Version 4.0: A Closer Look

FDA-iRISK® 4.0 is the latest, enhanced version of a free, web-based risk-assessment system developed by the U.S. Food and Drug Administration. 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, v4.0 enables users to efficiently build and conduct fully quantitative, probabilistic risk assessments of food-safety hazards. 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 risks and proposed interventions.

Broad View of FDA-iRISK

The figure below shows FDA-iRISK model structure. Users enter data to build scenarios that reflect the food-hazard and issues of interest, with support from built-in, standard data-entry templates. FDA-iRISK, with 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. Version 4.0 can produce results not only as predicted cases and DALYs, but also as QALYs and COI, among other public-health metrics.

What users can do with new features -- e.g.:

- Explicitly include probabilistic uncertainty and variability
- Use built-in predictive models (for microbial growth and inactivation)
- Import data (empirical distribution) from an external file
- Create a multi-food scenario of chronic exposure to a hazard in multiple foods
- Rank chemical hazards based on exposure
- Compare risks/changes in risks from multiple hazards among consumers with different dietary patterns.

The risk scenarios users build can include any or all steps in the food chain, 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 change the data in their scenarios to estimate the differences in public-health outcome; e.g., by focusing on subpopulations or by changing the variability and/or uncertainty of concentration of a contaminant in the food at different steps of the food chain. The tool has advanced modeling capacity, ability to report results in various ways, and distribution options for chemical and microbial contaminants. Graphical representations of dose-response and variability in contamination and consumption enable users to better understand and verify data.

The User's Role

Users enter data for seven elements, in templates that inform pre-structured models. The tool uses mathematical logic and 2D Monte Carlo simulation to integrate the data and generate results. The seven elements are:

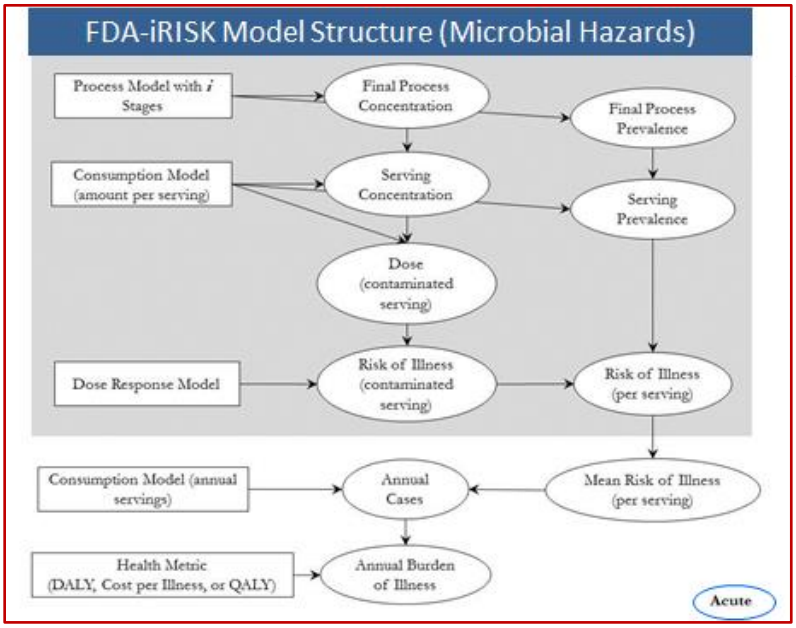
- **food**, **hazard**, and **population** of interest.
- models for **process** (i.e., processes through which prevalence and concentration of the contaminant in food units change at various steps in the food chain), **consumption** patterns, and **dose-response.** The process model allows users to, for example, describe rare-event contamination that occurs with probability of <0.1%; implement sampling and reject contaminated product; 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. Version 4.0 also provides a template for loss of QALYs and Cost of Illness.

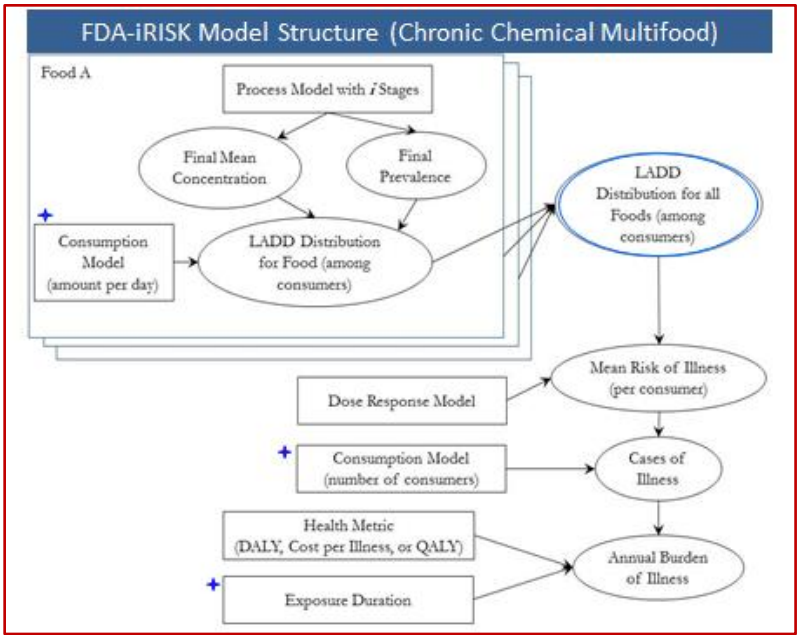
Users can develop a risk scenario with all seven elements, or an exposure-only model that takes into account only contamination in food and consumption patterns. This allows exposure-based ranking, which may prove useful when

users don't need to estimate number of illnesses, or when the data needed to define the dose-response model are inadequate. Besides the option to rebuild an entire scenario to evaluate a proposed intervention, 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 either one parameter or a set of parameters; this can expedite evaluation of up to six interventions or 30 sets of parameters simultaneously. As noted, FDA-iRISK can express results not only as DALYs, but also in other ways; for example, as mean risk of illness (average probability of illness from one eating occasion) or predicted total number of illnesses, per year, for a food-hazard combination. Users now receive notification of the status of their simulations, and can combine scenarios from different repositories in a single risk ranking.

Indirect Users Are Part of the Intended Audience

FDA-iRISK is intended for direct use by risk assessors and by food-safety professionals with some risk-modeling experience (not necessarily extensive). Advanced risk assessors may benefit from advanced features in v4.0, such as customizable settings for 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, for example, to inform food-safety decisions.





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, for a food-hazard scenario, or multi-food scenario to capture chronic exposure to a contaminant 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 public-health metrics.