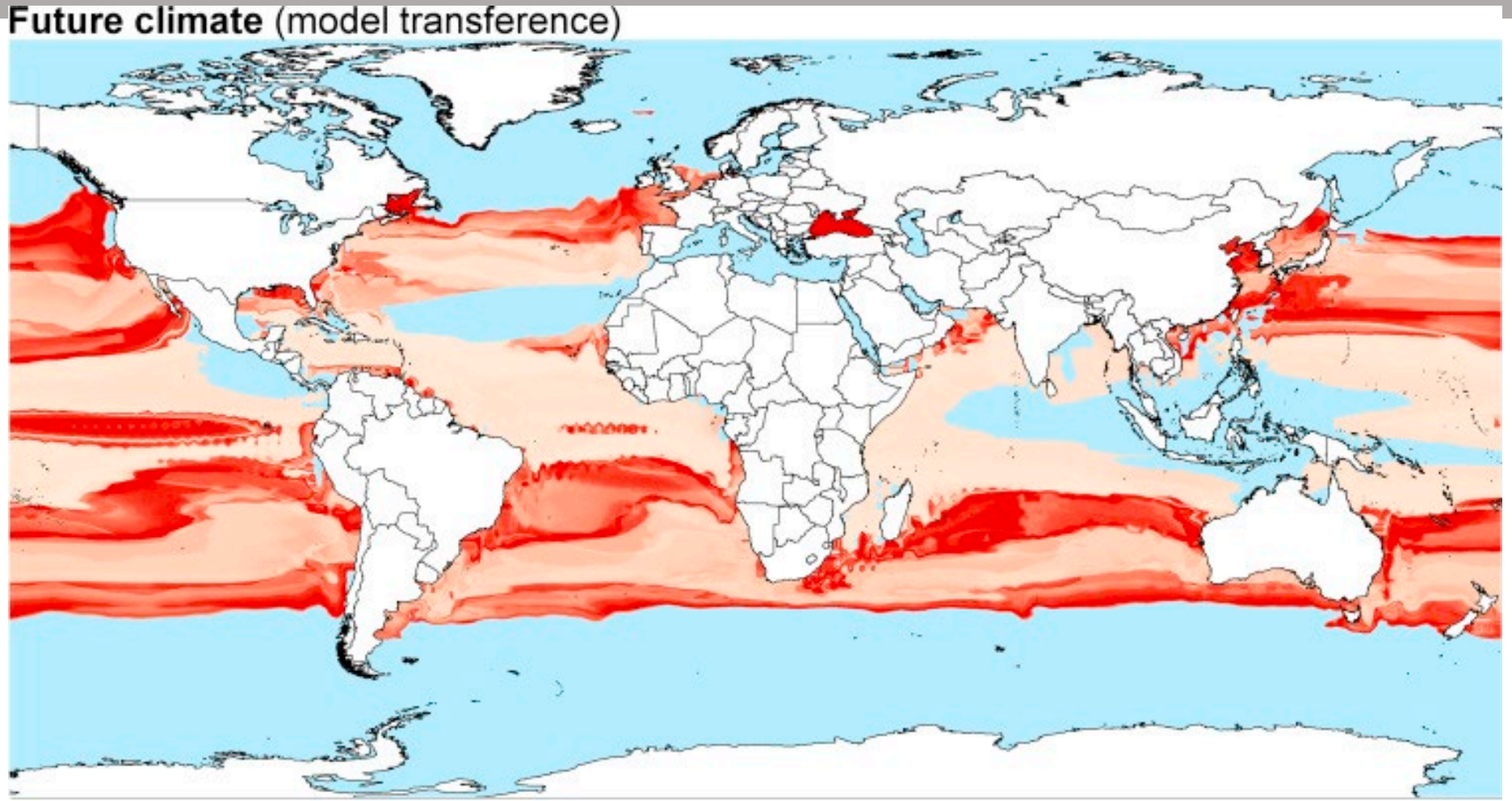
Vibrio cholerae proliferation in sea water: Current Climate

***Vibrio Cholerae*:** currently 760,000 global illness/24,000 death per year



Escobar LE et al. Acta Tropica 2015;149:202-11

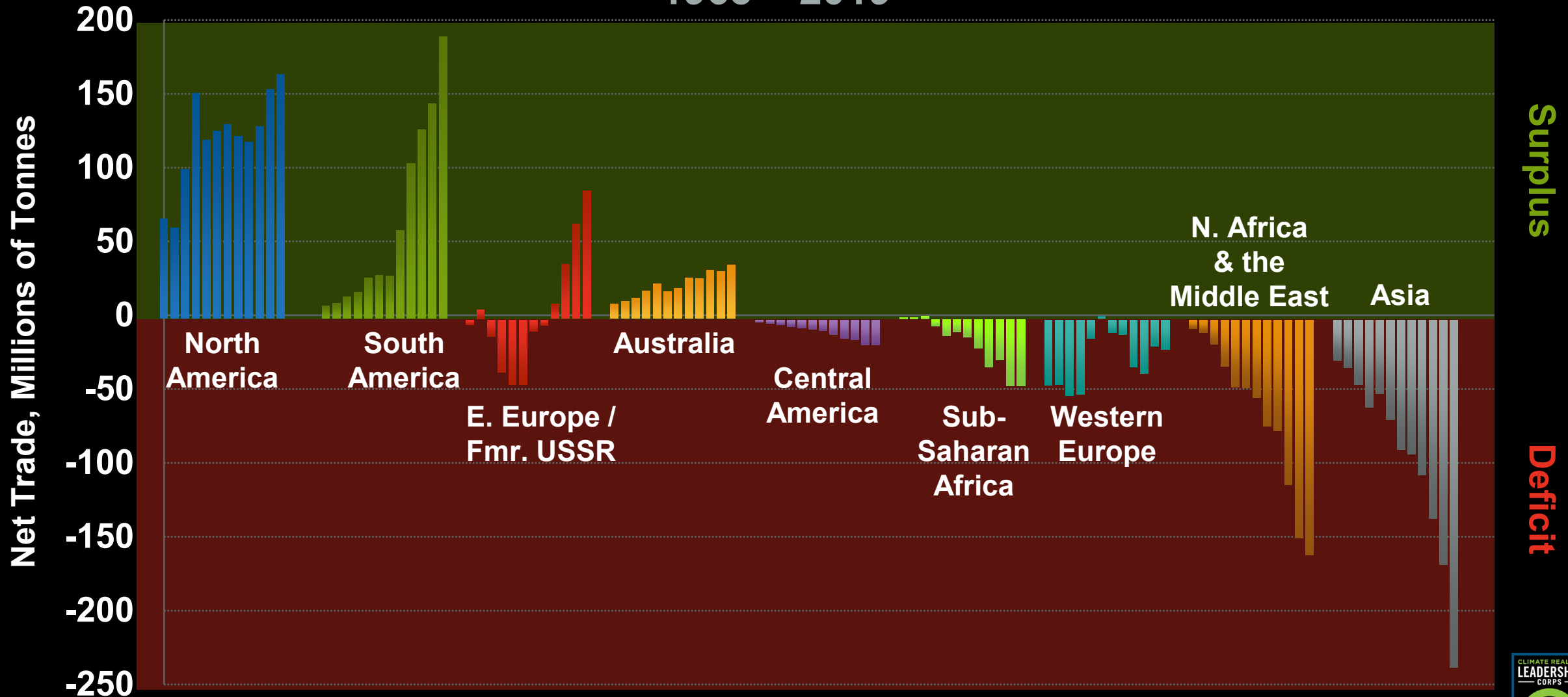
Vibrio cholerae proliferation in sea water:
Business-as-Usual Projection in 2100



Escobar LE et al. Acta Tropica 2015;149:202-11

Food Surpluses and Deficits

1965 – 2019



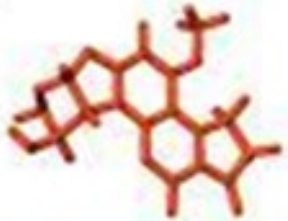
Projected Yield Declines For Each 1° C of Warming

These four crops make up two thirds of human caloric intake.

Data: Chuang Zhao, et al., "Temperature increase reduces global yields of major crops in four independent estimates," *PNAS*, August 29, 2017. Images: [Corn:] © EggHeadPhoto/Shutterstock; [Wheat:] © AlenKadr/Shutterstock; [Rice:] © ekotamak/Shutterstock; [Soy:] © Jiang HongYan/Shutterstock

Other Climate-Sensitive Challenges

- **Mycotoxins (At 2°C increase, aflatoxin, North America and Europ**
  - **Aflatoxins:** Peanuts, dried corn (maize), **tree nuts, certain spices**
  - **Ochratoxin A:** Coffee, raisins, wine, cereal grains, certain spices
  - **Patulin:** Fruits (apple and apple juice)
- Attraction of **pests, plant diseases, weeds**
- Changes in **pesticide use pattern is likely**
- Survival and **proliferation of the pathogen** (*e.g. Salmonella* serovars
- **Antibiotic use and antibiotic residue**
- Changes in **migration pathways** (*e.g.* for avian influenza)
- Changes in **carriers and vectors** (*e.g.* Zika virus)
- Changes in **natural ecosystem**
- **Phycotoxins**



microorganisms

MDPI

Editorial

The Threat of Antibiotic Resistance in Changing Climate

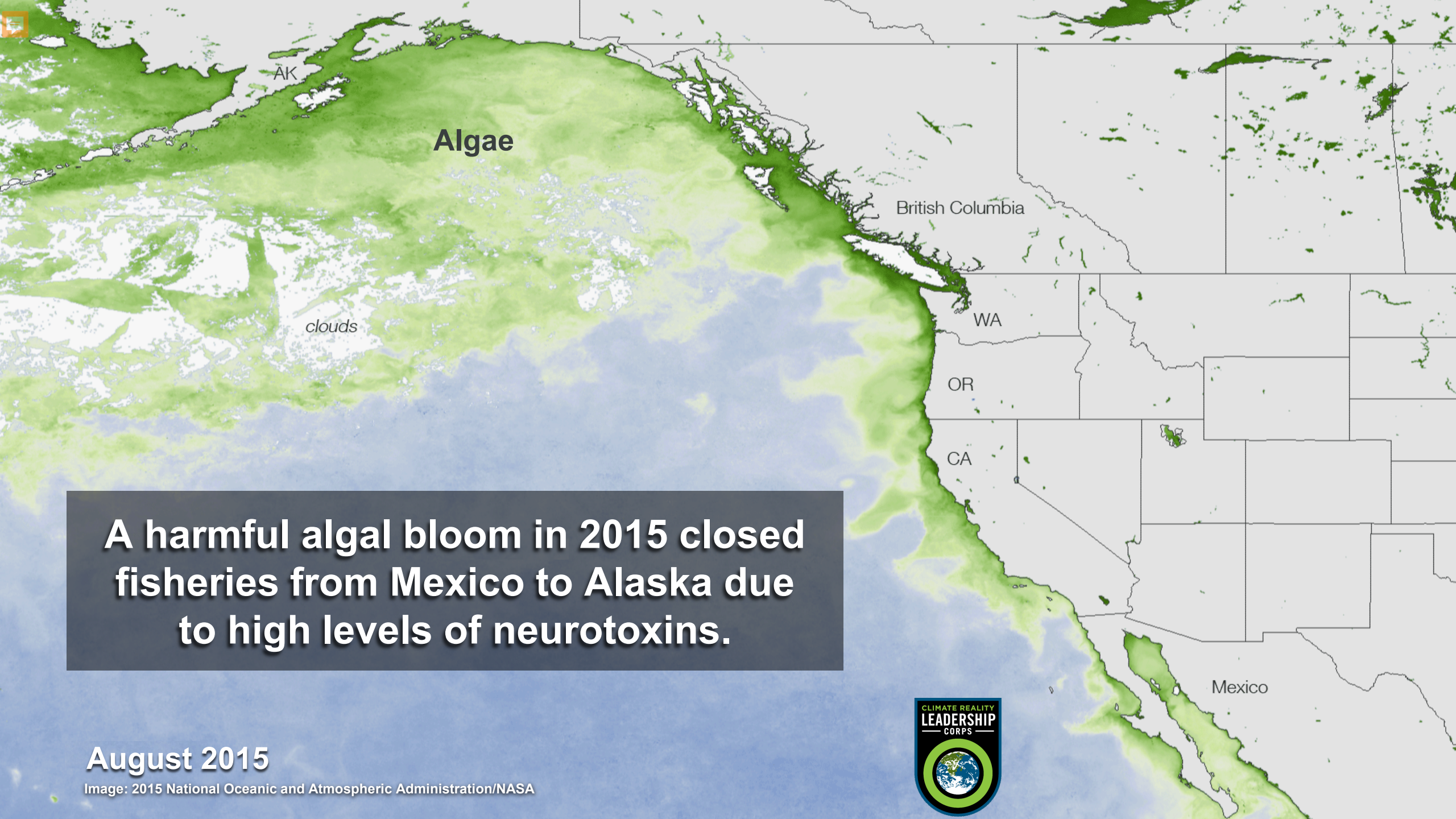
Aliyar Cyrus Fouladkhah [1,*], Brian Thompson [2] and Janey Smith Camp [3]

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: aliyar.fouladkhah@aya.yale.edu; Tel.: +1-970-690-7392

Received: 12 April 2020; Accepted: 14 May 2020; Published: 16 May 2020

check for updates

As the earliest form of life, microorganisms have elaborate mechanisms for adapting to changes



A harmful algal bloom in 2015 closed fisheries from Mexico to Alaska due to high levels of neurotoxins.

August 2015

Image: 2015 National Oceanic and Atmospheric Administration/NASA

CLIMATE REALITY LEADERSHIP CORPS

Biology | Aliyar Fouladkhah

Changing climate

A 'threat multiplier' for foodborne and waterborne infectious diseases and antibiotic resistance

Dr Aliyar Cyrus Fouladkhah of Tennessee State University is an Assistant Professor in Public Health Microbiology. His laboratory explores preventive measures for the spread of infectious diseases, antibiotic resistance, and food security in the landscape of changing climate. His research aims to provide better understanding of the ecology, epidemiology and effectiveness of control measures of enteric and environmental pathogens at planktonic and biofilm stages, including several foodborne and waterborne bacteria. His work contributes to reducing the current burden of premature morbidity and mortality associated with infectious diseases and antibiotic resistance.

According to the U.S. Centers for Disease Control and Prevention, achieving safe and healthier foods is one of the top ten achievements of 20th century public health. Despite the marked progress, considerable challenges remain to further assure the safety and security of food and water supplies, with one in six adults in the United States experiencing illness from foodborne pathogens in a typical year. Foodborne diseases cause an estimated 420,000 deaths worldwide each year. Furthermore, climate change is expected to enhance the spread of infectious diseases since changes in environmental temperatures appreciably augment the multiplication of bacterial pathogens.

The research group of Dr Aliyar Fouladkhah at Tennessee State University addresses these emerging and re-emerging challenges. His laboratory utilises new technologies, in Guatemala, Dominican Republic, and South Africa.

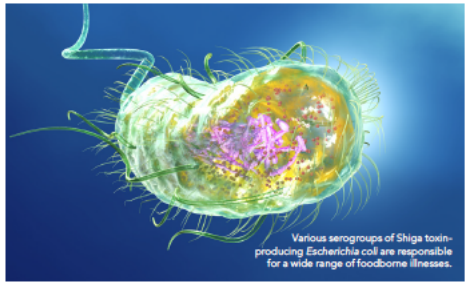
THE ROLE OF CLIMATE CHANGE

Microbial pathogens have an incredible ability to evolve and move towards 'fitness' in response to changes in their environment. Climate change will have pronounced effects on the proliferation, survival, and spread of microbial pathogens, and thus on the prevalence of foodborne and waterborne diseases. More than 200 diseases, known to be transmitted through contaminated food and water, may provide examples of the effects of climate change on the magnitude of infectious diseases. One example of this is salmonellosis, an infection caused by nontyphoidal *Salmonella enterica* serovars, which is currently responsible for over one million cases of foodborne illness in the United States in a typical year.

of these treatments is diminishing, with resistance in many of the common bacterial pathogens now categorised as a public health threat.

Dr Fouladkhah comments that, although there is a focus on identifying new classes of antibiotics, this strategy alone is not sufficient to alleviate the public health challenge of antibiotic resistance. He emphasises that a holistic 'one health' approach should be embraced, which includes limiting the use of current antibiotics to those individuals with dire need for antibiotic therapies and incorporating evidence-based stewardship programmes such as susceptibility testing and watchful waiting in hospitals. This also requires eliminating or minimising the prophylactic and sub-therapeutic use of antibiotics in animal husbandry as the spread of antibiotic resistance in animal populations could be very closely associated with human health complications. Additionally, continuing the search for new antibiotics and antimicrobials, implementing microbial hurdle validation studies in processing and manufacturing, and multiagency efforts to mitigate climate change could assure the control of antibiotics resistance.

Ultimately, Dr Fouladkhah states that the "climate change-induced antibiotic resistance threat will affect citizens of countries with suboptimal public heath



Various serogroups of Shiga toxin-producing *Escherichia coli* are responsible for a wide range of foodborne illnesses.

Climate change is one of the most significant public health challenges of our time and threatens the safety of our food and water supplies.

three bacteria of public health concern in waters of different temperatures (5, 25 and 37°C) and on stainless steel and rubber surfaces. They found that the bacteria included in the study could survive in surface water and form complex biofilms (a collection of microbes which stick to each other and the surface they live on) on abiotic surfaces, detectable for up to 28 days. These results suggest that the occurrence of contamination in water supplies can do not receive any additional processing or treatment before consumption.

Various serogroups of *Escherichia coli* (*E. coli*) are among the top causes of foodborne illnesses, in particular O157 *Shiga toxin-producing E. coli* (STEC) and non-O157 *Shiga toxin-producing E. coli* (nSTEC). The majority of illnesses relating to these serogroups are derived from foodborne infections.

Part III: *Impact Analyses*

Outreach Article Available at:

https://researchoutreach.org/articles/changing-climate-threat-multiplier-foodborne-waterborne-infectious-diseases-antibiotic-resistance/

Twitter @ResOutreach analysis

The link to your Twitter post

https://bit.ly/3elsr0a

Device stats

iOS 43%

Android 47%

Desktop 10%

Demographics

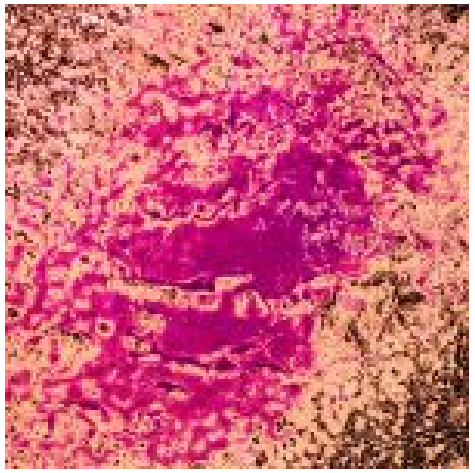
Male	Female	Unknown
57%	40%	3%

Key metrics for all content promoted on Twitter

Audience	Engagements
42605	3256

Top interests

Technology	Biology	Healthcare
68%	53%	48%



Biology | Aliyar Fouladkhah

Changing climate

A 'threat multiplier' for foodborne and waterborne infectious diseases and antibiotic resistance

Dr Aliyar Cyrus Fouladkhah of Tennessee State University is an Assistant Professor in Public Health Microbiology. His laboratory explores preventive measures for the spread of infectious diseases, antibiotic resistance, and food security in the landscape of changing climate. His research aims to provide better understanding of the ecology, epidemiology and effectiveness of control measures of enteric and environmental pathogens at planktonic and biofilm stages, including several foodborne and waterborne bacteria. His work contributes to reducing the current burden of premature morbidity and mortality associated with infectious diseases and antibiotic resistance.

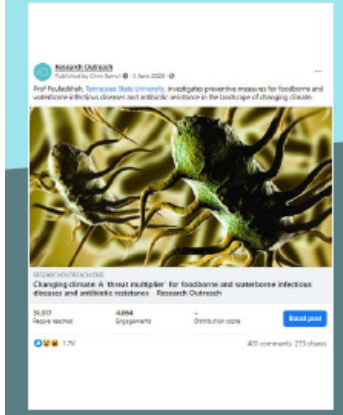
According to the U.S. Centers for Disease Control and Prevention, achieving safe and healthier foods is one of the top ten achievements of 20th century public health. Despite the marked progress, considerable challenges remain to further assure the safety and security of food and water supplies, with one in six adults in the United States experiencing illness from foodborne pathogens in a typical year. Foodborne diseases cause an estimated 420,000 deaths worldwide each year. Furthermore, climate change is expected to enhance the spread of infectious diseases since changes in environmental temperatures appreciably augment the multiplication of bacterial pathogens.

The research group of Dr Aliyar Fouladkhah at Tennessee State University addresses these emerging and re-emerging challenges. His laboratory utilises new technologies, in Guatemala, Dominican Republic, and South Africa.

THE ROLE OF CLIMATE CHANGE

Microbial pathogens have an incredible ability to evolve and move towards 'fitness' in response to changes in their environment. Climate change will have pronounced effects on the proliferation, survival, and spread of microbial pathogens, and thus on the prevalence of foodborne and waterborne diseases. More than 200 diseases, known to be transmitted through contaminated food and water, may provide examples of the effects of climate change on the magnitude of infectious diseases. One example of this is salmonellosis, an infection caused by nontyphoidal *Salmonella enterica* serovars, which is currently responsible for over one million cases of foodborne illness in the United States in a typical year.

Facebook.com/ResearchOutreach



The link to your Facebook post

https://bit.ly/2XsYRpR

Device stats

iOS 31%

Android 37%

Desktop 32%

Demographics

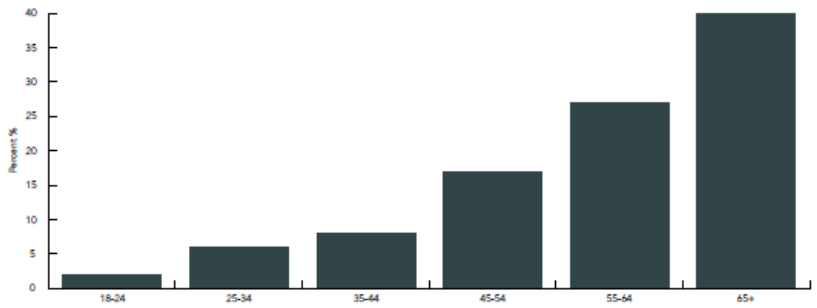
Male 65%

Female 35%

Key metrics for all content promoted on Facebook

People reached	Engagements
31317	4064

Age range



Biology | Aliyar Fouladkhah

Changing climate

A 'threat multiplier' for foodborne and waterborne infectious diseases and antibiotic resistance

Dr Aliyar Cyrus Fouladkhah of Tennessee State University is an Assistant Professor in Public Health Microbiology. His laboratory explores preventive measures for the spread of infectious diseases, antibiotic resistance, and food security in the landscape of changing climate. His research aims to provide better understanding of the ecology, epidemiology and effectiveness of control measures of enteric and environmental pathogens at planktonic and biofilm stages, including several foodborne and waterborne bacteria. His work contributes to reducing the current burden of premature morbidity and mortality associated with infectious diseases and antibiotic resistance.

According to the U.S. Centers for Disease Control and Prevention, achieving safe and healthier foods is one of the top ten achievements of 20th century public health. Despite the marked progress, considerable challenges remain to further assure the safety and security of food and water supplies, with one in six adults in the United States experiencing illness from foodborne pathogens in a typical year. Foodborne diseases cause an estimated 420,000 deaths worldwide each year. Furthermore, climate change is expected to enhance the spread of infectious diseases since changes in environmental temperatures appreciably augment the multiplication of bacterial pathogens.

The research group of Dr Aliyar Fouladkhah at Tennessee State University addresses these emerging and re-emerging challenges. His laboratory utilises new technologies, in Guatemala, Dominican Republic, and South Africa.

THE RÔLE OF CLIMATE CHANGE

Microbial pathogens have an incredible ability to evolve and move towards 'fitness' in response to changes in their environment. Climate change will have pronounced effects on the proliferation, survival, and spread of microbial pathogens, and thus on the prevalence of foodborne and waterborne diseases. More than 200 diseases, known to be transmitted through contaminated food and water, may provide examples of the effects of climate change on the magnitude of infectious diseases. One example of this is salmonellosis, an infection caused by nontyphoidal *Salmonella enterica* serovars, which is currently responsible for over one million cases of foodborne illness in the United States in a typical year.

researchoutreach.org website analysis

Changing climate: A 'threat multiplier' for foodborne and waterborne infectious diseases and antibiotic resistance

Aliyar Fouladkhah
Tennessee State University

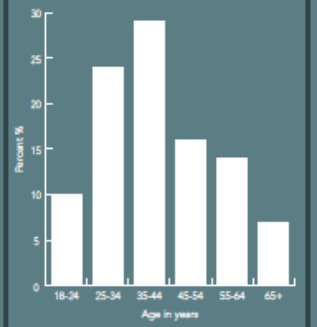
https://bit.ly/3600HB9

Demographics

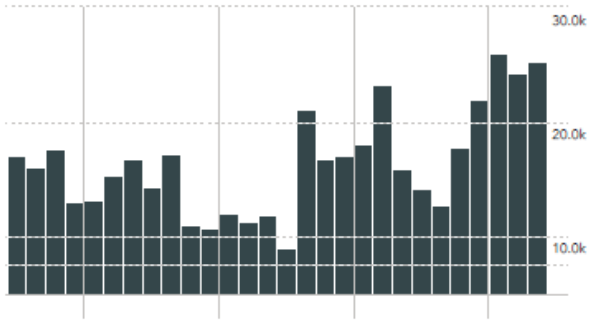
Male 49%

Female 51%

Age range

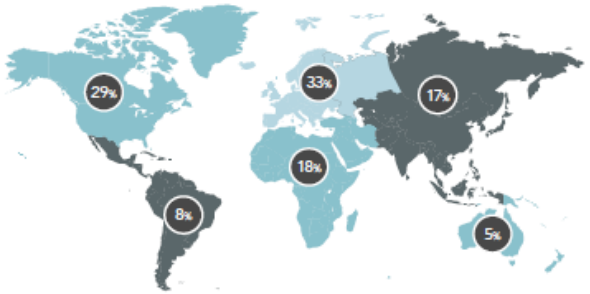


Number of visits for Research Outreach website

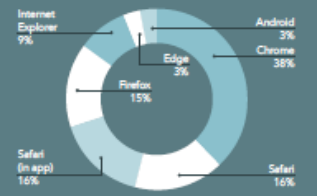


Total number of sessions	99,204
Total number of page views	134,592
Total number of users	82,553
Total number of pages/session	2.92

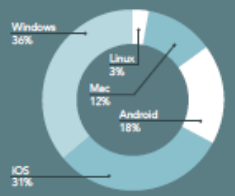
Geographical location of web viewers



Browser stats



Platform and device stats



Biology | Aliyar Fouladkhah

Changing climate

A 'threat multiplier' for foodborne and waterborne infectious diseases and antibiotic resistance

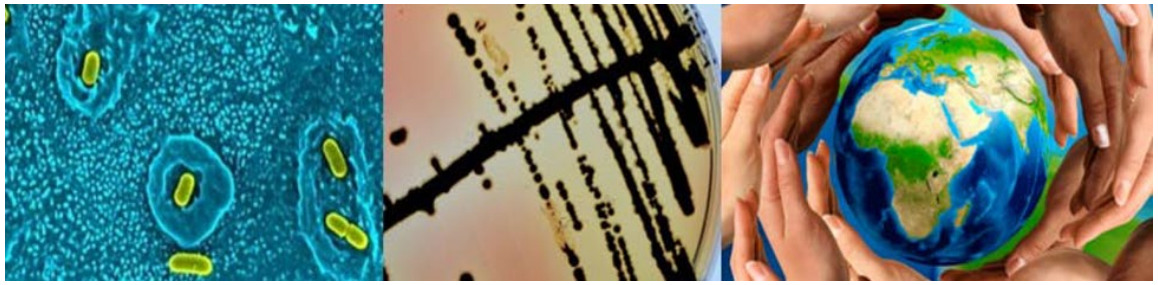
Dr Aliyar Cyrus Fouladkhah of Tennessee State University is an Assistant Professor in Public Health Microbiology. His laboratory explores preventive measures for the spread of infectious diseases, antibiotic resistance, and food security in the landscape of changing climate. His research aims to provide better understanding of the ecology, epidemiology and effectiveness of control measures of enteric and environmental pathogens at planktonic and biofilm stages, including several foodborne and waterborne bacteria. His work contributes to reducing the current burden of premature morbidity and mortality associated with infectious diseases and antibiotic resistance.

According to the U.S. Centers for Disease Control and Prevention, achieving safe and healthier foods is one of the top ten achievements of 20th century public health. Despite the marked progress, considerable challenges remain to further assure the safety and security of food and water supplies, with one in six adults in the United States experiencing illness from foodborne pathogens in a typical year. Foodborne diseases cause an estimated 420,000 deaths worldwide each year. Furthermore, climate change is expected to enhance the spread of infectious diseases since changes in environmental temperatures appreciably augment the multiplication of bacterial pathogens.

The research group of Dr Aliyar Fouladkhah at Tennessee State University addresses these emerging and re-emerging challenges. His laboratory utilises new technologies, in Guatemala, Dominican Republic, and South Africa.

THE ROLE OF CLIMATE CHANGE

Microbial pathogens have an incredible ability to evolve and move towards 'fitness' in response to changes in their environment. Climate change will have pronounced effects on the proliferation, survival, and spread of microbial pathogens, and thus on the prevalence of foodborne and waterborne diseases. More than 200 diseases, known to be transmitted through contaminated food and water, may provide examples of the effects of climate change on the magnitude of infectious diseases. One example of this is salmonellosis, an infection caused by nontyphoidal *Salmonella enterica* serovars, which is currently responsible for over one million cases of foodborne illness in the United States in a typical year.



Response of the Government: Food Safety Modernization Act

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**

Mandated by FSMA
PC QI Certifications

- 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.

Dr. Aliyar Cyrus Fouladkhah,

Faculty Director, Public Health Microbiology Laboratory, Associate Professor, Tennessee State University

Email: afouladk@tnstate.edu or

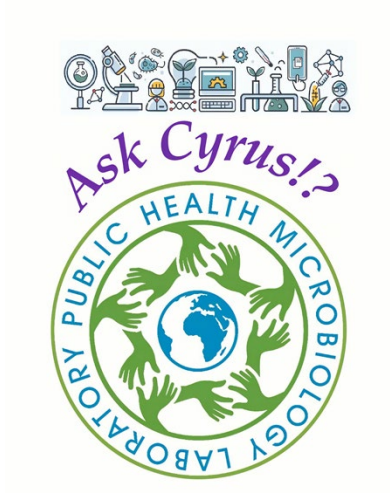
aliyar.Fouladkhah@aya.yale.edu (life-time alumni account)

Phone: (970) 690-7392

Website:

https://publichealthmicrobiology.education/

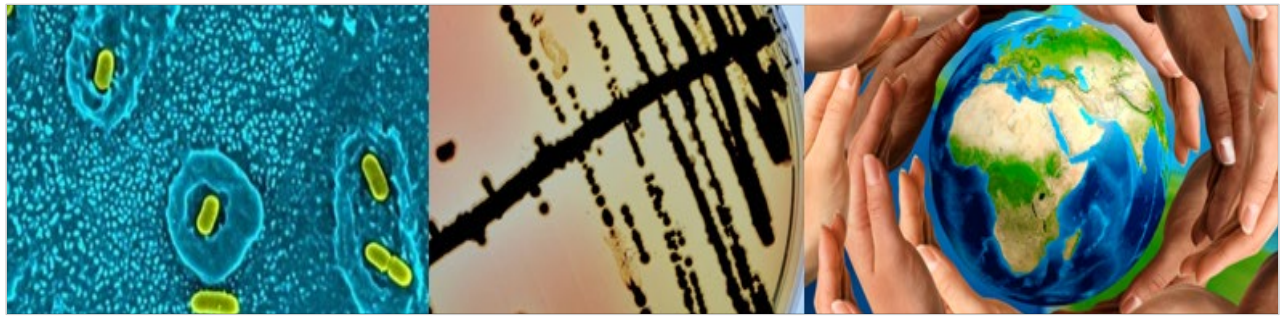
Contributions of members of the Public Health Microbiology laboratory is greatly acknowledged. Finding supports of the program funders are additionally and gratefully acknowledged.



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

Food Safety Modernization Act Certification

[12-5-2021]



Aliyar Cyrus Fouladkhah

Public Health Microbiology Laboratory

Cooperative Extension Program

Tennessee State University

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**

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

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.

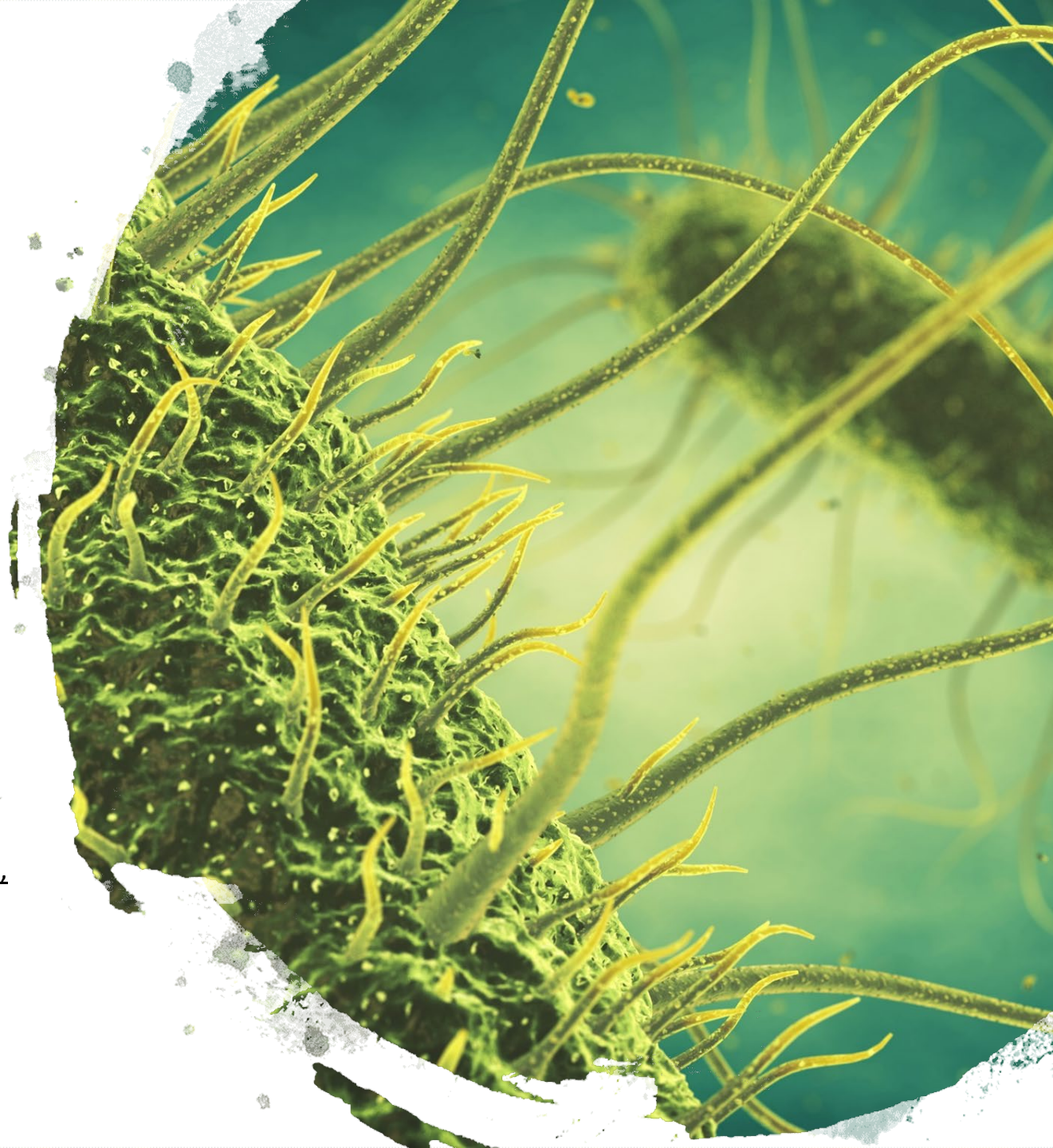
FSMA Implementation Schedule

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.



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**.

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.

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:

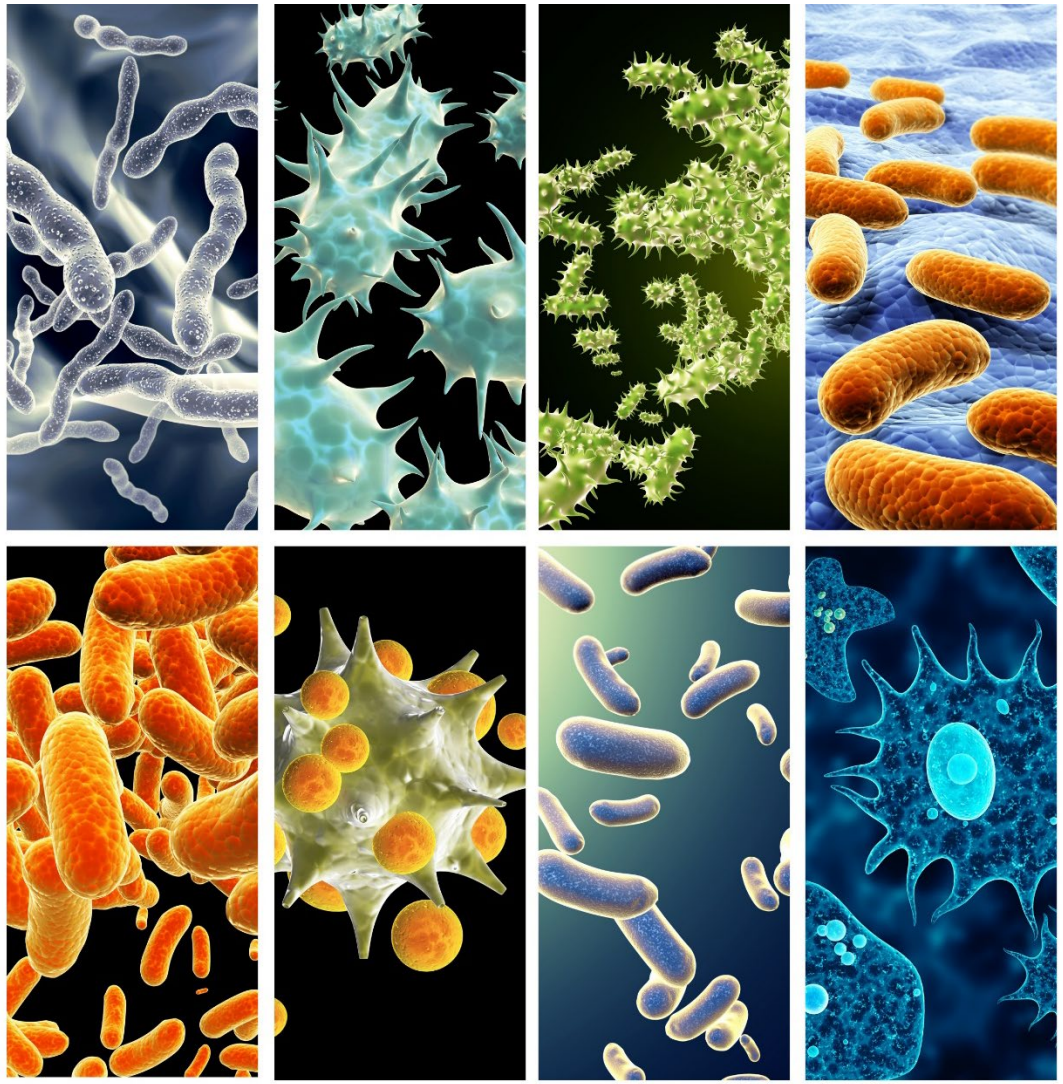
- Sanitation
- Employee training
- Environmental control and training
- Recall contingency plan
- Allergen control
- Supplier verifications
- Sanitary transportation

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)



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.

Human Food	Valérie Charest	Nov 2, 2022	Register	CAD 995	Contact	Live-Virtual Québec Canada	French	Virtual - Online, Web Based Live
Human Food	Valérie Charest	Mar 2, 2022	Register	CAD 995	Contact	Live-Virtual Québec Canada	French	Virtual - Online, Web Based Live
Human Food	Valérie Charest	Jun 15, 2022	Register	CAD 995	Contact	Live-Virtual Québec Canada	French	Virtual - Online, Web Based Live
Human Food	Cynthia Weber	Dec 27, 2021	Register	USD 799	Contact	Self-Paced, Online, Begin Anytime Work at Your Own Pace in CHINESE United States	Chinese	Virtual - Online, Web Based Live
Human Food	Cynthia Weber	Dec 6, 2021	Register	USD 799	Contact	Self-Paced, Online, Begin Anytime Work at Your Own Pace United States	English	Virtual - Online, Web Based Live
Human Food	Oscar Camacho	Jan 26, 2022	Register	USD 775	Contact	Napa CA United States	English	Virtual - Online, Web Based Live
Human Food	Matt McClure	Mar 21, 2022	Register	USD 799	Contact	No Travel Live Instructor in Real Time United States	English	Virtual - Online, Web Based Live
Human Food	Cynthia Weber	Dec 6, 2021	Register	USD 799	Contact	en línea 100% a su propio ritmo ¡Empiece en cualquier momento! United States	Spanish	Virtual - Online, Web Based Live
Human Food	Cynthia Weber	Dec 20, 2021	Register	USD 799	Contact	en línea 100% a su propio ritmo ¡Empiece en cualquier momento! United States	Spanish	Virtual - Online, Web Based Live

Preventive Control for Human Food: PC QI

- Our course 12-06-2021 to 12-8-2021
- THANK YOU NIFA and PHM Lab

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

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

Dear Dr. Aliyar,

Great talking to you this afternoon. Below is some preliminary information about the litigation we have:

We purchased an ingredient from [redacted] Corp, which was labeled as a Natural Flavor. It's use was as a natural preservative for a fresh cheese spread type of product.

This ingredient was successfully tested in our product and was used in the commercialization of our product which got sold to Cargill. After the product launched, Bavaria notified us of a potential allergen issue/update as a result of Lupin extract being present in their product which was deemed as an allergen. We had no problem with this, as we would handle it through a label update on our end and also at the customers end. However, during these conversations, we started suspecting that Bavaria was not being transparent as to the source of the lupin extract. After pushing them for full disclosure, they connected us with their supplier which told us in writing and vía conference call, that the lupin extract sent to [redacted] from Portugal was only sent to them as an experimental sample, and that it had not received approval to be used as a food ingredient for consumption.

Additionally, [redacted] had not followed or complied with the foreign material verification process by FDA and therefore sold us a product containing an ingredient illegally imported into the US.

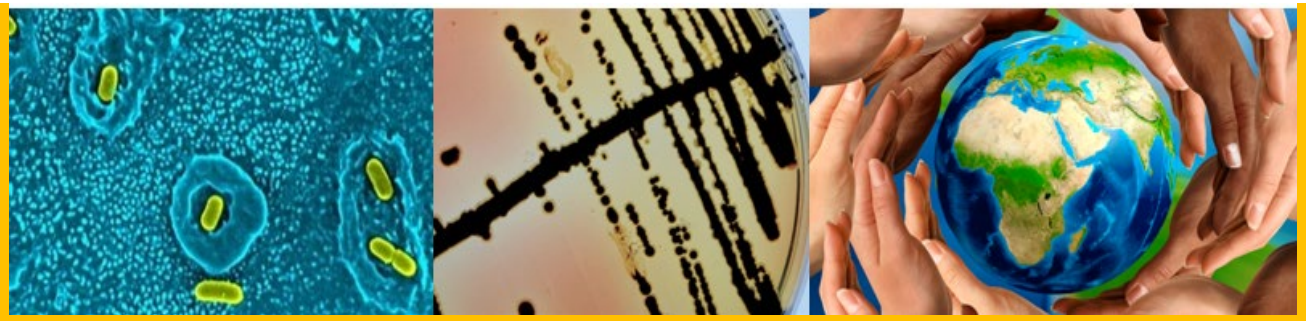
Once we learned about these details, we withdrew the product from Cargill causing us a 400k+ liability. We filed a law suit with [redacted] to recover these costs.

In summary, [redacted] sold an adulterated ingredient with an ingredient illegally imported, not GRAS listed, that contained an agricultural pesticide called BLAD that https://www.cev.com.pt/en/blad-active-ingredient/ which was not sold to them, but rather sent to them by CEV as an experimental sample.

Let me know if with this information you feel that you could help us and I will be happy to connect you with our attorneys.

I really appreciate it and look forward to hearing your thoughts.

Regards,



Food Labeling and Advertising
FDA's Generally Recognized as Safety List

12-08-2021

Tennessee State University, Nashville, TN

A. Fouladkhah: Faculty Director, Public Health Microbiology Laboratory

Food Labeling and Advertising

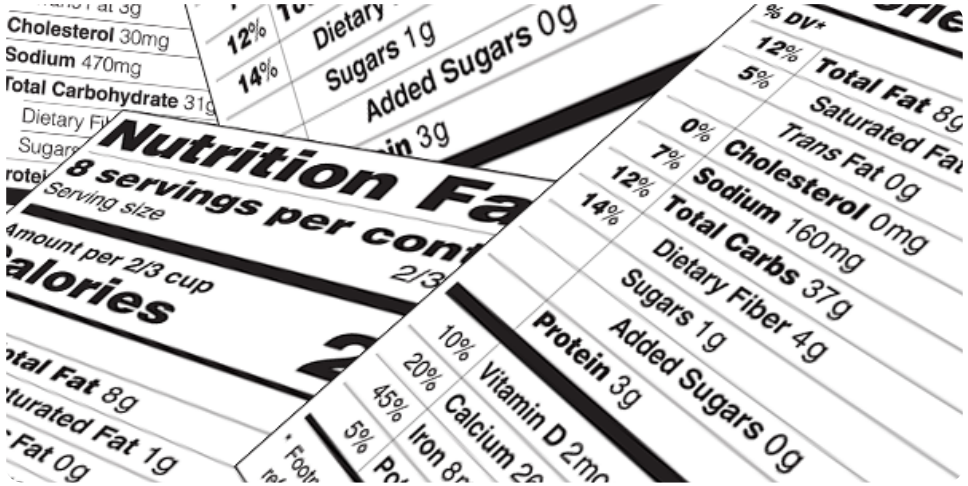
Food Labeling:

- **Valuable source of information** for consumers
- Could be **false, misleading**, or **true-but-trivial** marketing claims

e.g. Cholesterols-free potato chips; No Added sugar (added juice); Made with real fruit; N&A flavors; WONF vanilla extract

- **Challenge for consumers:**
- Distinguish the signal from noise

- **Challenge for policy makers:**
- Strengthening the signal to noise ration



Food Labeling and Advertising

Regulation for food producers:

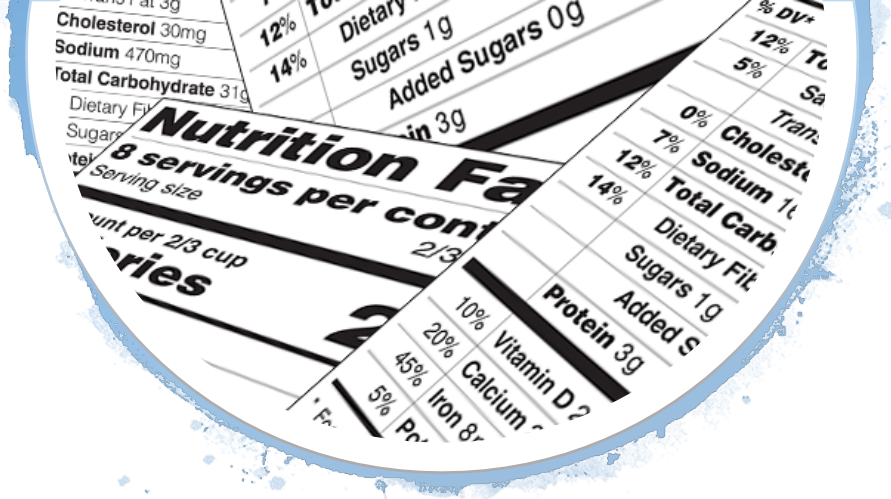
- Mandatory information
- Voluntary information: weakly regulated
- Voluntary information: strongly regulated
- Prohibited Claims

Consumers can get information:

- **Search** properties: comparing products in market
- **Experience** properties: relying on personal experience
- **Credence properties**: consumers cannot confirm product quality

e.g.: **organic** production; **country of origin**; **nutrition and health claims**; **humane treatment** of workers or animals (fair trade)

Food Labeling and Advertising



- The food industry is one of the United States' **largest manufacturing sector**
- **10 percent of all shipments** in the United States are associated food industry
- More than a **third of the world's top 50 food and beverage processing firms** are headquartered in the United States (CASE, 2021)
- **Efficiency and public health?**

FDA's Four Flavor Categories

- **Natural Flavors**
- **Natural With Other Natural Flavors (WONF)**
- **Artificial Flavors**
- **Natural and Artificial (N&A) Flavors**

Claims About Nutrition and Health

- Four Types of Claims are Possible for Food Products:
- (1) Nutrient Content Claim
- (2) Health Claim
- (3) Qualified Health Claims
- (4) Structure/Function Claims

- **All must be in close harmony with Dietary Guidelines for Americans**
- Must be evaluated by regulatory agencies

Claims About Nutrition and Health

(1) Nutrient Content Claim:

Describes level of nutrient or food component

e.g. "Low sodium," "Low fat," "High in oat bran."

Must follow **specific requirements** of NLEA

The Nutrition Labeling and Education Act of 1990 (NLEA)

Sodium as an example:

< 5 mg per reference amount*: "**Sodium Free**"

Reduced by at least 25% from reference amount "**Reduced Sodium**"

Reduced by at least 50% from reference amount "**Light in Sodium**"

140 mg or less per reference amount "**Low Sodium**"

Reference amount should be obtained from: ***Reference Amount Customarily Consumed (RACC)***

Claims about Nutrition and Health

(1) Nutrient Content Claim:

- **True-but-misleading claims** must be prohibited *e.g.* "*low-fat broccoli*"
- **Half-truth** and misleading claims must be prohibited

e.g. if the product: **Both high in saturated fat and high in fiber, the claim:**

Claim could not just mention "High in fiber"

Reason: Against the Dietary guideline: Food high in Saturated fat could not be promoted

Claims about Nutrition and Health

(2) Health Claim (aka *Real* or *Authorized* Health Claim)

- Connects a food product to **disease** **or health condition**

e.g. " may reduce the risk of heart diseases"

Another example: Adequate calcium and vitamin D as part of a healthful diet, along with physical activity, **may reduce the risk of osteoporosis later in life.**

- This **requires approval from Food and Drug Administration**
- Only approved if there is "**significant scientific agreement**"
- **Has to be derived from** a **statement from Dietary Guideline** or highly respected authorities/institutions (**IOM**)
- Usually, a **lengthy process and rare in food industry** ***[Oat and Cholesterol]***
- ***[Cost for clinical trials >$40K per patient, >$19m for a new drug]***

FDA U.S. FOOD & DRUG ADMINISTRATION

Authorized Health Claims That Meet the Significant Scientific Agreement (SSA) Standard

Approved Health Claims

Calcium, Vitamin D, and Osteoporosis

- 21 CFR 101.72 Health claims: calcium and osteoporosis
- Final Rule: Food Labeling; Health Claims; Calcium and Osteoporosis, and Calcium, Vitamin D, and Osteoporosis September 2008

Dietary Lipids (Fat) and Cancer

- 21 CFR 101.73 Health claims: dietary lipids and cancer

Dietary Saturated Fat and Cholesterol and Risk of Coronary Heart Disease

- 21 CFR 101.75 Health claims: dietary saturated fat and cholesterol and risk of coronary heart disease
- Interim Final Rule: Food Labeling; Health Claims; Dietary Saturated Fat and Cholesterol and Risk of Coronary Heart Disease December 2016

Dietary Non-cariogenic Carbohydrate Sweeteners and Dental Caries

- 21 CFR 101.80 Health claims: dietary noncariogenic carbohydrate sweeteners and dental caries
- Final Rule: Food Labeling; Health Claims; Dietary Noncariogenic Carbohydrate Sweeteners and Dental Caries May 2008
- Final Rule: Food Labeling; Health Claims; D-tagatose and Dental Caries July 2003
- Final Rule: Food Labeling; Health Claims; Dietary Sugar Alcohols and Dental Caries December 1997
- Final Rule: Food Labeling; Health Claims; Sugar Alcohols and Dental Caries August 1996

Fiber-containing Grain Products, Fruits and Vegetables and Cancer

- 21 CFR 101.76 Health claims: fiber-containing grain products, fruits, and vegetables and cancer

Claims about Nutrition and Health

(3) Qualified Health Claim

- Is a claim that **lack significant scientific agreement**
- **FDA allows such claim when some health benefit studies are available.**
- **Label should indicate:**
- **“** *FDA has determined that this evidence is limited and not conclusive”*
- They should also indicate “*This statement is not approved by FDA.”*

- “Scientific evidence suggests, but does not prove, that whole grains (three servings or 48 grams per day), as part of a low saturated fat, low cholesterol diet, **may reduce the risk of diabetes mellitus type 2**.”

- Could lead to **legal complication** for companies if not stated correctly.

Claims about Nutrition and Health

(4) Structure and Function Claim

- **Connects food to structure or function of human body**
- Most common in the food industry
- Allows food industry to **"hint" at health benefits**
- Does not requires FDA approval
- But companies would **need to have strong scientific evidence *[DGA or IOM]***

"***Prevents Osteoporosis***" is a **health claim** requires lengthily **FDA approval**

"***Builds strong bones***" is a **structure/function claim** that does **not require FDA approval**

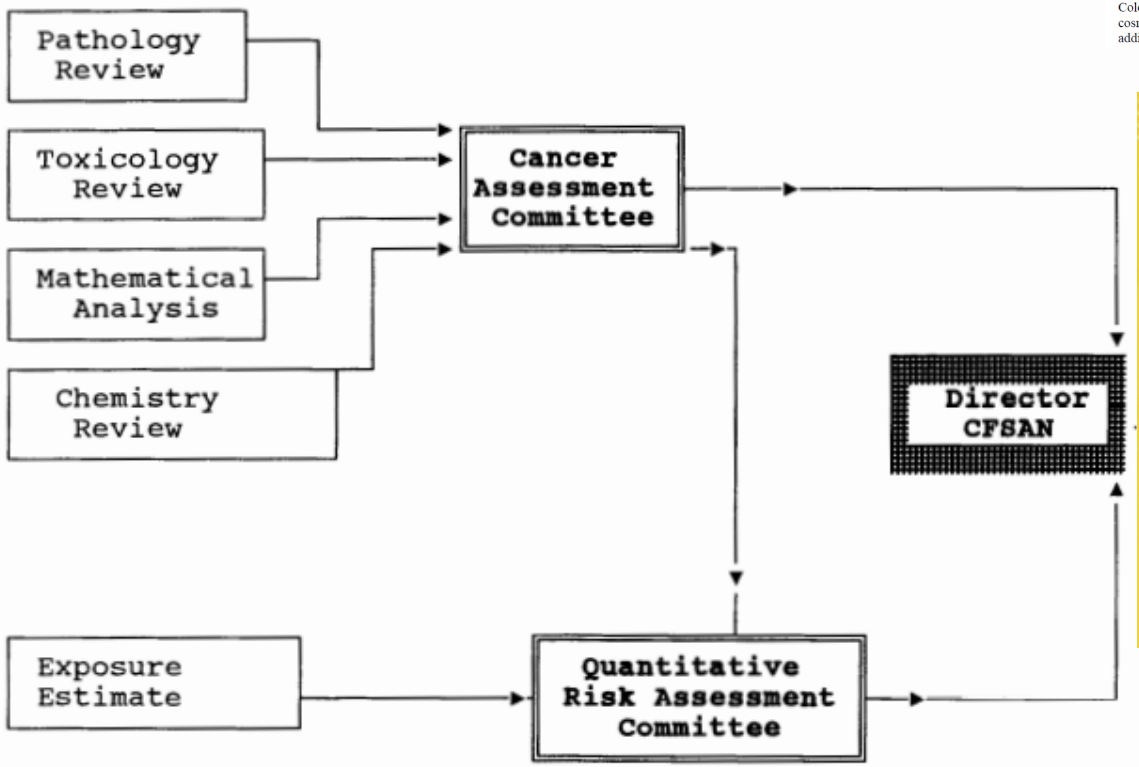
FDA GRAS LIST

- Any substance that is **intentionally added to food** is a **food additive**
- **All additives** are: subject to **premarket review and approval by FDA**, **unless those with GRAS status**
- Food Industry is **extremely dynamic** with many ingredients (**natural and artificial**)
- **Practically impossible** for companies to test all ingredients for safety
- There is a similar list (**Animal Food GRAS) for feed industry**
- **When an ingredient is not listed in GRAS list:**
- Manufacturer may obtain GRAS status by **applying to the FDA**
- This is much **less conservative than pharmaceutical industry**. [LD50 in animals/100]
- Takes over **10 years** to receive approval for new drugs [typically >$19 B]

Pre-market safety evaluation process

- **1958:** Congress enacted the **Food Additives Amendment** to the **Federal Food, Drug, and Cosmetic Act**
- **1960:** Color Additive Amendments to the **Federal Food, Drug, and Cosmetic Act**

Flow Chart Depicting the Various Groups Involved in the Assessment of Cancer Risk at the Center for Food Safety and Applied Nutrition (CFSAN) of the Food and Drug Administration



Chapter II

Agency Review of Toxicology Information in Petitions for Direct Food Additives and Color Additives Used in Food

A. Introduction

The food additive petition review process came into existence in 1958 when Congress enacted the Food Additives Amendment [1] to the Federal Food, Drug, and Cosmetic Act (the Act). [2] This Amendment provides a pre-market safety evaluation process for new substances added to food, "food additives." A similar statute, the Color Additive Amendments of 1960, [3,4] created analogous requirements for color additives used in foods, drugs, cosmetics, or medical devices. "Color additive" used in food is defined in section 201(t) of the Act; "food additive" is defined in section 201(s) of the Act.

Joint FAO/WHO Expert Committee on Food Additives (JECFA)

Guidance document for WHO monographers and reviewers evaluating food additives

(excluding enzyme preparations and flavouring agents)

FDA GRAS LIST

- GRAS (Generally Recognized as Safe) list of FDA:
- **Help producers avoid unnecessary testing**
- Provide a list of all **approved ingredients** and **approval concentrations *[e.g. nisin 900 IU/gram]***
- **Created in 1958** as amendment to Food and Drug Cosmetic Act
- Ingredients already in use **before 1958** received GRAS status **without testing (Old Additives)**
- **This created some problem:**
- Example: 1985 cinnamyl anthranilate (artificial cinnamon flavor) linked to liver cancer.
- **Was part of GRAS list from 1958 to 1985**, banned in 1985.

Generally Recognized as Safe (GRAS)

Share Tweet LinkedIn Email Print

"GRAS" is an acronym for the phrase **G**enerally **R**ecognized **A**s **S**afe. Under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act (the Act), any substance that is intentionally added to food is a food additive, that is subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excepted from the definition of a food additive.

- Under sections 201(s) and 409 of the Act, and FDA's implementing regulations in 21 CFR 170.3 and 21 CFR 170.30, the use of a food substance may be GRAS either through scientific procedures or, for a substance used in food before 1958, through experience based on common use in food Under 21 CFR 170.30(b), general recognition of safety through scientific procedures requires the same quantity and quality of scientific evidence as is required to obtain approval of the substance as a food additive. General recognition of safety through scientific procedures is based upon the application of generally available and accepted scientific data, information, or methods, which ordinarily are published, as well as the application of scientific principles, and may be corroborated by the application of unpublished scientific data, information, or methods.
- Under 21 CFR 170.30(c) and 170.3(f), general recognition of safety through experience based on common use in foods requires a substantial history of consumption for food use by a significant number of consumers.

FDA GRAS LIST

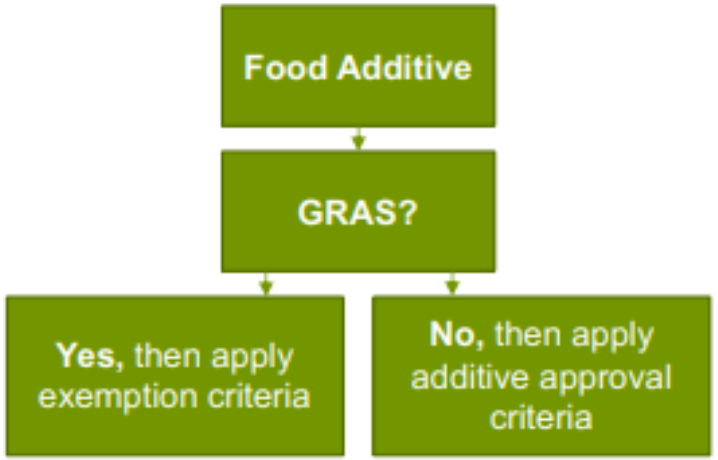
- A large online data inventory: **GRAS Notice Inventory**
- **Some decision controversial:**
- **Lysozyme**: an natural enzyme in human breastmilk
- In 2006, Artificially produced Lysozyme did not receive GRAS status for **infant formula**
- Other examples:
- **Caffeine** did not receive GRAS status for **caffeinated alcoholic beverages**
- ***Trans* fats** were part of GRAS list until 2015
- **Sodium chloride** is still on GRAS list, **IOM recommends removal**

FDA GRAS LIST

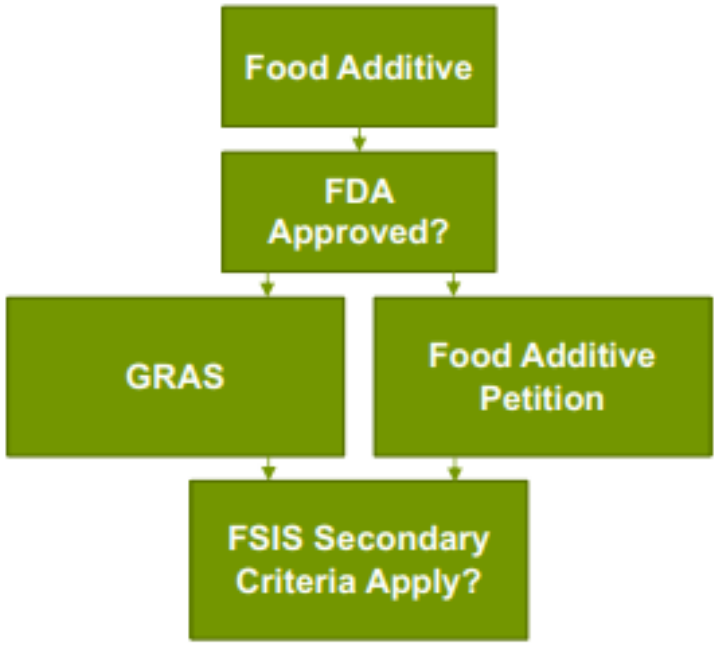
- **Major problems with GRAS list:**
- **Old additives** were not all reviewed
- Studies are not from **human clinical trials** (in vivo or animal studies) *[LD50 in animals divided by 100]*
- Do not consider the **additives synergism** *[Benzoic acid, sulfate, phosphoric acid, citric acid]*
- **Does not address color additives** (covered by FD&C act)
- **Does not address pesticides**
- **Does not address GMO**

- **Other agencies have additional requirements:**
- **USDA FSIS: additives for meat products**
- **Animal Food GRAS List**

FDA GRAS LIST



Food Additive Decision Tree for FDA Products



Food Additive Decision Tree for FSIS Products

Differentiating between **Food Additives** and **processing aids:**

Antimicrobials in meat industry
Enzymes (lactase) in dairy industry

Source: Institute of Food Technologists

Dr. Aliyar Cyrus Fouladkhah,

Faculty Director, Public Health Microbiology Laboratory, Tennessee State University

afouladk@tnstate.edu|
Phone: (970) 690-7392

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