FDA-iRISK
food safety modeling tool

From the Food and Drug Administration

- **estimates effectiveness of interventions at all steps of food-supply chain, from farm to consumer**
- **compares and ranks risks from multiple food / hazard combinations**
- **calculates public-health outcomes of variations in processing or handling practices**
- **useful for prioritizing, decision-making, resource allocation**

FDA-iRISK is an interactive, Web-based risk assessment tool the Food and Drug Administration (FDA) has made available to the public. It compares and ranks the risks posed by multiple food/hazard combinations that involve FDA-regulated products; risks that compete for public-health resources. Beyond ranking, FDA-iRISK enables users to estimate and compare the effectiveness of proposed interventions and control measures.

FDA-iRISK includes built-in templates, mathematical functions, and other features that enable users, from a variety of backgrounds, to build food-risk scenarios that reflect their real-world (or theoretical) food-safety issues. FDA-iRISK then performs calculations to compare and rank the risks and interventions, based on any or all steps of the foods' production/supply chains. The model can be used to conduct risk assessments that evaluate and compare a broad array of scenarios. Policy-makers and other decision-makers can use FDA-iRISK results to inform their prioritization and intervention decisions.

This tool was created to meet FDA's need for a risk-based, strategic approach to comparing, collectively and numerically, the public-health impact of the various pathogens, microbial toxins, and chemicals, in various foods, that may endanger our food supply. FDA-iRISK can express the estimated impact of proposed intervention or control measures in various ways, including widely used public-health metrics, such as DALYs; i.e., years of healthy life lost to illness or death. Although simply comparing the number of illnesses caused by various foodborne hazards is useful for some purposes, it doesn't reflect the severity of illness and the health toll the hazards take from their victims. DALYs do reflect those factors, providing risk managers with a way of balancing magnitude – number of illnesses from various hazards – with the likely public-health impacts of those hazards, in facing decisions about resource allocation.

Examples: what FDA-iRISK can compare

FDA-iRISK can compare public-health impact of microbial and chemical hazards regarding:

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

FDA-iRISK allows risk comparison across many facets of food production and safety. It includes built-in mathematical architecture for seven components of a food-risk scenario: food, hazard, population, food production/processing model, consumption patterns, dose-response model, and health effects. Flexibility and choice are prominent features of this 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.

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Examples of how FDA-iRISK can express results:

- **Mean risk of illness** (average probability of illness from one eating occasion)
- **Health-impact metric** (disability-adjusted life years – DALYs – i.e., healthy years of life lost to illness or death, per eating occasion or per year)
- **Ranking of risk** posed to various populations by different food/hazard combinations under various food-processing/handling practices

FDA-iRISK ensures broad accessibility and facilitate data sharing and integration, by FDA and the broader user community. The Web-based interface enables users across the world to share data and outcomes. FDA envisions that this tool will lead to an improved quantitative understanding of risk in the food-supply system. For example, one long-range potential is to provide centralized knowledge management; by capturing users' input and results, FDA-iRISK will, over time, build a consistent, documented, systematic, structured, quantitative picture of (1) risk in the food supply (2) scenarios for reducing the risk.

In the meantime, FDA will use FDA-iRISK to provide information about public-health impacts as input for risk prioritization, to inform risk management. For example, the model can inform decisions about allocation of resources for competing needs; about whether more detailed, in-depth risk assessments of a given food/hazard combination should be conducted; and about research priorities. FDA-iRISK is not intended to replace more complex, in-depth risk assessments of single food/hazard pairs; rather, it achieves a balance between complexity and practicality.

In October 2012, FDA made FDA-iRISK and a detailed tutorial available for public use. To access FDA-iRISK and the tutorial, please visit the FoodRisk.org Web site of the Joint Institute of Food Safety and Applied Nutrition (JIFSAN), the FDA partner that hosts the program. A recording of an introductory webinar also is available for public viewing on the JIFSAN site.

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 do nothing more than compare the public-health impact of two different hazards in one or more foods. But 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?

FDA-iRISK results are presented in a brief, straightforward table, which is accompanied by a full, detailed report, for the user's reference. From the brief table, users may choose whichever expression of results best suits their needs. For example, risk managers in the food industry might have more interest in results expressed as mean risk of illness (i.e., risk per serving), whereas government regulators might have more interest in the total DALY (i.e., risk per year) results. In either case, the results will answer for them such questions as "What are the 10 riskiest food/hazard pairs generated by my search, and in what order? Would the interventions I'm proposing reduce their risks, and by how much?"

December 2012