Risk Analysis at FDA: Food Safety
A science-based approach to policy decisions

As the nation's food supply becomes more global and complex, decisions about policies aimed at preventing contamination and illness have become even more important to the public's health. The Food and Drug Administration (FDA) uses risk analysis, a concept and framework fostered by the World Health Organization, to ensure that regulatory decisions about foods are science-based and transparent.

This fact sheet gives examples of how FDA's Center for Food Safety and Applied Nutrition (CFSAN) applies the concept of risk analysis, from tools that prioritize risks to those that calculate optimal interventions. It describes some tools CFSAN is developing, as emerging technologies present new possibilities for detecting and mitigating risks to the food supply. For example, CFSAN and NASA (the National Aeronautics and Space Administration) are conducting a pilot project that uses geospatial analysis to recognize patterns of contamination in crops. That model is helping us develop the ability to forecast high potential for contamination events in specific regions, at specific times and under various weather conditions.

Risk managers make decisions about food-safety policy.

Risk assessors provide information risk managers need to make science-based policy decisions.

Risk communication between risk managers and risk assessors ensures a coordinated approach. Includes communication with stakeholders/public.

Key Features of Risk Analysis

Built into the risk analysis framework is the concept that policy decisions about food depend on a continuous dialogue between policy makers ("risk managers") and scientists who produce data that inform those decisions ("risk assessors"). This not only helps ensure that policy decisions are relevant, but also that they are objective; that they are based on science.

Public input also is built into the framework, to help ensure the real-world relevance and feasibility of CFSAN's policy decisions, as well as transparency. For example, when CFSAN undertakes a project that will inform a policy decision, the Agency posts Federal Register notices to request input from the public, including the food industry and consumer groups, and may also hold public meetings.

Examples of Risk Analysis Tools at FDA

Tools developed by CFSAN, including collaborations with other Federal agencies, have addressed such public-health risks as *Listeria monocytogenes* in foods, hepatitis A virus in produce, and *Vibrio* in oysters. These and other completed projects can be viewed on the FDA web site (URL included on other side).

Tools with potential to considerably increase CFSAN's risk-analysis scope, and its impact on foodborne illness, are now under development. A few examples follow.

• **QPRAM** is a virtual laboratory that will predict and characterize risks from consumption of fresh produce that result from specific behaviors and practices on farms and during the processing and consumption of crops. QPRAM tracks each unit of produce and keeps a history of how, when, where, and by how much it was contaminated. The model can be used as a tool to optimize interventions in real-world scenarios. It can also be used not only to predict and help prevent future contamination events, but also in real-world "trace-backs," to predict the likely point at which produce was contaminated, so that products can be identified and removed from the market more quickly.

(cont'd.)

- **FDA-iRISK**® is an interactive tool that is available to the public, will generates results relatively quickly, and has built-in mathematical functions and libraries of templates. It estimates public- health risks from multiple pathogens or chemical toxins, in multiple foods, and the impact of various interventions, and compares and ranks the risks. Users can focus on any or all stages of a hazard / food combination's farm-to-fork supply system. Impact can be expressed as number of illnesses and as a public-health metric (DALYs). A Web-based interface enables users across the world to share data and outcomes.

- **The Virtual Deli** is a model that simulates, thousands of times per second, all the actions involved in preparation and serving of sliced deli meats to customers, based on observational studies of real-world practices. It's part of an interagency risk assessment (see definitions) on *Listeria monocytogenes* in the retail setting and is designed to estimate at what points in the deli contamination is most likely to occur and what interventions will be most effective in reducing contamination and illness. For example, the model can estimate the potential effectiveness of separating slicers for meat and cheese or of other changes in practices.

Definitions of Some Risk Analysis Tools at FDA

Risk profiles are comprehensive descriptions of a hazard, the supply and consumption chains of the foods it affects, and potential interventions. These types of risk assessments don't include models that estimate outcomes and comparisons of interventions.

Quantitative risk assessments are mathematical models into which risk assessors enter information from risk profiles and other sources. The outcomes are estimates of risk, usually measured as the likelihood of illness from consuming a serving of food, and number of illnesses, per year, among a population that eats the food. Risk assessments also estimate and compare reductions in contamination and/or illness that would be generated by specific interventions applied at specific points of the farm-to-fork continuum.

Quantitative risk assessments may consider:

- one hazard in relation to one food; also called product-pathway risk assessments or
- one hazard in relation to multiple foods or
- multiple hazards in relation to multiple foods (example: FDA-iRISK)

Decision-analysis tools
Decision-analysis tools under development by FDA consider the kinds of data and information above in a larger context, to increase the likelihood that proposed policies will be both adoptable and effective in real-world settings. In considering which interventions would result in the greatest public-health gains when evaluating a specific risk scenario, the tools take into account other factors; for example, the cost-effectiveness and feasibility of the interventions and the likelihood that industry or consumers would apply them. The tools consider the various elements collectively and generate solution sets of optimized priorities and choices.

A Global, Collaborative Effort

Given the scope of today's food supply, risk analysis is necessarily a global, collaborative effort. FDA plays a major role in setting the direction of the risk-analysis field through leadership and participation in the national and international risk-analysis communities. These communities include such bodies as the World Health Organization; the Interagency Risk Assessment Consortium, a collaboration of Federal agencies; and the Joint Institute for Food Safety and Applied Nutrition. For more information and examples of projects, please visit **http://www.fda.gov/Food/ScienceResearch/ResearchAreas/RiskAssessmentSafetyAssessment/default.htm**