FDA-iRISK® 5.0: A Closer Look

FDA-iRISK® 5.0 is the latest version of a web-based risk assessment system developed by the U.S. Food and Drug Administration's Human Foods Program. This interactive tool facilitates comprehensive, more rapid ranking of risks from food-hazard combinations and likely effectiveness of potential solutions, for risk managers to consider in making policy and other decisions.

As with previous versions, v5.0 enables users to efficiently build and conduct fully quantitative, fully probabilistic risk assessments of food safety hazards. With a built-in model framework and automated features, it enables users to systematically predict, compare, and rank the estimated (1) risks from multiple microbial hazards and chemical contaminants in multiple foods, and (2) effectiveness of proposed control measures and other changes in a food's farm-to-table pathway. FDA-iRISK generates results as public health metrics, providing risk managers with a means to compare the likely public health impact of food safety hazards and proposed interventions.

Broad View of FDA-iRISK

The figure below shows FDA-iRISK model structure. With many built-in functions, standard data-entry templates in FDA-iRISK, users enter data to build various scenarios that reflect foods, hazards, and issues of interest. FDA-iRISK, with the underlying Analytica™ Decision Engine software, then uses custom, built-in equations and algorithms to perform Monte Carlo simulations (variability only, or second-order with variability and uncertainty) in pre-structured models. The tool can produce results not only as predicted illnesses per year and as mean risk of illness (average probability of illness from one eating occasion), but also as other public health metrics; e.g., Disability-Adjusted Life Year (DALY), Cost of Illness (COI), and Quality-Adjusted Life Year (QALY) loss.

What Users Can Do, Highlighting New Features:

- Explicitly include probabilistic uncertainty and variability
- Use built-in predictive models and readily import data and models from ComBase (for microbial growth and inactivation)
- Readily import outputs from the FDA-OC App (e.g., for 2-class and 3-class mixed sampling plans)
- Correlate consumption across life stages
- Utilize an expanded flexible approach to defining diets with chronic multi-food consumption parameterized by consumers-only distribution and percentage of consumers
- Compare risks and changes in risks from multi-food scenarios of chronic exposure to one or more chemical hazards, as well as single-food scenarios of acute exposure to a microbial or chemical hazard
- Visualize intermediate estimates (e.g., prevalence and concentration), exposure estimates, and risk estimates (e.g., illnesses and DALYs) for scenarios

The risk scenarios users build can include any or all steps in the food chain, through to consumption, via pre-loaded process types. Changes in prevalence and concentration of a hazard in a single food, or multiple foods, can be simulated at any step of the chain, including changes resulting from interventions. Users can modify their scenarios and data to predict the differences in public health outcome; e.g., by focusing on subpopulations, consumption patterns, and conditions affecting concentration of a contaminant in the food at different steps of the food chain.

The User's Role

Users enter data for seven elements (below), in templates that inform pre-structured models. The tool uses mathematical logic and Monte Carlo simulation to integrate the data and generate results.

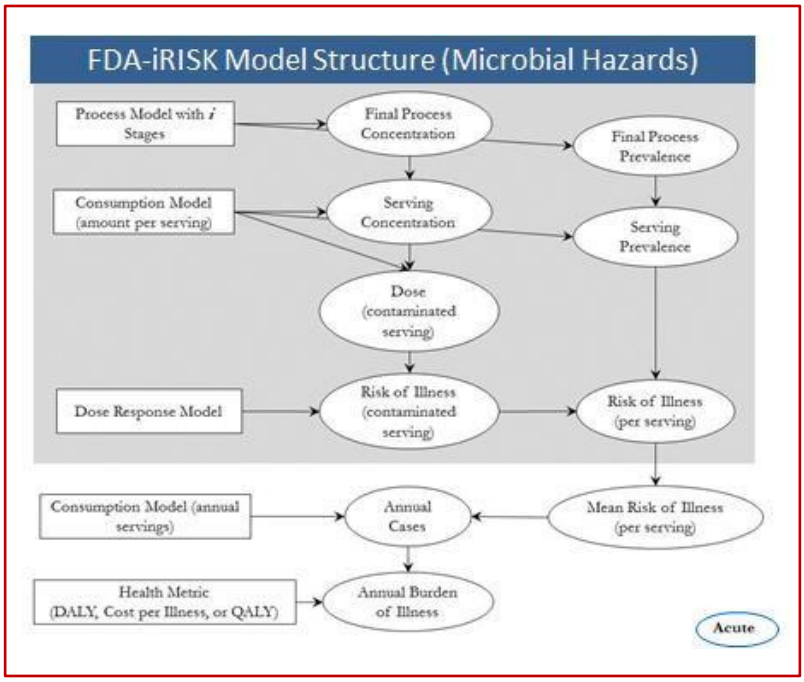
- **food**, **hazard**, and **population** of interest.
- models for **process** (i.e., processes through which prevalence and concentration of the contaminant in food units change at various steps in the food chain), **consumption** patterns, and **dose-response.** The process model provides built-in distribution options for chemical and microbial contaminants, and allows users to, for example, describe rare-event contamination that occurs with probability of <0.1%; implement sampling and reject contaminated product lots; and define parallel process pathways with variations in selected steps. Consumption patterns can be defined for different populations (to evaluate acute exposure), or multiple life stages of a given population consuming multiple foods (to evaluate chronic exposure). The dose-response model allows users to define correlation between uncertainty parameters, and define steadily (monotonically) decreasing dose-response to allow evaluation of health benefits.
- **DALY template –** reflects, e.g., severity of health outcomes in the population under consideration and the fraction each outcome comprises. FDA-iRISK saves these data and, like data entered for the other elements, allows subsequent users to adopt the completed template as is or to build on it, after which FDA-iRISK would again save the augmented template for future users. The tool also provides a health metric template for COI and loss of QALYs.

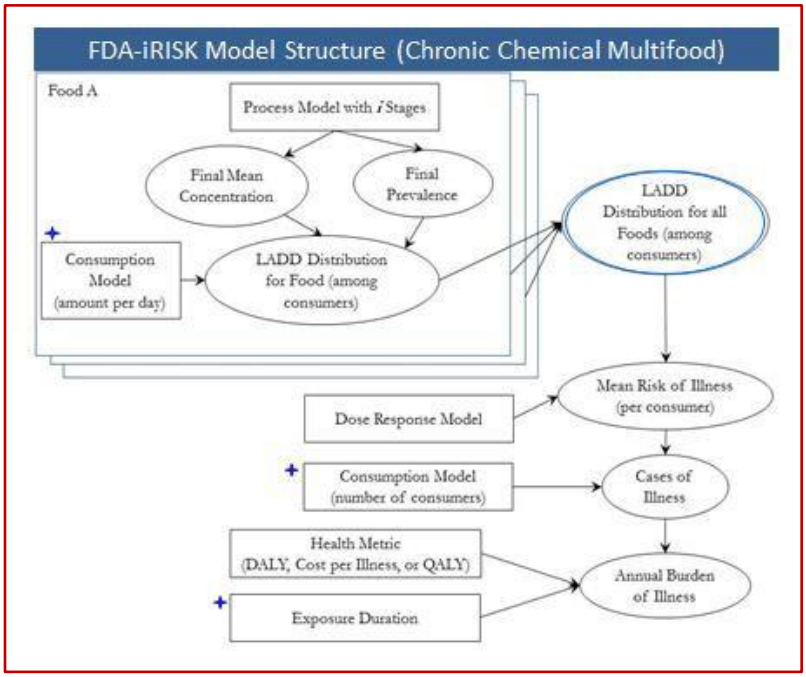
Users can develop a risk scenario with all seven elements or an exposure scenario that takes into account only contamination in food and consumption patterns, with the option to report the proportion of contaminated food units that exceed a concentration threshold for acute and chronic scenarios. Exposure-based ranking may prove useful when users don't need to estimate the number of illnesses, or when the dose-response model is not available. FDA-iRISK provides graphical representations of dose-response and variability in contamination and consumption for users to better understand and verify data and model inputs.

Besides the option to rebuild an entire scenario to evaluate proposed intervention(s), FDA-iRISK allows users to change the existing scenario at only the specific step(s) in the food chain at which the intervention(s) would occur, for a set or multiple sets of parameters simultaneously. FDA-iRISK provides a feature for streamlined sensitivity analysis parameterization, with which users can modify inputs in the process model, consumption model, dose-response, and health metric for various scenarios. FDA-iRISK has advanced modeling capacities, with which users can, for example, explicitly assess variability and uncertainty in model inputs (by second-order Monte Carlo simulation), import multi-food consumption models, predict pathogen growth and inactivation by importing data and models from ComBase (https://combase.errc.ars.usda.gov/), evaluate sampling from linkage to outputs from the FDA-OC App (https://foodsafetyrisk.org/OC/), use an expanded approach to defining diets, use stored process models for more efficient simulations of a large multifood scenario, and estimate DALYs per person per year for both chronic and acute exposures. The tool provides visualization of intermediate estimates (e.g., the distribution of microbial concentrations in contaminated products across process stages), exposure estimates for chronic chemical scenarios, and risk estimates (e.g., illnesses and DALYs) for microbial and chemical scenarios. Users can combine scenarios from different repositories in a single risk ranking. FDA-iRISK generates a full report, including a summary of risk estimates, and details of data and rationale entered by the user.

Indirect Users Are Part of the Intended Audience

FDA-iRISK is intended for direct use by risk assessors and food safety professionals with some risk modeling experience (not necessarily extensive). Advanced users may benefit from features such as customizable settings for probabilistic second-order Monte Carlo simulation, which can separate the impact of variability from that of uncertainty in the outcome of a risk assessment. However, risk managers are among the most important indirect users. They are most likely to be aware of the public health questions that can be addressed by FDA-iRISK and to initiate requests, and to put to practical use the results generated by the tool. FDA-iRISK is made available freely (https://irisk.foodrisk.org/) to help promote risk-based thinking and risk-based approaches to food safety management.





Process model: FDA-iRISK lists process types through which a hazard can change at various steps in the food chain (e.g., by growth, inactivation, conversion of pathogen cells to toxin, and contamination by transfer from the production and processing environment). The user chooses a process type for each step in the process model and populates it with data (including linkage to data from ComBase), for a food-hazard scenario, or multi-food scenario to capture chronic exposure to contaminant(s) in multiple foods.

Dose-response model: FDA-iRISK offers choices of pre-structured dose-response models. The user selects one and populates it with data. Equations are embedded and empirical models are acceptable; FDA-iRISK does the calculations.

Health metrics: For each hazard, FDA-iRISK provides a template for the user to enter data on severity and duration of potential health outcomes, including relative frequency of each outcome (i.e., among all outcomes from the hazard, the fraction that each outcome comprises). This template and the data entered in it are the means by which FDA-iRISK incorporates severity of illness (burden of illness) in risk estimates expressed as public health metrics.