FDA-iRISK® 2.0

food-safety modeling tool

- *compares and ranks risks from multiple combinations of foods and contaminants (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, processing or handling practices, and interventions*
- *is useful for prioritizing, decision-making, resource allocation*

FDA-iRISK® is an interactive, Web-based risk assessment tool the Food and Drug Administration (FDA or "we") developed and made publicly available in 2012. Version 2.0 is now available online, free of cost. We created this tool to meet our need to compare, numerically, the public-health impact of pathogens, microbial toxins, and chemicals in various foods that could endanger our food supply. FDA-iRISK ranks the risks posed by specific hazards (i.e., contaminants) in specific FDA-regulated foods; risks that compete for the agency's attention and public-health resources. FDA-iRISK also estimates and compares the effectiveness of proposed interventions and control measures. Policy-makers and others can use the results to inform prioritization and intervention decisions.

Features

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

By changing the risk scenarios to reflect interventions in food production, processing or handling, users can predict the reduction in risk that would occur if the interventions were implemented. Users can opt to change the data only in the relevant point in the existing scenario to simulate the intervention. This "sensitivity analysis" feature enables users to estimate the effectiveness of a proposed intervention more quickly than if they had to rebuild the entire scenario (although that, too, is an option).

FDA-iRISK can evaluate and compare risks across many facets of food production and a broad array of scenarios. Because of its built-in, automated features, FDA-iRISK 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. The latter, however, must be informed users; although FDA-iRISK provides the computational architecture, templates, and other automated features, users must populate them with data and assumptions to build their scenarios.

- **one hazard in different foods** (e.g., *Salmonella* in fresh produce vs. in spices vs. in nuts vs. in shell eggs)
- **multiple hazards in a single food** (e.g., leafy greens only: pathogenic *E. coli* vs. hepatitis A vs. *Cyclospora*)
- **multiple hazards in multiple foods** (e.g., *L. monocytogenes* in cheese, arsenic in apple juice, scombrotoxin in tuna, multiple other food/hazard pairs)

FDA-iRISK can express risk and predicted impact of interventions in various ways, including as public-health metrics, such as disability-adjusted life years, DALYs (years of healthy life lost to disability or death). This allows risk managers to consider both the number of illnesses associated with various food-contaminant combinations (and reductions associated with interventions) and the severity of those illnesses; important information when considering public-health impact and resource allocation. FDA-iRISK also can express results as mean risk of illness (average probability of illness from one eating occasion) and as predicted total number of illnesses per year for a food-contaminant combination, for various populations.

(over)

Some specific 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 in FDA-iRISK not only various hazards and foods, but also any stages of the food-supply system and various consumer subpopulations.

The production / processing models include a feature called "increase by addition process type" that accommodates rare contamination events. Although such events may be rare, their potential to result in illness may be considerable. This FDA-iRISK 2.0 feature can consider contamination that occurs with a probability of less than 0.1% in a food's production chain; e.g., 0.05% for pathogen contamination on heads of lettuce in the field. Users can also use a "maximum population density" feature to automatically limit pathogen growth used in calculations, to reflect generally accepted maximum populations of a pathogen in a food that supports its growth.

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, but skips dose response. 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 noted above). An exposure-only model may be particularly useful regarding chemicals; e.g., for providing output for comparison with an established reference point.

Global Implications

Among the many capacities of FDA-iRISK is that it creates an unprecedented platform for data sharing in the international food-safety risk assessment arena; e.g., users can build scenarios based on those of previous users. Over time, FDA-iRISK can capture data from scenarios and their outcomes to build a global picture of risks and interventions in the food supply.

To learn more about FDA-iRISK, 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/.

Ask FDA-iRISK®: what if?

As a simplified case study, consider the following. Decision-makers likely will find it helpful to know not only the number of illnesses associated with a hazard in a broad category of food (such as those addressed by attribution models) – for example, leafy greens, dairy products, or seafood – but also to see a breakdown by product. An example would be to look at specific dairy products, such as milk, ice cream, and cheese, rather than at dairy products as a whole. FDA-iRISK can produce estimates of the risk posed by each of those dairy products (vis-à-vis the pathogen, toxin, or chemical in question), for comparison.

As a risk manager, you might be faced with a food-safety situation that requires you to ask FDA-iRISK to compare the public-health impact of different hazards in different foods. Built into FDA-iRISK is the capacity also to ask, and get answers to, "what if" kinds of questions. What if we reduced the holding time or temperature for milk vs. various cheeses vs. high-fat dairy products, or changed other practices, at specific steps in those foods' production processes – by how much would the estimated public-health risk from the hazard in question change, for each of those products? For what populations, specifically? How would their risk-ranking change, relative to other food/hazard pairs? The sensitivity analysis feature in FDA-iRISK 2.0 allows users to relatively quickly evaluate alternative scenarios. FDA-iRISK results are presented in a brief, straightforward table, which is accompanied by a full, detailed report, for the user's reference.