IMPLICATIONS OF WHOLE GENOME SEQUENCING ON THE CONDUCT AND APPLICATION OF RISK ASSESSMENT IN FOOD SAFETY DECISION-MAKING

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Background

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.
- **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

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

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.

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.)?*
- *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?*

Proposal

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[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 Foos 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

Form a work group of interested IRAC members to:

- Explore the current application of WGS in food safety, e.g., epidemiological investigations and source tracking, and the types of data/information generated.
- Evaluate the potential opportunities and challenges in applying WGS information to advance the field of food safety QMRA: hazard identification, exposure assessment, hazard characterization, and risk characterization.
- Consider the application of the risk analysis framework and use of QMRA to guide the collection of targeted WGS data and related research.
- Consider implications of WGS in regulatory decision-making both directly (e.g., recalls) and as information used in QMRAs and other assessments of risk (e.g., in formulating food safety policies).

Expected Outcomes (FY2017-FY2018)

- **Review** of the scientific literature on WGS and assessing food safety risk and role in decision-making (FY 2017).

- **Webinars and symposia** among federal partners and invited scientists to derive a shared understanding of the emerging field of WGS and its current applications in epidemiology and potential applications to improve risk assessment and decision-making (FY 2017).

- **Roundtable** among national and international scientists to discuss how risk assessment can guide WGS research and how WGS can further improve food safety risk assessment. IRAC members and invited experts will also explore the broader application of WGS in food safety decision-making (FY 2017).

- **White paper** representing current U.S. federal thinking on the utility of WGS in assessing food safety risks, QMRA role in guiding the collection of WGS data, and corresponding implications on food safety decision-making. (FY 2018)

IRAC participants in this work group would communicate and interact regularly during FY 2017, mostly via email and telephone conferences. It is expected that there will be close interaction among agency representatives on this work group. If logistics and agency resources allow, the group will hold regular or semi-regular in-person meetings in the Washington, DC area.

Budgetary Requirements

No expenses are expected during FY 2017, with the exception of work group members' time, salary and possible travel. If a symposium or workshop proposal is accepted, the participants' conference registration and travel would constitute an FY 2017 or FY 2018 expense.