2016 IRAC Working Group
Statement of Work

January 19, 2016

APPROACHES TO DIETARY EXPOSURE ASSESSMENTS: OPPORTUNITIES FOR ENHANCEMENT OF INTERAGENCY COLLABORATION

Tentative List of Participating Agencies (additional participants welcome!)

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FDA Center for Food Safety and Applied Nutrition, Office of Analytics and Outreach	Judi Spungen (Working Group Chair), Alexandra Gavelek, Stephanie Briguglio, Debbie Smegal
FDA Center for Food Safety and Applied Nutrition, Office of Food Additive Substances	Diana Doell and Jessica Cooper (advised by Mike DiNovi)
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Background

Dietary exposure assessment, an essential component of risk assessment, involves integrating data on hazard levels in foods and data on the consumption of these foods by individuals across an entire population or during specific life stages (usually stratified by age or sex). The approaches and procedures used for dietary exposure assessment may vary among and within U.S. Government agencies conducting these assessments. Some of these differences in purpose and goals of these assessments may reflect differences in decision-making contexts (e.g., statutes). However, there are opportunities for enhanced collaboration, and greater harmonization of these approaches may be possible.

A previous IRAC Work Group, "Evaluation of Dietary Assessment Approaches and Needs," was formed in 2013 with the goal of conducting "a systematic and useful comparison of dietary assessment data sources and analytical tools, to better understand the ways in which agencies integrate dietary assessment in their decision-making process, and to determine whether IRAC members' dietary assessment needs are currently being met." This group produced a draft outline of a white paper and a list of questions about dietary exposure assessment (Attachments 1 and 2). The goal of the proposed new work group is to complete the systematic comparison of dietary assessment data sources and analytical tools used by different U.S. federal and international agencies for dietary exposure assessment.

Proposal

Form a work group of interested IRAC members to

1) Clarify the various decision-making contexts for which dietary exposure assessments are conducted and used.

2) Identify and summarize the different data sets or data sources and how various government agencies use the data to conduct dietary assessments.
3) Identify and summarize the approaches and procedures used for dietary exposure assessment in various agencies.
4) Identify and summarize the capabilities of currently available dietary assessment software packages.
5) Identify potential opportunities for increased collaboration or sharing among agencies to advance dietary exposure assessment capabilities.

Expected Outcomes (Deliverables)

1) A white paper describing dietary exposure assessment approaches used by U.S. Government agencies and the strengths, capabilities, and opportunities for advancement of dietary assessment tools, and/or
2) A summary of key findings published on Foodrisk.org, including links to the tools and other summary information.
3) A proposal for a symposium or workshop to present and discuss findings, possibly for the 2017 annual meeting of the International Society of Exposure Science, Society for Risk Analysis, or International Association for Food Protection.

Time Frame for Completion

It is expected that the white paper and the summary of findings for Foodrisk.org will be completed by the end of FY 2016. While the symposium or workshop would take place in FY 2017, the proposal for such a symposium will be due in FY 2016. IRAC participants in this work group would communicate and interact regularly during FY 2016, mostly via email and telephone conferences. Depending on the physical location and availability of work group members, regular or semi-regular in-person meetings in Washington, DC, may be desirable.

Budgetary Requirements

No expenses beyond work group members' time are expected during FY 2016. If a symposium or workshop proposal is accepted, the participants' conference registration and travel would constitute an FY 2017 expense to be paid for by the participants' agencies.

Attachment 1
Draft Outline of White Paper

September 27, 2013

This is a rough draft developed during a preliminary meeting. The draft will be finalized by the full workgroup which will start meeting in FY14.

Background

- Relevant Regulatory and Public Health Agencies
    - FDA (various Centers)
    - USDA (various Agencies)
    - EPA (various Offices)
    - CDC (?)
    - Others?
- Dietary Assessment Framework (to help introduce data sources and models)

Data Sources

- Consumption Survey Data
    - National Health and Nutrition Examination Survey/What We Eat in America (NHANES/WWEIA)
    - EPA Exposure Factors Handbook
    - Industry Surveys (e.g., Nestle FITS)
    - Continuing Survey of Food Intakes by Individuals (CSFII)
    - Food frequency surveys (Market Research Corporation of America 14-day food frequency survey
    - NPD Survey
    - Others?
- Nutrition and Recipe Data
    - EPA Food Commodity Intake Database (FCID)
    - USDA Food and Nutrient Database for Dietary Studies (FNDDS)
    - Food Intakes Converted to Retail Commodities Databases (FICRCD)
    - Others?
- Contaminant Data
    - USDA Pesticide Data Program
    - FDA Total Diet Survey
    - FDA and USDA enforcement and monitoring data
    - Industry market-basket surveys
    - Specialty commodity testing by other entities (e.g., contaminants in fish, wild harvested plants)
    - Others?
- Food availability/disappearance (ERS publications)

- Linkage to Customs Schedule B commodities (rice for example is categorized as broken, in the husk, milled or semi milled, or husked); linking food forms traveling in commerce to the recipes would be advantageous.

Software applications/model approaches

- Start with generic conceptual model of dietary exposure/contribution
- Comparison of capabilities, functions of specific applications and approaches
    - Dietary Exposure Evaluation Model-Food Commodity Intake Database (DEEM-FCID)
    - FARE
    - FARE-NET
    - Crème Food
    - Stochastic Human Exposure and Dose Simulation Model (SHEDS)
    - Cumulative and Aggregate Risk Evaluation System (CARES)
    - FDA ENVIRON database model (2004~6 vintage)
    - @Risk, Crystal Ball, other approaches

How agencies conduct dietary assessment

- What types of questions are answered?
- What approaches, including applicable software packages, are used?
- Do agencies have general rules or practices that govern which input data, model assumptions, and output statistics to use?
    - One-day vs. two-day survey, food frequency in lieu of intake data
    - Chronic, sub chronic or acute exposure
    - Total population, specific life stages (also vulnerable populations), special subgroups likely to more exposed than the general population (ethnic or racial groups, geographic region)
    - Average annual exposure, seasonal exposure, event-mediated exposure (Thanksgiving, Fourth of July, Cinco de Mayo, Super Bowl, wedding, hospitalization/sick)
    - Aggregate and cumulative assessments
    - Jurisdictional issues – only regulated entities or entire dietary contribution
    - Mean, median, percentiles, distributions, etc.
    - Model evaluation techniques – sensitivity analysis, error analysis, contribution analysis

International comparison

- EFSA, ILSI Europe…

Identify data gaps for implementing some approaches
Record any agency needs that have been identified

ATTACHMENT 2

June 17, 2014

Dietary Assessment IRAC Workgroup

SUMMARY OF FY14 ACTIVITIES

The workgroup met roughly every two months during the year and included members from FDA/CFSAN, FDA/CVM, USDA/AMS, USDA/ARS, USDA/FSIS, and USDA/NIFA. The workgroup collected "questions of interest" about dietary assessment that could be addressed cooperatively in the future. The questions point to issues where different agencies might take different approaches, or where there is no clear answer. If there is interest, any number of these questions could be addressed in a potential future IRAC workshop, with the goal of harmonizing various agency approaches in dietary assessment or understanding why different agencies might need to take different approaches.

FDA/CFSAN is currently developing several SOPs for dietary assessment. Reviewing and commenting on these SOPs was identified as a future potential task for IRAC or a repurposed dietary assessment workgroup.

Concentration data

- Do you use mean concentrations or individual concentration values (Monte Carlo analyses) in exposure/intake analyses? Or do you use median or log-mean concentration values instead of mean values?
- How do you deal with values below the LOD in developing means?
- How do you deal with values below the LOQ in developing means?

Consumption data/analysis

- Do you use NHANES Day 1 data? Each day separately (person-day analysis)? 2-day averages? Or FARE-NET data 10-14 day averages? What determines your use of each?
- Do you estimate usual intakes? If so, for what purposes? And if so, which method do you use?
- Do you estimate average serving size, daily consumption amount, annual consumption amount, total number of servings? How does your analysis differ for chemical and microbial contaminants?
- When do you use data from the latest NHANES vs. data from combined years? Do you base your judgment on sample sizes (for mean, 90th percentile, etc.), and if so, what are your cutoffs? Do you use the NHANES guidelines for minimum sample sizes?
- What statistical measures do you use for the distribution of food consumption, i.e. mean, median, standard deviation, variance, spread, percentile, lower/upper 95% limits, etc.? What intake upper percentile(s) do you use to characterize heavy users?
- What age groups do you use in analyses? Does this vary by situation? Specifically, what age range do you use to characterize women of childbearing age?