

FDA-iRISK[®] 4.0

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 food-supply chain, from farm to consumer*
- *calculates public-health outcomes of food-production practices and interventions*
- *is useful to risk managers and others, for decision-making; e.g., prioritization, resource allocation*

FDA-iRISK[®] is an interactive, Web-based risk-assessment tool 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 the public-health impact of proposed interventions. FDA-iRISK speeds 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 4.0 is now available to the public, at no charge. New features in v4.0 include substantial new capacities for the underlying modeling methods (notably second-order Monte Carlo simulation), data importing and results reporting, 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 food-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 changing the data in the risk scenarios, to simulate proposed interventions in food production, processing, or handling, users can predict the reduction in risk likely to occur if the interventions were implemented. A sensitivity-analysis feature enables users to 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.

FDA-iRISK can evaluate and compare risks across multiple facets of food production

Examples of what FDA-iRISK can do

- **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 a chemical hazard
- **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

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 results as mean risk of illness (e.g., average probability 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 in various ways, including as other public-health metrics, such as Disability-Adjusted Life Years (DALYs) and Cost of Illness (COI), and with v4.0, 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.

Some Feature Highlights

FDA-iRISK includes built-in mathematical architecture for seven elements of a food-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 any stages of the food-supply system and various consumer subpopulations.

The production/processing model includes a feature that accommodates rare contamination events (occurrence of less than 0.1% in a food's production chain), which, although rare, may have the potential to cause considerable illness. In v4.0, users can simulate variations in a given step or steps in the food-production ("processing") model they have already built, without having to rebuild that entire model; more easily predict the growth and inactivation of pathogens; and combine scenarios from different repositories in a single risk ranking.

In addition to the ability to build a risk scenario that includes all seven of the elements noted above, 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 (i.e., the amount of the contaminant required to cause illness – one of the seven elements).

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, to increase its power further.

To learn more about FDA-iRISK, or to register to use it, visit <https://irisk.foodrisk.org>. A recording of an introductory webinar is available at <http://foodrisk.org/exclusives/fda-irisk-a-comparative-risk-assessment-tool/>.