IRAC Work Group Project Summary & Action Plan

Exploration of the Implications of Whole Genome Sequencing on the Conduct and Application of Risk Assessment in Food Safety Decision-Making

Purpose

Evaluate and the implications of advancements in pathogen subtyping, using whole genome sequencing (WGS), on the conduct and application of food safety risk assessment in federal food safety decision-making. Concomitantly, evaluate the value of using a risk analysis framework to guide the collection of pathogen WGS from food, environment, and clinical samples along with metadata to inform various types of food safety risk management decisions.

Background

In December 2016, the Interagency Risk Assessment Consortium (IRAC) accepted an interagency proposal to explore the implications and application of whole genome sequencing in assessing food safety risks in federal decision-making.

Federal agencies increasingly rely on risk assessment using a variety of analytic tools to guide food safety decisions from production to consumption, such as on-farm controls to mitigate the spread of microbiological hazards and guidelines to effectively mitigate food safety risks. One scientifically-based analytic tool that has received broad acceptance nationally and internationally is quantitative microbiological risk assessment (QMRA). QMRA is well recognized as an objective, transparent, and structured approach for quantitatively evaluating risk management alternatives for mitigating food safety risks. QMRAs consist of four primary steps (FAO/WHO, 1999[1]):

- **Hazard Identification** – *The identification of the biological agent(s) capable of causing adverse health effects and which may be present in a particular food or group of foods.*
- **Exposure Assessment** – *The evaluation of the likely intake of a biological agent(s) via food as well as exposures from other sources if relevant.*
- **Hazard Characterization** (Dose-Response) – *The evaluation of the nature of the adverse health effects associated with biological agent(s) which may be present in food.*

[1] Codex Alimentarious Commission. 1999. Principles and Guidelines for the Conduct of Microbiological Risk Assessment. CAC/GL-30.

- **Risk Characterization** – An *estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment*

While the primary steps in a QMRA remain the same, the conduct and application of QMRAs as food safety decision-support tools has evolved over the past 20 years. QMRAs have been increasingly tailored to inform specific risk management decisions (Dennis et al., 2008, Dearfield et al., 2014[2]). As such, these QMRA frameworks have been used to inform the collection of targeted data to fill information gaps and enhance the usefulness of these predictive tools (Chen and Schaffner 2013).[3] However, just as QMRAs inform decisions on what data to collect or research to conduct, rapid advancement in science and information technology can change how QMRAs are conducted and the types of decisions they can inform.

With the rapid evolution in pathogen subtyping and broad acceptance and use of omics technologies such as whole-genome sequencing (WGS) for foodborne outbreak detection and source tracking, the Interagency Risk Assessment Consortium and others in the food safety risk assessment community anticipate[4,5,6] that this newer technology may also influence how food safety risks are assessed and managed, including the conduct and application of food safety QMRAs. Currently, there is limited exploration of the impact of WGS on the conduct and application of food safety risk assessment or how QMRA may provide a structure for guiding the collection of WGS data and related metadata to inform a broader array of well-defined risk management decisions.

WGS provides maximum resolution for DNA-based characterization of pathogens. While data interpretation remains a challenge (e.g., translation into physiological behavior), the rapidly decreasing costs, timely generation of more robust and discriminate subtyping information has led to increased use of WGS in foodborne disease surveillance and use in federal testing of foods and the environment. As these advancements in subtyping revolutionize outbreak surveillance, pathogen source tracking, and characterization of these hazards, including tracking drug resistance across the farm-to-table continuum, we wonder how best to leverage this tool to support decision-making. Specifically, we want to know:

- *What are the primary food safety decision contexts (e.g., recalls, major policies, etc.)?*

---

[2] SB Dennis, Kause J, Losikoff M, Engeljohn DL, and Buchanan RL. 2008. Using risk analysis for microbial food safety regulatory decision-making, pp. 137-176. *In* D.W. Schaffner (ed.), *Microbial Risk Analysis of Foods*. ASM Press, Washington, DC; KL Dearfield, Hoelzer K, and Kause JR. 2014. Review of various approaches for assessing public health risks in regulatory decision making: choosing the risk approach for the problem. *J Food Prot* 77(8): 1428-40 [2011-2013 IRAC Working Group deliverable: http://foodrisk.org/default/assets/File/IRAC_Work_Group_Clarification_of_the_Various_Approaches_for_Assessing_Risk_2011-2013.pdf (accessed November 28, 2016)].

[3] IRAC co-sponsored 2013 International Association for Food Protection symposia: *Making a Difference: Data Collection for Risk Assessments through Innovative Approaches* [available at: https://iafp.confex.com/iafp/2012/webprogram/Session1180.html (accessed March 2, 2017)]

[4] S. Brul, Bassett J, Cook P et al. 2012. 'Omics' technologies in quantitative microbial risk assessment. Trends in Food Science & Technology 27: 12-24.

[5] International Association for Food Protection European Symposium. Workshop: Next Generation MRA (Microbial Risk Assessment) – Integration of Omics Data into Assessment. Co-organizers: International Life Science Institute Europe, International Association for Food Protection, and the International Commission on Microbiological Specifications for Foods. 13-14 May, 2016. Athens, Greece. See: http://ilsi.org/wp-content/uploads/2016/08/ILSI-WS-Next-Generation-MRA_Prof.-Banati.pdf

[6] International Association for Food Protection European Symposium on Food Safety. How to Exploit Omics Data on Pathogen Behavior in Microbiological Risk Assessment: An Update on the Current Research. March 29, 2017. Brussels, Belgium. See: https://iafp.confex.com/iafp/euro17/webprogram/Session3629.html

- *How will this new science impact the various components of QMRA (hazard identification, hazard characterization, exposure assessment, and risk characterization)?*
- *Will changes be limited to the traditional components of food safety QMRAs or will these new data more broadly transform both the conduct and application of QMRAs?*
- *What are the opportunities and challenges in using WGS information in QMRAs?*
- *Can QMRA provide structure to collecting and interpreting WGS data (including meta data during traceback investigations) to further their utility in regulatory decision-making?*

Table 1. Work Group Members

Agency	Member
USDA, Food Safety and Inspection Service	Karen Becker, Philip Bronstein, Evelyn Mbandi, Uday Dessai, Emilio Esteban, Janell Kause,* Kis Robertson Hale, Gurinder Saini
FDA, Center for Food Safety and Applied Nutrition	Marc Allard, Eric Brown, Sherri Dennis*, Sofia Santillana Farakos
CDC, National Center for Emerging and Zoonotic Infectious Diseases	Arthur Liang
CDC, National Institute for Occupational Safety and Health	Brett Green
FDA, Office of Foods and Veterinary Medicine	Barry Hooberman
NIH, National Institute of Allergy and Infectious Diseases	Robert Hall
USDA, Agricultural Research Service	Andy Hwang
USDA, Animal and Plant Health Inspection Service	Wendy Hall, Randall Levings, Tod Stuber
USDA, National Institute for Food and Agriculture	Max Teplitski
USDA, Office of the Chief Scientist	Sheila Fleischhaker

*Co-leads: Janell Kause (U.S. Department of Agriculture, Food Safety and Inspection Service) and Sherri Dennis (Food and Drug Administration, Center for Food Safety and Applied Nutrition)

Working Group members and staff volunteered to explore the implications of WGS on key components of conducting food safety risk assessment (e.g., hazard identification, exposure assessment, hazard characterization/dose-response, and/or risk characterization; Table 2).

Table 2. Risk Assessment Subgroups*

Sub-Groups	Member
Hazard Identification • Mar. 22nd meeting -- responses to specific questions, 1-3 (p. 5) • Apr. 19th meeting – responses to specific questions, 4-5 (p. 5) • Jun. 22nd meeting – primary themes to all 6 questions (p.5)	Michael Bazaco, FDA Stephanie Defibaugh-Chavez, FSIS Uday Dessai, FSIS Emilio Esteban, FSIS Brett Green, CDC Wendy Hall, APHIS Randall Levings, APHIS Arthur Liang, CDC Tamika Payne, FSIS

	Aurelie Pohl, FDA Tod Stuber, APHIS Max Teplitski, NIFA Jie Zheng, FDA
Exposure Assessment • Apr. 3rd meeting -- responses to specific questions, 1-3 (p. 5) • Apr. 26th meeting – responses to specific questions, 4-5 (p. 5) • Jun. 28th meeting – primary themes to all 6 questions (p.5)	Karen Becker, FSIS Yi Chen, FDA Eric Ebel, FSIS Kathy Gensheimer, FDA Brett Green, CDC Andy, Hwang, ARS Sofia Santillana Farakos, FDA Kis Robertson Hale, FSIS Mike Williams, FSIS
Hazard Characterization • Apr. 6th meeting -- responses to specific questions, 1-3 (p. 5) • Apr. 27th meeting – responses to specific questions, 4-5 (p. 5) • Jun. 27th meeting – primary themes to all 6 questions (p.5)	Karen Becker, FSIS Uday Dessai, FSIS Eric Ebel, FSIS Sheila Fleischhaker, OCS Robert Hall, NIH Andy Hwang, ARS Julie Kase, FDA Randall Levings, APHIS André Markon, FDA Kis Robertson Hale, FSIS Sofia Santillana Farakos, FDA Mike Williams, FSIS
Risk Characterization • Apr. 7th meeting -- responses to specific questions, 1-3 (p. 5) • Apr. 24th meeting – responses to specific questions, 4-5 (p. 5) • Jun. 13th meeting – primary themes to all 6 questions (p.5)	Marc Allard, FDA Eric Ebel, FSIS Barry Hooberman, FDA Cary Parker, FDA

*Sherri Dennis (FDA) and Janell Kause (FSIS) will be actively involved in all sub-groups.

Key Questions

Specific questions to be addressed by the subgroups:

i. What unique information/ knowledge does WGS data provide to this component of QMRA?
ii. What risk management questions (i.e., primary decision context) could be addressed by utilizing WGS data in this component of QMRA?
iii. What kinds of WGS and related data are needed to enhance its utility for use in risk assessment?
iv. What other observations do you have that would benefit from additional discussion/review by the IRAC WGS workgroup?
v. What are the current knowledge gaps in applying WGS information to QMRA and what information is needed?
vi. How can WGS information be used to assess risk outside of a QMRA (e.g., risk profile)?

Work Group Activities

I. Identified **types of risk management decisions and related questions** for the application of WGS in evaluating food safety risks, including issues related to exposure (persistence, resistance/survival) and severity of outcomes (virulence, antimicrobial resistance affecting treatment of foodborne illness).

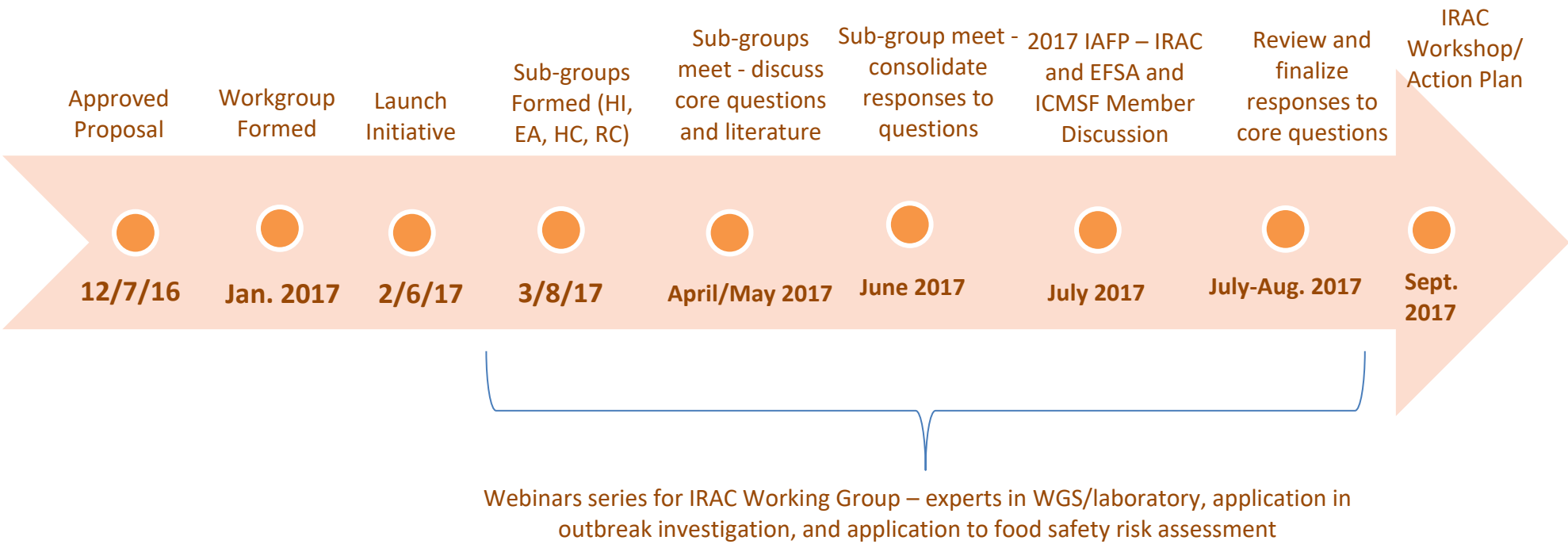
II. **Reviewed the scientific literature** on WGS and assessing food safety risk and role in decision-making. Literature was shared on secure website on Foodrisk.org {see Attachment 1).

III. **Held educational webinars** among federal partners and invited national and international experts to derive a shared understanding of the emerging field of WGS and its current application in epidemiology and potential application to improve risk assessment and decision-making (see Attachment 2)

IV. **Hosted a scientific workshop** to explore the practical application of whole genome sequencing (WGS and meta data to advance microbial risk assessment and expand the use of WGS beyond outbreak detection and pathogen sourcing (See Attachment 3). [Note: Biographies of Work Group members and Workshop participants are provided in Attachment 4.]

V. **Developed an interagency action plan** based on discussions among work group members and workshop exercise to identify and prioritize potential next steps in applying WGS in assessing food safety risks.

Work Group Timeline



Work Group Action Plan

On September 27, 2017, the Interagency Risk Assessment Consortium Work Group held a 1-day workshop to explore the practical application of whole genome sequence data through the exploration of two cases studies – understanding genomic differences in *Listeria monocytogenes* strain characteristics (e.g., virulence and resistance to interventions) for isolates from a market basket survey of ready-to-eat foods collected from retail and evaluating differences in *Salmonella* strains (e.g., based on virulence) associated with poultry.

Workshop attendees participated in an exercise to derive a prioritized list of potential "next steps" to be considered in advancing the application of whole genome sequencing data to food safety risk assessment in the context of the two presented case studies (i.e., *Salmonella* in poultry or *Listeria monocytogenes* in ready-to-eat foods). This structured, facilitated exercise was intended to individually generate a broad range of practical, creative, and original options for "next steps" from all workshop participants[7] in a short period of time. As part of an assigned team, participants individually identified options and then as a group, assigned options into categories. Both teams working concurrently in response to the same "case study" had time to review the other team's categorization of options. The two teams working on the same case study then came to consensus on the top "next steps" (based on category) and "report out" to the larger group.

Participants identified a total of 376 potential ideas for "next steps" for applying WGS to assessing *Listeria monocytogenes* risks from ready-to-eat foods and *Salmonella* in poultry. These ideas fell into several broad categories, including:

- data needs (e.g., genomic and predictive microbiological research, collection of more robust epidemiological data, and targeted microbiological testing along the supply chain),
- data mining of existing WGS data,
- broader engagement of experts to include risk assessors in discussions on WGS and current findings in epidemiology,
- enhanced data interpretation and sharing (across disciplines – risk assessors, epidemiologists, WGS experts – to derive a shared understanding of findings), and

[7] The benefit of this exercise is the derivation of a large number of ideas in a short period of time from workshop participants who represent a wide array of relevant scientific and technical expertise in food safety (i.e., risk assessment, whole genome sequencing, microbiology and epidemiology) from across the U.S. federal government.

- cross-disciplinary collaboration on initial pilots applying WGS to assessing food safety risk.

The IRAC Workgroup utilized the findings from the September 2017 Workshop to derive key next steps. Based on current needs and available resources, the five primary next steps are:

- **Collaboration:** Create mechanisms to encourage and enable strong collaboration among the multi-disciplines – risk assessors, epidemiologists, microbiologists, informatics, and WGS technical experts. One aspect of this collaborative effort is the need to overcome barriers to communication among these disciplines.

- **Engagement:** Now that there was a cross federal government discussion, we need to broaden the circle to include industry and international experts.

- **Data Needs/Research:** Identify key data needs and potential funding sources for research in those areas.

- **Pilot Project(s):** Have an 'early win' IRAC endorses the need for an in depth exploration of the risk-related findings of the WGS analysis of isolates from the Interagency *Listeria* Market Basket Study[8]. In particular, it is anticipated that analysis of the data from this study compared to analysis of samples collected a decade ago[9] could help answer a number of questions concerning the risk to consumers. . IRAC also endorses next steps in evaluating subtypes of Salmonella of concern useful to guide risk-based approaches to mitigate salmonellosis associated with meat and poultry products.

- **Meta-data**: Identify the types of meta-data that needs to be collected or more readily available to fully utilize WGS data in risk assessment. IRAC notes that to fully utilize meta-data in subsequent analyses, the data should be standardized and of high quality. [Note: a list of the types of data in the GenomeTrakr submission template that are made public are: sample number (e.g., FDA Accession # i.e., CFSAN#), Genus, Entity submitting the WGS data (e.g., FDA, or Minnesota Department of Health), Collection year of the sample, Sample source or isolate (e.g., food, environment), Country, State (if in the U.S.), and NCBI BioProject#].

The Work Group co-Chairs[10] have agreed to present the "next steps" for applying WGS to food safety risk assessment to the primary U.S. interagency group leading efforts on whole genome sequencing, i.e.,

[8] See Luchansky et al, 2017. Survey for *Listeria monocytogenes* on ready-to-eat foods from retail establishments in the United States (2010-2013): assessing potential changes of pathogen prevalence and levels in a decade. J. Food Prot. 80:903-921.
[9] Gombas et al., 2003. Survey of *Listeria monocytogenes* in ready-to-eat foods. J. Food Prot. 66:559-569.
[10] USDA-FSIS and FDA-CFSAN are the primary regulatory agencies with responsibilities (i.e., under Executive Order 12866 and, for USDA, under Public Law 103-354, 1994 Reorganization Act for Agriculture) for the advancement and application of science-based risk assessments addressing foodborne pathogens to guide federal food safety decisions

Interagency Collaboration on Genomics and Food Safety (Gen-FS[11]). It is through collaboration and consultation with Gen-FS, that the IRAC will ensure alignment in goals and activities for expanding the application of WGS in food safety and also leverage the systematic approaches in risk analysis and the risk assessment framework to target WGS data and meta-data collection efforts and effectively inform specific risk management decisions in food safety.

This Work Group, and the corresponding workshop input, provided a strong initial foundation for cross-agency discussions and the development of this initial interagency action plan to move forward to broaden the application of WGS by utilizing this emerging data to advance food safety risk assessment.

[11] The Interagency Collaboration on Genomics and Food Safety (Gen-FS) is a federal group established in 2016 to lead U.S. efforts related to the application of WGS in food safety. This interagency group is led by executives from the Department of Health and Human Service's Centers for Disease Control and Prevention, Food and Drug Administration, and the National Institutes of Health/National Center for Biotechnology Information and by U.S. Department of Agriculture's Food Safety and Inspection Service, Animal and Plant Health Inspection Service, and the Agricultural Research Service.

Attachment 1. Scientific Literature Reference List

1. Abhyankar, W., et al., *'Omics' for microbial food stability: Proteomics for the development of predictive models for bacterial spore stress survival and outgrowth.* International Journal of Food Microbiology, 2017. **240**: p. 11-18.
2. Allard, M.W., et al., *High resolution clustering of Salmonella enterica serovar Montevideo strains using a next-generation sequencing approach.* BMC Genomics, 2012. **13**: p. 32.
3. Allard, M.W., et al., *Practical Value of Food Pathogen Traceability through Building a Whole-Genome Sequencing Network and Database.* J Clin Microbiol, 2016. **54**(8): p. 1975-83.
4. Brul, S., et al., *'Omics' technologies in quantitative microbial risk assessment.* Trends in Food Science & Technology, 2012. **27**(1): p. 12-24.
5. Cook, P., *Challenges in the application of omics to risk assessment.* 2011.
6. Davies, H., *A role for "omics" technologies in food safety assessment.* Food Control, 2010. **21**(12): p. 1601-1610.
7. EPA/USDA, *Microbial Risk Assessment Guideline: Pathogenic Microorganisms with Focus on Food and Water.* 2012.
8. FAO/WHO, *Applications of Whole Genome Sequencing in food safety management.* 2016.
9. Franz, E., et al., *Exploiting the explosion of information associated with whole genome sequencing to tackle Shiga toxin-producing Escherichia coli (STEC) in global food production systems.* Int J Food Microbiol, 2014. **187**: p. 57-72.
10. Franz, E., et al., *Genetic features differentiating bovine, food, and human isolates of shiga toxin-producing Escherichia coli O157 in The Netherlands.* J Clin Microbiol, 2012. **50**(3): p. 772-80.
11. Franz, E., et al., *Molecular hazard identification of non-O157 Shiga toxin-producing Escherichia coli (STEC).* PLoS One, 2015. **10**(3): p. e0120353.
12. Havelaar, A.H., et al., *Future challenges to microbial food safety.* International Journal of Food Microbiology, 2010. **139, Supplement**: p. S79-S94.
13. Henk, C.d.B., et al., *Rapid Whole-Genome Sequencing for Surveillance of Salmonella enterica Serovar Enteritidis.* Emerging Infectious Disease journal, 2014. **20**(8): p. 1306.
14. Henriques, A.R., J.M. Cristino, and M.J. Fraqueza, *Genetic Characterization of Listeria monocytogenes Isolates from Industrial and Retail Ready-to-Eat Meat-Based Foods and Their Relationship with Clinical Strains from Human Listeriosis in Portugal.* J Food Prot, 2017. **80**(4): p. 551-560.
15. Hill A.A., M. Crotta, B. Wall, L. God, S.J. O'Brien, and J. Guitian, *Towards an Integrated Food Safety Surveillance System: A Simulaiton Study to Explore the Potential of Combining Genomic and Epidemological Metadata.* R. Soc. Open Sci. **4**: 160721 [http://dx.doi.org/10.1098/rsos.160721]
16. *Hingston*, P., et al., *Genotypes Associated with Listeria monocytogenes Isolates Displaying Impaired or Enhanced Tolerances to Cold, Salt, Acid, or Desiccation Stress.* Frontiers in Microbiology, 2017. **8**(369).
17. Hoffmann, M., et al., *Tracing Origins of the Salmonella Bareilly Strain Causing a Food-borne Outbreak in the United States.* J Infect Dis, 2016. **213**(4): p. 502-8.
18. ILSI, *Next Generation Microbiological Risk Assessment: Integration of Omics Data into Risk Assessment.* 2016.
19. ILSI, *Integration of Omics into Assessment. Introduction to the International Life Sciences Institute, Europe (ILSI Europe)*, P.D. Bánáti, Editor. 2016: Athens, Greece.
20. Jackson, B.R., et al., *Implementation of Nationwide Real-time Whole-genome Sequencing to Enhance Listeriosis Outbreak Detection and Investigation.* Clin Infect Dis, 2016. **63**(3): p. 380-6.

21. Jofré, A., et al., *Closing gaps for performing a risk assessment on Listeria monocytogenes in ready-to-eat (RTE) foods: activity 1, an extensive literature search and study selection with data extraction on L. monocytogenes in a wide range of RTE food.* EFSA Supporting Publications, 2016. **13**(12).
22. Lambert, D., et al., *Baseline Practices for the Application of Genomic Data Supporting Regulatory Food Safety.* J AOAC Int, 2017.
23. Liu, C., N. Hofstra, and E. Franz, *Impacts of climate change on the microbial safety of pre-harvest leafy green vegetables as indicated by Escherichia coli O157 and Salmonella spp.* Int J Food Microbiol, 2013. **163**(2-3): p. 119-28.
24. Membré, J.-M. and S. Guillou, *Latest developments in foodborne pathogen risk assessment.* Current Opinion in Food Science, 2016. **8**: p. 120-126.
25. NAS, *Using 21st Century Science to Improve Risk-Related Evaluations.* 2017.
26. Nastasijevic, I., et al., *Tracking of Listeria monocytogenes in meat establishment using Whole Genome Sequencing as a food safety management tool: A proof of concept.* International Journal of Food Microbiology, 2017. **257**: p. 157-164.
27. Nielsen, E.M., et al., *Closing gaps for performing a risk assessment on Listeria monocytogenes in ready-to-eat (RTE) foods: activity 3, the comparison of isolates from different compartments along the food chain, and from humans using whole genome sequencing (WGS) analysis.* EFSA Supporting Publications, 2017. **14**(2).
28. Pielaat, A., et al., *A foresight study on emerging technologies: State of the art of omics technologies and potential applications in food and feed safety. REPORT 1: Review on the state of art of omics technologies in risk assessment related to food and feed safety.* 2013.
29. Pielaat, A., et al., *First step in using molecular data for microbial food safety risk assessment; hazard identification of Escherichia coli O157:H7 by coupling genomic data with in vitro adherence to human epithelial cells.* International Journal of Food Microbiology, 2015. **213**: p. 130-138.
30. Ronholm, J., et al., *Navigating Microbiological Food Safety in the Era of Whole-Genome Sequencing.* Clinical Microbiology Reviews, 2016. **29**(4): p. 837-857.
31. Stevens, E.L., et al., *The Public Health Impact of a Publically Available, Environmental Database of Microbial Genomes.* Frontiers in Microbiology, 2017. **8**(808).
32. Tong, W., et al., *Genomics in the land of regulatory science.* Regulatory Toxicology and Pharmacology, 2015. **72**(1): p. 102-106.
33. Wang, S., et al., *Food safety trends: From globalization of whole genome sequencing to application of new tools to prevent foodborne diseases.* Trends in Food Science & Technology, 2016. **57, Part A**: p. 188-198.

Attachment 2. Invited Educational Webinars

Date: March 16, 2017**,** 12:30-2 pm ET (facilitator: Randy Duverna, FSIS/Science Staff) **Presenter:** Dr. Eric Brown, Director, Division of Microbiology Office of Regulatory Science, Center for Food Safety and Applied Nutrition, US Food and Drug Administration **Presentation:** *WGS 101: The Rationale, Mechanics, and Impact of WGS for Food Safety* **Location:** USDA/FSIS, Room 9-199, Patriot Plaza III, 355 E. Street SW, Washington, DC; Webinar	• 67 federal employees attended (60 via webinar) • **Agencies**: APHIS, ARS, CDC-NCEZID, CDC-NIOSH, FDA-OFVM, FDA-CFSAN, FSIS, NIFA, USDA-OCS
Date: April 13, 2017, 1-2:30 pm ET **Presenter:** Dr. Ian Williams, Chief, Outbreak Response and Prevention Branch, Division of Foodborne, Waterborne,& Environmental Division, National Center for Emerging and Zoonotic Infectious Diseases, Center for Disease Control and Prevention Office of Regulatory Science, Center for Food Safety and Applied **Presentation:** *Whole Genome Sequencing: The Transformation of Surveillance and Outbreak Investigation for Foodborne and Enteric Pathogens* **Location:** Webinar (facilitator: Jude Smedra, FSIS/Science Staff)	• 40 federal employees attended (via webinar) • **Agencies**: AMS, APHIS, ARS, CDC-NCEZID, CDC-NIOSH, FDA-OFVM, FDA-CFSAN, FSIS, NIFA, USDA-OCS
Date: May 24, 2017, 3-4 pm EDT **Presenter: Martin Wiedmann,** Gellert Family Professor in Food Safety, Department of Food Science, Cornell University **Presentation:** *hqSNP, wgMLST and the WGS alphabet soup: what epidemiologists need to know* **Location:** Webinar hosted by Cornell University; slide set and recordings can be found at: https://nyfoodsafety.cals.cornell.edu/molecular-epidemiology/webinars	• 28 federal employees attended (via webinar) • **Agencies**: APHIS, ARS, CDC-NCEZID, CDC-NIOSH, FDA-OFVM, FDA-CFSAN, FSIS, NIFA, USDA-OCS
Date: October 11, 2017, 1-2:30 pm ET **Presenter:** Dr. Arie Havelaar, Professor, Microbial Risk Assessment and Epidemiology of Foodborne Diseases, Emerging Pathogens	• 119 federal employees

Institute, University of Florida; Dr. Trudy Wassenaar, Director, Molecular Microbiology and Genomics Consultants, Zotzenheim, Germany **Presentation:** *Whole Genome Sequencing – Application in Quantitative Microbial Risk Assessment* **Location:** Webinar (facilitator: Jude Smedra, FSIS/Science Staff)	attended (via webinar) **Agencies**: APHIS, ARS, CDC-NCEZID, CDC-NIOSH, FDA-OFVM, FDA-CFSAN, FSIS, NIFA, USDA-OCS
Date: October 18, 2017, 1-2:30 pm ET **Presenter:** Dr. Francisco Zagmutt, EpiX Analytics; Dr. Paul Morley, Professor, Colorado State University, Ft. Collins, Colorado **Presentation:** *Assessing Antimicrobial Resistance Risks in Food: Can We Do Better Using Whole Genome Sequencing?* **Location:** Webinar (facilitator: Jude Smedra, FSIS/Science Staff)	• 107 federal employees attended (via webinar) **Agencies**: APHIS, ARS, CDC-NCEZID, CDC-NIOSH, FDA-OFVM, FDA-CFSAN, FSIS, NIFA, USDA-OCS

Attachment 3. 2017 Federal Government Workshop: Exploration of the Implications of Whole Genome Sequencing on the Conduct and Application of Risk Assessment in Food Safety Decision-Making

This workshop[12] provides a forum for federal partners to explore the application of whole genome sequencing (WGS) data to advance how federal agencies assess microbiological food safety risks for purposes of guiding risk management decisions. It is the culmination of multi-disciplinary, cross-agency discussions on how WGS may provide improved data, including enhanced epidemiological linkage of clinical cases of illness to food source, insights to new intervention options to reduce contamination and prevent foodborne illnesses, and an enhanced understanding of consumer exposure to specific strains of a foodborne pathogen that result in illness.

WGS provides maximum resolution for DNA-based characterization of pathogens. While data interpretation remains a challenge (e.g., translation into physiological behavior), the rapidly decreasing costs, timely generation of more robust and discriminate subtyping information has led to increased use of WGS in foodborne disease surveillance and use in federal testing of foods and the environment. As these advancements in subtyping revolutionize outbreak surveillance, pathogen source tracking, and characterization of these hazards, including tracking drug resistance across the farm-to-table continuum, the challenge is how best to leverage this tool to support risk-based decision-making. Specifically, this workshop will consider the application of WGS to assess food safety risks with a focus on:

- *The primary food safety decision contexts (e.g., recalls, major policies, etc.);*
- *How this new science impacts the various components of quantitative microbial risk assessment (QMRA) – hazard identification, hazard characterization, exposure assessment, and risk characterization;*
- *How this new data might lead to changes or inform traditional components of food safety QMRAs and/or transform the approaches used to assess food safety risks altogether;*
- *The opportunities and challenges in applying WGS information to QMRAs; and*
- *The use of the QMRA framework to provide structure to collect and interpret WGS data (including meta data during traceback investigations) to further their utility in regulatory decision-making*

This workshop will utilize these identified key themes to further advance the future utilization of WGS within the context of assessing food safety risks, including the conduct of quantitative microbial risk assessment (QMRA), through exploration of practical case studies. The expected outcome of the workshop will be an action plan to further advance the future utilization of WGS within the risk assessment framework.

[12] The FY 2017 IRAC workshop, *Implications of Whole Genome Sequencing on the Conduct and Application of Risk Assessment in Food Safety Decision-Making*, was developed based on input from the IRAC Working Group and federal participation in interagency discussions, literature review, and information provided by international and national experts on risk assessment, epidemiology, and WGS.

AGENDA

U.S. Food and Drug Administration

Room 1A-002, Wiley Building

5001 Campus Drive, College Park, MD 20740 (College Park Metro stop)

September 27, 2017

9:00 am	Registration	
9:30 am	Welcome	Sherri Dennis
9:45 am	Opening Remarks .	Steve Musser David Goldman
Session I.	**Process for Evaluating the Implications of Whole Genome Sequence Data In the Conduct and Application of Food Safety Risk Assessments**	
10:15 am	Current Findings from IRAC Work Group (What Risk Assessment Is; WG Process, Application of WGS)	Max Teplitski
Session II.	**Case Studies: Practical Application of WGS to Strengthen Food Safety Risk Assessment**	
10:45 am	*Listeria monocytogenes* in Ready-to-Eat Foods	Yuhuan Chen
11:00 am	Evaluating Public Health Risk from *Salmonella* in Poultry Slaughter and Processing Environments	Danah Vetter
11:15 am	Q&A	All Participants
11:30 am	**Lunch (On your own)**	
Session III:	**Brainstorming Exercise: Practical Next Steps and Data Needs**	
12:30 pm	Purpose and Process for Group Exercise	Uday Dessai
12:45 pm	Workshop Brainstorming Session (Multi-disciplinary Teams)	All Participants
2:00 pm	Workshop Teams Report Out	
3:00 pm	Closing Remarks: Interagency Collaboration, Research and Pilots	Janell Kause
\3:30 pm	Meeting Ends	

Attachment 4. Biographies of Work Group Members and Workshop Participants

Marc W. Allard, Ph.D.
Senior Biomedical Research Services Officer and Research Area Coordinator of Genomics, Center for Food Safety and Applied Nutrition
Food and Drug Administration – DHHS
Marc W. Allard received his Ph.D. in biology in 1990 from Harvard University. Dr. Allard was the Louis Weintraub Associate Professor of Biology at George Washington University for 14 years from 1994 to 2008. Dr. Allard joined the Division of Microbiology in FDA's Office of Regulatory Science in 2008 where he uses Whole Genome Sequencing of foodborne pathogens to identify and characterize outbreaks of bacterial strains, particularly *Salmonella, E. coli,* and *Listeria*. Dr. Allard is a Senior Biomedical Research Services Officer and he specializes in both phylogenetic analysis, as well as the biochemical laboratory methods which generate the genetic information in the GenomeTrakr database, which is part of the NCBI Pathogen Detection web site.

Michael Bazaco, Ph.D., M.S.
Epidemiologist, Division of Public Health Informatics and Analytics
Centers for Food Safety and Applied Nutrition
Food and Drug Administration – DHHS
Michael Bazaco is the emerging infectious disease and food safety lead in the Epidemiology Branch, Division of Public Health Informatics and Analytics, Office of Analytics and Outreach, Center for Food Safety and Applied Nutrition, Food and Drug Administration (FDA). He serves as FDA technical co-lead on the Interagency Food Safety Analytics Collaboration (IFSAC), a tri-agency (FDA, USDA-FSIS, and CDC) analytical partnership focused on attribution of foodborne illness in the United States. Dr. Bazaco leads multiple collaborative food safety- and emerging foodborne pathogen-related projects for IFSAC and for the Epidemiology Branch. After receiving his BS in Biology at Virginia Tech, where he focused on microbiology and immunology, and his MS in Food Microbiology at Virginia Tech, as well, he completed his Ph.D. in Epidemiology at the University of Pittsburgh Graduate School of Public Health.

Karen Becker, D.V.M., M.P.H.
Director, Applied Epidemiology Staff, Office of Public Health Science
Food Safety and Inspection Service – USDA
Since 2013, Karen Becker has served as the Director of the Applied Epidemiology Staff within FSIS's Office of Public Health Science. She earned a Bachelor of Arts from Brown University; a Doctorate of Veterinary Medicine from the University of Illinois's College of Veterinary Medicine, a Masters in Public Health from Johns Hopkins University and is board certified by the American College of Veterinary Preventive Medicine. From 1998-2000, Dr. Becker was a CDC Epidemic Intelligence Service Officer based in North Carolina with a focus on infectious diseases and surveillance during natural disasters such as the major hurricanes North Carolina experienced during her EIS assignment at the health department. In 2000, she joined the Department of Health and Human Service's Office of Global Heath based in Washington DC as a Preventive Medicine Fellow to focus on international programs such as Foot and Mouth Disease Control, zoonotic disease control and Field Epidemiology Training Programs. Following September 11, 2001 through 2006, Dr. Becker served as a senior public health advisor to the U.S. Department of Health and Human Service's Office of Public Health Emergency Preparedness. From 2006-2010, Karen was on detail by U.S. Department of Agriculture's Foreign Agricultural Service to the U.S. Agency for International Development's Africa Bureau to assist with the prevention and control of avian influenza as well as other zoonotic and livestock disease threats impacting public health and agricultural development. Before joining the Food Safety and Inspection Service, she has also served as a public health advisor to the Department of Homeland

Security's National Biosurveillance Program. Since 1987 Dr. Becker has maintained her veterinary clinical license and enjoys integrating clinical and epidemiologic skills into public health practice.

Philip Bronstein, Ph.D.
Director, Science Staff, Office of Public Health Science
Food Safety and Inspection Service – USDA
Philip Bronstein is a microbiologist by training and currently serves as the Director of the Science Staff at the U.S. Department of Agriculture, Food Safety and Inspection Service (FSIS) in the Office of Public Health Science (OPHS). FSIS regulates meat, poultry, and egg products to ensure that they are safe, wholesome, and properly labeled. The Science Staff within OPHS provides scientific support to the agency for a wide variety of microbiological, chemical, and food technology related issues.

Eric Brown, Ph.D., M.Sc., FAAM
Director, Division of Microbiology, Office of Regulatory Science
Center for Food Safety and Applied Nutrition
Food and Drug Administration – DHHS
Eric W. Brown has been with the Food and Drug Administration's Center for Food Safety and Applied Nutrition since 1999 and currently serves as Director of the Division of Microbiology in the Office of Regulatory Science. Here, he oversees a group of 60 food safety microbiology researchers and support scientists engaged in a multi-parameter research program to develop and apply microbiological and molecular genetic strategies for detecting, identifying, and differentiating bacterial foodborne pathogens such as *Salmonella, Listeria,* and shiga-toxin producing *E. coli*. Recently, his laboratory has been instrumental in adapting next-generation sequencing technologies to augment foodborne outbreak investigations and to ensure preventive control and compliance standards at the FDA including the establishment of the GenomeTrakr whole-genome sequencing network for food safety. Dr. Brown received his M.Sc. in Microbiology from the National Cancer Institute/Hood College joint program in the biomedical sciences in 1993 and his Ph.D. in Microbial Genetics from The Department of Biological Sciences at The George Washington University in 1997. He has conducted research in microbial evolution and genetics as a research fellow at the National Institutes of Health, the U.S. Department of Agriculture, and as an Assistant Professor of Microbiology at Loyola University of Chicago. He has been a member of the American Society for Microbiology since 1994 and was recently inducted as a Fellow of the American Academy of Microbiology in 2015. He has co-authored more than 170 refereed publications and book chapters on the molecular differentiation, evolutionary genetics, and ecological persistence of bacterial pathogens.

Michelle Catlin, Ph.D.
Director, Risk Assessment and Analytics Staff, Office of Public Health Science
Food Safety and Inspection Service – USDA
Michelle Catlin is the Director of the Risk Assessment and Analytics Staff within the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS), Office of Public Health Science. She oversees the conduct of regulatory food safety risk assessments to guide federal food safety policies related to meat, poultry and egg products. Michelle also directed FSIS's Food Defense Assessment Staff and was the founding director of FSIS's Data Analysis and Integration Staff. Prior to joining USDA-FSIS Michelle was with The National Academies, where she served as a study director in the Board on Health Promotion and Disease Prevention of the Institute of Medicine and the Board on Environmental Studies and Toxicology of the National Research Council. She received her M.Sc. in pharmacology and toxicology from Queen's University, Canada, and a Ph.D. in environmental health (Toxicology Program) from the University of Washington. Dr. Catlin has worked on numerous National Academies

reports, including *Copper in Drinking Water*, *Toxicological Effects of Methylmercury*, *Arsenic in Drinking Water: 2001 Update*, and *Environmental Decisions in the Face of Uncertainty*.

Yi Chen, Ph.D.
Research Microbiologist, Office of Regulatory Science
Center for Food Safety and Applied Nutrition
Food and Drug Administration – DHHS
Yi Chen is the subject matter expert for *L. monocytogenes* in the Office of Regulatory Science, Center for Food Safety and Applied Nutrition, Food and Drug Administration. Dr. Chen has been working on the detection, enumeration and whole genome sequencing analysis of *L. monocytogenes*. He has published numerous peer reviewed articles on the method development of *L. monocytogenes*, behavior of *L. monocytogenes* in food matrices, and whole genome sequencing analysis of *L. monocytogenes*, especially those involved in human illnesses. He has generated a lot of microbiological and genomic data that can contribute to the risk assessment of *L. monocytogenes*. He has been the scientific contact for *L. monocytogenes* testing in various FDA field assignments, outbreak investigations and laboratory analyses. He has also been a technical resource for the greater scientific community. He currently serves as a member of ISO *L. monocytogenes* Work Group, the General Referee for AOAC International and editorial board member for *Applied and Environmental Microbiology.*

Stephanie Defibaugh- Chávez, Ph.D.
Senior Microbiologist, Science Staff
Office of Public Health Science
Food Safety and Inspection Service – USDA
Stephanie Defibaugh-Chávez is a Senior Microbiologist with the Science Staff in the Office of Public Health Science at the USDA Food Safety and Inspection Service in Washington, DC. Since joining FSIS in 2010, Stephanie has primarily contributed to the Agency mission as a technical subject matter expert for microbiological issues associated with FSIS-regulated meat, poultry and egg products. In recent years, Stephanie has been an active influence on FSIS efforts to incorporate WGS analyses into regulatory decision-making processes. Before joining OPHS, Dr. Defibaugh-Chávez was an ORISE postdoctoral fellow in the Microbiology Division of the Office of Regulatory Science at the FDA Center for Food Safety and Applied Nutrition working on molecular method development for detection of foodborne pathogens, including *Salmonella* spp. and *Clostridium botulinum* and its associated toxins. She received a B.S. in Chemistry from University of Louisiana at Lafayette in 1999 and attended graduate school at the University of Arkansas in Fayetteville, AR, where she graduated with both M.S. in Chemistry and a Ph.D. in Cell and Molecular Biology.

Sherri B. Dennis, Ph.D.
Director, Division of Risk & Decision Analysis
Center for Food Safety and Applied Nutrition
Food and Drug Administration – DHHS
Sherri Dennis serves as the Director of the Division of Risk and Decision Analysis in the Office of Analytics and Outreach, Center for Food Safety and Nutrition (CFSAN), Food and Drug Administration. The Division supports Center/Agency strategic initiatives and regulatory decision-making by conducting risk assessment and evaluation of contaminants (microbial and chemical) and naturally occurring toxins in CFSAN-regulated products. Dr. Dennis has facilitated creative improvements in risk assessment research and the development of mathematical models

to support science-based risk management and policy decisions. She has been invited to serve on numerous agency, interagency, and international workgroups addressing a wide range of scientific and technical topics including information quality, peer review, avian influenza, *Listeria monocytogenes*, thresholds for allergens and gluten in food, and inorganic arsenic in juice and rice. Currently, Dr. Dennis co-chairs the Interagency Risk Assessment Consortium Policy Council.

Uday Dessai, M.S., M.P.H., Ph.D.
Senior Advisor Public Health, Office of Public Health Science
Food Safety and Inspection Service – USDA
As the Senior Public Health Advisor in the Office of Public Health Science, Uday Dessai leads major FSIS programs including the National Antimicrobial Resistance Monitoring System (NARMS) and antimicrobial resistance (AMR) activities, whole genome sequencing (WGS) and interagency collaborations, role of science in policy development, strategic planning and adoption of scientific innovations in FSIS. In his previous roles as the Director of Science Staff, Director of Microbiology Division and the Branch Chief in Risk Assessment Division, Dr. Dessai led a number of programs of national significance. These include the national microbiological baseline studies, the national advisory committee on microbiological criteria for foods (NACMCF), microbiological and residue issues with domestic and international implications, and risk assessment and exposure modeling - to inform policy considerations. To accomplish FSIS' food safety - public health goals, Dr. Dessai collaborated with stakeholders and led multidisciplinary teams of experts on highly significant microbiological issues (*E. coli* O157:H7, STECs, *Salmonella*, *Listeria*, *Campylobacter Toxoplasma* and microbiological baselines), BSE and Harvard BSE Risk Assessment, and NACMCF charges and development of recommendations (e.g., FSIS new technology, Agricultural Marketing Service specifications, Norovirus and Department of Defense Microbiological Criteria). Dr. Dessai has had the opportunity to deeply immerse into sciences during his sojourn in academia through advanced training, research and teaching in diverse scientific disciplines. These include agriculture, food and nutritional sciences, microbiology (food, environment), molecular biology and biotechnology (gene constructs/expression, development of transgenic, cell and tissue culture), public health/epidemiology, risk assessment/analysis and information technology. Dr. Dessai currently serves on numerous agency, interagency and international workgroups to address issues related to ARM, NARMS, WGS, and scientific innovations.

Eric Ebel, D.V.M., M.S.
Senior Veterinary Medical Officer, Risk Assessment and Analytics Staff
Office of Public Health Science
Food Safety and Inspection Service – USDA
Eric Ebel is a staff officer with responsibility for conducting quantitative food safety risk analyses. He is board certified in preventive medicine and epidemiology; and is also an Associate in the Society of Actuaries. Dr. Ebel has worked in public practice for nearly 30 years and has been involved in risk modeling for much of his career.

Emilio Esteban, D.V.M., M.B.A., M.P.V.M., Ph.D.
Executive Associate for Laboratory Services, Office of Public Health Science
Food Safety and Inspection Service – USDA
Emilio Esteban oversees the activities of the U.S. Department of Agriculture, Food Safety and Inspection Service (FSIS) laboratories including the disciplines of microbiology, chemistry and pathology. The data that is generated by the labs is the foundation for documenting the effectiveness of FSIS' food safety policies. Laboratory data provides empirical verification of HACCP control, identification of violations, and support of recall activities. Under his tenure, the laboratories have maintained the high quality of the analytical results while

increasing the throughput. He has focused on streamlining the sampling process from the collection point at the plant to the reporting of results. Under his leadership the laboratory system is also reducing the number of independent data management systems allowing for a more flexible and responsive IT infrastructure. Dr. Esteban is also the Chair for the Codex Alimentarius Commission Committee on Food Hygiene. This committee is where international food hygiene standards are defined for international trade.

Sofia Santillana Farakos, Ph.D.
Interdisciplinary Scientist, Office of Analytics and Outreach
Center for Food Safety and Applied Nutrition
Food and Drug Administration – DHHS
Sofia Santillana Farakos is an Interdisciplinary Scientist and Project Manager in the Risk Analysis Branch of the Office of Analytics and Outreach (Division of Risk and Decision Analysis) at the U.S. Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition. Sofia joined FDA in September 2013. Her areas of expertise include predictive modeling, risk assessment and food microbiology and more specifically modeling *Salmonella* in low moisture foods. She holds a Ph.D. in Food Science from The University of Georgia and an MS in Food Science from Wageningen University.

Sheila Fleischhaker, Ph.D., J.D.
Senior Advisor of Nutrition and Food Safety
Office of the Chief Scientist – USDA
Sheila Fleischhacker is a Senior Advisor of Nutrition and Food Safety at the US Department of Agriculture Office of the Chief Scientist, on detail from the National Institute of Diabetes and Digestive and Kidney Diseases Office of Nutrition Research. She specializes in identifying public health nutrition research opportunities and gaps with an emphasis on the role of environmental and policy strategies for promoting healthy eating and reducing health disparities. Dr. Fleischhacker received a B.S. (2000) and J.D. (2007) with a Certificate in Health Law from Loyola University Chicago and Ph.D. in Integrative Biosciences/Nutritional Sciences from The Pennsylvania State University (2004).

Kathleen F. Gensheimer, M.D., M.P.H.
Medical Officer, Division of Public Health Informatics and Analytics
Center for Food Safety and Applied Nutrition
Food and Drug Administration – DHHS
Gensheimer serves as a Medical Officer with the Epidemiology Branch, Division of Public Health Informatics and Analytics, Office of Analytics and Outreach, Center for Food Safety and Applied Nutrition, Food and Drug Administration (FDA). She provides authoritative medical and epidemiological advice, guidance, assistance, interpretation, and recommendations regarding food safety, as well as working to promote collaboration with multiple partners from within and outside of FDA, including laboratory, public health, agriculture, and regulatory partners at the state and local level. In addition to serving on the Advisory Board of the One Health Initiative and the Editorial Advisory Board of *Infectious Disease News*, Dr. Gensheimer is an Associate Editor for *Emerging Infectious Diseases*. Dr. Gensheimer previously served for 5 years in the FDA Office of Foods and Veterinary Medicine as Chief Medical Officer and Director of the Coordinated Outbreak Response and Evaluation Network, where she oversaw foodborne outbreak investigations, and for 28 years as State Epidemiologist in Maine, where much of her work involved surveillance, response, and prevention of foodborne-related issues of public health concern. She received her medical degree from the University of Rochester School of Medicine and completed her MPH at Harvard University.

Brett J. Green, Ph.D.
Research Biologist, National Institute for Occupational Safety and Health
Centers for Disease Control and Prevention – DHHS
Brett Green serves as a Research Biologist in the Health Effects Laboratory Division in the National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention. The Division is the primary laboratory research arm of NIOSH tasked to scientifically establish causes and mechanisms of disease and injury in the workplace. Dr. Green's laboratory-based research program is at the forefront of occupational allergen characterization and microbial biohazard assessment research. Bioaerosol exposure assessment methods including ITS amplicon sequencing have been used in support of NIOSH Health Hazard Evaluations. Currently, Dr. Green serves on a number of agency, interagency, domestic and international workgroups addressing topics including occupational health, allergen exposure, indoor air quality, mold, aerobiology, and biohazard monitoring.

Robert H. Hall, Ph.D.
Programs Officer
National Institute for Allergy and Infectious Diseases
National Institutes of Health -- DHHS
Robert Hall is a Program Officer in the Enteric and Hepatic Diseases Branch, Division of Microbiology and Infectious Diseases, National Institute for Allergy and Infectious Diseases within the National Institutes of Health. He is responsible for programs in cholera, other vibrioses, and diagnostics for enteric and hepatic diseases; including research and product development efforts directed towards basic research, epidemiology, and the development of novel vaccines, therapeutics, and diagnostics. He was previously in the Center for Food Safety and Applied Nutrition of the Food and Drug Administration, where he conducted research and developed detection methods for food-borne pathogens. Robert is U.S. secretariat for the U.S. Japan Cooperative Medical Sciences Program Panel on Cholera and Other Bacterial Enteric Infections, and he is co-Editor in Chief for the journal *JMM-Case Reports.* Robert obtained his degree in microbiology from the University of Aberdeen (Scotland) and his doctorate from University College, London (England). He is an elected fellow of the Royal Society for Public Health and the Royal Society of Tropical Medicine and Hygiene.

Wendy F. Hall, D.V.M., Ph.D.
Assistant Chief, Environmental and Risk Analysis Services
Animal and Plant Health Inspection Service – USDA
Wendy Hall serves as an Assistant Chief for Environmental and Risk Analysis Services within Policy and Program Development, Animal and Plant Health Inspection Service (APHIS), where she leads the Environmental Analysis Support staff. The EAS staff primarily provides analytical support, including human health risk assessments, spatial analyses and environmental justice considerations in support of APHIS environmental compliance documentation. Dr. Hall earned her doctorate in Zoology focusing on evolutionary ecology. She is also a licensed veterinarian and has worked in small animal/exotic private practice. Dr. Hall applies her broad base of academic and work experience to engage scientists and professionals from diverse backgrounds to collaborate on issues of mutual interest and concern. Dr. Hall represents APHIS on several collaborative interagency technical groups, covering relevant interdisciplinary topics such as invasive species, environmental justice, climate change adaptation, and food safety. While she represents APHIS on the Interagency Risk Assessment Consortium, her work with the consortium preceded her tenure at APHIS; it started in 1999 when she created the Food Safety Risk Analysis Clearinghouse (now known as Foodrisk.org) for the Joint Institute for Food Safety and Applied Nutrition.

Barry Hooberman, Ph.D., M.P.H.
Team Lead, Risk Analytics Staff, Office of Foods and Veterinary Medicine
Food and Drug Administration – DHHS
Barry Hooberman serves as the Team Lead for the Risk Analytics Staff in the Office of Foods and Veterinary Medicine (FVM). The mission of the Risk Analytics Staff is to: 1) establish risk-informed priorities that drive FVM Program decision-making, resource allocation, and performance measures; 2) to ensure that risk information is consistently analyzed, widely communicated, and easily accessible across the FVM program; and 3) conduct descriptive and predictive analytics to support FVM Program activities. Dr. Hooberman has worked extensively on risk analysis issues relating to the use of antimicrobials in food-producing animals, the regulation of genetically engineered animals, animal cloning, and animal feed safety.

Andy Hwang, Ph.D.
Research Food Technologist, Eastern Regional Research Center
Agricultural Research Service – USDA
Andy Hwang is a research scientist with the Residue Chemistry and Predictive Microbiology Research Unit of the Eastern Regional Research Center in the Agricultural Research Service (ARS) at the U.S. Department of Agriculture. His research mainly focuses on the development of microbiological models that are incorporated into the USDA Pathogen Modeling Program (PMP). The PMP contains approximately 60 predictive models that can be used to predict the growth and inactivation of foodborne bacteria, primarily pathogens, under various intrinsic and extrinsic environmental conditions and has seen applications in food product and process development, regulatory compliance, and risk assessment. Andy is also involved in research to develop intervention technologies and new methodologies for developing predictive models. Before joined ARS, Dr. Hwang was a research microbiologist with Nestle Product Technology Center. Dr. Hwang is ARS technical representative in the IRAC and an Institute of Food Technologist certified Food Scientist and serves as associate editor for the Food Safety and Microbiology section of the Journal of Food Science.

Julie Ann Kase, Ph.D.
Research Microbiologist, Center for Food Safety and Applied Nutrition
Food and Drug Administration – DHHS
Julie Ann Kase is a research microbiologist in the Division of Microbiology in the Office of Regulatory Science, Center for Food Safety and Nutrition (CFSAN), Food and Drug Administration (FDA). The Division supports Center/Agency strategic initiatives and regulatory decision-making by developing and validating methods for the detection and characterization of various microorganisms in CFSAN-regulated products. For nearly 20 years, Dr. Kase has worked as a bench-level environmental and food microbiologist. Eight of those years have been spent at the FDA focusing on improving the FDA's ability to detect and characterize non-O157 Shiga toxin-producing *E. coli* (STEC) and *Brucella*. She is an author of several FDA Bad Bug Book chapters and currently serves as a subject matter expert on STEC. In addition, she has been involved in many agency and cross-FDA Center collaborations including real-time PCR training courses, method validations, and technical workgroups. Dr. Kase has served on the FDA BAM Council since 2010 and was appointed as a technical expert to the National Advisory Committee on Microbiological Criteria for Foods in 2015.

Janell Kause, M.P.P., M.P.H.
Scientific Advisor for Risk Assessment, Office of Public Health Science
Food Safety and Inspection Service – USDA
Janell Kause serves as the Scientific Advisor for Risk Assessment at the U.S. Department of Agriculture, Food Safety and Inspection Service (FSIS). She provides leadership and guidance on the development, adaptation and

application of risk assessment to guide federal food safety policies and programs. She has primarily focused on strengthening interagency collaboration and stakeholder engagement in the conduct of food safety risk assessments, enhancing transparency of the data and underlying science used to guide decisions, and promoting increased collaboration among federal partners, industry, academia and consumer groups to collectively address food safety concerns. She has been invited to serve on numerous agency, interagency, and international workgroups addressing topics ranging from public-private partnerships and enhanced science-based decision-making to risk-informed approaches to prevent foodborne illness. Currently, she co-chairs the Interagency Risk Assessment Consortium Policy Council and, since March 2015, serves as FSIS's Agency Scientific Integrity Officer.

Arthur P. Liang, M.D. M.P.H.
Senior Advisor for Food Safety
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention -- DHHS
Art Liang is currently the Senior Advisor for Food Safety, Division of Foodborne Waterborne & Environmental Diseases at the Centers for Disease Control and Prevention (CDC). He is the former Director of the CDC Food Safety Office. He has been a CDC Epidemic Intelligence Service officer and the Chief of the Communicable Disease Division, Hawaii Department of Health. He currently serves on the Executive Committee of the National Advisory Committee on Microbiological Criteria for Foods. He is also serves on the Center for Produce Safety Board of Directors and the Food Safety Summit Education Advisory Board, and is a Fellow of the American College of Preventive Medicine. He is board certified in General Preventive Medicine and Public Health. He has a BA from Oberlin College, an MPH in International Health and Epidemiology from the University of Hawaii; and MD from the University of Maryland.

Randall Levings, D.V.M., Ph.D., M.S.
Scientific Advisor
Science, Technology & Analysis Services, Veterinary Services
Animal and Plant Health Inspection Service, USDA
Randall L. Levings serves in a technical project lead and representation role for Veterinary Services. His past positions include Director, National Veterinary Services Laboratories (U.S. national reference veterinary diagnostic laboratory) and Director, Center for Veterinary Biologics Laboratory (testing laboratory for the sole regulatory authority for veterinary vaccines and commercial diagnostics in the U.S.). Dr. Levings co-led the development and led operation of the National Animal Health Laboratory Network (a multi-state network testing for high-consequence diseases). He also co-led the development of the National Centers for Animal Health (co-locating animal disease diagnostic, biologics evaluation, and research). He was involved in multiple animal disease outbreak responses. His current research interest is comparative humoral immunity. He received a B.A. (Biology) from the University of Missouri-Columbia, and his D.V.M., M.S. (Immunology) and Ph.D. (Veterinary Microbiology) degrees from Iowa State University.

André Markon, Ph.D., M.P.H.
Epidemiologist, Division of Public Health Informatics and Analytics
Center for Food Safety and Applied Nutrition
Food and Drug Administration – DHHS
Dr. Markon is international lead in the Epidemiology Branch, Division of Public Health Informatics and Analytics, Office of Analytics and Outreach, Center for Food Safety and Applied Nutrition, Food and Drug Administration (FDA). He specializes in infectious diseases epidemiology, including food- and vector-borne diseases, as well as

analytical methods and metrics innovations for food safety-related studies. Dr. Markon joined the Epidemiology Branch after a Presidential Management Fellowship that included participation on the White House Office of Science, Technology, and Policy's Innovation Toolkit: Design Thinking Team and collaboration with the FDA Office of the Commissioner, Office of Public Health Strategy and Analysis on veterinary antimicrobial resistance and pharmacoepidemiology projects. He completed his MPH and PhD at the University of Michigan Rackham Graduate School/School of Public Health.

Cary Parker, M.P.H.
Epidemiologist, Division of Public Health Informatics and Analytics
Center for Food Safety and Applied Nutrition
Food and Drug Administration – DHHS
Cary Parker is a cross-cutting research and outreach lead in the Epidemiology Branch, Division of Public Health Informatics and Analytics, Office of Analytics and Outreach (OAO), Center for Food Safety and Applied Nutrition (CFSAN), Food and Drug Administration (FDA). Her responsibilities include serving as FDA communications lead and FDA technical co-lead on the Interagency Food Safety Analytics Collaboration (IFSAC), a tri-agency (FDA, USDA-FSIS, and CDC) analytical partnership focused on attribution of foodborne illness in the United States. In addition, she is working on analyses of the temporal and geospatial flow of imported foods in multi-state outbreaks, as well as investigations of the characteristics of different consumer types (such as consumers of unpasteurized milk products), among several other food safety-related projects. Cary previously conducted policy-oriented research at the FDA CFSAN OAO DPHIA Consumer Studies Branch and post-marketing pharmacoepidemiological reviews of adverse events related to new drug products at the FDA Center for Drug Evaluation and Research. Prior to joining FDA, Cary completed a two-year fellowship at CDC, where she worked on surveillance of foodborne disease outbreaks. Cary received her BS in Psychology and Certificate in Human Development from Duke University. She completed her MPH in Epidemiology at The George Washington University – Milken Institute School of Public Health.

Tamika Payne, Ph.D.
Microbiologist/Interdisciplinary Risk Assessor,
Risk Assessment and Analytics Staff, Office of Public Health Science
Food Safety and Inspection Service – USDA
Tamika Payne is a Microbiologist and Interdisciplinary Risk Assessor with the Risk Assessment and Analytics Staff in the Office of Public Health Science at the USDA Food Safety and Inspection Service. In her role at FSIS, Tamika provides the foundation for scientifically sound, evidence-based and data-driven decisions concerning FSIS-regulated food products. Before joining RAAS in 2015, Tamika was a Postdoctoral Fellow in the Division of HIV/AIDS Prevention at the Centers for Disease control. Tamika earned her Bachelors of Science in Biological Science from the University of Maryland, Baltimore County and her Ph.D. in Molecular Genetics and Microbiology from Duke University. Her dissertation work focused on genetic regulation of the CD8+ T cell response to HIV-1 infection.

Aurelie Pohl, D.V.M.
ORISE Fellow, Risk Analysis Branch
Center for Food Safety and Applied Nutrition
Food and Drug Administration – DHHS
Aurelie Pohl is an ORISE Fellow in the Risk Analysis Branch, Division of Risk and Decision Analysis in the Office of Analytics and Outreach (OAO), Center for Food Safety and Nutrition, Food and Drug Administration. She is a

public health veterinarian whose research interests include foodborne pathogens, food safety risk assessments and epidemiology. Previously she completed a two-year American Association for the Advancement of the Sciences Science and Technology Policy Fellowship with the Risk Assessment and Analytics Staff at the US Department of Agriculture's Food Safety and Inspection Service. Prior to her fellowship she was a clinical veterinarian for 9 years. She is a 2005 graduate of Virginia-Maryland Regional College of Veterinary Medicine in Blacksburg, VA and a 2001 graduate of McGill University in Montreal, Canada with a Bachelor's of Science in biology. Currently, she is completing a Masters of Public Health program with the University of Florida.

Kis Robertson, M.P.H., D.V.M.
Deputy Director, Applied Epidemiology Staff, Office of Public Health Science
Food Safety and Inspection Service – USDA
Kis Robertson Hale is the Deputy Director of the Applied Epidemiology Staff (AES) in the Food Safety and Inspection Service's Office of Public Health Science. Before her current position, she served as a Senior Epidemiologist in AES for several years, providing scientific leadership on projects related to foodborne outbreaks, consumer complaint surveillance, and undeclared allergens. She is also a Captain in the U.S. Public Health Service. CAPT Robertson Hale obtained her Bachelor of Science degree from the Georgia Institute of Technology, her veterinary degree from Tuskegee University, and her Masters in Public Health from the University of Minnesota. In 2008, she participated in the Centers for Disease Control and Prevention's Epidemic Intelligence Service program and in 2010, she worked in the Maryland Department of Health and Mental Hygiene as a CDC Preventive Medicine Fellow.

Gurinder Saini, Ph.D.
Acting Director, Risk Assessment and Analytics Staff
Office of Public Health Science
Food Safety and Inspection Service – USDA
Gurinder Saini serves as the Branch Chief for applied analysis group in the office of Data Integration and Food Protection at the U.S. Department of Agriculture, Food Safety and Inspection Service (FSIS). He provided leadership and guidance on various type of data analysis and development of the automated tools to do the data analysis related to the development of food safety policies and programs. After joining the Risk Assessment and Analytics Staff, he is working on various risks assessment models and collaborating with other offices within FSIS to develop of new analytical tools.

Tod Stuber, B.S.
Computational Biologist
National Veterinary Services Laboratories
Animal and Plant Health Inspection Service – USDA
Ten years as Microbiologist at NVSL leading the molecular development and diagnostic testing for our Mycobacteria and Brucella section. Followed by six years as Computational Biologist working with whole genome sequencing (WGS) where we have two MiSeq and one Ion Xpress instrument providing a steady flow of data. In the last six years my focus has been testing new programs, growing computational resources, script development, validation, reporting, and educating end users and those new to managing and handling WGS. Script development has included pipelines which automate and provide sample identification, and high resolution genotyping for bacterial and viral isolates.

Max Teplitski, Ph.D.
National Program Leader, Institute of Food Safety and Human Nutrition
National Institute for Food and Agriculture – USDA
Max Teplitski is a National Program Leader in Food Safety and Microbiology at the U.S. Department of Agriculture (USDA), National Institute for Food and Agriculture. Prior to joining USDA, he was a professor at the University of Florida, a G.E. Burch Fellow in Theoretical Medicine at the Smithsonian Institution and a Fulbright Specialist in Agriculture. He authored over 70 publications on ecology of human pathogens, genetics and genomics of interactions between microorganisms and their hosts.

Mike Williams, M.S, M.S, Ph.D.
Mathematical Statistician, Risk Assessment and Analytics Staff
Office of Public Health Science, Food Safety and Inspection Service – USDA
Mike Williams currently serves as a senior risk analyst with responsibility for conducting quantitative food safety risk analyses He has held staff positions in Forest Service Research and the Veterinary Services Division of the Animal and Plant Health Inspection Service, as well as risk assessment positions in within the Food Safety and Inspection Service.

Jie Zheng, Ph.D.
Research Microbiologist, Division of Microbiology
Center for Food Safety and Applied Nutrition
Food and Drug Administration - DHHS
Jie Zheng currently serves as a Research Microbiologist in the Molecular Methods and Subtyping Branch within the Division of Microbiology at the Food and Drug Administration (FDA) Center for Food Safety and Applied Nutrition (CFSAN). Dr. Zheng received her Ph.D. in Food Science from University of Maryland at College Park, MD in 2006. Dr. Zheng joined the laboratories at CFSAN in 2008 after her two-year post-doc training at UMD. She has been engaged in development of SNP-based detection, identification and subtyping methods for various phyletic and pathovar divisions of pathogenic *Salmonella*. Dr. Zheng is one of the PIs on the newly formed Human Pathogens on Plants research group where she focuses on her research in *Salmonella* adaptation in food matrix and plant using next generation sequencing technology and development of related intervention strategies.