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Train-the-Trainer Public Health & Food Safety Workshop & Process Authority Consultation in Jamaica

Trip Report (March 2022)

USAID Assignment on February 28 to March 12, Kingston, Jamaica

Dr. Aliyar Cyrus Fouladkhah, PhD, MPH, CFS, CPH
Founding Director, Public Health Microbiology Foundation
Associate Professor, Tennessee State University
Yale School of Public Health Alumnus



It was a lifetime honor for me to serve as a volunteer in Jamaica again. I had a chance to hold this workshop for the instructors of Ebony Park HEART academy, discussing important topics associated with public health microbiology, microbial food safety, climate change, infectious diseases, and food processing. Additionally had a chance to visit and provide practical Current Good Manufacturing Practices (cGMP) recommendations for the Agro-Processing plant of the academy.

The academy is a prestigious tax-payer-funded agency in Jamaica with several branches across the island that provide important training and education opportunities to Jamaican students to address education equity and contribute to the economy of Jamaica by workforce development. In this report, you can find excerpts of my teaching material, information about the workshop, the participants, their evaluation of the workshop, and recommendations for the academy.

A similar certification program had been recently conducted in Mexico on December 6, 2021, and in California on January 26, 2022, and was costing \$779 and \$775 per participant, respectively. This workshop was funded by the Public Health Microbiology Foundation and thus participants received the certification and the workshop manual at no cost. Thus, the cost-saving for the host (18 instructors of the academy) for the workshop and consultation is conservatively estimated at \$13,950 USD (c. 2.1 million Jamaican Dollars).

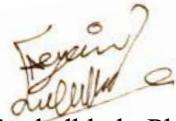
Special thanks are necessary for great colleagues in the Washington and Jamaica Partners of America program who additionally supported this event by USAID funds and their contributions for harmonizing the events of this two-week workshop and consultation. Specifically, I would like to sincerely thank Ms. Susanna Meyer and Ms. Marsha Johnson from Washington and Jamaica USAID offices, respectively, for their outstanding support. Additionally, the support and assistance of Mr. Fitz Hoad, the field officer of the program are sincerely and gratefully appreciated.

Finally, I would like to thank the instructors of the Ebony Park HEART Academy for their willingness to learn and incorporate the material of the workshop as part of their everyday teaching curriculum. I am grateful for the vivid and scholarly discussions we hold during the workshop and commend their willingness to update their knowledge with the new, emerging, and cutting-edge information discussed during the course of this assignment. Below is the list of my recommendations for this host. I wish all the colleagues of the academy increasing success in their effort in workforce development and improving the education equity in Jamaica.

Recommendations

1. **Choosing the proper regulatory agency for the academy commodities.** In order to be in harmony with regulations in North America, it is recommended that meat and meat-based products follow the recommendations articulated under the Hazard Analysis Critical Control Point (HACCP) regulations, and the remaining of the commodities follow the information discussed associated with Preventive Control for Human Food regulation of the Food Safety Modernization Act. This, in addition to following the local regulatory requirements, will augment the competitiveness of local products for further export to North America, a key priority for the academy and academy stakeholders.
2. **Incorporating workshop teaching material into the Ebony Park HEART academy teaching curriculum.** Discussions were held with 18 instructors who participated in the workshop and the Section Head and the instructors expressed wiliness to incorporate information from this current workshop into the teaching curriculum of the academy. This includes new information on public health microbiology, microbial food safety, infectious diseases under the landscape of climate change, and the use of additives and processing aids in food manufacturing.
3. **Improving control of allergen cross-contact, labeling, and improving traceability of the products produced in the academy.** Extensive information was provided to declare current “big 8” allergens (and the new allergen that will be added to the list in early 2023), minimizing the risk of cross-contact with allergens and improving the traceability of the products.
4. **Reducing the risk of cross-contamination with microbial pathogens during the operation.** Practical and adaptable interventions were discussed with the operators and quality control members of the agro-processing plant of the academy. Specifically, for:
 4. a. **Eliminating bacterial biofilm formation in niche and hard-to-reach areas in the immediate vicinity of the food-contact surfaces.**
 4. b. **Use of microbiologically cleanable material in the production area.**
 4. c. **Eliminating potential breeding-grounds for environmental pathogens such as *Listeria monocytogenes* in the immediate vicinity of the food contact surfaces and ready-to-eat commodities.**
 4. d **Eliminating standing water and improvement in Sanitation Standard Operating Procedures of the processing plant to reduce risk of cross-contamination of final products with microbial pathogens.**

Submitted with best wishes,



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

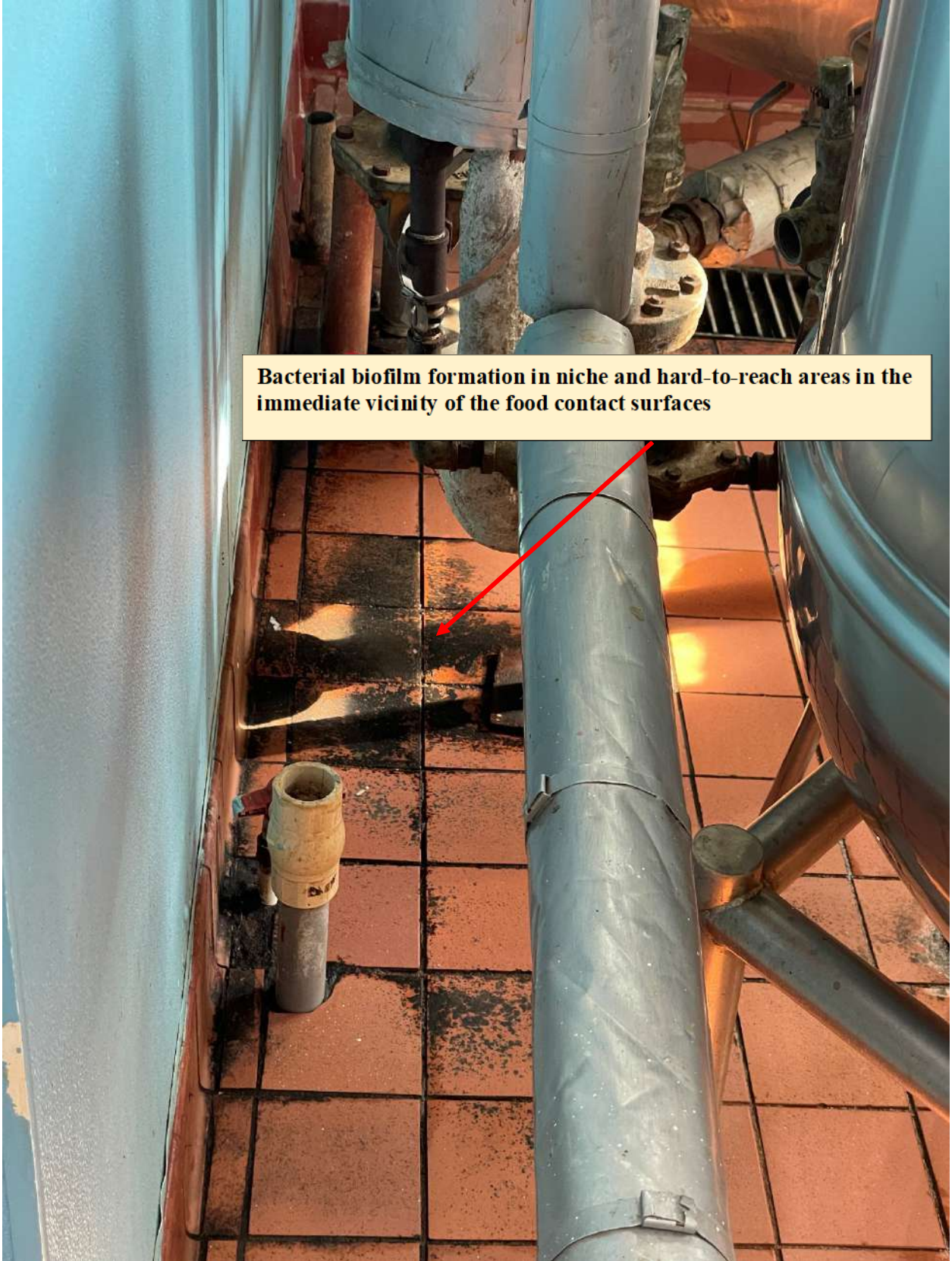
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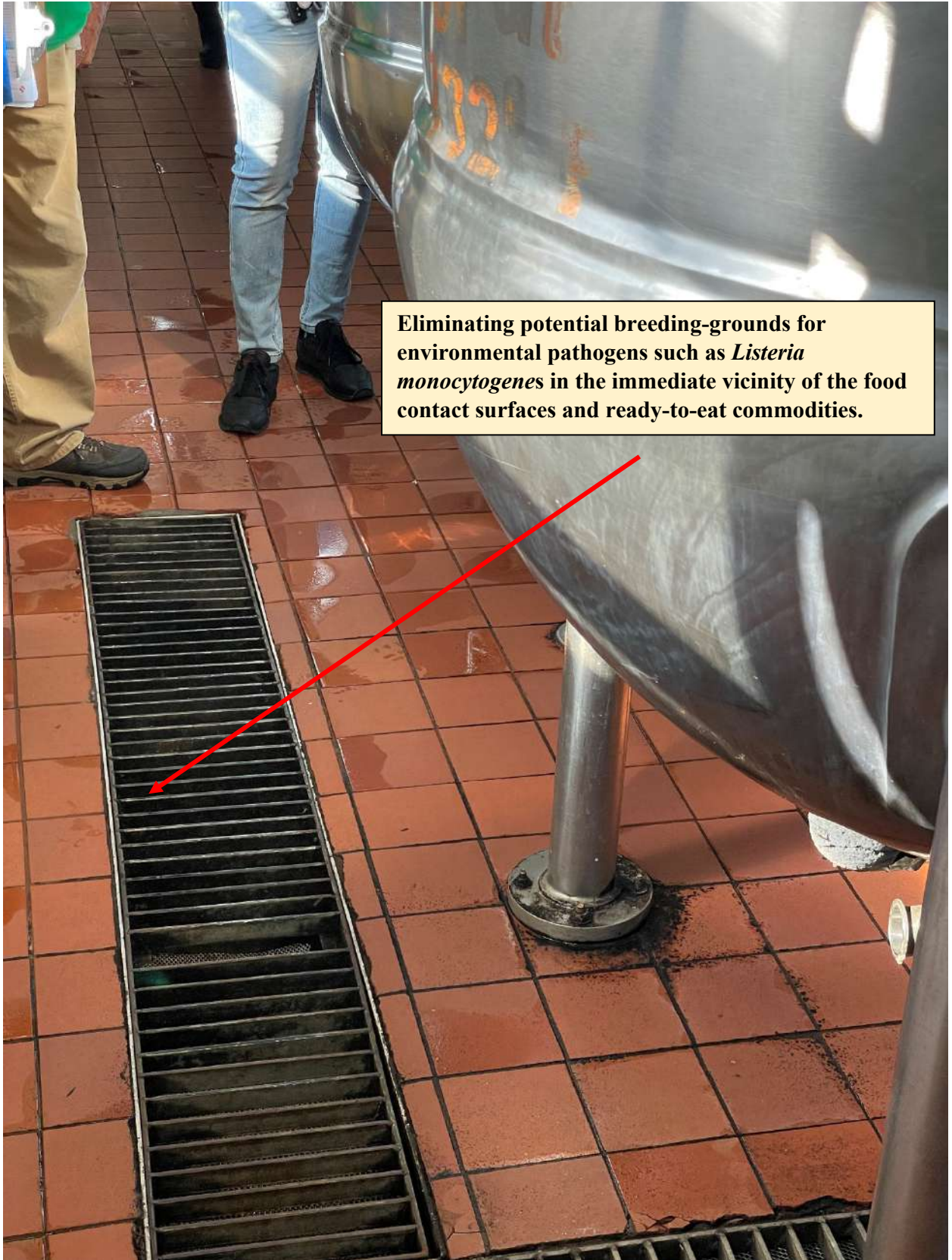




Bacterial biofilm formation in niche and hard-to-reach areas in the immediate vicinity of the food contact surfaces



Use of microbiologically cleanable material in the production area. Wooden surfaces are not microbiologically cleanable







Mr. Fitz Hoad, Field Officer of USAID Jamaica, Partners of America (right)
Ms. Selma Khani, Section Head, Ebony Park HEART Academy (left)
March, 9, 2022- Photos Courtesy: Aliyar Cyrus Fouladkhah



EBONY PARK ACADEMY AGRO-PROCESSING PLANT

The Recommendations



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



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

ASSIGNMENT TITLE (found on Scope of Work):

Food Safety Preventive Control Specialist

EXECUTIVE SUMMARY

Please include a 3-4 paragraph summary of major accomplishments during your assignment, a summary of key findings and recommendations, and observations of impact or progress to date.

It was a lifetime honor for me to serve as a volunteer in Jamaica again. I had a chance to hold this workshop for the instructors of Ebony Park HEART academy, discussing important topics associated with public health microbiology, microbial food safety, climate change, infectious diseases, and food processing. Additionally had a chance to visit and provide practical Current Good Manufacturing Practices (cGMP) recommendations for the Agro-Processing plant of the academy.

BACKGROUND and OBSERVATIONS

Briefly summarize, in 3-6 paragraphs, the purpose and objectives of your assignment, background information on hosts, and other contextual information that may help future volunteers.

The academy is a prestigious tax-payer-funded agency in Jamaica with several branches across the island that provide important training and education opportunities to Jamaican students to address education equity and contribute to the economy of Jamaica by workforce development. In this report, you can find excerpts of my teaching material, information about the workshop, the participants, their evaluation of the workshop, and recommendations for the academy.

Please also discuss any broad observations related to the country, sector, and/or Farmer-to-Farmer activities based on your initial meeting(s) with the hosts. How has the host progressed? What are the host's obstacles and opportunities?

ACTIVITIES

In 3-6 paragraphs, please summarize discussions held, workshops conducted, lectures or clinics given, or other

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services or activities performed during your assignment.

HOSTS

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.

I would like to thank the instructors of the Ebony Park HEART Academy for their willingness to learn and incorporate the material of the workshop as part of their everyday teaching curriculum. I am grateful for the vivid and scholarly discussions we hold during the workshop and commend their willingness to update their knowledge with the new, emerging, and cutting-edge information discussed during the course of this assignment. Below is the list of my recommendations for this host. I wish all the colleagues of the academy increasing success in their effort in workforce development and improving the education equity in Jamaica.

RESULTS

In 2-4 paragraphs, describe any changes you expect will occur as a result of your work. If applicable, describe any recommendations from previous Farmer-to-Farmer volunteers that hosts have adopted. Did you observe any other impacts from Farmer-to-Farmer? Were there separate local interventions that may impact results?

Special thanks are necessary for great colleagues in the Washington and Jamaica Partners of America program who additionally supported this event by USAID funds and their contributions for harmonizing the events of this two-week workshop and consultation. Specifically, I would like to sincerely thank Ms. Susanna Meyer and Ms. Marsha Johnson from Washington and Jamaica USAID offices, respectively, for their outstanding support. Additionally, the support and assistance of Mr. Fitz Hoad, the field officer of the program are sincerely and gratefully appreciated. The provided report discusses results of this assignment in further detail.

NEXT STEPS and FUTURE VOLUNTEER NEEDS

- 1. Choosing the proper regulatory agency for the academy commodities.** In order to be in harmony with regulations in North America, it is recommended that meat and meat-based products follow the recommendations articulated under the Hazard Analysis Critical Control Point (HACCP) regulations, and the remaining of the commodities follow the information discussed associated with Preventive Control for Human Food regulation of the Food Safety Modernization Act. This, in addition to following the local regulatory requirements, will augment the competitiveness of local products for further export to North America, a key priority for the academy and academy stakeholders.
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 - 4. d Eliminating standing water and improvement in Sanitation Standard Operating Procedures of the processing plant to reduce risk of cross-contamination of final**

John Ogonowski and Doug Bereuter Farmer-to-Farmer Program
Volunteer Recommendations Form

Name of Volunteer: Dr. Aliyar Cyrus Fouladkhah

Country of Service: Jamaica **Dates of Trip:** February 28, 2022 to March 12, 2022

# of Persons <i>Formally</i> Trained ¹ – male:	4	
# of Persons <i>Formally</i> Trained – female:	14	
# of Persons <i>Formally</i> Trained – Non-Binary:	0	
# of Persons <i>Formally</i> Trained who are Youth:	3	
# of Persons <i>Formally</i> Trained – total:	21	

****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
Choosing the proper regulatory agency for the academy commodities	Ebony Park HEART Academy	12 months after competition of assignment
Incorporating workshop teaching material into the Ebony Park HEART academy teaching curriculum.	Ebony Park HEART Academy	12 months after competition of assignment
Improving control of allergen cross-contact, labeling, and improving traceability of the products produced in the academy.	Ebony Park HEART Academy	12 months after competition of assignment
Reducing the risk of cross-contamination with microbial pathogens during the operation.	Ebony Park HEART Academy	12 months after competition of assignment

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.*

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/>

**Public Health & FSMA Preventive Control for Qualified Individual (PC QI) Workshop
March 1 to 3 2022, Lead Instructor: Dr. Aliyar Cyrus Fouladkhah* February 22, 2022**

Dear participants,

It is my pleasure to welcome you to our 2022 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 for Food Safety Modernization Act (FSMA) Preventive Control for Qualified Individuals (PC QI) training. This workshop will be held in person for the industry, academia, and NGO members of the Ebony Park in Kingston/Clarendon Jamaica. Due to ongoing national and global respiratory pandemic/endemic participants are requested to adhere to public health guidelines including wearing high-quality masks and practicing social distancing to minimize the risk of respiratory disease transmission.

In-person participants are expected on March 1 to 3 2022, during the below-mentioned times. We will additionally hold optional meetings on March 4, 2022 for further specific and one-by-one discussions/consultation 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 weblink and 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 national and global commerce while ensuring the public's health.

If you have any question about the workshop, please take the liberty in contacting me at +1(970) 690-7392 or via email (aliyar.fouladkhah@aya.yale.edu).

Best wishes,

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

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



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Tennessee State University**

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3500 John A. Merritt Boulevard, Nashville, TN 37209
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Email: afouladk@tnstate.edu or aliyar.fouladkhah@aya.yale.edu
Webpage: <https://publichealthmicrobiology.education/>

Workshop Schedule:

Tuesday, March 1, 2022 (required): 8:30 am to 5:00 pm

- ✚ Introductions from instructor and participants
- ✚ FSMA Overview*
- ✚ Food Safety Under the Landscape of Climate Change*
- ✚ Chapters 1 to 7^

Wednesday, March 2, 2022 (required): 8:30 am to 5:00 pm

- ✚ Exotic and Transboundary Diseases*
- ✚ Chapters 8 to 12^

Thursday, March 3, 2022 (required): 8:30 am to 5:00 pm

- ✚ Labeling and Claims and GRAS List*
- ✚ Chapters 13 to 16
- ✚ Watching 2 vidoes: Regulation Overview and FSMA Technical Assistance
- ✚ Awarding of the certificates

Friday, March 4, 2022 (Optional): 8:30 am to 5:00 pm

- ✚ One-on-one consultation with a process authority
- ✚ Individual discussions about product safety and regulatory affairs

* *From the public health microbiology foundation, ^from the FSPCA curriculum*

**For completion of 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_2azDBwx12MR4WNM



The Assignment



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



FARMER-TO-FARMER VOLUNTEER ASSIGNMENT FORM

Partners of the Americas’ USAID-funded Farmer-to-Farmer Program (F2F) provides technical assistance to agricultural producers, organizations, agribusinesses, and universities in Latin America and the Caribbean. Through F2F, U.S. specialists spend two to three weeks on specific technical assignments, working directly with counterparts in the region to address local needs.

GENERAL INFORMATION

Type of Volunteer Requested: Food Safety Preventive Controls Specialist
Country: **Jamaica**
Country Project: Rural Adaptation and Resilience
Best Dates for Volunteer Visit: 2 Weeks February-March 2022

PROJECT OVERVIEW

The objective of the Farmer-to-Farmer (F2F) Jamaica Rural Adaptation and Resilience Country Strategy (RAR) is to increase the resilience of vulnerable populations to the impacts of changing climate and weather patterns. The project will involve a crosscutting approach, focused primarily in rural agricultural communities, to increase awareness, build capacity, and promote mitigation and adaptation strategies for increased volatility of weather patterns and its detrimental effects on Jamaica’s agriculture sector. 20% of Jamaica’s employed population works in the farming sector. Volunteer assignments will target this population with training on climate-smart agriculture, irrigation planning, and other activities that add to farmer resilience.

Assignment will be a follow-up to a virtual assignment in Food Safety by volunteer Dr Aliyar Fouladkhah in May 2021 and also HACCP and Food Safety Training with Pradeep Patnaik, Sept 2021.

ASSIGNMENT PURPOSE AND EXPECTED RESULTS

The Ebony Park Heart Academy wishes to build the capacity of its academic and production staff in Food Safety Preventive Controls Alliance (FSPCA) for integration into the colleges’ curriculum and to operate and maintain an existing food processing facility to meet local and international Food Safety standards.

A F2F volunteer is needed to instruct those assigned staff members in the rigors of establishing and maintaining FSPCA standards in all facets of the institution’s academic and commercial operations.

It is expected that at the end of the assignment the staff will be aware of the requirements of meeting FSPCA, how to adjust curriculum content for training students, and how to track the changes required for the processing plant to meet the standard.

This assignment contributes to the broader goals and objectives of the Rural Adaptation and Resilience



project by introducing the Internationally accepted concept of Food Safety to a rural, vocational training institution which is critical to providing skilled labor to the value-added commercial food sector which is largely based in processing rural farm commodities.

DESIRED QUALIFICATIONS OF VOLUNTEER

- Education: PhD in Food Science
- Experience: 10 Years' Experience
- Language: Training language will be English
- Experience working in a developing country preferred
- Flexibility

EXPECTED DELIVERABLES

- Training for 18 members of staff from the Ebony Park HEART Academy
- Training Material & sponsored FSPCA Certification for staff achievement of competency.
- F2F trip report (to be completed on the final Friday of the assignment)
- F2F Recommendations Form (to be completed on the final Friday of the assignment)
- One blog post on your F2F experience

PARTNER ORGANIZATION(S) & HOST ORGANIZATION(S)

The Host will be the Ebony Park HEART Academy NTA. Ebony Park Academy, was launched in 1987. Located in Toll Gate, Jamaica, the objective thrust of the institution is to provide training in Agricultural Business Development and Production activities. Ebony Park HEART Academy, which is rated as the top HEART Trust/NTA institution in the island for training and certification in agriculture, occupies over 500 acres of land. Practical and vocational training is the core feature of the institution’s largely agricultural curriculum which segways into other areas of training: Hospitality, Food and Beverage Handling and commercial food processing.

RESOURCES TO BE CONTRIBUTED BY HOSTS AND LOCAL PARTNERS

- Coordinate the work in the field and provide technical personnel to accompany the volunteer;
- Provide in-country transportation, office space for meetings, and facilities for trainings and/or workshops; and
- Provide supplies, equipment, and other resources for training activities.

ASSIGNMENT ITINERARY (GENERAL)

A more detailed itinerary will be prepared once the volunteer and travel dates are confirmed. After



receiving a detailed itinerary, volunteers are encouraged to directly contact field staff to ask specific questions regarding their assignment.

Accommodations: F2F will directly reserve and pay for all hotels in the field.

Transportation: F2F field staff will arrange airport pickup and provide all transportation to and from hotels in the field.

Food: Volunteers will be provided a per diem to cover meals and incidental expenses. The F2F field staff will help in identifying places to eat.

USAID CLASSIFICATION OF VOLUNTEER ASSISTANCE AND ACTIVITIES

Primary classification for volunteer assistance (select one)

- Technology Transfer
- Organizational Development
- Business/Enterprise Development
- Financial Services
- Environmental Conservation
- Administrative

The primary classification of the type of value chain activity (select one)

- Information and Input Support Services (extension services, input supplies, veterinary services, etc.)
- On-Farm Production
- Processing (primary and final product transformation, storage, transportation, etc.)
- Marketing (branding, advertising, promotion, distribution, sales, etc.)

PERSUAP – Volunteer Assignment Type

- Type 1 Volunteers provide direct assistance for the use or procurement of pesticides and are likely to recommend and/or provide advice on specific pesticide active ingredients or products.
- Type 2 Volunteers provide indirect assistance for the use or procurement of pesticides; they are not expected to recommend or provide advice on specific pesticide active ingredients or products.
- Type 3 Volunteers are not expected to be involved in pesticide issues.
- Type 4 Volunteers work on a separately-funded USAID project/activity which may have a PERSUAP governing its operations related to the use and procurement of pesticides.

RECOMMENDED PREPARATION



- Please thoroughly read and follow the instructions provided in the volunteer orientation manual.
- Bring comfortable shoes for walking and a hat for sun protection.
- Bring any videos, posters, PowerPoints, or other materials that are important to your training and activities; if translation is required, please send materials to the field staff at least two weeks before your assignment. We recommend you bring these materials uploaded on both a USB flash drive and to cloud storage (ex: Google drive) as flash drives may be prone to viruses.
- The F2F field office has a projector, flash drives, and other materials that can be used for trainings and workshops.
- Please advise the field staff if you have any specific dietary restrictions, special medical needs, food allergies, etc.
- The F2F field staff will provide a cell phone to contact field staff and make emergency calls.
- When you arrive at the airport, please wear your F2F hat so the field staff can recognize you.

CONTACT INFORMATION

PARTNERS TECHNICAL EXCHANGE JAMAICA LIMITED

1-5 ALTAMONT CRESCENT, KINGSTON 5, JAMAICA

OFFICE PHONE: (876) 622-2798

Country Director : Marsha Johnson – (876) 584-0453, mjohnson@partners.net

Administrative Assistant: Simone Williams – (876) 314-8529, swilliams@partners.net

Field Officer: Garret Lewin – (876) 547-6696, glewin@partners.net

Field Officer: Fitz Hoad – (876) 480-6143, fhoad@partners.net

Workshop Certificates of Completion



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



FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

Audrene Thomas

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

03/03/2022

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Jason Wan, Interim Director
Institute for Food Safety and Health

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Gerald Wojtala, Executive Director
International Food Protection Training Institute

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Steve Mandernach, Executive Director
Association of Food and Drug Officials



Certificate # ae4fcee





FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

Caleen Walker

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

03/03/2022

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Steve Mandernach, Executive Director
Association of Food and Drug Officials



Certificate # 3bf3b045





FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

Calvin Weise

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

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Steve Mandernach, Executive Director
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Certificate # 0c909899





FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

Carl Norman

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

03/03/2022

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Steve Mandernach, Executive Director
Association of Food and Drug Officials



Certificate # 2f77732e





FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

Casandra Hurd-Archer

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

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03/03/2022

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Steve Mandernach, Executive Director
Association of Food and Drug Officials



Certificate # 2ecce4d9





FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

Channalee Campbell

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

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Dr. Aliyar Cyrus Fouladkhah

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Certificate # 40d7a406





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Steve Mandernach, Executive Director
Association of Food and Drug Officials



Certificate # 0303c141





FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

Hermine Rodney

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

03/03/2022

A handwritten signature in black ink, appearing to read 'Jason Wan', written over a horizontal line.

Jason Wan, Interim Director
Institute for Food Safety and Health

A handwritten signature in black ink, appearing to read 'Gerald Wojtala', written over a horizontal line.

Gerald Wojtala, Executive Director
International Food Protection Training Institute

A handwritten signature in black ink, appearing to read 'Steve Mandernach', written over a horizontal line.

Steve Mandernach, Executive Director
Association of Food and Drug Officials



Certificate # d1414a0a





FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

Humayne Sutherland-Palmer

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

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Association of Food and Drug Officials



Certificate # a9513fa3





FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

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is awarded to

Kadian Kennedy

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Steve Mandernach, Executive Director
Association of Food and Drug Officials



Certificate # 2b28cc84





FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

Kayon Ellis

in recognition for having successfully completed
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Steve Mandernach, Executive Director
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Certificate # 7b7227a9





FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

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is awarded to

Kirk Williams

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Steve Mandernach, Executive Director
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Certificate # 0991df48





FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

Nathalee Cameron-Forbes

in recognition for having successfully completed
the Food Safety Preventive Controls Alliance course:
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Steve Mandernach, Executive Director
Association of Food and Drug Officials



Certificate # 97ff3a47





FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

Nordia McFarlane Cassell

in recognition for having successfully completed
the Food Safety Preventive Controls Alliance course:
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Steve Mandernach, Executive Director
Association of Food and Drug Officials



Certificate # eece33ef





FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

Paulette A. E. Wright

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

delivered by Lead Instructor

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completed on

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Certificate # ddc5da6





FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

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is awarded to

Romaine Gordon

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the Food Safety Preventive Controls Alliance course:
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International Food Protection Training Institute

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Steve Mandernach, Executive Director
Association of Food and Drug Officials



Certificate # c4aa8aaa





FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

Selma Khani

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

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International Food Protection Training Institute

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Steve Mandernach, Executive Director
Association of Food and Drug Officials



Certificate # a39888e5





FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

Terrence Thomas

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

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Association of Food and Drug Officials



Certificate # 4bd7dc89



Excerpts of Teaching Slides



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






Food Safety
Modernization Act
Certification

[3-1-2022]

Aliyar Cyrus Fouladkhah
Public Health Microbiology Laboratory
Cooperative Extension Program
Tennessee State University

1



Food Safety Modernization Act (FSMA)

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

2

Regulatory Landscape of Food Industry Before FSMA

Very small companies:

Exemption from federal requirements, need to follow state policies

Restaurant operations:

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

Food Safety Inspection Service (FSIS) of USDA:

Meat, Poultry and Egg products, HACCP requirements

Food and Drug Administration of DHHS:

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

Farmers and other food products:

No federal regulation



3

Mandated by FSMA

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



Not mandated by FSMA

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

4

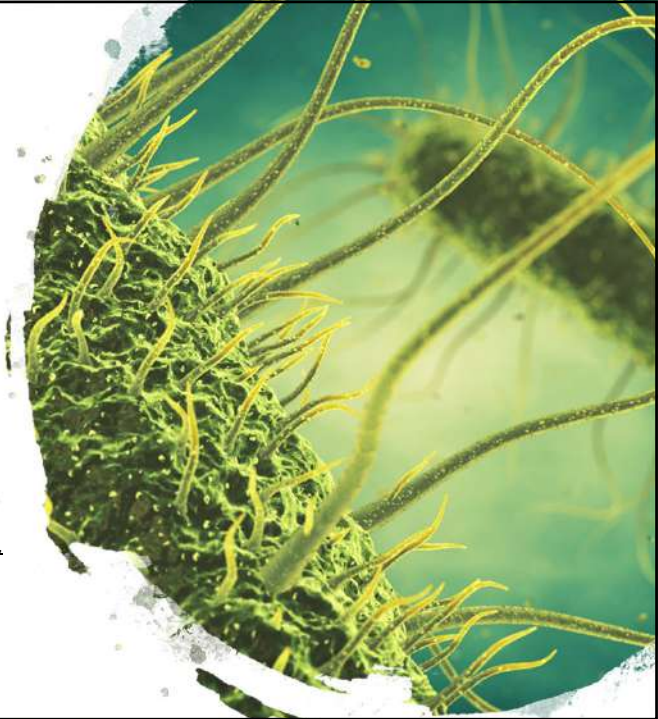
FSMA Implementation Schedule

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

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

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

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



5

Produce and Preventive Rules and Land-grant Institutions

- Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (**Produce Rule**): **Producers**
- Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (**Preventive Rule**): **Processors**
- Large producers and processors
- Small and medium size producers and processors
- Very small (hobbyists) producers and processors (local and cottage industry)
- Many of small and medium size entrepreneur will require assistance from the nations 75 land-grant institution for **safe and economical access to market.**



6

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

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

Modified Requirements:

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



7

Requirements of Preventive Rule cGMP-Current Good Manufacturing Practices

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

Exemption:

- (1) Businesses that store agricultural commodities
- (2) Businesses that selling directly to a manufacturing facility like canning operation (vertically integrated farms)

Main Principles:

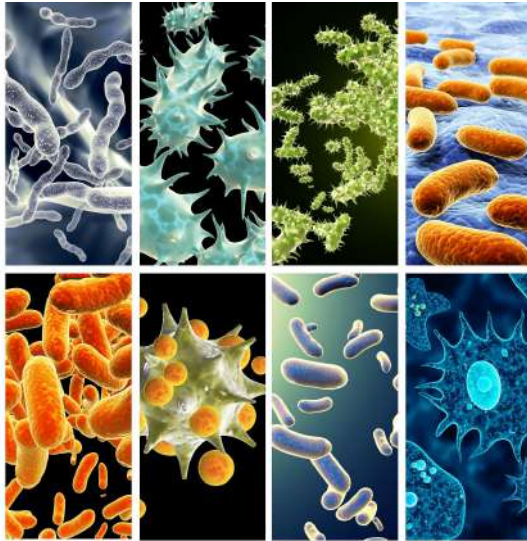
- Sanitation
- Employee training
- Environmental control and training
- Recall contingency plan
- Allergen control
- Supplier verifications
- Sanitary transportation



8

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

- Previous a 7-step plan for FSIS HACCP, 12-step plan for Codex HACCP, and currently 5-step plan for HARPC:
- **Hazard analysis**
- Identification and implementation **preventive controls**.
- **Monitoring** the performance of controls.
- Developing **corrective actions** for preventative deviation.
- **Verification and recordkeeping** of preventative controls effectiveness
- 2.5 day workshop Preventive Control Qualified Individuals (PC QI)



9

Preventive Rule: Implementation and compliance dates

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

Modified Requirements:

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


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

10

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 3-01-2022 to 3-4-2022
- Thank you:



11



FSPCA PREVENTIVE CONTROLS FOR HUMAN FOOD

Exercise Workbook

Including Food Safety Plan Worksheets

Developed by the **FSPCA**
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE



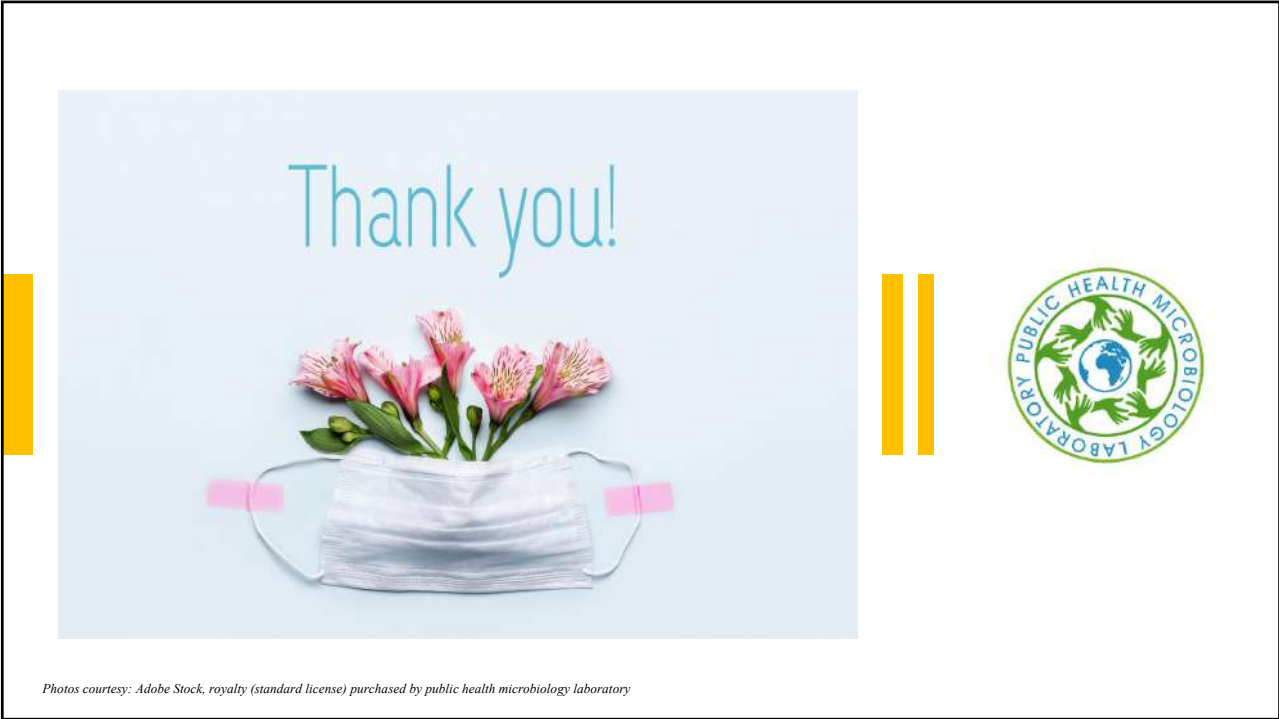
FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

Preventive Controls for Human Food

First Edition - 2016

Participant Manual

12



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

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

Ahlyar Cyrus Fomladkhan, PhD, MPH, MACE, CFS, CPH
Associate Professor, Tennessee State University
Faculty Director, Public Health Microbiology Laboratory
Founding Director, Public Health Microbiology Foundation
Tennessee State University

E21 USAID Program
March 1-3, 2022
Kingston, Jamaica
Ebony Park Academy

1

Brief Introduction to my Program

2

- 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.

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 Public Health | sas Certified Base Programmer for SAS®

Website: <https://publichealth.yale.edu/education/degrees/mph/advanced>
Video: <https://www.youtube.com/watch?v=IGVNBf0t8>

3

**Public Health Microbiology Laboratory
Tennessee State University**
MPH Curriculum Food Safety and Applied Epidemiology (now under CEPH certification)

- ❖ 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)

Website: <https://publichealthmicrobiology.education/>

PROSPECTIVE STUDENTS, EDUCATORS, AND STAKEHOLDERS

92 Website performance: 4/22/2020

* Pending account setting and internal administrative approval.
** Sub-recipient of Southern Farmer, Admin Awards.

4

Public Health Microbiology Laboratory Current Members

Current Graduate Students (Primary Advisor/Degree Chair: A. Fouladkhal)

- Sudive Aras (2018-)**, Graduate Research Assistant, (PhD candidate, Biological Sciences c. Food Microbiology)
- Jothi 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:

- Akilyah Sumlin* (2018-)**, *Dean Scholar/Undergraduate Research Assistant*
- Simen Asefaw (2019-)**, *Undergraduate student (advisor for senior project)*
- Kennedy Miller (2020-)**, *Undergraduate student (advisor for senior project)*




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


- Mr. Shahid Chowdhury***, Research Technician (2016-present)
- Dr. Niamal Kabir, PhD**, Post-doctoral Research Associate (2018-2021).
- Ms. Amir Kachingsha, MS**, Data Visualization Intern and Web Editor (2018-present).
- Dr. Naraghi, PhD, MSPH**, Visiting Scholar (2020-present).

Current Graduate Student Committee:

- Sareya Singh Hamal, PhD candidate**, Biological Sciences con. Food Microbiology (Committee member).
- Yan Tian, PhD student**, Biological Sciences con. Genomics & Immunology (Committee member).
- Zedonta Williams, MS student**, M.S. degree in Food and Animal Sciences (Committee member).

* Supported by office of the Dean



5

Students Awards Adviser: A. Fouladkhal > 45 awards and Scholarships (2017-2020)

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

Public Health Microbiology Laboratory



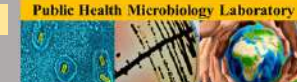



**2020 Tennessee Academy of Science
Virtual Health and Medical Sciences Division**
1st (S. Wadood), 2nd (S. Aras), 3rd (N. Kabir); Adviser: A. Fouladkhal

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

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

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.

6

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

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

A. Fouladkhal: Competition Founder and Director

- 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. Fouladkhal)
- Current AFRI Application Pending

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

Emerging Leader Categories:
1st Place (Gold): Dr. M. Naraghi, University of Tennessee Knoxville, Knoxville, TN
2nd Place (Silver): Dr. D. Naraghi, University of Tennessee Knoxville, Knoxville, TN
3rd Place (Bronze): Dr. S. Aras, University of Tennessee Knoxville, Knoxville, TN

Graduate to Oral Competition for Undergrads:
1st Place (Gold): Dr. S. Aras, University of Tennessee Knoxville, Knoxville, TN
2nd Place (Silver): Dr. D. Naraghi, University of Tennessee Knoxville, Knoxville, TN
3rd Place (Bronze): Dr. M. Naraghi, University of Tennessee Knoxville, Knoxville, TN

Graduate to Poster Competition for Undergrads:
1st Place (Gold): Dr. S. Aras, University of Tennessee Knoxville, Knoxville, TN
2nd Place (Silver): Dr. D. Naraghi, University of Tennessee Knoxville, Knoxville, TN
3rd Place (Bronze): Dr. M. Naraghi, University of Tennessee Knoxville, Knoxville, TN

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






2019 Graduate Oral Competition Winners:
1st Place (Gold): Dr. S. Aras, University of Tennessee Knoxville, Knoxville, TN
2nd Place (Silver): Dr. D. Naraghi, University of Tennessee Knoxville, Knoxville, TN
3rd Place (Bronze): Dr. M. Naraghi, University of Tennessee Knoxville, Knoxville, TN

2019 Graduate Poster Competition Winners:
1st Place (Gold): Dr. S. Aras, University of Tennessee Knoxville, Knoxville, TN
2nd Place (Silver): Dr. D. Naraghi, University of Tennessee Knoxville, Knoxville, TN
3rd Place (Bronze): Dr. M. Naraghi, University of Tennessee Knoxville, Knoxville, TN

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

2018 Graduate Competition Winners:
1st Place (Gold): Dr. S. Aras, University of Tennessee Knoxville, Knoxville, TN
2nd Place (Silver): Dr. D. Naraghi, University of Tennessee Knoxville, Knoxville, TN
3rd Place (Bronze): Dr. M. Naraghi, University of Tennessee Knoxville, Knoxville, TN

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

7

Teaching in Tennessee and Internationally

Graduate Course in Food Policy and Regulations

2020 Student Evaluation:

- "...Dr. Fouladkhal 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:




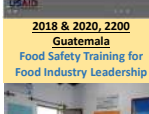





- "Dr. Fouladkhal is an excellent professor. He does the absolute best job of making students feel comfortable making discussion in class and is exceptionally knowledgeable in the area of food sciences. The in class exercises are definitely helpful to make sure the lectures are being retained and assists 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. Fouladkhal. I learned so much in the class and my knowledge on food policies and regulation has increased a thousandfold."
- "Everything was well organized, 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. Fouladkhal."
- "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, 2022 Haiti (Distant Appointment) Haiti Government, Fortification with iron, vitamin b12, and zinc**
- 2019, Philippi Township, Cape Town, South Africa: HIV Prevention Training**
- 2018 & 2020, 2200 Guatemala** Food Safety Training for Food Industry Leadership
- 2017 Santiago, Dominican Republic** USAID Public Health and Microbiology Training Faculty and Staff of ISA University

8

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/tpa/>

(2) Additionally, Serve on State Variance

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

Serving as FSPCA Lead Instructor since 2016:


(3) Preventive Control Qualified Individual (PC QI) Certifications. Meeting requirements drug administration.



ASSOCIATION OF FOOD AND DRUG OFFICIALS

9

Food Processing Support Center of Public Health Microbiology Foundation



Outreach Clients:
Food Processing Support Center
(Updated January 2022)

Stakeholder Profile:
Food Processing Center Clients
(Updated January 2022)

- Start-up Entrepreneurs: 33%
- Established Companies: 67%



Demographics:
Clients Received Supported
(Updated January 2022)

- Female: 48%
- Male: 52%

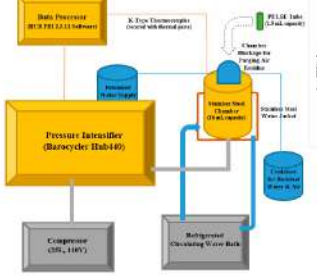

10

Research Responsibility:


- Elevated Hydrostatic Pressure
- Bacterial Biofilm
- Effects of Climate Change on infectious disease

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

Alison et al., 2018



High Pressure Processing, Public Health Microbiology Laboratory

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

11

Coming Soon...





Ask Cyrus!?

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

<https://publichealthmicrobiology.education/ask-cyrus>

12



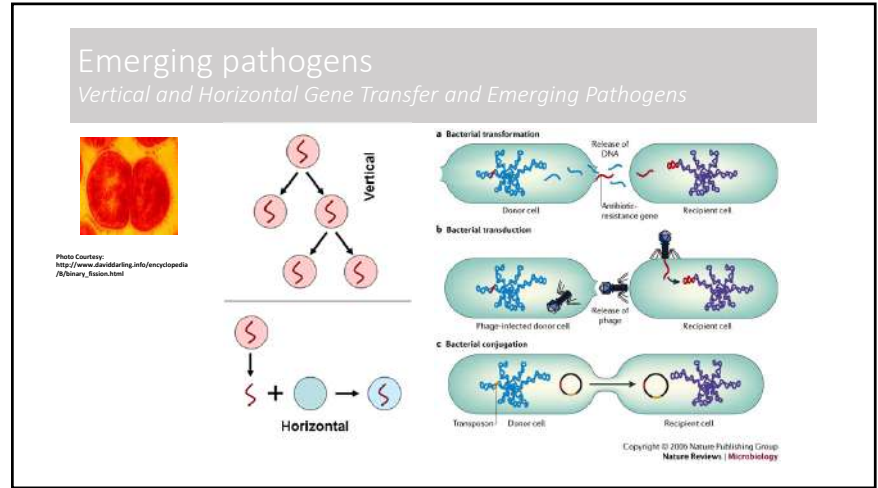
Epidemiology of Foodborne Diseases



13

Emerging pathogens

Vertical and Horizontal Gene Transfer and Emerging Pathogens



Vertical

Horizontal

a Bacterial transformation
 Release of DNA
 Donor cell
 Recipient cell

b Bacterial transduction
 Phage-infected donor cell
 Release of phage
 Recipient cell

c Bacterial conjugation
 Transposon
 Donor cell
 Recipient cell

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 Nature Reviews | Microbiology

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Horizontal Gene Transfer

(a) Conjugation:
 Resistant donor cell → DNA exchange through pilus → Non-resistant recipient cell → Resistant transconjugant cell
 Plasmid- or transposon-borne ARG

(b) Transduction:
 Resistant, infected donor cell → Lysis, cell death → Phage carrying bacterial ARG → Transport to and infection of a non-resistant recipient cell → Resistant transducant cell (in lysogenic growth)

(c) Natural transformation:
 Resistant donor cell → Cell death, lysis → Free DNA w/ intact ARG → Transport to and uptake by competent, non-resistant recipient cell → Resistant transformant cell
 ARG (chromosomal or plasmid-borne)

Donn, 2012

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Planktonic cells and Biofilm Communities

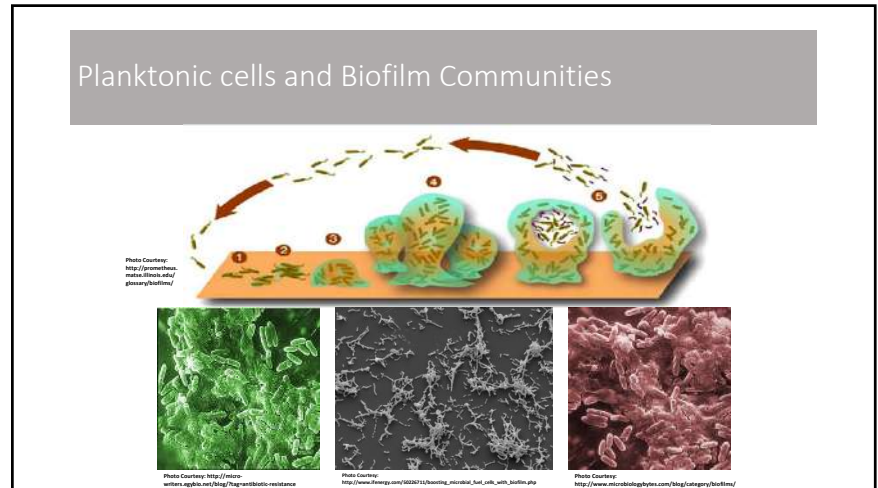


Photo Courtesy: <http://www.dailymail.co.uk/health/article.html?search=antibiotic>

Photo Courtesy: <http://www.farmhouse-microbiocentral.com/glossary/biofilm/>

Photo Courtesy: http://www.arsen.org/682072/biofilm_microbial_fat_sph_with_bacteria.php

Photo Courtesy: <http://www.microbiologybytes.com/0109/Conjugation/Biofilm/>

16

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

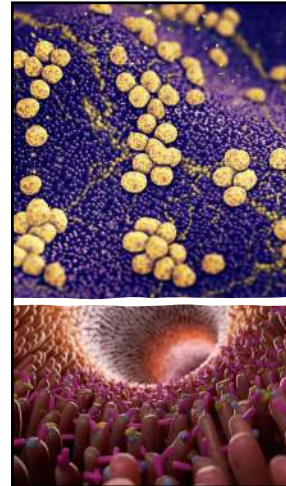
- **Leading etiological agents for illnesses:** *Norovirus* (58%), Nontyphoidal *Salmonella* serovars (11%), *Clostridium perfringens* (10%), and *Campylobacter* spp (9%).
- **Leading etiological agents for hospitalization:** Nontyphoidal *Salmonella* serovars (35%), *Norovirus* (26%), *Campylobacter*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



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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



22

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)
- *Campylobacter* (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

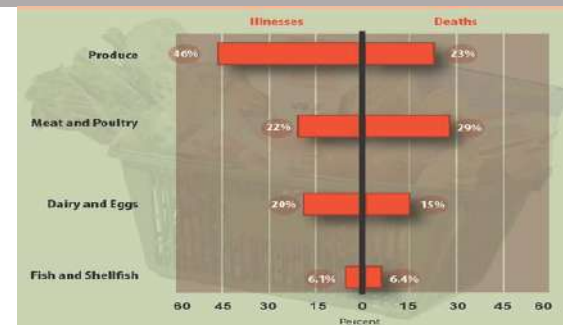
Source: WHO, 2019

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

23

CDC Estimates of Food Safety Burden

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



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

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Are these outbreaks associated with corporates and lager manufactures?

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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

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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

27

Water Safety Study

microorganisms | HDPPI

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

Madhavi K. Kotha, Sudha Anu, Sreerama Reddy, Madhulatha Choudhury and Mylen Cyren Elizabeth Kallath

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Received: 16 February 2020; Accepted: 11 March 2020; Published: 17 March 2020

Public Health Burden of Waterborne Disease

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

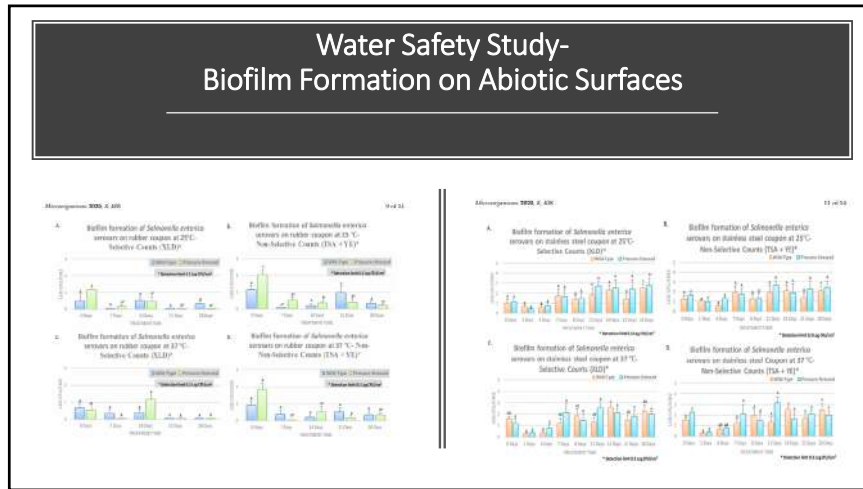
601,000 illness; 118,000 hospitalization; 6,630 deaths, and cost the economy up to \$ 8.77 billions.

A: Fate of *L. monocytogenes*, *Escherichia coli* O157:H7 and *Salmonella enterica* serovars in Surface Water at 5 °C

B: Fate of *L. monocytogenes*, *Escherichia coli* O157:H7 and *Salmonella enterica* serovars in Surface Water at 25 °C

C: Fate of *L. monocytogenes*, *Escherichia coli* O157:H7 and *Salmonella enterica* serovars in Surface Water at 37 °C

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Impact of Climate Change on Foodborne and Waterborne Infectious Diseases

30

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

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Climate Change and Public Health Microbiology

Non-typhoidal Salmonella enterica serovars

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

Climate Change:

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

At our current rate (2021 IPCC report)

- o >1.5 °C by 2040
- o >4.8 °C by 2100

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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

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Vibrio cholerae proliferation in sea water: Current Climate

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

Suitability

- 0.45 - 0.54
- 0.26 - 0.45
- 0.10 - 0.25
- 0.02 - 0.10
- 0.03

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

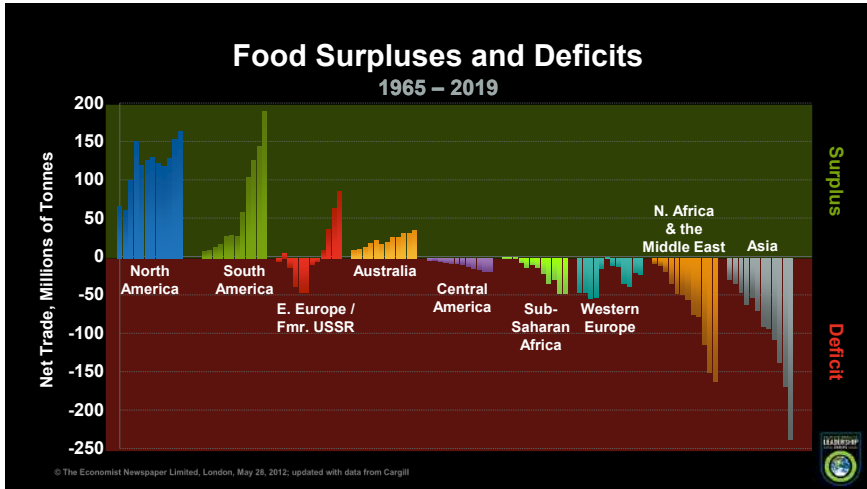
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Vibrio cholerae proliferation in sea water: Business-as-Usual Projection in 2100

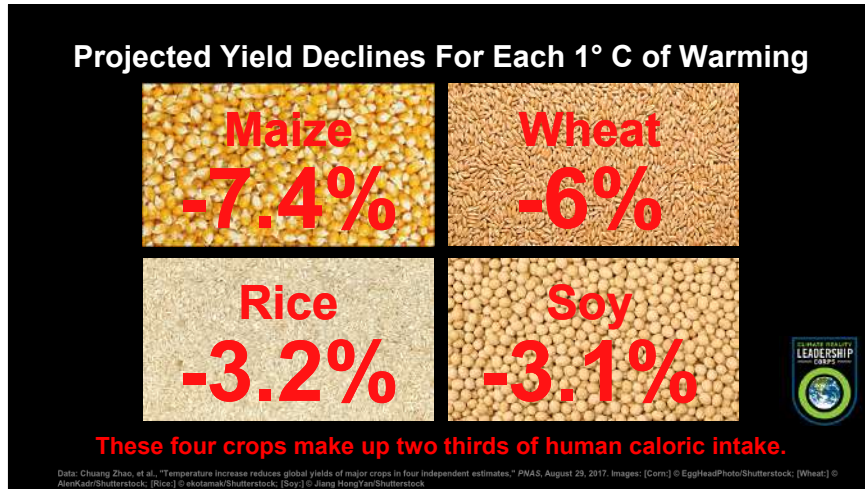
Future climate (model transference)

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

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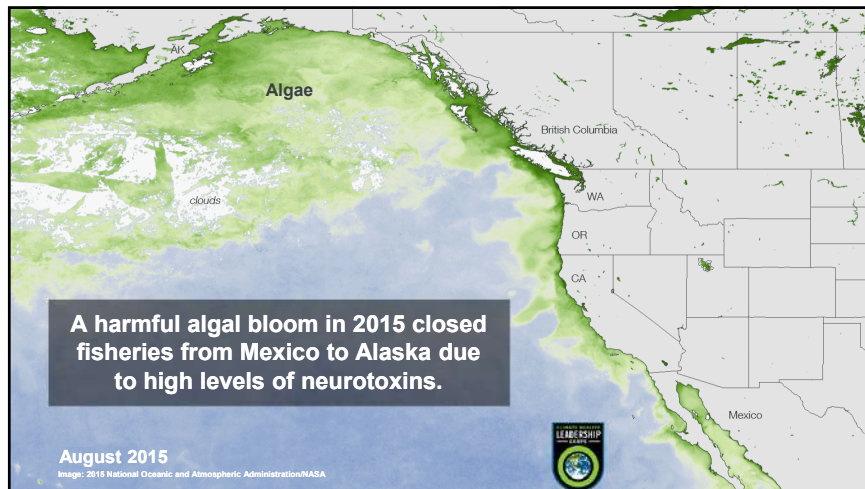
37

Other Climate-Sensitive Challenges

- **Mycotoxins** (At 2°C increase, aflatoxin, North America and Europe)
 - **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**

The Threat of Antibiotic Resistance in a Changing Climate

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Changing climate

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

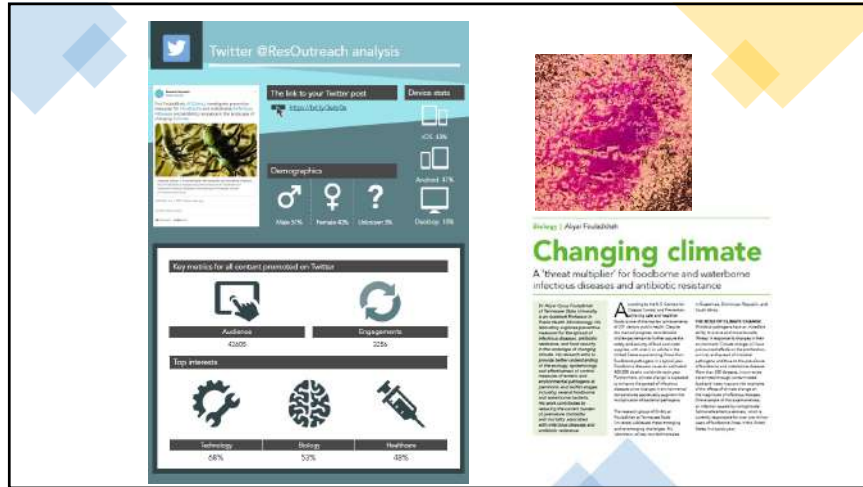
Part III: Impact Analyses

Outreach Article Available at:
<https://researchoutreach.org/articles/changing-climate-threat-multiplier-foodborne-waterborne-infectious-diseases-antibiotic-resistance/>

IMPACT ANALYSIS
Issue RO 114

Aliyar Fouladkhah

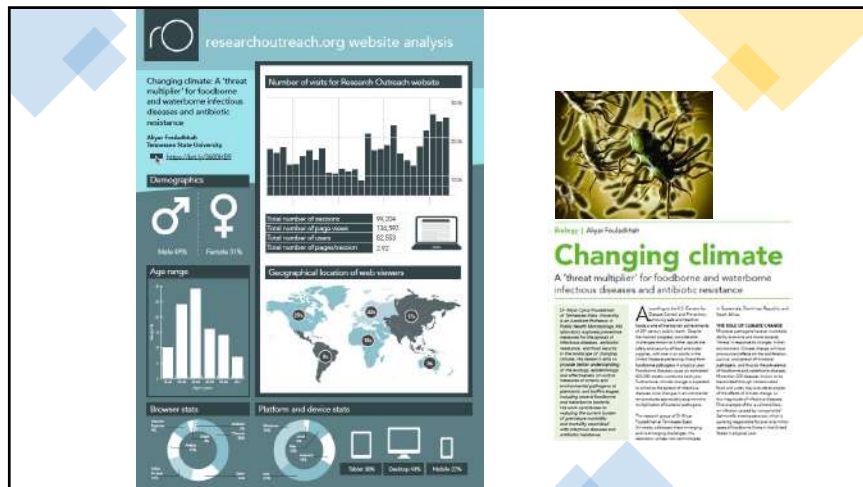
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*Response of the Government:
Food Safety Modernization Act*


44



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**

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Mandated by FSMA PC QI Certifications	Not mandated by FSMA
<ul style="list-style-type: none"> Food manufacturing (processors) Farmers and growers (producers) Transportation, retailers Imported foods Third party laboratories Local, state, and federal agencies Foreign governments 	<ul style="list-style-type: none"> 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.


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Thank you!







Dr. Aliyar Cyrus Foadkhah,
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Email: afoadkhah@tnsu.edu or aliyar_foadkhah@yva.vale.edu
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Contributions of members of the Public Health Microbiology Laboratory is gratefully acknowledged. Funding supports of the program leaders are additionally and graciously acknowledged.



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

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CLIMATE REALITY LEADERSHIP CORPS

Public Health Microbiology Laboratory



Climate Change in Picture

Public Health Microbiology Laboratory
Tennessee State University, Nashville, TN
A. Fouladkhah: Director, Public Health Microbiology Laboratory
3-3-2022 Kingston, Jamaica

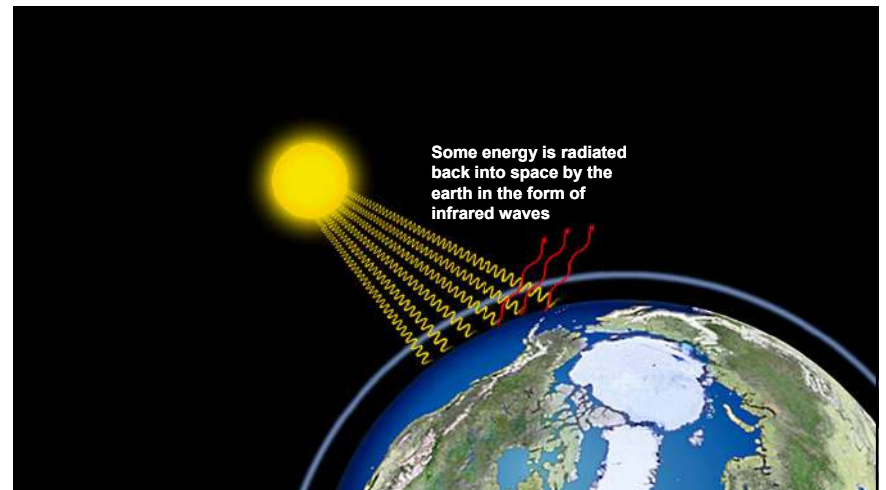
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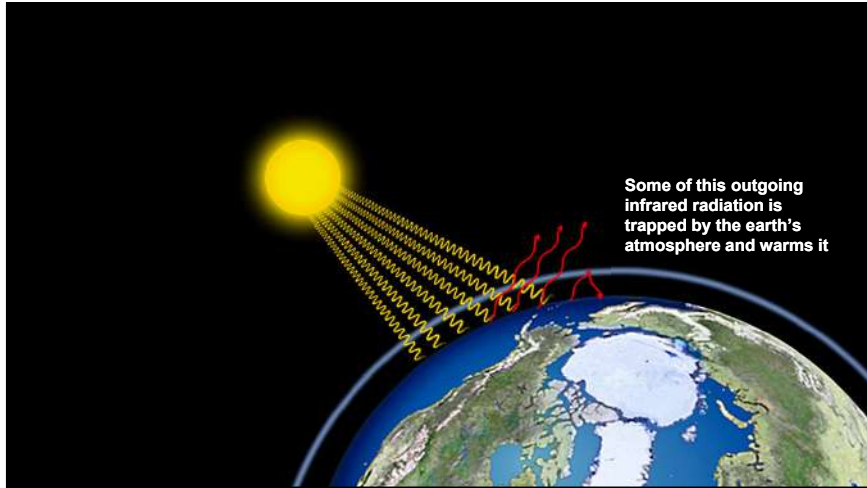
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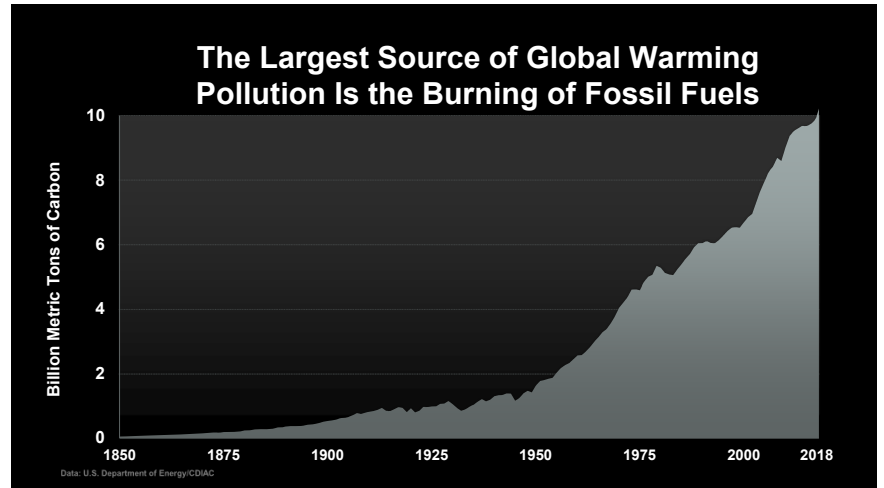
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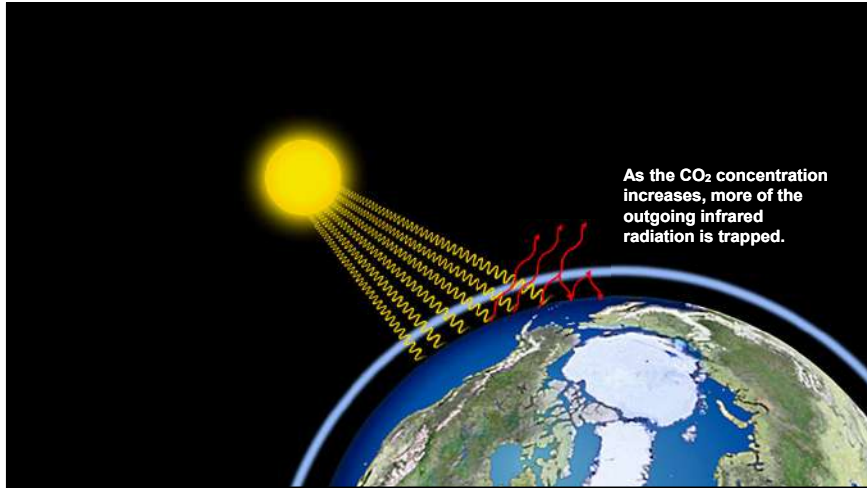
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The energy trapped by man-made global warming pollution is now “...equivalent to exploding

600,000

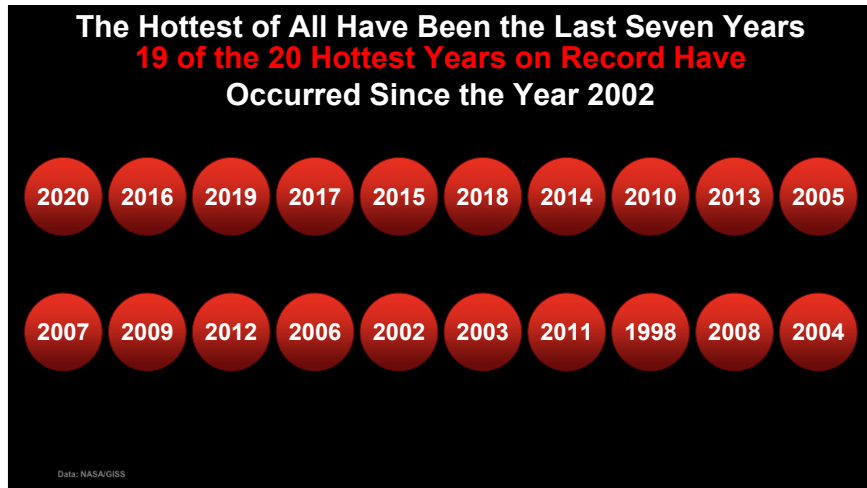
First-generation atomic bombs per day 365 days per year.”

James Hansen
Former Director, NASA Goddard Institute for Space Studies

11



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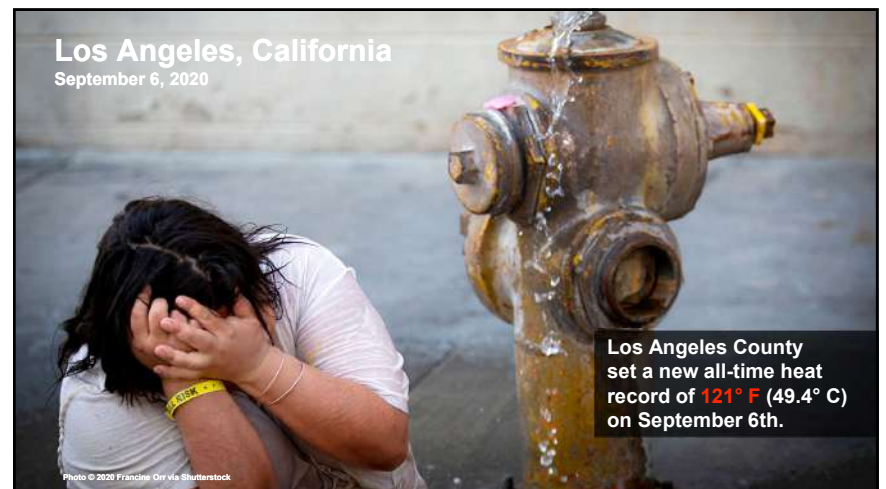
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The U.S. Southeast is projected to warm up to 8 °F this century.

14

Of the 100 U.S. counties projected to suffer the worst impacts of the climate crisis, 97 are located in the U.S. South.

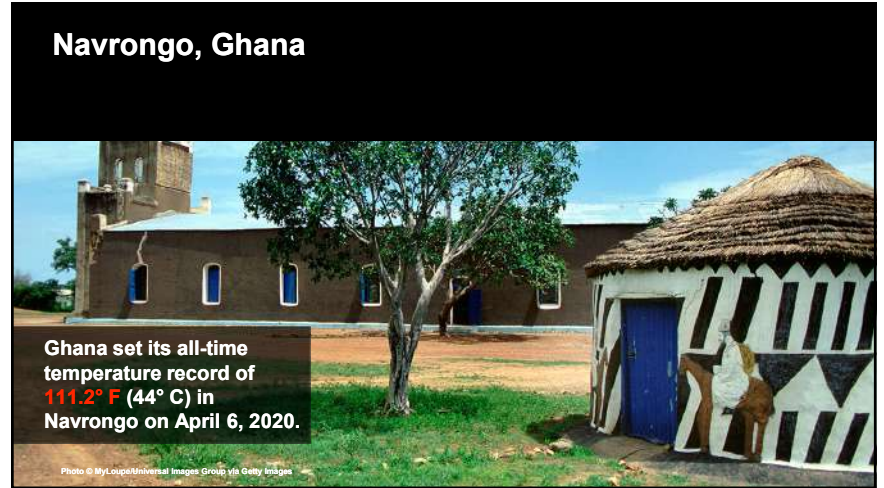
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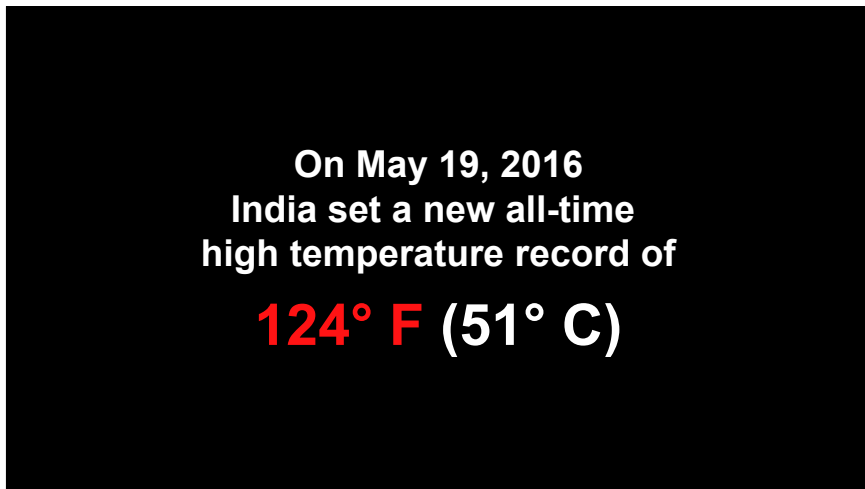
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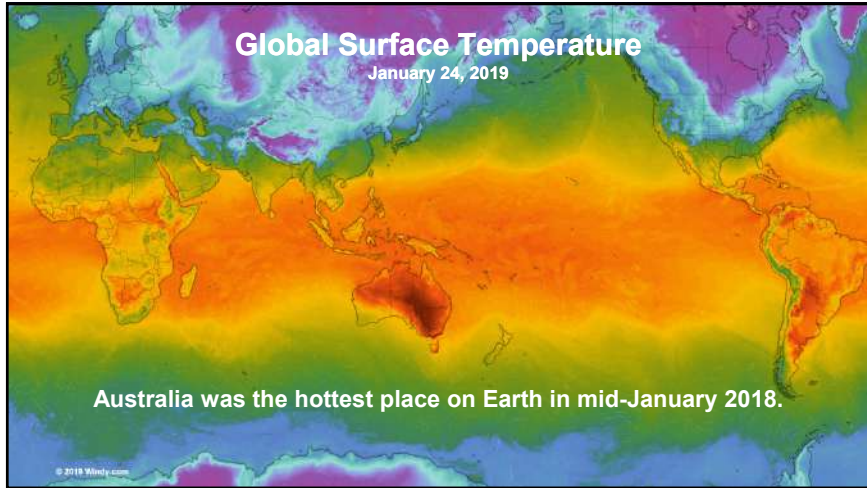
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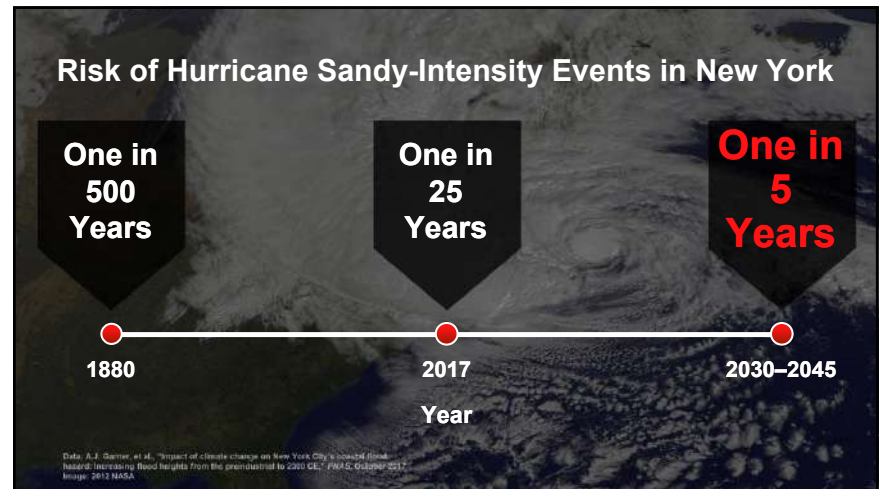


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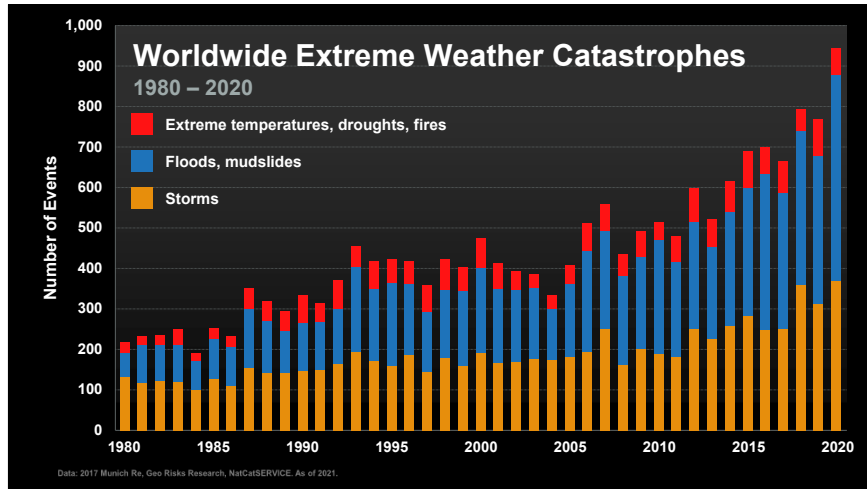
“Unrestrained climate change means we will see many more Harveys in the future.”

Michael Mann
Director, Earth System Science Center, Penn State
August 2017

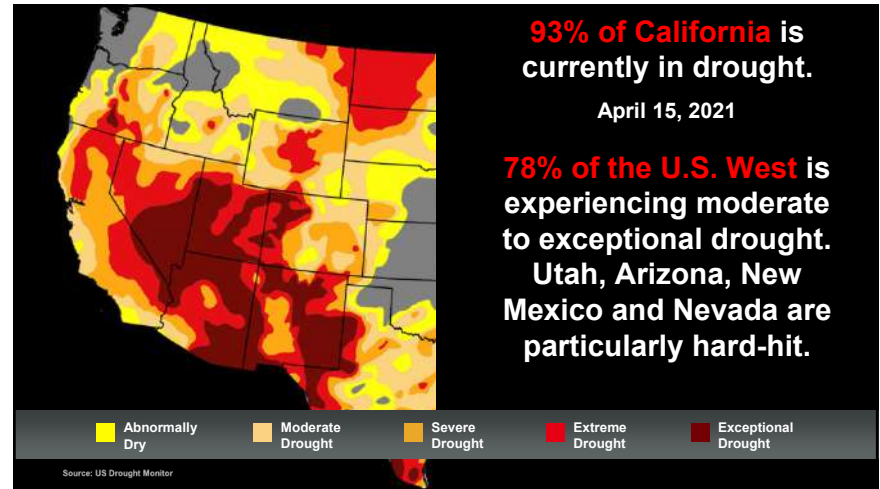
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The Swiss Army had to airlift water to thousands of cows affected by drought.

Rossinière, Switzerland
August 7, 2018

© 2018 Reuters/Deia Balibouse

41



Saint-André-de-Corcy, Ain, France
July 23, 2017

© 2017 Kostas K. Riga AP Images

42



Gila National Forest, New Mexico
June 24, 2018

The Buzzard fire burned over 50,000 acres.

© U.S. Forest Service/Gila National Forest

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Edwards, Colorado
April 1, 2018

The **fire season** in the U.S. west is now **105 days longer** than in 1970.

Photo: © 2018 Chris Dillman-Viel Daily via AP Source: Climate Central/Weddy's Wildfire—A Fiery Future, 2016

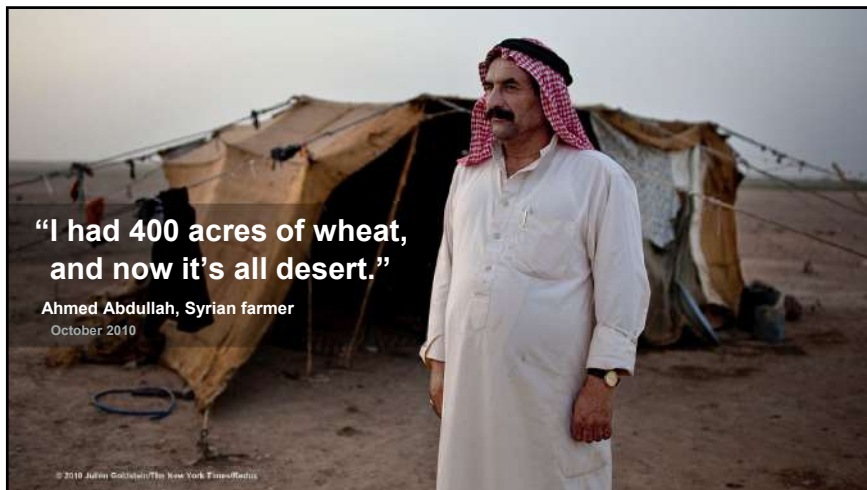
44



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The 2006 – 2010 drought turned **60%** of Syria’s fertile land into desert

...and drove **1.5 million people** into Syria’s already crowded cities

48

“...the Syrian minister of agriculture
...stated publicly that economic and social fallout
from the drought was
‘beyond our capacity as a country to deal with.’”

Cable from the U.S. Embassy in Damascus
to the State Department

November 8, 2008

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United Nation Building Entrance, NY, USA

"Human beings are members of a whole,
In creation of one essence and soul.
If one member is afflicted with pain,
Other members uneasy will remain.
If you have no sympathy for human pain,
The name of human you cannot retain."

Poem from S. Shirazi 1210-1291



50

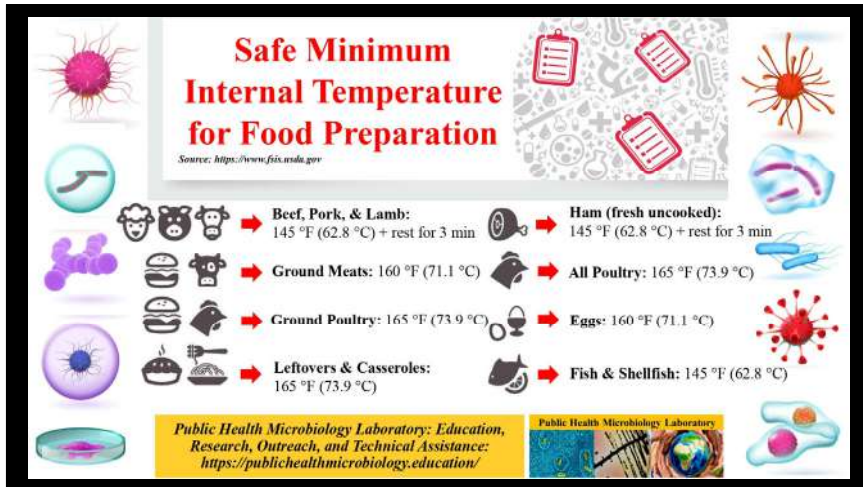
“In future, the climate in large parts of
the Middle East and North Africa
could... render some regions
uninhabitable,
which will surely contribute to
the pressure to migrate.”

Jos Lelieveld
The Max Planck Institute for Chemistry
May 2016

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The **heat index** in
Bandar Mahshahr reached
165° F
(74° C) on July 31, 2015

52

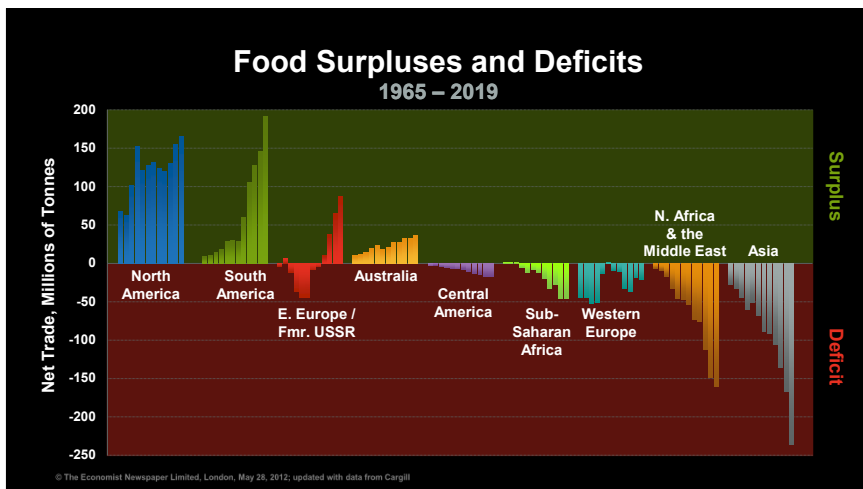


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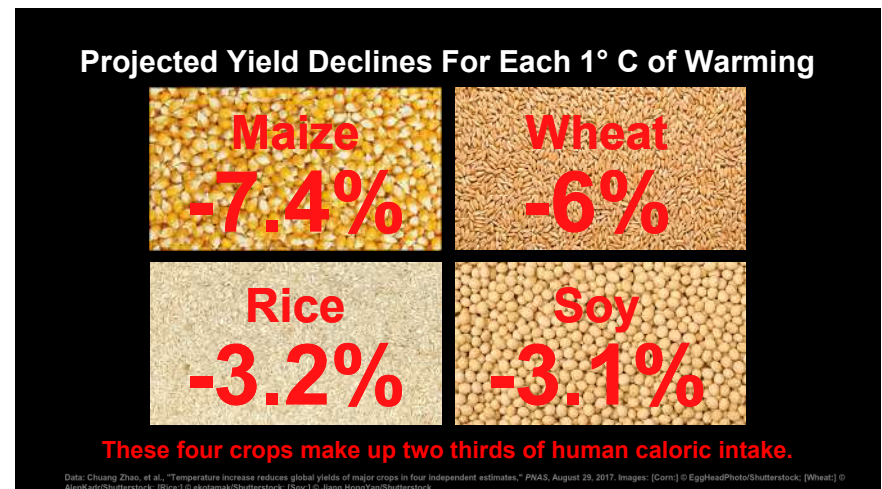
The world could see over
1 billion climate migrants
by the end of this century.

The Lancet Countdown Report
October 2017

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55



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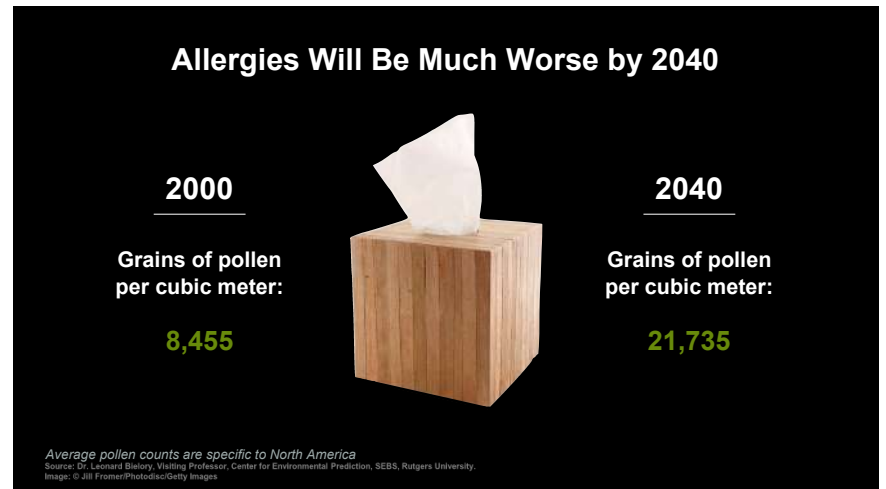
57



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60

We now risk losing up to **50% of all land-based species** in this century

Most common blood pressure medication (ACE Inhibitor- Captopril) is originally isolated from a snake Venom...
We only have access to non-extinct species.



Source: Nicholas Stern, *The Economics of Climate Change*
Photo: © Dirk Ercken/istockphoto

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Bacterial Multiplication

Binary Fission: 20 minutes or less when intrinsic and extrinsic factors are optimal.

Time	# of Bacteria
0 minutes	1
20 minutes	2
40 minutes	4
1 hour	8
2 hours	64
4 hours	4,096
6 hours	262,144
8 hours	16,777,216
12 hours	68,719,476,736

Bacteria	Estimated Infective Dose*
<i>Salmonella</i> serovars	<10 cells
Shiga toxin-producing <i>E. coli</i>	10 to 100 cells
<i>Cronobacter sakazakii</i>	10 to 100 cells
<i>Listeria monocytogenes</i>	<1000 cells
<i>Campylobacter</i> spp.	5000 to 10,000 cells
<i>Staphylococcus aureus</i>	>100,000 cells
<i>Vibrio cholerae</i>	1,000,000 cells

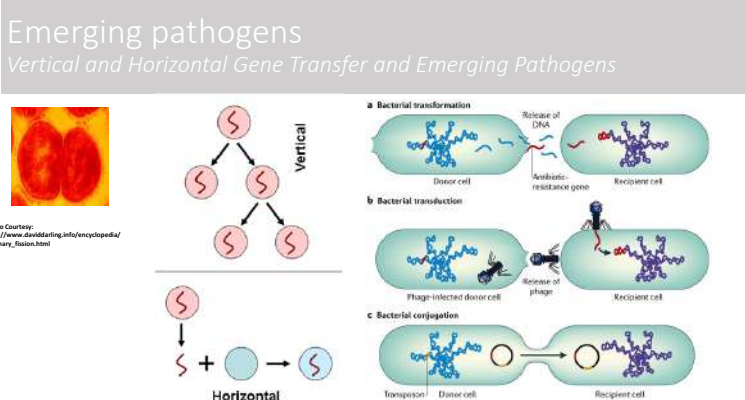
* Calculated for oral ingestion based on epidemiological data from outbreaks and human feeding trials of volunteers. Data obtained from WHO of Food and Drug Administration (2006).

Public Health Microbiology Laboratory: Education, Research, Outreach, and Technical Assistance: <https://publichealthmicrobiology.ca/active/>

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Emerging pathogens

Vertical and Horizontal Gene Transfer and Emerging Pathogens



a Bacterial transformation
Release of DNA from donor cell. Recipient cell takes up DNA and integrates resistance gene.

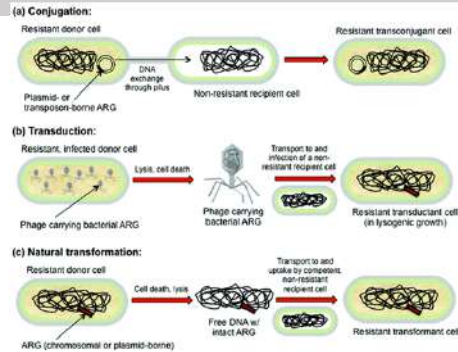
b Bacterial transduction
Phage-infected donor cell releases phage. Phage injects DNA into recipient cell.

c Bacterial conjugation
Donor cell transfers DNA to recipient cell via a pilus.

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Nature Reviews | Microbiology

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Horizontal Gene Transfer

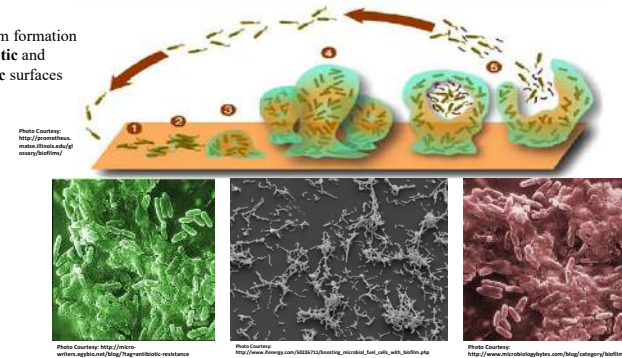


Donn, 2012

65

Planktonic cells and Biofilm Communities

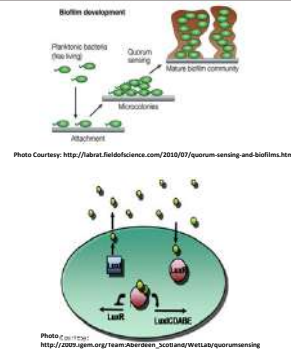
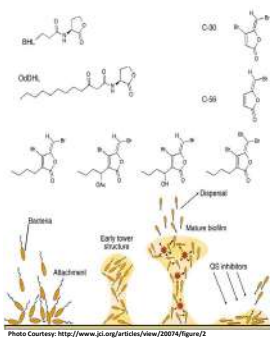
Biofilm formation on biotic and abiotic surfaces



66

Quorum Sensing and Biofilm formation

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



67

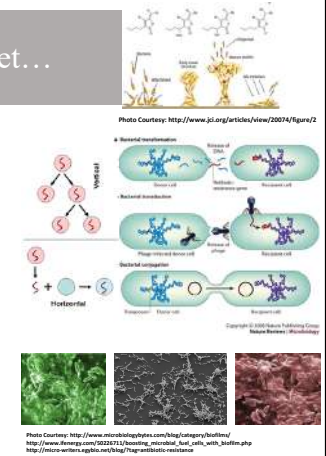
Infectious Diseases is a Moving Target...

- It is estimated only 1% of microbial community has been identified.
- Currently **etiologic agent** of 80.3% of foodborne illnesses, **56.2% of hospitalization**, and 55.5% of deaths remain unknown (in a typical year, Scallan et al., 2011).

“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



68

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

73

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

74

Vibrio spp.

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

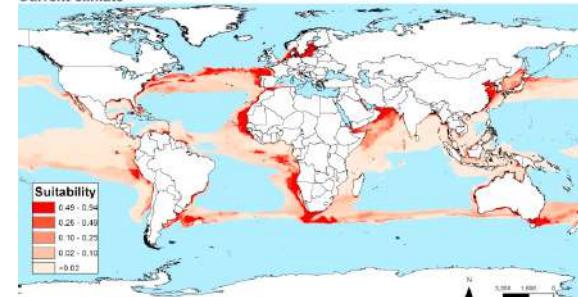
- Causing about 80,000 illness and 100 death annually in the United States.
- Infection symptoms vary depending on strain, ranging from diarrhea to high fever
- Vibrio is a halophilic bacterium and is a major concern in aquaculture industry
- Primary sources: Salt water environments and seafood
- Requires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

75

Vibrio cholerae proliferation in sea water: Current Climate

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

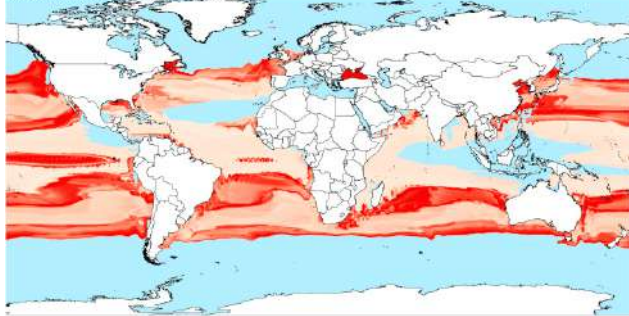


Escobar LE et al. Acta Tropica 2015;149:202-11

76

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

Future climate (model transference)



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

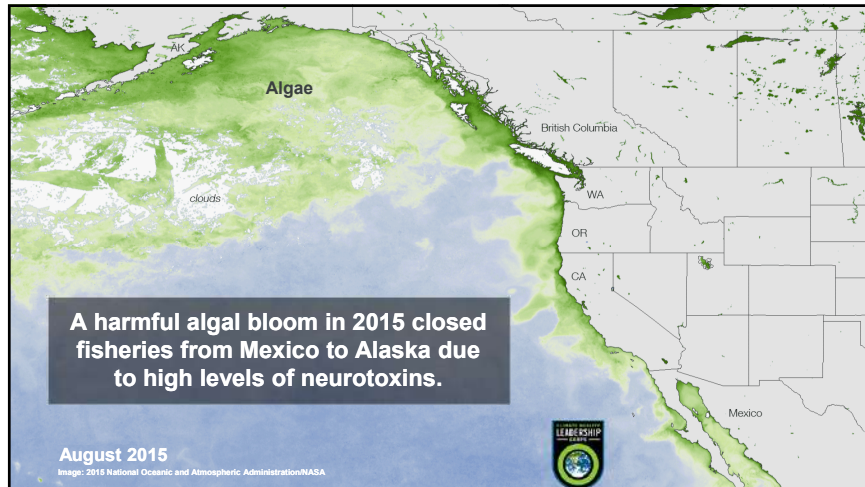
77

Other Climate-Sensitive Challenges

- **Mycotoxins** (At 2°C increase, aflatoxin, North America and Europe)
 - **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**



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August 2015

Image: 2016 National Oceanic and Atmospheric Administration/NASA

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Changing climate

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

On August 12, 2015, a harmful algal bloom (HAB) in the Pacific Northwest of the United States and Canada closed fisheries from Mexico to Alaska due to high levels of neurotoxins. This event highlights the impact of climate change on food and water safety.

Impact Analyses

Outreach Article Available at:
<https://researchoutreach.org/articles/changing-climate-threat-multiplier-foodborne-waterborne-infectious-diseases-antibiotic-resistance/>

research OUTREACH
Connecting science with society

IMPACT ANALYSIS
Issue RO 114

Aliyar Fouladkhal

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Twitter @ResOutreach analysis

The link to your Twitter post: <https://t.co/8u3k1a>

Device stats: Android 47%, Desktop 18%

Demographics: Male 57%, Female 42%, Unknown 1%

Key metrics for content promoted on Twitter:

Actions	Engagements
4200	226

Key interests:

Technology	Biology	Healthcare
66%	33%	46%

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

By Alyar Cyrus Fouladkhah, Associate Professor of Public Health Microbiology, Tennessee State University

Abstract: Climate change is expected to have a significant impact on the global food and water systems. The resulting changes in the environment will lead to an increase in the number of foodborne and waterborne infectious diseases and antibiotic resistance. This is because the changing climate will lead to an increase in the number of foodborne and waterborne pathogens, and a decrease in the effectiveness of antibiotics. The resulting changes in the environment will lead to an increase in the number of foodborne and waterborne pathogens, and a decrease in the effectiveness of antibiotics. The resulting changes in the environment will lead to an increase in the number of foodborne and waterborne pathogens, and a decrease in the effectiveness of antibiotics.

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Facebook.com/ResearchOutreach

The link to your Facebook post: <https://www.facebook.com/ResearchOutreach>

Device stats: Android 57%, Desktop 17%

Demographics: Male 49%, Female 51%

Key metrics for all content promoted on Facebook:

People created	Engagements
8727	886

Area range chart showing engagement trends from 2015 to 2017.

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

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researchoutreach.org website analysis

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

Alyar Fouladkhah, Tennessee State University

Demographics: Male 49%, Female 51%

Age range: 18-24, 25-34, 35-44, 45-54, 55-64, 65+

Browser stats: Chrome 38%, Safari 14%, Mozilla 12%

Platform and device stats: Tablet 28%, Desktop 14%, Mobile 57%

Number of visits for Research Outreach website: [Bar chart showing visits from 2015 to 2017]

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

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83

Thank you!

Public Health Microbiology Laboratory
Alyar Cyrus Fouladkhah, PhD, MPH

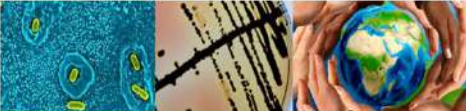
Dr. Alyar Cyrus Fouladkhah, Faculty Director, Public Health Microbiology Laboratory, Associate Professor, Tennessee State University
Email: afoulad@tnstate.edu or afoulad@publichealthmicrobiologyeducation.com
Phone: (970) 690-7392
Website: <https://publichealthmicrobiologyeducation.com>

Contributions of members of the Public Health Microbiology Laboratory in greatly acknowledged. Funding supports of the program leaders are additionally and gratefully acknowledged.

Ask Cyrus!
PUBLIC HEALTH MICROBIOLOGY LABORATORY

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


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Foodborne Diseases of Public Health Importance and Transboundary Diseases

FSMA PC QI Workshop, Jamaica
3-3-2022

Aliyar Cyrus Fouladkhah, PhD, MS, MPH, CFS, CPH
Faculty Director, Public Health Microbiology Laboratory




1

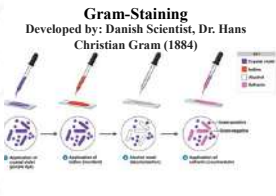
Anthrax

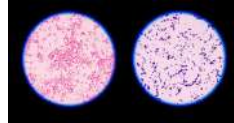
- Causative agent: *Bacillus anthracis*
- A **Gram-positive** and **spore-forming** bacteria
- Can be found as a spore in the **soil worldwide**
- Spores **viable for decades in soil**
- **In the US:** Dakotas, northwest Minnesota, Texas, and Nevada
- Common in parts of Africa, Asia, and Middle East
- In Human:
 - Skin
 - Intestine
 - Inhalation
- Animal disease
 - Septicemia and rapid death

Types of pathogen



Gram-Staining
Developed by: Danish Scientist, Dr. Hans Christian Gram (1884)






2

Anthrax


- Spores highly infective
- Remain effective during aerosolization
- Low lethal dose
- High mortality
- Person-to-person transmission rare
- **Symptoms** begin between **one day** and **two months** after the infection



3

Anthrax- Control and Treatment

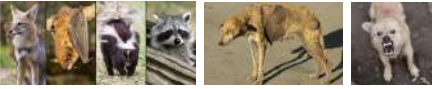
- **Four types in human:** Cutaneous (skin); Inhalation; Gastrointestinal; Injection anthrax
- Vaccine for livestock annually to prevent
- Personal Protective Equipment
 - When handling sick animals
- Disinfection:
 - **Sporicidal agents:** 5% formaldehyde, 2% glutaraldehyde, 10% sodium hydroxide
 - **Sterilization:** chlorine dioxide, formaldehyde gas, heating to 121°C for at least 30 minutes
- **Antibiotics:** effective for humans when **prescribed early**
- **Zoonotic Disease**




4

Pseudorabies

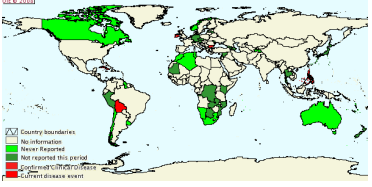
- Contagious viral diseases from herpes family
- Primary concern in domesticated pigs and feral swine (around 75 million hogs in the United States in 2021)
- Primarily spread through direct animal-to-animal (nose-to-nose)
- Other mammals
 - Reproductive
 - Nervous system
- Humans are not affected
- Could be a ubiquitous virus in some area
- Eradicated in many countries
 - Still occurs in parts of world
- Current USDA Surveillance to detect any potential case





-Different than rabies that is an important zoonotic diseases.
-Rabies death in the U.S. now < 5 per year
-About 59,000 annually worldwide (>98% from stray dogs)

Source: CDC, 2021




USDA 2021

5

Pseudorabies


- Transmission:**
 - Direct contact,
 - Reproductive,
 - Aerosol,
 - Ingestion
- Incubation period: 2-6 days**
- Common symptoms:**
 - Neurological
 - Respiratory issues
 - Itching intensively
 - Stillbirths and abortion
- Morbidity and mortality up to 100%**
- Neonates are particularly susceptible to the virus**



6

Pseudorabies

- Considered a **reportable disease**
- Could lead to **economic and trade restrictions**
- Treatment usually not recommended**
- Current **control practices:**
 - Depopulation** of the diseased
 - Test and removal** of carries
 - Offspring segregation**
- Vaccine available** in some countries for affected animals



7

Prevention of Pseudorabies

- Isolation:** new or returning animals before entry into the herd
- Disinfect** vehicles, equipment, premises, footwear
- Separation of pigs and feral swine
- USDA extensive **surveillance program**
 - All 50 states are current free since **April 2008 (commercially)**
 - Feral swine remain as a reservoir of the pathogen





Source: USDA APHIS accessed 2021

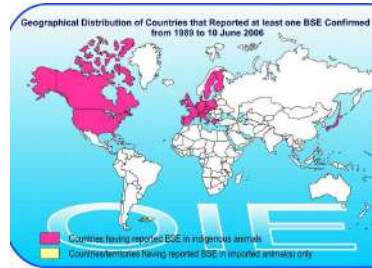


8

BSE- Bovine Spongiform Encephalopathy

Commonly known as *Mad Cow Disease*

- Caused by **prions** (infectious protein particles)
- **Cattle and humans** are susceptible
- A neurological disease that could be fatal
- **Transmitted by:**
 - Consumption of **scrapie-infected feed**
 - **Spontaneous mutation**
- Distribution is worldwide



9

Symptoms of BSE

- In Cattle
 - Incubation period is 2-8 **years**
 - Initial signs are mild and subtle
 - At final stages
 - tremors
 - loss of balance
 - death
- In Humans
 - **Unknown incubation period** (many years to many decades)
 - Neurological signs
 - Depression and schizophrenia-like symptoms
 - Could lead to death



10



BSE Management

- **Very resistant infectious agent (sanitization very difficult)**
- **Currently no effective treatment or vaccine**
- Prevention:
 - **Surveillance program and testing**
 - **Restriction in trade**
 - **Animal feed regulation** (bone meals and mammalian products)
- Outbreak in 2001-2002 in United Kingdom: Cost the industry 3.7 billion Euro

11

Brucellosis

- Caused by bacteria (several species)
(Genus *Brucella* e.g. *B. melitensis*, *B. abortus*, *B. suis*, and *B. canis*)
 - **Highly infectious** (N95 or KN95 mask during farm visits?)
 - Easily aerosolized
- **Transmission:**
 - Ingestion
 - Inhalation
 - Direct contact
- **Signs in animal:**
 - Reproductive complications
- **Signs in humans:**
 - Cyclic fever and
 - Flu-like symptoms



12

Brucellosis- Treatment & Prevention

- Treatment: long-term antibiotics (Problem: Diversity of causative agents)
 - Prevention:
 - Vaccination of calves
 - Minimizing exposure to wildlife
 - Segregation of infected animals
 - Disinfection of environment
 - No vaccine available for human
- Main infection source for human:**
- Contaminated milk, cheese, and ice-creams
 - Handling farm animals (glove, goggles, secondary outfit +mask?)
 - Hunting Activities



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Equine Encephalitis Viruses



- Three viruses:
 - Eastern (EEE)
 - Western (WEE)
 - Venezuelan (VEE)
- Transmitted by mosquitoes (**vector-borne disease**)
- **Birds** could be **asymptomatic carrier**
- **Clinical signs** in human and Equids (Horses, mules, donkeys)
 - No to mild signs to
 - Flu-like illness
 - Encephalitis in small proportions
 - **Can also infect a wide range of animals including:** mammals, birds, reptiles, and amphibians

14

Equine Encephalitis Viruses

- The viruses are **very unstable** in environment
- **Supportive care** is the only current treatment
- **Vaccine are available** for Equine
- **Vaccine for human very expensive** primarily for:
 - Researchers
 - Public health workers with enhanced exposure
- **Travel Clinics for International Travel**



15


Hendra Virus

- Viral disease **consider as emerging** (first observed in Australia)
- Natural infections had been **reported only** in:
 - Horses
 - Humans (first reported in 1994, very rare and under-reported)
- Current transmission by:
 - Fruit bats
 - **Bodily fluids and urine** of those infected
- Clinical signs in horses
 - Sudden respiratory signs
 - Nasal discharge
 - Fever
 - Encephalitis
 - Sudden death
- Clinical signs in Humans
 - Flu-like illness
 - respiratory complications
 - **Highly fatal in human, could be as high as 2 in 3 cases**



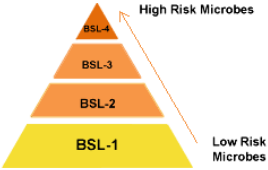
16

Hendra Virus



- Little is known about pathogen
- **People at risk:**
 - Those occupational or recreational exposure to horses
 - Those living close to "Flying fox" bats (genus *Pteropus*)
 - Researchers
- Highest level of security (CDC biosafety level 4) needed for studying the pathogen (around 4 labs in the US and <50 in the world, as of 2021 [US has about 1,500 BSL3])
- Could cause high mortality in humans
- Currently no treatment option is available

(Great topic for term paper)




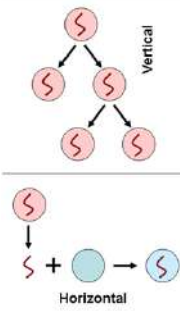
17

Main Bacterial Pathogens Associated with Animal and Human Health Diseases

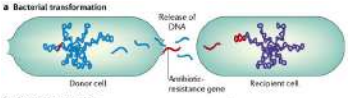
18

Emerging pathogens


Diversity, moving towards "fitness" and Emerging Pathogens

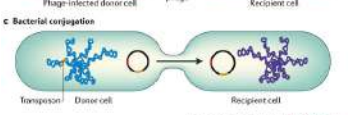
a Bacterial transformation



b Bacterial transduction



c Bacterial conjugation

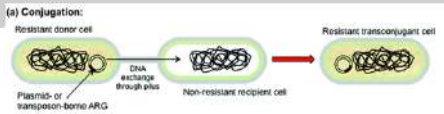


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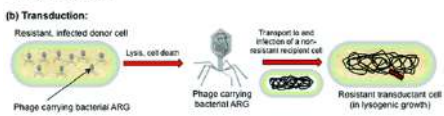
19

Horizontal Gene Transfer

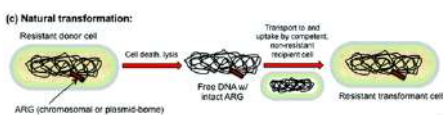
(a) Conjugation:



(b) Transduction:



(c) Natural transformation:



ARG (chromosomal or plasmid-borne)

Donn, 2012

20

Planktonic cells and Biofilm Communities

Photo Courtesy: <http://www.microwriters.eggbot.net/2017/04/09/planktonic-cells/>

Photo Courtesy: <http://www.microwriters.eggbot.net/2017/04/09/planktonic-cells/>

Photo Courtesy: <http://www.microwriters.eggbot.net/2017/04/09/planktonic-cells/>

21

Quorum Sensing and Biofilm formation *Shiga toxin-Producing E. coli and antibiotics treatment*

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

Photo Courtesy: <http://habrat.feldofscience.com/2020/07/quorum-sensing-and-biofilms.html>

Photo Courtesy: http://2009.ipm.org/Team/Abdenar_Scottland/WetLab/quorum-sensing

22

Infectious Diseases in Animals and Human is a Moving Target...

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

“Emerging” Pathogens:

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

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

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

Photo Courtesy: <http://www.microwriters.eggbot.net/2017/04/09/planktonic-cells/>

Photo Courtesy: <http://www.microwriters.eggbot.net/2017/04/09/planktonic-cells/>

Photo Courtesy: <http://www.microwriters.eggbot.net/2017/04/09/planktonic-cells/>

23

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

New outbreaks linked to Italian style meats; one third of patients hospitalized

Almost 200 sick in UK-wide Salmonella outbreak

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

Eat Smart chopped salad kit recalled in Canada over Listeria concerns

Raw goat milk recalled because of positive test for Campylobacter

24

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 caused 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)

25

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%).

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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



27

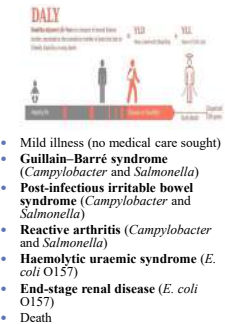
Significant Foodborne Pathogens of Public Health

Concern: Considering DALY and QALY (Scallan et al., 2015)

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

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

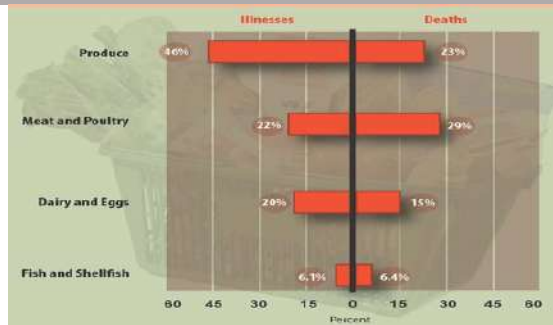
62% bacterial agents; 29% parasitic agents; 9% viral agents



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CDC Estimates of Food Safety Burden

<http://www.cdc.gov/foodborneburden/attributions-image.html#foodborne-illnesses>

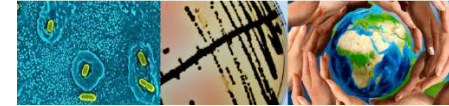


*Chart does not show 5% of illnesses and 2% of deaths attributed to other commodities. In addition, 1% of illnesses and 25% of deaths were not attributed to commodities; these were caused by pathogens not in the outbreak database, mainly *Toxoplasma* and *Vibrio vulnificus*.

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Foodborne Pathogens of Public Health Concerns >200 foodborne diseases

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



30

Salmonella serovars

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

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

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

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Salmonella serovars

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

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Salmonella serovars



Centers for Disease Control and Prevention
CDC 24/7: Saving Lives. Protecting People™



U.S. FOOD & DRUG ADMINISTRATION

Salmonella Outbreaks Linked to Backyard Poultry

Investigation Notice

Posted July 23, 2021

One to four sick people in a child younger than 5 years. Don't let young children touch chicks, ducklings, or other backyard poultry.

Fast Facts

- Illnesses: 672 (198 new)
- Hospitalizations: 157 (54 new)
- Deaths: 2 (0 new)
- States: 47 (0 new)
- Investigation status: Active



Pet Turtles: Cute But Commonly Contaminated with Salmonella

Turtles commonly carry bacteria on their outer skin and shell surfaces that can make people very ill. Deckors and bearded dragons can also infect people.



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Staphylococcus aureus

Foodborne Diseases

- Infection
- Intoxication
- Toxicoinfection

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

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

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

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Campylobacter spp.

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

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

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

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Bacillus cereus

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

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

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

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Bacillus cereus

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



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Shiga Toxin-Producing *Escherichia coli* (STEC)

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

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

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

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Shiga Toxin-Producing *Escherichia coli* (STEC)

- **Animals that can spread *E. coli* O157 to humans include:**
 - Cattle, especially calves (As high 80% in some herds), [**Concentrated and genetic similarity**]
 - Goats
 - Sheep
 - Deer
- *E. coli* infection very common in **cats and puppies younger than one week**.
- **Colostrum**, plays a pivotal role in protecting a newborn the animal's undeveloped immune system against *E. coli* infection.
- As high as **80% of agricultural animals** could carry various serogroups of shiga-toxigenic *E. coli* without having symptoms



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Vibrio spp.

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

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

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

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Yersinia enterocolitica

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

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

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

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Listeria monocytogenes

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

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

Sources: ICMSF 1995 and Bad Bug Book 2nd edition

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Cronobacter Sakazakii

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

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

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Thank you!

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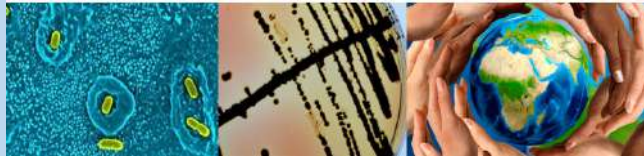


Food Labeling and Packaging Claims FDA's Generally Recognized as Safety List

3-03-2022

Tennessee State University, Nashville, TN

A. Fouladkhah: Faculty Director, Public Health Microbiology Laboratory



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Food Labeling and Advertising

Food Labeling:


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

e.g. Cholesterol-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



2



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)

3



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**

4

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**



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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)**



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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



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Claims about Nutrition and Health



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

(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 or health claim]**

Approved Health Claims

Calcium, Vitamin D, and Osteoporosis

- 21 CFR 101.79 Health claim: 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 101.77 Health claim: dietary lipids and cancer

Dietary Saturated Fat and Cholesterol and Risk of Coronary Heart Disease

- 21 CFR 101.75 Health claim: 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-energetic Carbohydrate Sweeteners and Dental Caries

- 21 CFR 101.80 Health claim: dietary non-energetic carbohydrate sweeteners and dental caries
- Final Rule: Food Labeling: Health Claims: Dietary Non-energetic Carbohydrate Sweeteners and Dental Caries May 2008
- Final Rule: Food Labeling: Health Claims: D-xylose and Dental Caries July 2003
- Final Rule: Food Labeling: Health Claims: Dietary Sugar, Alcohol and Dental Caries December 1997
- Final Rule: Food Labeling: Health Claims: Sugar, Alcohol and Dental Caries August 1996

Fiber-containing Grain Products, Fruits and Vegetables and Cancer

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

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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.



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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** require **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**

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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]



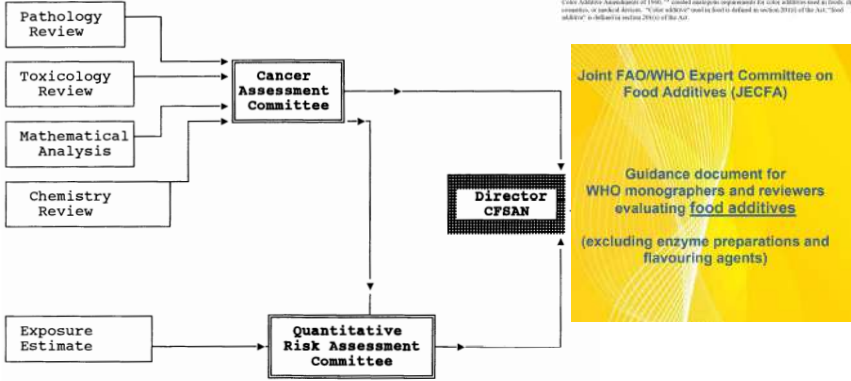


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Pre-market safety evaluation process

- 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 under the authority of 1958 when Congress passed the Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act. The Amendment provides a pre-market safety evaluation process for new substances added to food. "Food additive." A single entity, the Color Additive Amendments of 1960. "Color additive" means any substance that, when added to food, dyes, cosmetics, or varnishes. "Color additive" means both as defined in section 201(j) of the Act. "Food additive" includes section 201(i) 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)

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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)



"GRAS" is an acronym for the phrase Generally Recognized As Safe. Under sections 201(e) 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 exempt from the definition of a food additive.

- Under sections 201(e) 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 170.30(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.

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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**



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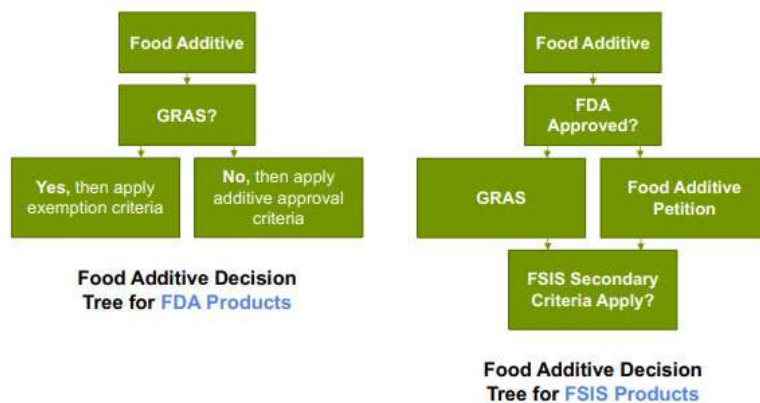
FDA GRAS LIST

- **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**



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FDA GRAS LIST



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

Antimicrobials in meat industry
Enzymes (lactase) in dairy industry



Source: Institute of Food Technologists

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Participants and Participants' Evaluation of the Workshop



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

Partners of the Americas Farmer-to-Farmer Program

Training Sign-in Sheet

Volunteer: Aliyar Fowladkhah
 Host: Ebony Park HEART NTA
 Department: FARMER TO FARMER
 Community: Clarendon
 Topic: FSPCA Training & Certificate

Field Officer: Fitz Hood
 Date: 01/03/2022
 Municipality: Ebony Park, Clarendon
 Town: May Pen

No.	First and Last Name	Male	Female	Non-Binary	29 years or younger	Profession	Email	Phone Number	Signature
	Caleen Walker		✓			Instructor	KayCaleen866@yahoo.com	339-7535	<i>C Walker</i>
	Cassandra Hurd Archer		✓			Instructor	Cassandra_hurd-archer@heartnta.org	896-0432	<i>Archer</i>
	Paulette A. Whiff		✓			Instructor	pauletto99@yahoo.com	2764245541	<i>Whiff</i>
	Karen Whittshire		✓			Demonstrator	BuzanneKW1970@gmail.com	453-8399	<i>Whittshire</i>
	Hermine Rodney		✓			Instructor	hermine_rodney@hotmail.com	430-4597	<i>HR</i>
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	Nordica Cassell					Teacher	nordicamefairlane@gmail.com	876 3766842	<i>Nordica</i>
	Channa Lee Campbell		✓			Teacher	baileychannalee@gmail.com	561 0425	<i>Channa</i>
	Hermine Palmer		✓			Feedler	Sutherlandhermine@yahoo.com	7828670	<i>Hermine</i>
	Carl Norman	✓				Farm Supervisor	Carl-norman46@yahoo.com	835 3581	<i>Carl</i>

Males: 4 Females: 11 Non-Binary: 0 Total: 15 Youth(15-29 years): 1

Field Officer Signature: *[Signature]* Volunteer Signature: *[Signature]* Dr. Aliyar Cyrus Fowladkhah



Partners of the Americas Farmer-to-Farmer Program

Training Sign-in Sheet

Volunteer: Alyer Fouladkheh Field Officer: Fitz Hoed
 Host: Ebony Park HEART NTA Date: 01/03/2022
 Department: FARMER TO FARMER Municipality: Ebony Park, Clarendon
 Community: Clarendon Town: May Pen
 Topic: FSPCA Certification Training

No.	First and Last Name	Male	Female	Non-Binary	29 years or younger	Profession	Email	Phone Number	Signature
	Humayne Sutherland Palmer		✓			Teacher	Sutherlandhumayne@yahoo.com	282-8670	[Signature]
	Channa Lee Campbell		✓			Teacher	baileychannailee@gmail	661-0425	[Signature]
	Nathalee Cameron Forbes		✓			Instructor	nathaleecameronforbes@gmail.com	(876) 834 2911	[Signature]
	Audrene Thomas		✓			Instructor	audrenetom36@gmail.com	(976) 536-4949	[Signature]
	Hermine Rodney		✓			Instructor	hermine_rodney@hotmail	876-430-4577	[Signature]
	KAYON ELLIS		✓			Instructor	kayon_ellis@heart-nta.org	876-792-3132	[Signature]
	KIRK William	✓				Instructor	Kirk_william@heart-nta.org	876-990 6000	[Signature]
	Cassandra Huel Archer		✓			Instructor	Cassandra_huel-archer@heart-nta.org	1876-876-0432	[Signature]
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	Nordica Cisseil		✓			Teacher	nordiamcfairlane@gmail	876 376 6392	[Signature]
	Kardian Kennedy		✓			Programme Coordinator	Kardian_Kennedy@heart-nta.org	876 356-3413	[Signature]
	Terrence Thomas	✓			✓	Instructor	terrence_thomas@heart-nta.org	876-777-7045	[Signature]
	Paulette A E Wright		✓			Instructor	paulet099@yahoo.com	876 422 5541	[Signature]
	Caleen Walker		✓			Instructor	Kapcalceen86b@yahoo.com		[Signature]
	Calvin Weise	✓				Insti. Manager	calvin.weise@heart-nta.org	876.590-5914	[Signature]

Males: 4 Females: 12 Non-Binary: 0 Total: 16 Youth(15-29 years): 1

Field Officer Signature: [Signature] Volunteer Signature: [Signature] Dr. Alyer Cyrus Fouladkheh



Partners of the Americas Farmer-to-Farmer Program

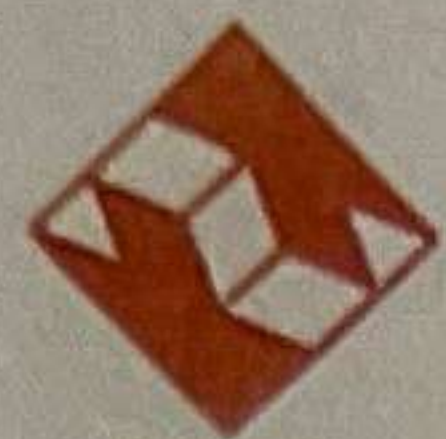
Training Sign-in Sheet

Volunteer: ALYAR FOULADKHAN Field Officer: FITZ HOAD
 Host: EBONY PARK - NTA Date: 4 MARCH 2022
 Department: FARMER TO FARMER Municipality: Ebony Park
 Community: Ebony Park Town: MAY PEN
 Topic: FSPCA Certification Training

No.	First and Last Name	Male	Female	Non-Binary	29 years or younger	Profession	Email	Phone Number	Signature
	Caleen Walker		✓			Instructor	KayCaleen866@gbh.com	876 339-7535	<i>C Walker</i>
	Hermine Rodney		✓			Instructor	hermine-rodney@hotmail	876-430-4597	<i>H Rodney</i>
	Waren W. White		✓			Demonstrator	SuzanneKW1970@gmail	753-8399	<i>W White</i>
	Paulette AE Wright		✓			Instructor	Paulette99@yahoo.com	424 5541	<i>P Wright</i>
	Cassandra Hurd Archer		✓			Instructor	Cassandra.hurd-archer@heart	896-0432	<i>C Archer</i>
	Nordia McFarlane Cavell		✓		✓	Instructor	nordiamcfarlane@gmail	876 3766842	<i>N Cavell</i>
	Channalee Campbell		✓			Instructor	baileychandler@gmail	561 0025	<i>C Campbell</i>
	Nathalie Cameron Forbes		✓			Instructor	nathaleecameronforbes@gmail	876) 834-2811	<i>N Forbes</i>
	Kathleen Kennedy		✓			Program Coordinator	Kathleen.Kennedy@heart-nat.org	816 356-3413	<i>K Kennedy</i>
	Romaine R. Gordon	✓				Instructor	romaine.gordon@hotmail.com	876 873 5862	<i>R Gordon</i>
	H. Sutherland Palmer		✓		✓	Teacher	Sutherland.humayre@gbh	782 8670	<i>H Palmer</i>
	Terrence Thomas	✓				Instructor	terrence-thomas@heart-nat.org	777-7045	<i>T Thomas</i>
	Kirk Williams	✓				Instructor	kirk-williams@heart-nat.org	876-990-6000	<i>K Williams</i>
	Calvin Weise	✓				Inst. Manager	Calvin-Weise@heart-nat.org	876 590 5914	<i>C Weise</i>

Males: 4 Females: 10 Non-Binary: 0 Total: 15 Youth(15-29 years): 2

Field Officer Signature: *[Signature]* Volunteer Signature: *[Signature]* Dr. Alyar Fouladkhan



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Training Sign-in Sheet

Volunteer: ALIYAR FOULADKAH
Host: Ebony Park NTA
Department: FARMER TO FARMER
Community: Clarendon
Topic: FSPCA Certification Training

Field Officer: Fitz Hoad
Date: 09/03/2022
Municipality: Ebony Park
Town: _____

No.	First and Last Name	Male	Female	Non-Binary	29 years or younger	Profession	Email	Phone Number	Signature
	Shua Choi		✓			Programme Coordinator	selmagkhai@heart-nta.org	876 808-1606	
	Paulito A. Wright		✓			Instructor	paulito99@yahoo.com	434 5541	
	Kedion Kennedy		✓			Programme Coordinator	Kedion.Kennedy@heart-nta.org		
	Terence Thomas	✓				Instructor	terence.thomas@heart-nta.org	777-7045	
	Humayre Palmer				✓	Instructor	humayre@stlouisbirdcare.org	282-8670	
	Carl Norman	✓				Farm Supervisor	Carl.Norman46@yahoo.com		
	Cassandra Noel Archer		✓			Instructor	Cassandra.Noel-Archer@heart-nta.org	1876 896-0432	

Males: 2 Females: 5 Non-Binary: 0 Total: 7 Youth(15-29 years): 1

Field Officer Signature:

Volunteer Signature: **Dr. Aliyar Cyrus Fouladkahan**



Partners of the Americas Farmer-to-Farmer Program

Training Sign-in Sheet

Volunteer: ALYAR FOULEADKHAN

Field Officer: FITZ WARD

Host: EBONY PARK NIA Trng Int

Date: 08/03/2022

Department: FARMER TO FARMER

Municipality: Cleveland

Community: EBONY PARK

Town: _____

Topic: FSPCA Training Certificate

No.	First and Last Name	Male	Female	Non-Binary	29 years or younger	Profession	Email	Phone Number	Signature
	Kiosha Griffiths		✓		22	trainee	Kioshagriffiths@gmail.com	1876-386-9470	K Griffiths
	Keryuri Brown	✓				FARM ATTENDANT	Keryuri.brown10@gmail.com	1876-354-1609	K. Brown
	Channalee Campbell		✓			Instructor		876 561 0425	
	Maren Wiltshire		✓			Demonstrator	Belzonne KW 1970 org	453-8399	M Wiltshire
	Sheldon Price	✓				Demonstrator	shelpnce22@yahoo.com	894-5855	Sheldon

Males: 2 Females: 3 Non-Binary: 0 Total: 5 Youth(15-29 years): 3

Field Officer Signature: [Signature]

Volunteer Signature: [Signature] Dr. Alyar Gyms Fouleadkhan



Partners of the Americas Farmer-to-Farmer Program

Training Sign-in Sheet

Volunteer: ALYAR FOULEDBKHAN
Host: EBONY PARK NTA Trng Int
Department: FARMER TO FARMER
Community: EBONY PARK
Topic: FSPCA Training Certificate

Field Officer: FITZ WARD
Date: 08/03/2022
Municipality: Cleveland
Town: _____

No.	First and Last Name	Male	Female	Non-Binary	29 years or younger	Profession	Email	Phone Number	Signature
	Kiosha Griffiths		✓		22	trainee	Kioshagriffiths@gmail.com	1876-396-9470	K Griffiths
	Kenyuri Brown	✓				FARM ATTENDANT	KenyuriBrown10@gmail.com	1876-354-1609	K. Brown
	Charndalee Campbell		✓		✓	Instructor		876 561 0425	
	Marion W. H. Shire		✓		✓	Demonstrator	Berzanne KW 1970 dig mail	453-8399	M. W. Shire
	Sheldon Price	✓				Demonstrator	shelpnce22@protonmail.com	894-5855	Sheldon

Males: 2 Females: 3 Non-Binary: 0 Total: 5 Youth(15-29 years): 3

Field Officer Signature: [Signature]

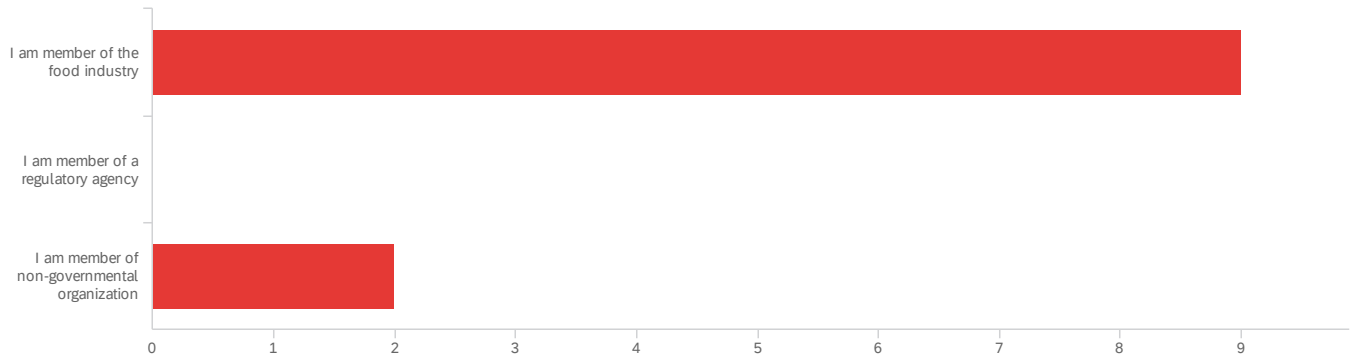
Volunteer Signature: [Signature] Mr. Alyar Gyms Fouldedkhah

Default Report

2022 FSMA PC QI Workshop (3-1 to 3-2022): Lead Instructor: Dr. Aliyar Cyrus Fouladkhah - Copy - Copy

March 7, 2022 12:53 PM MST

Q1 - What is your primary career association?

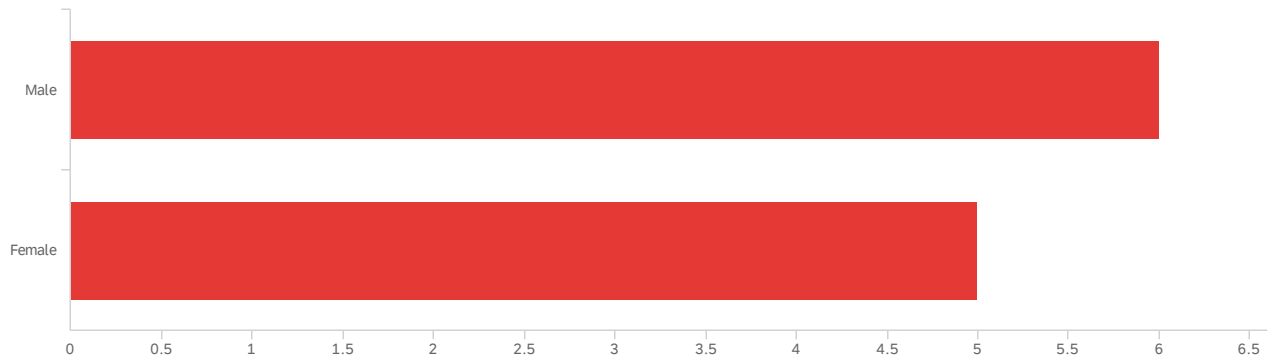


#	Field	Minimum	Maximum	Mean	Std Deviation	Variance	Count
1	What is your primary career association?	1.00	3.00	1.36	0.77	0.60	11

#	Field	Choice Count
1	I am member of the food industry	81.82% 9
2	I am member of a regulatory agency	0.00% 0
3	I am member of non-governmental organization	18.18% 2
		11

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	1.45	0.50	0.25	11

#	Field	Choice Count
1	Male	54.55% 6
2	Female	45.45% 5

11

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	97.82	2.52	6.33	11
2	My instructor communicated effectively.	71.00	100.00	95.91	8.15	66.45	11
3	My instructor stimulated my interest in the subject.	62.00	100.00	89.64	14.64	214.23	11
4	My instructor answered questions thoroughly.	83.00	100.00	96.09	5.07	25.72	11
5	My instructor treated all students with respect.	89.00	100.00	98.55	3.23	10.43	11
6	I would recommend this instructor to my friends.	93.00	100.00	98.91	2.35	5.54	11
7	My knowledge of the subject increased as a result of this workshop.	87.00	100.00	96.45	4.98	24.79	11
8	This workshop made a significant contribution to my career.	83.00	100.00	96.91	5.07	25.72	11

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...

I would like him to know that he is socially aware, customer focused and displays overall competence in SEL competences. His expertise is well appreciated.

It was very informative and easy to understand.

Great workshop and very relevant training

I really appreciated the training to the max.

Good

Very effective and interactive workshop

Very good but would really like more of this

It was a thorough and interesting workshop

End of Report