Vol. 4 No. 1 Winter 1999

ORACBA News

United States Department of Agriculture Office of Risk Assessment and Cost-Benefit Analysis

OF WHAT USE ARE DOSE-RESPONSE RELATIONSHIPS FOR HUMAN PATHOGENS?

James D. Wilson, Resources for the Future

The long-neglected problem of microbial contamination in food has been given increased attention in the last 3 to 4 years. The need for dose-response information about microbial illnesses to inform policy decisions in this arena has been identified in research deliberations. Not everyone may understand just how this kind of information, and thus what research, will be useful. Experience with how the Food and Drug Administration employs comparable information about the effects of chemicals in food provides some useful guidance for research.

In regulating chemicals in food, FDA uses information on humans' reactions to chemicals in two different ways, reflecting the different ways such chemicals are treated legally. FDA regulates substances not normally part of food, according to the Food, Drug, and Cosmetic Act, enacted in 1938 and significantly modified in 1958. This act distinguishes between substances deliberately incorporated in food to impart useful properties such as preserving freshness, and those which are unavoidably present and whose presence is tolerated. The first group-- "additives"--includes food colors, processing aids, preservatives, and, for legal purposes, animal drugs. The second group--"contaminants"--includes anything not specifically approved for food use and pesticide residues. (This group includes non-chemical contaminants such as rodent hairs.) In general, FDA may not consider values other than safety in approving additives; if a substance is judged "reasonably certain" to produce "no harm" when used as intended, FDA is supposed to approve its use. Conversely, for contaminants, FDA must balance several often-competing objectives, including safety, food costs, and practicality of the regulatory action. These legal requirements imply very different risk assessment needs. For additives, FDA reaches a judgment on an intake level that will be without effect. For contaminants, FDA needs to know the likelihood of harm, given different regulatory approaches.

Naturally, reality is more complex than this description implies. First, animal drugs are conceptually more like contaminants than additives: we would prefer that no drug residues be present. To be approved, they must be shown to be both safe for use in animals and effective for that use, so FDA considers several values other than safety in food, yet the statutory language closely resembles that used for additives. Second, pesticide residues were considered "additives" until 1996, when the act was amended to make them "not additives." Obviously, the safety of pesticide residues is evaluated by the Environmental Protection Agency, not FDA, and EPA must consider a number of other societal values in deciding whether to approve any particular pesticide. As this is written, EPA's practices for judging safety of residues are undergoing a tumultuous evolution. However, as with animal drugs, the statutory safety standard is that used for food additives.

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Evaluating Food Additives: Safety Assessment

For a new food additive to be approved, FDA must be convinced that it will be safe when used as intended. Over the years, "safe" has come to mean "no detectable injuries are associated with use of that additive." This standard is eminently practical; FDA does not act on the mere possibility that use of some additives will cause harm. (That is, it acts on theoretical possibilities only in the case of "carcinogens;" the famous Delaney Clause requires such action.) Because this standard is "negative"-- *i.e.*, based on not finding harm-- it absolutely requires an inference from those who evaluate the properties of additives. For decades, this inference has been based on judgments about doses that will cause "no effect." At one time, this judgment was reached using results of tests in humans; since the 1930s, animal test results have been used for this purpose. During the 1920s and 1930s, FDA scientists and their peers in academia and industry compared results of tests in humans with observations of "effect" and "no effect" in standardized laboratory rats and mice, and established an empirical relation between these two kinds of observations.

This empirical relation led to a remarkable procedure for identifying a safe level of intake for a new substance. This level, called "Acceptable Daily Intake (ADI)," is usually obtained by taking one one-hundredth of the largest dose observed to cause "no observed adverse effect" in the available set of data from a chronic animal test which displays the smallest "lowest observed adverse effect." That is, manufacturers hoping to gain approval of a new additive bring to FDA the observations from several animal tests, including long-term feeding studies in lab rats and mice. FDA scientists evaluate these tests to assure that they have been done correctly, according to standard protocols, and choose from all these the data set that includes the smallest dose level at which some harm was observed. That data set is called the "critical study." From this critical study, the largest dose level observed not to cause harm ("NOAEL") is selected. This level is divided by 100 to identify the daily intake judged to be the largest that will cause no harm in the entire U.S. population, even if intake continues at that average rate for a lifetime.

This empirical procedure is "scientific" because it is based on sound observations. But it violates normal scientific practice in a number of particulars, especially in its selection of only one of many studies as the basis for the ADI. It is very much a risk management tool, and a successful one. In more than 50 years of use, during which thousands of additives have been evaluated, only one failure has occurred. In that case, scientists in the United States and Canada underestimated the amount of beer stevedores would drink, by a factor of 10, and approved a cobalt-based foam stabilizer, which caused kidney failures in this small group.

Note also that this procedure very explicitly incorporates a risk-benefit balance. This balance was described succinctly by Arnold Lehman, then chief scientist at FDA, in a 1955 paper: "This factor of 100 appears to be high enough to reduce the hazard of food additives to a minimum and at the same time low enough to allow the use of some chemicals which are necessary in food production or processing."

Before 1958, when the Food, Drug, and Cosmetic Act was amended, FDA could not approve additives (other than food colors) before their use in food took place. In principle, the agency could only act after the fact, and ban use of substances found not to be safe. In practice, because this FDA action dooms any new food additive, manufacturers sought, and frequently received, assurance that FDA would not ban their new product. The price of this assurance was production of test data that FDA could use to judge safety. By 1955 the essential features of using animal test results to infer the "no effect" dose of a new substance, and thus its safety when used in food, were well established. The 1958 amendments assume that this system of judging safety would be used.

So since the mid-1950s FDA and other food safety agencies worldwide have employed results of animal tests to infer the amounts of food additives that will cause "no effect" in humans. These agencies do not attempt to draw inferences about what may happen if intakes greater than the "safe" level occur. Foods containing large enough quantities of additives to exceed this level are illegal and will not remain long in commerce. It is of no consequence to the agencies what harm may occur if safe intake levels are exceeded. Thus, in a real sense, FDA and sister agencies do not need to know anything about human dose-response relations for chemicals approved as additives.

Food Contaminants: Assessing Risk

For contaminants, FDA must balance safety against any impact of regulation on the food supply. To do so FDA must be able to judge the risk posed by different levels of contaminant in food, specifically those being considered as possible regulatory alternatives. To do this the agency must be able to predict dose-response, unless all the regulatory alternatives lead to estimated intakes that can be considered safe.

Under the original Pure Food Act of 1907, FDA dealt with contaminants by banning them. Any detectable amount was too much. Of course, analytical methods were crude, and amounts detectable were quite large. As analytical chemistry advanced, however, detection limits decreased, and banned chemicals began to be found widely in foods at very small concentration. For instance, a century ago phenol was occasionally added to foods in large amounts. FDA banned this use. Then phenol was found very commonly in foods at low levels. It's an essential part of the flavor of coffee, among other things. So FDA began to set "action levels" for contaminants--concentrations in food below which the agency would not regard the food as "adulterated" and seize it. Under provisions of the 1938 Food, Drug, and Cosmetic Act, these levels must balance safety against "quality and abundance of the food supply." That is, FDA's actions on contaminants must not raise the price of food so much that health is affected.

Consider a real case. Aflatoxin is a very nasty liver poison produced by molds of the *Aspergillus* family. Ingestion of aflatoxin is associated with both acute and chronic liver damage, and with an increased incidence of liver cancer, at least in areas where hepatitis B virus is endemic. The mold grows on seeds and nuts in periods of high humidity. It commonly infects peanuts, corn, cottonseed, and similar foods grown in the South. The strength of the infection varies with weather conditions; a hot, dry summer followed by a very wet autumn favors its growth. In bad years, a substantial proportion of the peanut crop will be infected. The fraction of peanuts containing detectable amounts of aflatoxin will be large enough to cause a big jump in the price of peanuts, if all of these were to be destroyed. Peanuts are very high in protein and provide an important source of protein in the diets of poor children. Therefore, if all aflatoxin-containing peanuts were banned, in bad years the price of peanuts and peanut butter would soar, and the diets of children in low-income households would suffer.

When it faced this problem several years ago, FDA concluded that it could not simply ban aflatoxin-containing peanuts. Instead, FDA set an action level--10 micrograms aflatoxin per kilogram of peanuts (10 ppb)--that it judged small enough to be health-protective, and large enough that even in the worst years the price of peanuts would not be severely affected. This action level was recently reviewed; the conclusion that it is adequately health-protective was reinforced. In most years, aflatoxin levels are well below the action level. In bad years, removing from consumption those lots with above the action level protects our health.

The point here is that FDA's decision is not a simple one. The agency has many options. These options can be expressed in terms of the action level which could be set at either 5 ppb, 20 ppb, 12 ppb, 8 ppb, or whatever. To be able to decide which level is appropriate, FDA must have some notion of the effects these different action levels may have on both health and food cost. That is, the agency must know something about the relation between the amount of aflatoxin ingested and the harm that may ensue.

So for regulating contaminants, FDA needs to know the relationship between amount of chemical taken in and the probability of harm at that level. That is, FDA needs to know the dose-response. There exist manifold difficulties in estimating these dose-response relations; each case is unique.

Application to Microbial Food Safety

Consider how USDA and FDA intend to regulate microbial content of foods in order to reduce incidence of "food poisoning." Both talk about "HACCP" — "Hazard Analysis Critical Control Points." This method is based on a broadly used analytical approach to improving product quality and requires detailed understanding of the manufacturing processes used in each plant that converts raw agricultural products to food, from cutting meat to canning tomatoes. To be a useful tool for food safety, there must exist safety standards, such as the number of microbes per unit of processed product that are tolerable. That is, as with the

criteria used to judge chemical food safety, the tolerance levels for microbes in food will represent a balance between safety and cost.

Thus, the HACCP method requires knowing two things: how many microbes are in or on each unit of processed product, and how many of them must be present for someone to get sick. Right now, practically speaking, neither of those things can be easily known. We possess technology to measure microbial levels in foods, but these measurements take so long that they are not useful for controlling food processing. By the time results are obtained, the food is either spoiled or long gone. So for HACCP to be a useful method for assuring food safety, we must be able to measure microbial content in real time. Research to develop fast-turnaround methods has and deserves the highest priority in the new food safety research program.

We also do not know how many bugs are required to make us sick, except in a very general way. Complicating the picture here is the number of different kinds of microbes that may cause sickness. Relatively few different pathogenic species are commonly found in food, but each of these species includes a very large number of strains. We know most about a few very potent strains of microbes such as *E. coli*; these are the ones that cause epidemic illnesses, and receive attention from the medical community. We do not know much about the strains that cause disease infrequently, if at all. We don't even know how many strains might exist. Further, these living things can mutate, and new strains come into being without warning. So we have the problem of dealing with a large number of standards for a large number of strains of various microbial species. One approach could be to treat all, say, *E. coli*, as though they were the notoriously potent O157:H7 strain. However, the cost of doing this, in destroyed meat, etc., is likely to be unacceptably large. Unless strain-specific analytical methods become available, a policy decision will have to be made weighing the probability that any *E. coli* is as potent as the worst against what that would cost.

What this dilemma implies to me is that society will need to know something about dose-response for the most potent microbes. These are relatively few in number (a few tens). Setting control limits for these will require making the difficult tradeoff between certainty and cost. This means that we need to make good estimates of the relation between numbers of microbes ingested and sickness, for these potent strains.

For the majority of strains, less potent than the few nastiest, it will probably suffice to say that at or less than some dose the likelihood of subsequent illness is small. That is, ingesting these bugs can be considered safe as long as the number taken in is less than some tolerable limit. We do not need to know what causes harm, in these cases, but what is safe.

There may be yet another use for dose-response information in making major policy decisions and justifying them before the International Trade Organization. For any such decisions, those affected will certainly want to know about the tradeoffs. They will demand to know how much difference it may make to choose some regulatory scheme rather than the one preferred by the government. For this kind of risk-risk or cost-benefit discussion, we will need to be able to estimate dose-response. Knowing how much is safe won't cut it.

Research Needed

Just as the information needed differs among the decisions to be made, so will the research that is needed to develop this information differ. These differences suggest first that the primary focus for research on the relation between numbers of food borne pathogens and human illness ought to be on humans. Experiments in animals ought to be supportive of human-based research and used to explore questions that cannot be addressed in human studies. Data from animal experiments should be used to help interpret what we know based on human studies, and should not serve as the basis for establishing safe intake levels.

The human studies must include both epidemiology and volunteer studies. We must extract much more information than heretofore from the food-poisoning episodes that occur. Very powerful mathematical methods are available to help in this effort. But some kinds of data can only be obtained from controlled experimentation.

For the less-potent strains, human experiments to determine "no effect" levels will be particularly useful.

It would be a natural tendency for food safety researchers to look to FDA's food additives safety assessment as a model for dealing with food borne pathogens. They

might expect to develop predictive animal models for human disease to use as the basis for regulation. I suggest that doing so would be a mistake. Recall that the procedures used in food additives regulation required some three decades' research and development, and that R & D followed some two decades' experience with evaluations based on epidemiology and volunteer experiments. Consider also that the procedures were intended to be applied to thousands of substances about which little was known. Doubtless the research and development of useful animal models would not require several decades today; we know so much more (and, one hopes, nothing like a World War II will intervene.) Yet the number of truly different microbial species involved is not large. The number of varieties may be large, and new ones will appear, but we know much more about any new strain of, say, *Salmonella*, than we know about most newly discovered chemicals. So the burden of predicting safe intake levels for the different microbes today will be much less than it was for different chemicals at the analogous time, half a century ago.

The return to policy makers and the public in developing animal models for these screening purposes will not be worth the investment.

Also not particularly useful, at least not soon, will be new models for interpreting dose-response functions and "mechanistic" mathematical models. We already have more than adequate tools for the first purpose. Any "mechanistic" modeling must be carefully tailored to support experimental or epidemiologic studies.

As noted, policy makers will need more detailed information on dose-response in a few cases. Whatever policies we use to regulate food processing, at some point we will have to justify these before the World Trade Organization. To do this, we will need at least two good cases that illustrate the value tradeoffs that have been made in erecting the policies. So pick two or three cases, and work to develop the necessary information.

Conclusions

Information on the relation between amount of chemical ingested and illness is used by FDA in two different ways. For regulating food contaminants, FDA needs to know how much makes people sick. The agency needs this information to balance the risk of illness caused by contaminants against the risk caused by higher prices for food. For contaminants, FDA does a consequence analysis.

For regulating food additives, FDA needs to know the "largest" intake that does not cause sickness. The procedure used to identify the ADI represents a balance between being certain of safety and approving useful food additives. It required some 30 years' research and development, and a substantial amount of deliberation among the regulatory agencies, affected industry, and scientists in academia.

Regulatory agencies and other policy makers will need to know details of dose-response for a few food borne pathogens in the not too distant future, to justify major policy choices including defense of American policies for regulating imports.

When short-turnaround methods for analyzing microbial numbers in foods become available, there will be a need to set "acceptable intake" standards for the kinds of microbes found in foods, at which time it will be necessary to identify the levels of intake that cause no injury.

Director's Corner by Nell Ahl

Bovine Spongiform Encephalopathy (BSE) is a neurological disease of cattle. The weight of evidence suggests that the agent may be transmitted to humans through ingestion of affected tissues. Because USDA is responsible for both animal health through the Animal and Plant Health Inspection Service, and human health through Food Safety Inspection Service, these agencies with assistance from ORACBA, developed a cooperative agreement to support a risk analysis for both animal and human health. That agreement was finalized in July of 1998, with the Harvard School of Public Health (HSPH), Center for Risk Analysis (HCRA) as the prime cooperator with secondary support from Tuskegee University (TU), Center for Computational Epidemiology.

As with all risk analyses, getting input from the public and groups that may be regulated is important. To that end, FSIS, APHIS, ORACBA, HCRA, and TU came together in a public meeting to discuss the scope of the

risk analysis. The output from the public meeting is found on the websites for both FSIS and APHIS [APHIS: <http://www.aphis.usda.gov/oa/bse>; FSIS: <http://www.fsis.usda.gov/oa/topics/bse.htm>]. Public comments were accepted until October 16. An executive summary of the cooperative agreement with HSPH is presented here. Check the websites, read the Statement of Work, and send your comments to ORACBA <aahl@oce.usda.gov>. More news of the risk analysis will be provided in future issues.

COOPERATIVE AGREEMENT:
Risk Analysis of Transmissible Spongiform Encephalopathies in Cattle and the Potential for Entry of the Etiologic Agent(s) into the US Food Supply.

BACKGROUND
Transmissible spongiform encephalopathies (TSEs) are chronic, fatal diseases affecting the central nervous system of certain species of mammals. TSEs are found in sheep and goats as scrapie; in humans as Creutzfeldt-Jacob Disease (CJD), new variant CJD, Gerstman-Straussler-Scheinker disease, fatal familial insomnia, and kuru; in deer and elk as chronic wasting disease (CWD); in cats as feline spongiform encephalopathy; in mink as transmissible mink encephalopathy (TME); and in cattle as bovine spongiform encephalopathy (BSE). Other cases of TSE have been reported in some exotic ruminants and exotic cats.

BSE was first diagnosed in 1986 in the United Kingdom, and has affected more than 170,000 British cattle. Other countries with confirmed cases of BSE in native cattle include Belgium, France, Ireland, Luxembourg, the Netherlands, northern Ireland, Portugal, and Switzerland.

The United States Department of Agriculture (USDA) is responsible for protecting both human and animal health and both will be considered in this analysis. Although BSE has not been detected in the United States, the USDA is sponsoring this study to evaluate the current programs to protect the national herd and human health, and to help identify whether further measures would provide an additional layer of security.

OBJECTIVES, TIME FRAME AND DELIVERABLES
There are two objectives to this study, one focused on animal health and one focused on human health.
1. Assess potential pathways for entry of transmissible spongiform agents, including the BSE agent, into U.S. cattle.
2. Assess the potential pathways for entry of transmissible spongiform agents, including the BSE agent, into the U.S. food supply.
The study will take two years and result in technical reports to the USDA and one or more manuscripts for journal publication.

USDA Risk Assessor in Profile:
Dr. Richard Fite

ORACBA often gets questions from people who want to know how to become a risk assessor: What type of education, job experience, and skills are needed? We reply risk assessors come from broad and varied backgrounds that do not fit into any prescribed set of criteria. Our featured risk assessor profile this issue provides another example of the diverse backgrounds and interests of USDA risk assessors.

Dr. Richard Fite, Acting Chief of Risk Analysis Systems (RAS) for APHIS Policy and Program Development, received his professional degree in veterinary medicine from the University of Pennsylvania. After a 2-year stint as a field veterinary medical officer for APHIS, he returned to UP for a post doctoral program in poultry pathology. After completion, he managed the poultry laboratory at the University of New Hampshire (UNH).

It was during his tenure at UNH that Richard became a Kellogg Foundation Fellow. The goal of the Kellogg National Fellowship Program is to stimulate leadership development of young American professionals. Through the fellowship program, Richard participated in an informal internship at the World Bank where he developed his interests in agricultural economics and

international trade issues. After receiving a master's degree in Public Administration from Harvard University's Kennedy School, Richard consulted for the World Bank in Kenya.

Richard returned to APHIS in 1989 to join the Policy and Program Development unit. He has worked with RAS since 1992 and has been acting Chief since mid-1997. A year (1995-96) on the staff of Senator Frank Lautenberg provided further insight into the legislative process and the development of national policy.

When asked what led him into risk assessment, Richard quickly replied that it was his interest in international development and trade as well as his interest in developing better analytical techniques to support Agency decision making. Of particular interest to Richard is the challenge of doing meaningful quantitative risk assessment when much of the available evidence is qualitative in nature. He is also concerned about the incorporation of sometimes inappropriate economic parameters into risk assessments for sanitary and phyto-sanitary issues and trade.

Current problems related to the World Trade Organization and international trade of plants, animals, and products are the central focus of APHIS' Risk Analysis Systems. RAS has worked closely with Veterinary Services and Plant Protection and Quarantine, the two APHIS program units involved with these issues. Richard has a strong interest in developing closer linkages with the academic community to stimulate its participation in international trade issues. He initiated a cooperative agreement between APHIS and Tuskegee University and has been working more recently with Colorado State University and the University of Maryland.

News of ORACBA

Plans for ORACBA began in late 1994. By design, it was to be a small, flexible group to facilitate bringing together resources to implement risk assessment and cost-benefit analysis requirements for major USDA regulations. Since the Office of the Chief Economist was already in place and reviewing economic analyses for rulemaking, the primary activity for ORACBA was to strengthen science-based risk assessment activities for major USDA regulations. The small core of permanent personnel included a Director, Deputies to oversee specific regulatory issues (e.g., economics, conservation, human health, animal health, ecology, plant health), and a Program Assistant. Dr. Nell Ahl had the good fortune to be selected as the first Director for ORACBA, and Marion Green is our Program Assistant. Currently, Drs. Ronald Meekhof, Michael McElvaine and Steven Shafer are the Deputies.

With relatively few experienced risk assessors in USDA and methods lacking for farm-to-table food safety and conservation risk assessments, how were USDA agencies to cope? It was a time of downsizing, so hiring of experienced risk assessors by the agencies was not feasible. How was USDA to accomplish risk assessments for its major regulations? The answer: through education and training, coordination within and between Federal agencies and departments, technical guidance for risk assessment (by ORACBA or by experts from the larger risk community), and provision of risk information resources to those completing the risk assessments.

ORACBA has a number of collaborators to advance and encourage good risk assessment in USDA. They have come from USDA, FDA, EPA, academia, the American Association for the Advancement of Science (AAAS) Risk Fellowship Program, the risk consulting community, and the Graduate School USDA. At any given time, we may have up to seven individuals, not permanent ORACBA staffers, working on projects. Some collaborations are on-going and some are intermittent, as the interest and need arises.

Each year, through an on-going Memorandum of Understanding with USDA's Agricultural Research Service (ARS), two scientists are detailed to work with ORACBA. During FY 98, Dr. Ron Christianson of the research laboratories at Clay Center, Nebraska, participated in developing a generic model for risk assessment for *E. coli O157:H7* in ground beef. The model outline will aid preparation of a farm-to-table risk assessment for ground beef contemplated by FSIS. Dr. Ali Sadeghi, environmental scientist, of the ARS Beltsville Agricultural Research Center has worked with USDA's Natural Resources Conservation Service (NRCS) to refine models for microbial survival in runoff

from manure management activities. Dr. Sadeghi's experiences in ORACBA complement his work in Beltsville so well that he will retain a working relationship with ORACBA for FY 99.

Dr. Linda Abbott was detailed to ORACBA from APHIS in March 1998 and will continue on detail through FY 99. She is the link in a close working relationship with USDA's Office of Pesticide Management and Policy. Linda's background is in ecology and risk assessment modeling. Her work has been focused on support for farmland conservation efforts of the USDA's Farm Service Agency's (FSA) Conservation Reserve Program (CRP). Dr. David Mauriello from the Environmental Protection Agency (EPA) research staff has been on temporary detail to ORACBA for FY 98. As ecologists and modelers, Dave and Linda have worked together with FSA analysts on technical biological support for the CRP.

We are pleased with the work of three scientists from the AAAS Risk Science Fellowship Program. This Program provides early to mid-career scientists and engineers with training in risk assessment and gives them an opportunity to work on science and policy projects. The Fellows for FY 98 included Drs. Jennifer Kuzma, Mark Powell, and Mark Tumeo. All three have made substantial contributions to USDA activities this year.

Each year brings a changing cast of individuals to work with ORACBA and USDA agency projects related to human health and environmental issues. During FY 99, Drs. Sadeghi, Abbott, and Mauriello will continue with us. In addition, through the MOU two ARS scientists will begin work with ORACBA later in the fall. The AAAS Risk Fellowship Program brings three new scientist-Fellows and expands the program to include FDA: Drs. Terri Dunahay, Claire Narrod, and Tina Rouse sponsored, respectively, by ERS, FSIS, and FDA/Center for Food Safety and Applied Nutrition (CFSAN). Also, we are pleased to have Samantha Goldstein working with us on a special detail; she is employed by USDA's Office of Budget and Program Analysis (OBPA) and is a graduate student at Virginia Polytech Institute and State University.

The growing collaborative and collegial network of scientists-risk assessors in USDA is one accomplishment of which we are proud. We welcome inquiries about collaboration: details, special projects, training assignments, sabbaticals, IPAs, or other potential interactions.

October Risk Forum:

The October Risk Forum seminar was presented by Dr. Ron A. Sequeira of the APHIS Center for Plant Health Science and Technology in Raleigh, North Carolina. Ron's presentation focused on his application of a Geographic Information System (GIS) approach to a risk assessment for a controversial regulated organism, *Tilletia indica*, the fungus that causes Karnal bunt of wheat. For Plant Protection and Quarantine operations, agricultural pest risk is a function of the probability of pest entry, probability of pest establishment, and expected magnitude of the outcome from such an event. Most risk assessments to date for Karnal bunt have emphasized analysis of the likelihood of introduction. The GIS-based analysis enhances our understanding of Karnal bunt risk by assuming entry occurs readily and focusing on the distribution of subsequent disease incidence. Plant disease develops only when a susceptible host and a virulent pathogen occur together in an environment conducive for their interaction. In this risk assessment, the likelihood of Karnal bunt occurrence was predicted by layering the risk factors as GIS mapping layers. Wheat susceptibility was determined with a plant development simulation model. Average temperature conditions conducive for infection by *T. indica* during wheat anthesis (when wheat is susceptible) were mapped from weather data collected over several decades at a county or finer scale. Based on the likelihood of coincident host susceptibility and conducive temperatures, Karnal bunt risk was categorized as high, medium, or low. This procedure demonstrated that weather conditions prevailing in an average year during anthesis of winter and spring wheat in most of the United States are not favorable for infection. Medium risk occurs in sections of a very few counties. Furthermore, counties with the highest probability of infection are not high-production or high-value regions, so consequences of disease development are low. Thus, wheat grown in the great majority of

production regions in the United States is at low risk from Karnal bunt. Such uses of GIS-based information offer many applications in risk assessments and management for pests and other spatially distributed hazards in the environment.

November Risk Forum:

Dr. Tom Oscar of the Agricultural Research Service's Microbial Food Safety Research Unit at the University of Maryland Eastern Shore presented the November Risk Forum on "The Food Animal Risk Model for Poultry Pathogens (FARM-PP)." The FARM-PP model is a risk assessment model focused at the individual poultry production plant level. One of the goals of the model is to provide risk assessors and risk managers at production plants with an easy-to-use model to estimate the public health risks associated with pathogen contamination.

The output of the model is an estimate of the public health impact related to various plant production and meal preparation scenarios. The severity of symptoms expected with various doses of the pathogens is used to define six categories of impact, ranging from those people who are infected but have mild symptoms and seek no medical attention to those who die. The model addresses multiple pathogens and currently includes *Salmonella* and *Campylobacter*. Dr. Oscar contrasted *Salmonella* and *Campylobacter* to illustrate the importance of considering the microbial ecology of the pathogen when constructing the risk model.

The FARM-PP model was constructed using off-the-shelf software. To achieve the goal of ease-of-use, the model and information provided by the user is not overly complex. The model runs quickly and could reasonably be used at a poultry production plant. The Risk Forum concluded with a hands-on demonstration of the model.

More information about the model and other research conducted by the Microbial Food Safety Research Unit can be found at its web page, http://www.arserrc.gov/internet/mfs/index.html.

Risk Resources

The USDA/FDA Foodborne Illness Education Information Center provides information about foodborne illness prevention to educators, trainers, and organizations developing education and training materials for food workers and consumers. The Center is housed at the Food and Nutrition Information Center (FNIC) of the National Agricultural Library (NAL), USDA, in Beltsville, Maryland.

The Foodborne Illness Educational Materials Database is a compilation of consumer and food worker educational materials developed by universities; private industry; and local, state, and federal agencies. This includes computer software, audiovisuals, posters, games and teaching guides for elementary and secondary school education; training materials for the management and workers of retail food markets, food service establishments and institutions; educational research and more. The Center's resource lists and databases, as well as many other food and nutrition-related links, can be accessed through the Internet at the URL http://www.nal.usda.gov/fnic/foodborne.

The Hazard Analysis Critical Control Points (HACCP) Training Programs and Resources Database provides up-to-date listings of HACCP training programs, HACCP resource materials, and HACCP consultants offering training programs or resources. Its intended users are educators, trainers, field staff in Extension, Food Safety and Inspection Service (FSIS) personnel, FDA personnel, private sector food processing plants and organizations, and others interested in identifying HACCP training resources. Other FNIC resources include FOODSAFE, an interactive electronic discussion group intended as a communication tool to link professionals interested in food safety issues; the

Food Safety Index, which links to more food safety and HACCP Internet information; and several FNIC publications.

For more information about the databases or to contribute materials and/or information, contact Cindy Roberts, Information Specialist, at (301) 504-5719 (tel), (301) 504-6409 (fax), Internet: foodborne@nal.usda.gov.

Risk Calendar

January 1999

January 13. The Risk Forum will be from 10 to 11:30 a.m. in the Whitten Building, 107-A. A panel will discuss "Wildlife Habitat Implications of Alternative Conservation Reserve Program Management Practices: An Application of Adaptive Risk Information Analysis." For information, please call us at (202) 720-8022.

January 19-22. The Graduate School, USDA is offering a new course, "Ecological and Environmental Risk Assessment." For information regarding the course, call Dr. Al Officer at (202) 314-3432, or E-mail: alvin_officer@grad.usda.gov.

January 19-22. The "10th Annual USDA Interagency Research Forum on Gypsy Moth and other Invasive Species" will be held in Annapolis MD. Contact Michael McManus, Chair of the Program Committee at (203) 230- 4322, or FAX (203) 230-4315.

February 1999

February 10. The Risk Forum will be from 10 to 11:30 a.m. in the Whitten Building, 107-A. The guest speaker will be Dr. Stephen Anderson of the Georgetown Center for Food and Nutrition Policy. The topic of his talk is the risk assessment of fluoroquinilone use in food animal production. For information, call us at (202) 720-8022.

March 1999

March 2-5. The Harvard School of Public Health will be offering "Analyzing Risk: Science, Assessment, and Management." Contact Crista Martin, Harvard School of Public Health, Center for Continuing Professional Education, 677 Huntington Avenue, LL-23, Dept. C, Boston, MA 02115-6096. Telephone: (617) 432-1171, Fax: (617) 432-1969, or E-mail: contedu@sph.harvard.edu. For information on other courses offered by the HSPH see http://www.hsph.harvard.edu/ccpe/ccpe.html.

March 10. The Risk Forum will be from 10 to 11:30 a.m. in the Whitten Building, 107-A. The guest speaker will be Dr. Dennis King of the University of Maryland's Center for Environmental Science. The title of his talk is "Dealing With Risk in Environmental Trading: Cases in Wetland Mitigation, Crediting Carbon Sequestration, and Prioritizing Noxious Weeds." For information, call us at (202) 720-8022.

March 22-April 2. "Quantitative Risk Assessment" will be offered by Dr. David Vose in the Washington, DC area. For information, contact Dr. Tina Rouse at E-mail: trouse@oce.usda.gov or Dr. Alvin Officer, Graduate School USDA, at (202) 314-3432, or E-mail: alvin_officer@grad.usda.gov.

March 23-26. The Graduate School USDA will be offering "Introduction to Risk Analysis" in Washington, DC. For information regarding the course, call Dr. Al Officer at (202) 314-3432, or E-mail: alvin_officer@grad.usda.gov.

March 25-26. The Second Biennial International Risk Assessment and Policy Association (RAPA) Meeting will be held in Washington, DC. Contact RAPA at Franklin Pierce Law Center at (603) 228-1541,or E-mail: www.flpc.edu.tfield/Rapa.htm

April 1999.

April 6-9. The Harvard School of Public Health will be offering "Benefit-Cost Analysis for Environmental, Health, and Safety Regulation." See the HSPH March course listed above for further information.

April 8. The Risk Forum will be from 10 to 11:30 a.m. in the Whitten Building, 107-A. The guest speaker will be announced at a later date. For information, call us at (202) 720-8022.

April 11-14. National Conference on Environmental Decision Making, National Center for Environmental

Decision Making Research. Contact NCEDR at (423) 974-3939 or FAX (423) 974-4609.

The **ORACBA** Newsletter reports risk analysis activities in the U.S. Department of Agriculture, upcoming meetings and events, and other activities supporting the development and use of risk assessment in USDA. This quarterly newsletter is available at no charge to risk assessment professionals in USDA. Send comments or address changes to: USDA, ORACBA, Room 5248-S, Mail Stop 3811, 1400 Independence Avenue, SW, Washington, D.C. 20250-3811. Call (202) 720-8022, or fax (202) 720-1815.

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