FDA-iRISK® 5.0
food-safety modeling tool

- *Compares and ranks risks from multiple combinations of foods and hazards (microbial and chemical)*
- *Predicts effectiveness of interventions at any step of the food supply chain, from farm to consumer*
- *Calculates public health outcomes of food production practices and interventions*
- *Informs decision-making for risk managers and others (e.g., prioritization, resource allocation)*

FDA-iRISK® is an interactive, web-based risk assessment tool the Human Foods Program in the Food and Drug Administration (FDA or "we") has developed to inform prioritization and intervention decisions about food safety. We created this tool to meet our need to compare the public health impact of foodborne hazards (e.g., pathogens, naturally occurring toxins, and chemical contaminants) that could endanger our food supply, and to evaluate the public health impact of proposed interventions. FDA-iRISK expedites and enhances the process of building mathematical models that enable users to rank the risks posed by specific hazards in foods. Since the initial launch in 2012, FDA has continued to expand this innovative tool, and version 5.0 is now available to the public, at no charge. Advanced features include substantial capacities for the underlying modeling methods (notably second-order Monte Carlo simulation), linkage to other tools and databases, and enhancements to the web interface.

Features

Through a built-in model framework that includes templates and mathematical functions, FDA-iRISK automates the risk assessment modeling process, enabling users to build risk scenarios that simulate real-world (or theoretical) food safety issues. FDA-iRISK then performs calculations that predict the public health outcomes of the scenarios according to the risks they pose to consumers.

By modifying the scenarios and data to reflect existing or possible changes in various practices in food production, processing, or handling, users can evaluate the impact that interventions would be expected to have on consumer exposure and foodborne illness. A feature for streamlined sensitivity analysis parameterization enables users to quickly simulate variations in any of the model inputs, including steps of the food production pathway. Users can estimate the effectiveness of a proposed intervention or a set of interventions more quickly than if they had to rebuild the entire scenario (although that, too, is an option). The results provide risk managers with likely public health outcomes of various scenarios, as options.

Examples of FDA-iRISK Functionality:

- **Assess risks and interventions for:**
  - one hazard in different foods
  - multiple hazards in a single food
  - multiple food-hazard combinations
  - acute exposure to a hazard (microbial and chemical) and chronic exposure to one or multiple chemical hazards
- **Assess risks and health benefits from various dietary patterns**
- **Separate and quantify variability vs. uncertainty**
  The impact on a risk assessment's results of variations in a food, its production and handling, and the hazard being considered vs. impact of insufficient data about them

FDA-iRISK can evaluate and compare risks across multiple facets of food production and a broad array of scenarios. Because of its built-in, automated features, it can be used not only by experienced risk modelers, for whom it can expedite risk assessment, but also by users who might not have extensive mathematical modeling experience.

FDA-iRISK can express risk as mean risk of illness from one eating occasion and predicted total number of illnesses per year for a food-contaminant combination, for various populations. FDA-iRISK can also express risk and predicted impact of interventions as other public health metrics, such as Disability-Adjusted Life Year (DALY), Cost of Illness (COI), and Quality-Adjusted Life Year (QALY) loss. This allows risk managers to consider not only the number of illnesses associated with various food-contaminant combinations (and reductions associated with interventions), but also the severity of those illnesses, as well as their impact on quality of life and costs; important information when considering public health impact and resource allocation. Results generated by FDA-iRISK are presented in a brief, straightforward table, accompanied by a full, detailed report, for the user's reference.

Additional Highlights

FDA-iRISK includes built-in mathematical architecture for seven elements of a risk scenario: food, contaminant, population, food production/processing model, consumption patterns, dose-response model, and health effects. Flexibility and choice are prominent features of the tool; for example, users may include in the scenarios they create not only various hazards and foods, but also conditions at one or more stages of the food supply system and various consumer subpopulations.

The production/processing model includes a feature that accommodates rare contamination events (e.g., occurrence of less than 0.1% in the food production chain), which, although rare, may have the potential to cause considerable illness. Moreover, users can predict the frequency of concentration exceedance for acute and chronic scenarios. New features in v5.0 enable users to incorporate correlations across life stages into consumption models; parameterize chronic multifood consumption with consumers-only distribution and percentage of consumers; use stored process models for more efficient simulations of a large multifood scenario; visualize intermediate estimates (e.g., prevalence and concentration), exposure estimates, and risk estimates; and import data and models from i) ComBase to predict pathogen growth and inactivation and ii) the FDA-OC App to evaluate the impact of sampling.

In addition to the ability to build a risk scenario that includes all seven of the elements, another useful feature is the ability to develop "exposure only" models that take into account contamination in food and consumption patterns. This allows users to calculate the amount of consumers' exposure to the contaminant in question, when they do not need to estimate the number of illnesses or when the literature or other sources lack the data that would be needed to populate the dose-response model.

Among the many capacities of FDA-iRISK is that it creates an unprecedented platform for data sharing; e.g., users can build scenarios based on those of previous users who opt to voluntarily share their data. It can also be linked with other tools or databases; for example, v5.0 includes linkages to import outputs from the FDA-OC App and data and models from ComBase readily.

To learn more about FDA-iRISK, or to register to use it, visit https://irisk.foodrisk.org. Recordings of introductory webinars are available at https://www.foodrisk.org/resources/display/2.