Analysis to Support Regulations and Metrics Development

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Lettuce, Enterohemorrhagic E. coli and Irrigation Water: Application of FDA's iRISK Tool for Rapid Risk Assessment to Support Proposed Produce Regulation
The Food Safety Modernization Act of 2011 requires FDA to develop regulations that set risk-based standards for produce safety. We applied FDA's iRISK tool to perform a quantitative risk assessment to estimate the predicted effectiveness of some of the provisions of the proposed produce regulation with respect to one example commodity and one example pathogen. iRISK is a comparative risk assessment model that had been previously developed in collaboration with experts within and outside the government and has undergone an external peer review of the underlying structure and mathematical. The risk assessment evaluated the combination of fresh-cut lettuce, enterohemorrhagic E. coli (EHEC), and irrigation water with and without preventive controls in place. Risk scenarios representing six types of farms were developed in iRISK through a systematic analysis of available data. The iRISK Lettuce-EHEC risk scenarios provide estimates of the probability of EHEC illness from consumption of fresh-cut lettuce contaminated at varying levels as a result of contamination from irrigation water in addition to other on farm sources. We also used the sensitivity analysis capability of the model to evaluate the impact on predicted cases of the timing of the irrigation and the assumption of the EHEC vs. E. coli ratio in the irrigation water. This is a case study for the application of the iRISK tool to rapidly address specific risk management questions. iRISK will be made available at www.foodrisk.org in late 2012.

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Interagency Risk Assessment for L. monocytogenes in Retail Delis
Control of *Listeria monocytogenes* represents a particular challenge for the ready-to-eat (RTE) food industry due to the common presence and persistence of *L. monocytogenes* in virtually all environments along the food continuum. The 2003 FDA/FSIS *L. monocytogenes* risk identified RTE deli meats as the food vehicle responsible for most human listeriosis cases. A subsequent FSIS Comparative Risk Assessment suggested that up to 83% of human listeriosis cases linked to RTE deli meats may be attributable to products contaminated at retail, possibly explaining in part why the frequency of human cases has not declined as expected. To better understand the factors that contribute to contamination of RTE products at retail and evaluate which interventions would be effective to further prevent listeriosis, FSIS and FDA conducted the Interagency Retail *Listeria monocytogenes* Risk Assessment. This risk assessment, developed through collaboration among federal partners and academia with input from industry and consumer groups, provides insight for retail food safety strategies. This presentation will include an overview of the risk assessment model, studies commissioned to fill data needs, and the impact of retail practices (e.g., worker behavior, sanitation, and temperature control) on the risk of listeriosis from RTE foods prepared at the deli counter.

Régis Pouillot
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Quantitative assessment of the risk of listeriosis from soft-ripened cheese consumption in the United States and Canada
A risk assessment model developed to estimate the risk of listeriosis associated with soft-ripened cheese produced and consumed in both the United States and in Canada, has all of the usual features of quantitative microbial risk assessment and several enhancements. The model considers farm and processing plant sources of L. monocytogenes contamination, growth under changing conditions during 'traditional' and 'stabilized process' cheese-making, and growth in a solid medium. The baseline model considers the manufacture of cheese made from pasteurized milk, using a 'stabilized cheese' process, where the source of contamination is from environmental L. monocytogenes in the processing plant. An alternative model for raw milk cheese considers environmental contamination on farm and in the processing plant and

contamination from mastitic cows. The results inform FDA and Health Canada about the impact of strategies designed to reduce listeriosis such as: i) changes to current regulations for 60-day aging; ii) mitigations that lead to some log reduction in bulk milk contamination; and, iii) testing programs for milk and/or finished product cheeses.

Methods for Risk Informed Decision making

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Addressing chemical contaminants without established regulatory limits in meat, poultry, and egg products: the de minimis level approach
As part of the U.S. National Residue Program for Meat, Poultry, and Egg Products (NRP), the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) tests animal products for residues of veterinary drugs and for the presence of other potentially harmful chemical and environmental contaminants, including pesticides and heavy metals. The purpose of this testing is to ensure that the United States' supply of these commodities is not adulterated and therefore safe for human consumption. Levels of registered veterinary drugs and registered pesticides detected in edible animal tissues are evaluated against maximum permissible levels set by the Food and Drug Administration and the Environmental Protection Agency. To complement this approach, FSIS developed a structured process for calculating "De Minimis Levels" (DMLs) for potentially harmful contaminants that do not have established maximum permissible levels. Toxicological data and established health-based guidance values form the starting point. The inclusion of relative source contribution data (taking into account exposure from non-dietary sources and dietary sources that are not meat, poultry and egg products) and dietary consumption data allows FSIS to derive a DML from the toxicological data. The DML is the level of a contaminant in animal tissue at which there is no public health concern. The DML will be used to contextualize positive test results, to prioritize sampling resources, and to help determine whether additional steps are needed to protect consumers. Along with systematic hazard identification and ranking, the detection of unexpected and emerging chemicals, and improved sampling and laboratory methods, the derivation of benchmarks such as De Minimis Levels is an integral part of a strengthened and public-health-based National Residue Program.

Isabel Walls
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Leveraging epidemiology and risk assessment methods to inform risk-based food safety decisions

Revising Analytical Methods in Response to New Data or Information

Robert H. Hall
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Too Much Cholera, Too Little Vaccine: Disease Transmission Models and Decision-Making
Cholera is a severely dehydrating water-borne infection that, if untreated, can kill half of those affected. Although seemingly simple to control through sustained treatment of drinking water and human fecal waste, cholera has relentlessly advanced to endemicity in over 50 countries.

Managing cholera epidemics traditionally involves clinical care; then reducing transmission through water, sanitation, hygiene (WaSH) programs, awareness, and education. Integrating a newly-available cholera vaccine may also reduce the susceptible population. Modeling can estimate the necessary vaccination coverage, however the published values of key parameters show great uncertainty, e.g. in the source and dose of infection; duration and scale of asymptomatic carriage, disease, case reporting, and shedding; cholera dynamics in the aquatic reservoir, and the appropriate multiplier for the hyper-infectiousness of freshly-shed patient stool. Additional uncertainties in endemic cholera include serotype replacement, phage susceptibility, host immunity, and weather. Overall, parameter values ranged across 1 to 5 orders of magnitude. An alternative approach estimating *R0* during cholera epidemics found a wide range across departments (Haiti) and provinces (Zimbabwe). In Haiti *R0* ranged from 1.06 (Nippes) to 2.63 (Artibonite); in Zimbabwe from 1.11 (Mashonaland East) to 2.72 (Matabeleland South):

values necessitating vaccination coverage from 6.9% - 81.0%. Modeling predicts that vaccination is most effective early in the epidemiological curve, i.e. before *R0* can be determined.

The addition of cholera vaccine to the armamentarium represents the first major advance since antimicrobials and oral rehydration were introduced 50 years ago. However, cholera remains a formidable and unpredictable foe, and interventions will have to be rigorously optimized to fulfill the high ambitions.

Linda Abbott
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Using a systems approach to retrospective regulatory review: quantifying economic impact and potential risk reduction due to cumulative regulatory actions in an agricultural watershed in Washington

We expand our 2011 retrospective analysis of concurrent regulatory actions in two small, economically important, agricultural watersheds in Yakima County, WA to assess the cumulative effects on agricultural producers of designating critical habitat for endangered species and the subsequent pesticide restrictions resulting from consultations by the Environmental Protection Agency with the National Marine Fisheries Service. The regulatory impact analysis for the 2006 rule establishing salmonid critical habitat forms the basis for the retrospective analysis. This approach goes beyond the scope of retrospective regulatory review outlined in the two recent Executive Orders to assess the cumulative impact on agricultural producers from a series of endangered species consultations for pesticide registration by a different federal agency than the one that issued the habitat designation rule. We examine the impact of the critical habitat designation on several different interrelated systems in the watersheds including salmon, agriculture and pest populations. Empirical data from a variety of federal and state sources are combined to assess economic impact of the critical habitat designation and subsequent consultations in the two watersheds.

Aaron Niman
Aaron Niman, U.S. Environmental Protection Agency, Office of Pesticide Programs

EPA Dietary Exposure Assessment of Pesticides: Overview and Evaluation of Updated Consumption Data on Commodity Intake and Exposure

Under the Federal Insecticide, Fungicide, and Rodenticide Act and Food Quality Protection Act, U.S. EPA is required to evaluate the health risks of pesticide residue present in the U.S. food supply. To support this effort, U.S. EPA's Office of Pesticide Programs (OPP) assesses dietary pesticide exposure using quantitative exposure modes that incorporate nationally representative survey data on food consumption and food pesticide residue. During the presentation, OPP's dietary exposure assessment methodology will be described with an emphasis on critical surveys, including (i) CDC's National Health Assessment and Nutrition Examination Survey (NHANES), (ii) USDA's What We Eat In America (WWEIA) food consumption survey, and (iii) USDA's Pesticide Data Program. Additionally, the presentation will also describe recent updates to OPP's dietary models and data systems. These efforts include updating U.S. EPA's Food Commodity Intake Database (FCID), which is a food recipe database that translates foods as reported eaten by NHANES survey participants to individual food ingredients and agricultural commodities.