



# IRAC Work Group Process & Findings

*2017 Federal Workshop: Application of WGS to Assess Food Safety Risk*

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# IRAC's Role

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- Coordinates Federal agencies efforts & ensures communication that develop or use food safety risk assessment tools

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- Comprehensive view of existing and emerging public health needs for risk assessment

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- Streamlines and creates synergies:
  - Information sharing about methods, projects, research needs, events & problems
  - Opportunities for collaboration & solutions

# Work Group & Objectives

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- Implications of WGS for quantitative microbiological food safety risk assessment
    - hazard identification
    - exposure assessment
    - hazard characterization
    - risk characterization
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- Opportunities and challenges in using WGS to advance QMRA
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- Implications of applying WGS to QMRA in regulatory decision-making

## Member Agencies:

- **Department of Agriculture**
  - ❖ Agricultural Marketing Service
  - ❖ **Agricultural Research Service**
  - ❖ **Animal and Plant Health Inspection Service**
  - ❖ Economic Research Service
  - ❖ Food and Nutrition Service
  - ❖ **Food Safety and Inspection Service**
  - ❖ National Agricultural Statistics Service
  - ❖ **National Institute of Food and Agriculture**
  - ❖ **Office of the Chief Scientist**
  - ❖ Office of Pest Management Policy\*
  - ❖ Office of Risk Assessment and Cost Benefit Analysis
- **Department of Commerce**
  - ❖ National Oceanic and Atmospheric Administration
- **Department of Health and Human Services**
  - ❖ Centers for Disease Control and Prevention
    - **National Center for Emerging and Zoonotic Infectious Diseases**
    - **National Institute for Occupational Safety and Health**
  - ❖ Food and Drug Administration
    - **Center for Food Safety and Applied Nutrition**
    - Center for Veterinary Medicine
    - **Office of Foods and Veterinary Medicine**
  - ❖ **National Inst. of Health, Natl. Institute of Allergy and Infectious Dis.**
- **Environmental Protection Agency**
  - ❖ Office of Pesticide Programs
  - ❖ Office of Water
- **U.S. Agency for International Development**

# Work Group Process

## 1. Review of the Scientific Literature

- 33 articles via foodrisk.org

## 3. In-Depth & Round-Robin Discussions

- 12 meetings total (4 sub-groups; 3 meetings; oral and written responses to 6 core questions)

## 5. Conference/Expert Input

- International Association for Food Protection
- Discussions with national/international experts
- Follow up discussions with European Food Safety Authority (EFSA)

## 7. Action Plan

- Utilize prioritized “next steps” from workshop
- Coordination/consultation with Gen-FS

## 2. Educational Webinars

- Mar.-May 2017: WGS 101 (Brown & Allard); Transformation of surveillance & outbreak investigations(Williams); WGS: What epidemiologists need to know (Wiedmann)
- Oct: WGS/QRMA (Havelaar/Wasserman); WGS/AMR (Zagmutt/Morley)

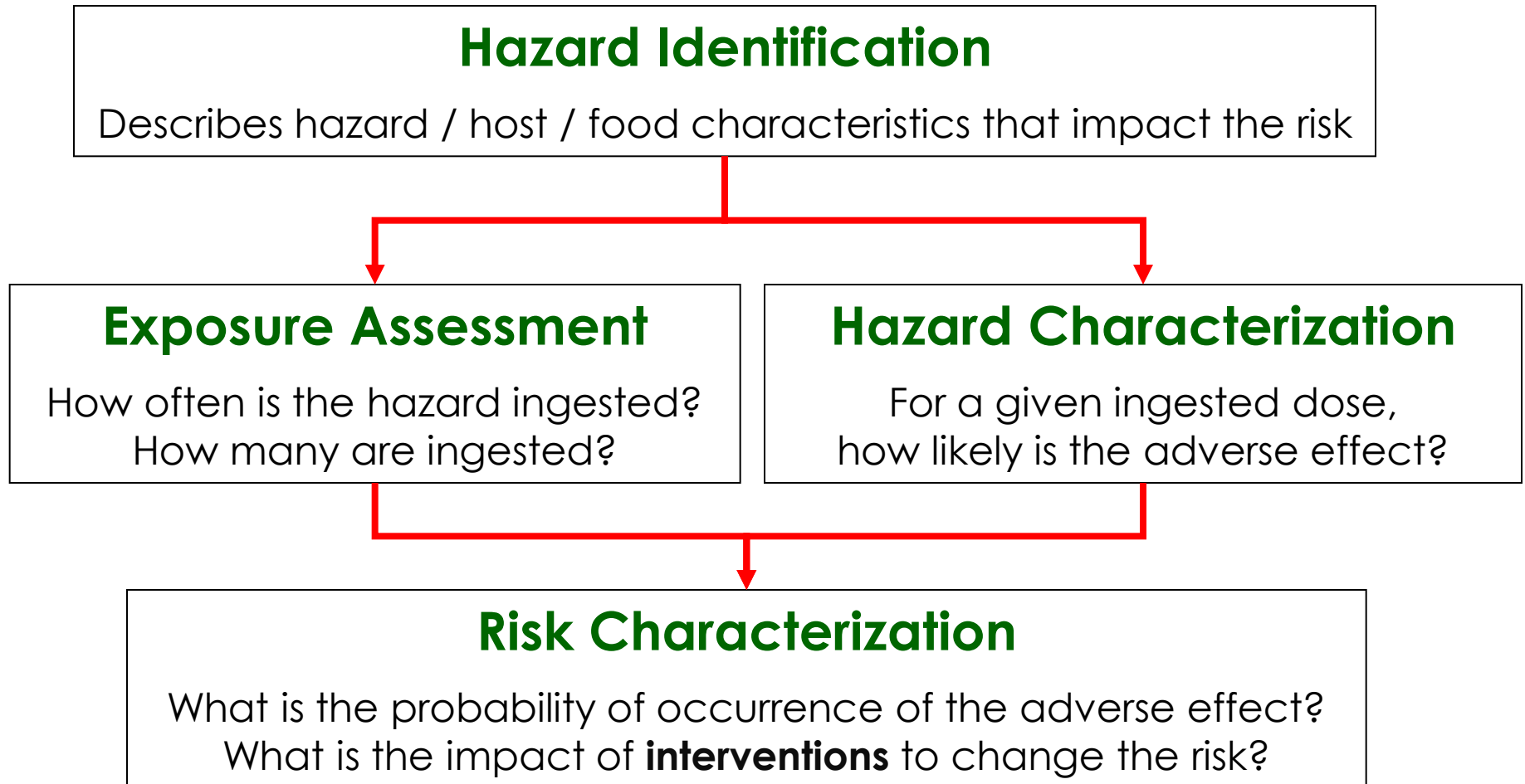
## 4. Identification of Key Themes

- Development of major themes, outcomes of the sub-group discussions

## 6. Federal Workshop

- Consideration of case studies/practical application
- Derivation of prioritized “next steps”

# Components of Risk Assessment



# Sub-Group Discussion Questions



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

# Findings – Themes

- Opportunities
- Challenges
- Data Needs
- Ideas for “next steps”

# “Opportunity” Themes

- **Refined definition and characterization of bacteria as ‘hazards’**
  - Precise definition of microbial hazards associated with health outcome (genes of concern related to illness (e.g., AMR, virulence) (hazard identification)
  - Better profile of microbial hazard characteristics to survive, persist, grow in environment and specific foods (hazard characteristics integral to exposure)
  - Alternatively: Evaluate “hazard” in a non-traditional sense (as a group of genes)

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  - Better profile of microbial hazard characteristics to survive, persist, grow in environment and specific foods (hazard characteristics integral to exposure)
  - Alternatively: Evaluate “hazard” in a non-traditional sense (as a group of genes)
- **Improved attribution of cases of foodborne illness to specific foods (discriminatory power of WGS data in evaluating clinical and food isolates)**
  - Use WGS data to supplement epidemiological investigations to link previously “sporadic cases” to an outbreak (better case definition, consumer demographics, etc.)
  - Non-traditional outbreak investigation to identify “new food vehicles” based on strains in product linked to clinical isolates
  - Reduce the CDC statistic of “80%” unknown causes of foodborne illness” - improve certainty of food vehicles
  - Narrow down outbreak cluster (which pathogen, food, etc. causing/ not causing illness)

# “Opportunity” Themes

- **Improved “evidence” base for decision-making; enhance certainty of linkage between cases, foods, sources, risk factors**
- **“Big data”; hazard-based “flags” of concern (predictive analytics)**
- **Use WGS to understand (or eliminate potential) environmental sources of microbial hazard & understand changes over time**
  - Geographic distribution of microbial hazards by strains and AMR (ecology)
  - More data on sporadic illness/small outbreaks, better understanding of where on the farm-to-table continuum that contamination occurs; also “when” and maybe “how”
  - Better information on routes (some new) to run different “what if” scenarios and provide more robust information on benefits of risk management interventions

# “Opportunity” Themes

- **WGS will not necessarily simplify exposure assessment – but can provide insights to explain what mitigations may or may not work for different strains**
- **Use WGS for microbial hazards to create a “threshold” of safety (much like chemical risk assessment) ( “safety assessment”)**
- **Could we model events that lead to outbreaks – i.e., to inform root cause analysis and identify causes in the outbreak.**

# “Challenge” Themes

- **Expression of genes (translation of genomic info. to phenotype)**
  - Need to know if genes are expressing or if multiple genes expressing that result in increased severity or higher likelihood of illness
  - Changing gene expression and implications for assessing food safety risk
- **Application of WGS in food safety (primarily outbreak detection/pathogen sourcing) – emerging field**
- **In general, more robust meta-data from outbreak investigation to link environment/food/cases with specificity useful for systems modeling**
- **More information needed on “host” factors for susceptibility**

# “Challenge” Themes

- **Consideration of complete genomic information for a hazard – info. on ability to cause illness (e.g., virulence) and factors that contribute to presence/persistence and growth (exposure dose)**
  - Some risk assessments for *Salmonella* moving away from modeling growth from production to consumption (works for certain risk management options)
- **Further evolution of interpretation of WGS (harmonized interpretation; identification of markers, etc.)**
- **Assurance of data quality (reproducible), etc.**

# “Data Needs” Themes

- Which markers/genes associated with phenotypes (e.g., which factors indicate virulence, persistence)
- “Host” factors for susceptibility
- Studies to understand interrelationship between “dose” versus “virulence” (and AMR) in likelihood of specific adverse health outcome
  - Example of two risk situations: illness from hazard is severe but the hazard does not survive vs. high prevalence of hazard but low infectivity

# “Data Needs” Themes

- Dose-response data (from animal studies) for specific pathogenic strains (defined w/ certain genomic markers)
- Predictive microbial data from studies to evaluate growth of specific pathogenic strains (defined w/ certain genomic markers)
- Enhancing information gathering/sharing from experiences using WGS during “watches” and investigations of foodborne outbreaks
  - Share after action reports w/ additional risk information
  - More metadata – type of hazard/food, patient demographics/host characteristics, severity of illness/outcome, source attribution, and information on where hazard introduced, and attenuating factors (consumer storage, supply chain sanitation/cross-contamination, failed interventions, etc.)

# “Data Needs” Themes

- Baseline – environmental survey and non-outbreak data to help make sense of the outbreak information
- Presence of certain genes result in increased severity, persistence or higher likelihood of illness
- We need to learn from past experiences (e.g., wPFGE, serotyping advances)
- Need a lot of experimental work to understand the connections – food matrix, food properties, interactions



# “Next Step” Themes

- Which pathogens do we focus on first?
  - *Listeria monocytogenes* – more epidemiological/WGS data
  - *Salmonella* – most cases of illness in U.S.
- Use information gleaned from outbreak investigations using WGS to identify a set of risk management questions
  - Triage: lab studies, data collection efforts (including epi. Investigations), and assessments of risk (risk profile, QMRA)
- We still have a lot of questions and a case study could help provide direction.
  - Revisit risk assessment for pathogen-product pair to explore value of WGS information
- We need to learn from past experiences (e.g., wPFGE, serotyping advances)
- Need to lay out near term and long term goals

# Summary

- Just beginning in-depth cross-disciplinary discussion on WGS to assess risk as WGS is emerging to support outbreak investigation
  - Many questions remain
  - Clear potential to strengthen foodborne attribution of cases
  - Collection of metadata (robust) will help to provide a link between cases/food vehicles/environment (essential for assessing risk)
  - Detailed information may provide insight on which interventions may mitigate a hazard (difficult) and those that do not seem to matter (more likely)
  - Laboratory studies may benefit from clear “information needs” from QRMA and/or WGS application in epidemiological investigation

# Take Aways

- Need to lay out near term and long term goals
- Requires on-going cross-disciplinary collaboration and dialogue to include risk assessors
- Near term: WGS support of epi. linkage of cases/foods/environment/risk factors -enhance the certainty of QMRA predictions (“informs QMRA”)
- Exploration of case studies useful for moving from discussion to application of WGS to quantitative microbial risk assessment
- Long term: Interlinked “big data” may result in predictive analytics as a reality for assessing potential risks (“flags”) – requires investment in data, data quality control, data management

