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ORACBA News

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

Risk Assessment and Cost-Benefit Analysis Issues Associated With Antimicrobial Use in Food Animal Production

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Introduction

Risk assessment and cost-benefit analysis are two quantitative tools used in risk analysis and science-based decision-making. Generally, risk analysis is considered to be comprised of: 1) risk assessment, the process of identifying a hazard and evaluating the risk as to the likelihood and magnitude of the consequences of an adverse event; 2) risk management, the pragmatic decision-making process concerned with regulating the risk; and 3) risk communication, the open exchange of information and opinions about risk, leading to better understanding and better management decision-making.[1] Cost-benefit analysis has been used in many fields and is currently used by government agencies to measure the impacts of alternative options in risk management decision-making.

The controversy regarding the public health risks associated with the use of antimicrobials in food animals has continued for over 25 years. This paper will posit, for discussion and dialog purposes only, one avenue by which a risk analysis of this issue might be developed to aid in assessing this controversy.

Risk Assessment

Risk assessments are best conducted by interdisciplinary teams, and in the case of antimicrobial use in food animal production, this team should include biological scientists, clinicians, chemists, toxicologists, and representatives from any other relevant science. Risk assessors and risk managers plan the assessment process together and determine the scope and scale of the assessment. The combination of assessors and managers assures that the risk assessment is conducted with

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management objectives in mind.

The risk assessment team formulates the issues to be addressed in the assessment. Key objectives of the assessment are to identify the risks associated with the use of antimicrobials in food animal production and determine the magnitude of each identified risk.

Risks associated with the use of antimicrobials:
Identified risks may include: development of resistance by human pathogens; development of resistance by animal pathogens; antimicrobial residues on food products; changes in the distribution of pathogen populations; and antimicrobials in animal wastes. Of foremost concern, undeniably, is the potential for development of antimicrobial resistance by human pathogens. The mechanisms by which this might occur have been examined and addressed extensively in the literature.[2,3,4]

There may be risk differences with subtherapeutic versus therapeutic use of antimicrobials in food animal production. Differences in risks may depend on the pathogen type and class of compound, and may be related to the extent of resistance development, and the quantities of residues and pathogens found on food animal products and in food animal waste. Animal waste concerns are significant in the environmental arena, particularly with regard to organic farming practices.

Magnitude of identified risks:
Determining the probability of occurrence and the magnitude of each of these potential risks may prove to be very difficult, and in some cases, impossible due to the lack of information. Ideally, identifying the pathways of exposure to the risks combined with dose-response curves developed under well-controlled laboratory conditions would lead to quantitative estimations of risk. There are also confounding factors which should be considered to evaluate the relative risks associated with antimicrobial use in animals, particularly, how to compare and measure resistance that is developing as a result of antimicrobial use in humans. Data on this confounding factor are limited. In addition, data are limited on antimicrobial consumption, antimicrobial use in agriculture, and the prevalence of resistant zoonotic pathogens in food animals and food of animal origin.[5] In general, quantification of the risks associated with the use of antimicrobials in food animal production may not be possible. In this case, a qualitative evaluation of risk may be all that can be presented to the risk managers or decision-makers at present.

Risk Management
There are several regulatory alternatives available to diminish or control present and predicted risks associated with the use of antimicrobials in food animal production. The standard "default" option is "no change" in current licensing and registration of antimicrobials for this use. The other option involves various combinations of restricting or eliminating subtherapeutic and therapeutic uses. Within this option is a spectrum of combinations of restrictions based on class of compound and pattern of use. There are trade-offs associated with each unique combination.

The overarching issues of risk substitution or trade-off in changes in antimicrobial use include, but are not limited to: 1) human health and welfare; 2) animal health and welfare; 3) quality and quantity of animal-derived protein; and 4) environmental concerns.

In the 1997 Report of the World Health Organization Meeting, "The Medical Impact of the Use of Antimicrobials in Food Animals," it was stated that, "In light of shrinking public resources and the increasing need to conduct scientifically-substantiated risk assessments for prioritizing public health action, national policies on the use of antimicrobials in animals must balance the possible benefits to livestock production against the medical risk and public health consequences deriving from their use." The role that antimicrobials play in maintaining our current animal production practices has not been fully elucidated or quantified. The United States has a high-quality, low-cost, consistent supply of animal-derived protein as a

result of these production methods. In addition, it has been proposed that current intensive production practices have reduced the environmental "footprint" of livestock production, freeing up land resources for other uses.[6] The use of antimicrobials in animal feed has reduced the toxic pollutant content of wastes, lowering methane, urea, and ammonia. However, the use of antimicrobials also potentially changes the pathogen types and loads in wastes that may eventually be applied to crops for human or animal consumption. An associated concern is the impact on environmental flora that may result from antimicrobial or metabolite residues in animal wastes. Environmental concerns associated with the use of antimicrobials in food animals have not received comprehensive attention.

As previously mentioned, cost-benefit analysis (CBA) has long been used as a tool to aid in risk management decision-making and is now required in the regulatory impact analyses of many Federal agencies. CBA allows for consideration of the economic impacts and the distribution of costs and benefits associated with alternative regulatory options. CBA does not serve as a sole decision criterion. What CBA does provide is a basis of comparison, in a common metric (i.e., dollars), of alternative options within a regulatory decision.

Factors that may be evaluated in a cost-benefit analysis of regulatory alternatives for antimicrobial use in food animal production include, but are not limited to: 1) human health care costs; 2) food availability for human consumption;[7] 3) food prices;[7] 4) production costs;[7] 5) level and distribution of farm income;[7] 6) trade impacts; 7) cost of new drug development; and 8) environmental impacts. The economic impacts of each of these factors, and the magnitude and distribution of the impacts, will differ for each regulatory alternative or combination considered.

Risk Communication

Risk communication is a tool to provide a forum for interchange among all those concerned about the risks identified in the assessment. It is important, for this publicly and politically sensitive issue, that we promote communication between health scientists, industry, government, consumer groups, and other interested parties in order to improve the decision-making process.

Summary

The use of antimicrobials in food animal production is a complex issue that needs comprehensive consideration. All perspectives are needed to make informed decisions regarding this issue. Risk assessment, risk management, and risk communication--the triad of the risk analysis process--can promote better decision-making through communication amongst all parties, scientifically sound characterization of the risks, objectivity, and transparency in the decision-making process.

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2. Mitchell M, Yee A: Antibiotic use in animals and transfer of drug resistance to humans: should we stop treating animals with these drugs? *Dairy, Food Environ. Sanit.* 15(8):484-487, 1995.
3. Miller R: Bacterial gene swapping in nature. *Sci. Am.* 67-71, January 1998.
4. Perreton V, Schwartz F, Cresta L, et al.: Antimicrobial resistance spread in food. *Nature* 389:801, 1997.
5. World Health Organization: The medical impact of the use of antimicrobials in food animals. Report of a WHO Meeting, Berlin, Germany, 13-17 October 1997.
6. McOrist S: Growth Enhancers. Proceedings of the WHO Workshop on the Medical Use of Antimicrobial Drugs in Food Animals, Berlin, Germany, 13-17 October 1997.
7. USDA Economics, Statistics, and Cooperatives Service: Economic effects of a prohibition on the use of selected animal drugs. Agricultural Report No. 414, 1978.

The views expressed here are those of the authors and do not necessarily reflect USDA policy.

Director's Corner
by Nell Ahl

For the next 3 issues, each of the USDA AAAS fellows will write an article for this column. The AAAS fellows are Jennifer Kuzma, Mark Powell, and Mark Tumeo. They provide scientific support for ORACBA risk assessment activities.

"Risk Communication Utopia"
by Jennifer Kuzma

Those familiar with risk analysis have undoubtedly heard about the importance of **risk communication** as one of its three components. There are several definitions of risk communication with variations of words and ideas:

- process of exchanges about how best to assess and manage risks among academic, regulatory practitioners, interest groups, and the general public.[1]
- process by which the results of risk assessment and risk management are communicated to decision makers and stakeholders.[2]
- open two-way exchange of information and opinion about risk leading to better understanding and better risk management decisions.[3]
- methods that explain the risks to lay people, so that their perceptions of the situation are not distorted.[4]

One may agree or disagree with these definitions; but perhaps what is more important than the exact definition of risk communication are the **features** of risk communication. In other words, "What is important for **risk communication**?" This article will try to describe some features, that in the author's view, constitute successful risk communication.

Education is as important as information. Risk communicators need to envision themselves not only as information providers, but as educators. Experts often do not give the public or colleagues from other disciplines enough credit for being able to understand the complexities of their disciplines. Therefore, they withhold information and oversimplify discussions about risk under the pretext that "they wouldn't understand." Each of us needs to start with the premise that the public, stakeholders, decision-makers, or whom ever it is we are trying to communicate with have the ability to fully understand the issues and that it is our job to facilitate and enhance their understanding. Risk assessment scientists must be confident that managers and the general public can understand their fields. Managers must be confident that the public and risk assessment scientists can understand the decision-making process. We must have **respect** for each other's capabilities. General teaching tools, such as the use of visual diagrams, examples, anecdotes, participatory exercises, and analogies, should be incorporated into risk communication activities. In turn, those not involved directly in the assessment or management process have a responsibility to educate risk assessors, managers, and communicators, about their concerns and experiences. Often this information will be useful to the assessment and management activities. We have a lot to **learn from each other.**

No two individuals are the same. People will perceive risks in different ways based on many variables, including culture, age, gender, geographic location, and profession. We all have different experiences and have been exposed to different hazards. Therefore, it is important not to "target" messages to a particular group, but rather to convey honest, educational messages and to hold public fora about risk issues. There is a spectrum of reactions which will occur from various groups given a particular risk issue. The adage "you can't please everyone all of the time" holds true. What we can do is **listen** and **respond** to everyone.
Using the words "no risk" is dishonest. Whether friends are trying to convince you to water ski or officials are describing a current situation, we have often heard people say "There is absolutely no

risk." I argue that this statement is false. There is risk in everything we do. Risk is defined by many as the "chance or possibility that a hazard or adverse event could occur." It is difficult to conceive of a no-risk action or situation. For example, breathing imposes a risk (e.g., contaminated air), reading a newspaper imposes a risk (e.g., increased heart rate due to anxiety or even joy), sitting in a chair imposes a risk (e.g. the chair could break and one could fall and break a bone)--the list goes on. Therefore, the first step to successful risk communication is to help people understand that risks surround every situation and that a given risk mitigation strategy may lead to an increase in substitute risks.

Comparing risks when communicating. Even though every situation has risk, there are different magnitudes and attributes of the risks for each situation. How do we communicate these differences to the public? Should we compare more familiar, everyday risks to unfamiliar risks when communicating? When should we make quantitative comparisons of magnitude? A discussion about these questions is held in "Risk Assessment and Risk Management in Regulatory Decision-Making" by the Presidential/Congressional Commission on Risk Assessment and Risk Management (1997, volume 2). The general conclusion of the discussion was that "Risk comparisons can be helpful, but they should be used cautiously and tested if possible." The National Research Council in 1989 suggested that "There are proven dangers in comparing familiar and unfamiliar risks, natural and manufactured risks, and voluntary and involuntary risks, such comparisons can be perceived as minimizing a risk." Perhaps as a guiding principle, we should compare risks only when they share several common features such as the same kind of hazard or same method of exposure.

Trust. Dr. Lynn Frewer of the Institute of Food Research in the United Kingdom (UK) gave ORACBA's December Risk Forum. She has extensively studied risk communication issues as they relate to food safety. At the forum, she stated that in the UK, government regulators and scientists were the least trusted risk communicators. Why? Perhaps one reason is that in the past, the public has not been invited to participate during critical stages of the decision-making process. Risk communication needs to begin before risk assessment and risk management activities. Public fora should be held during the process, not after the decisions are made. Information should be made accessible to the public. Websites should accompany current risk assessment/risk management issues. These websites should provide an opportunity for visitors to provide electronic input about their concerns and ideas. As each one of us knows from personal experience (e.g., with friends, spouses, children), it takes time and tests of reliability to earn trust. There is **hope** for risk analysts to gain trust, as long as we adopt high standards for communicating.

1. Powell, D. and W. Leiss. "Mad Cows and Mother's Milk: The Perils of Poor Risk Communication" (1997).

2. MacDiarmid, S.C. "Risk Analysis, International Trade, and Animal Health" *in* Fundamentals of Risk Analysis and Risk Management, ed. V. Molak, CRC Press, Boca Raton (1997).

3. ORACBA/USDA and CFSAN/FDA "Introduction to Risk Assessment: A Short Course" (October 1997).

4. Glossary of "Fundamentals of Risk Analysis and Risk Management, ed. V. Molak, CRC Press, Boca Raton (1997).

USDA Risk Assessment Group in Profile:
Plant Protection and Quarantine, APHIS

The Animal and Plant Health Inspection Service (APHIS) of USDA administers the Federal Plant Pest Act (FPPA). This legislation authorizes APHIS to regulate the importation and interstate movement of commodities that pose plant health (phytosanitary) risks. APHIS also invokes this authority to regulate the field testing of genetically engineered organisms which are or may be plant pests. The APHIS mission also includes facilitating the entry of U.S. agricultural products into foreign countries. This profile provides a brief overview of the programs within the APHIS Plant Protection and Quarantine (PPQ) unit that are engaged in phytosanitary risk assessment and risk management. PPQ is located in Riverdale, MD.

Biological Assessment and Taxonomic Support (BATS) Program. BATS, headed by Rebecca Bech, consists of the National Identification Services (NIS) Staff and the Biological Analysis Team (BANT). Under the direction of Senior Operations Manager Michael Firko, the NIS Staff is responsible for identifying plant pests intercepted at ports-of-entry, categorizing the quarantine status of exotic organisms, and maintaining pest interception data on known and potential pest organisms found during quarantine inspections. The Senior Operations Manager for BANT is Edwin Imai. BANT evaluates risks associated with the movement of plant pests into the U.S., interstate movement between containment facilities and from containment into the environment; develops safeguards to mitigate the phytosanitary risks from commodities imported to or transiting the U.S.; and prepares environmental assessments as required by the National Environmental Policy Act.

BANT conducts two basic types of phytosanitary risk assessments: commodity-based risk assessments (e.g., potential phytosanitary hazards that may be associated with citrus imports from a particular region); and organism-based risk assessments (e.g., the risk posed by the introduction of Mediterranean fruit fly into California from Hawaii via passenger airline traffic). Depending upon the magnitude of the regulatory decision, the amount and type of data available, and the scope of the analysis, BANT conducts risk assessments that are qualitative (is the organism a phytosanitary hazard?), ordinal (is the expected damage high, medium, or low?), quantitative (is the risk of introduction greater than X?), probabilistic (what is the predicted distribution of damage?), or some combination thereof. Some examples of qualitative commodity pest risk assessments produced by BANT include: the Importation of Belgian and Dutch Leeks, Romanian Garlic and Swiss Shallots Into the United States; and the Importation of Papaya Fruit (Carica papaya) from Brazil into the Continental United States. The assessment of the Importation of Fresh Citrus Fruits (Sweet orange, *Citrus sinensis*, Lemon, *C. limon*, Grapefruit, *C. paradisi*) from Argentina into the Continental United States provides an example of a probabilistic commodity pest risk assessment prepared by BANT.

Biotechnology and Scientific Services (BSS) Program. The BSS Program, under the directorship of John Payne, regulates the importation, interstate movement, and environmental release of certain genetically engineered plants and microorganisms (under 7 Code of Federal Regulations part 340). The Biotechnology Evaluation (BE) Division is led by Deputy Director Arnold Foudin. Based on determinations that they have no potential to pose a plant pest risk and are as safe to grow as any other variety of the same plants, BSS no longer regulates the environmental release of approximately 30 genetically engineered plant varieties.

The Center for Plant Health and Science Technology. The CPHST is currently under construction at the Centennial Campus of North Carolina State University. When completed, the Center will house a multidisciplinary scientific staff that undertakes collaborative efforts with Federal

and State agencies, academic institutions, and the private sector. The activities of the CPHST will include: conducting complex phytosanitary risk analyses; developing long-term risk-benefit analyses for phytosanitary regulatory activities; assessing avenues of plant pest and disease introduction into the U.S. and the pathways for potential spread of pest species within the U.S.; assessing and improving the efficiency of pest exclusion and control methods; and providing scientific and technical training. For further information concerning APHIS/PPQ programs engaged in phytosanitary risk assessment and risk management, point your Internet web browser to: http://www.aphis.usda.gov/ppq

January Forum: Dr. Stephen Crutchfield

Dr. Stephen Crutchfield of the USDA Economic Research Service (ERS), Food Safety Branch, spoke about "ERS Research on the Economics of Food Safety Risks" at the January ORACBA Risk Forum.

Dr. Crutchfield addressed three major topics: 1) microbial pathogens in meat and poultry, 2) pesticide residues in produce, and 3) nitrates in drinking water. One highlight of the talk was the cost-benefit analysis of Hazard Analysis and Critical Control Point (HACCP) processes, where the estimated benefits of pathogen reduction, as quantified by reduced illness, were found to exceed the estimated costs of implementing HACCP.

Additional highlights included a comparison of the public perception of pesticide residue risks to the estimated risk, and an evaluation of how much consumers are willing to pay to reduce their nitrate consumption from drinking water. Methods for the economic estimation of costs and benefits, such as the contingent evaluation method (CVM) and "cost of illness" method, were presented.

The seminar and discussion that followed provided a sense of the progress in and difficulties of quantifying the costs and benefits of health issues. To learn more about food safety research and other projects at ERS, visit the agency's website, http://www.econ.ag.gov

February Risk Forum: Dr. Stan Kaplan

Dr. Stan Kaplan of Bayesian Systems, Inc., spoke about "Probabilistic Risk Assessment and the Theory of Inventive Problem Solving" at the February Risk Forum. Dr. Kaplan is very well known in the field of risk analysis and an expert on Bayes Theorem.

Dr. Kaplan spoke first about the "Words of Risk Analysis," defining risk as three questions: 1) What can happen? 2) How likely is it? and 3) What are the consequences? He then provided examples of various risks which fit this definition. Dr. Kaplan presented the fundamental logic behind Bayes Theorem and its importance in risk analysis, particularly in describing probability and uncertainty. Bayes Theorem is an evidence-based approach to complex problem solving. His talk also included discussions about scenario development and TRIZ, a Russian acronym for the "Theory of the Solution of Inventive Problems."

ORACBA was honored to have Dr. Kaplan speak, and his presentation provided clarity to complex topics in risk analysis. To learn more about Bayes Theorem and Bayesian Systems, Inc., visit the organization's website, http://www.bayes.com

March Risk Forum: Dr. Patricia Millner

Dr. Patricia Millner of the USDA Agricultural Research Service (ARS) at the Beltsville Agricultural Research Center (BARC) spoke about "A Systems Approach to Determine Effects of Preharvest Use of Manures on Postharvest Fruit and Vegetable Quality and Food Safety." Dr. Millner is the research leader in the Soil Microbial Systems Lab at BARC.

Dr. Millner described the manure cycle by tracing the movement of manure from the animal to the soil, to the forage crop, and then back to the animal. She described the types of pathogens that could be transported in the manure cycle and identified those parts of the cycle which contribute to pathogen transport or the establishment of reservoirs of pathogens on the farm. Dr. Millner identified several types of farming practices which influence the transport of pathogens.

The discussion following the seminar provided insight into how the manure cycle is addressed in the FDA "Draft Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables" and the USDA Organic Standards. The role of the EPA in the regulation of manure was also discussed. To learn more about Dr. Millner's research, visit the Soil Microbial Systems Lab website at http://www.arsusda.gov/smsl/smslhome.html.

Risk Resources

The World Wide Web has become an increasingly valuable source of information for risk analysis information. It can be a source of basic scientific information and data, announcements on meetings and conferences, and a resource for computer models (both source and executable code). While the potential array of sites of interest to risk assessors and managers is extremely diverse, the following provides some of the more easily accessible sites that also contain links to other resources. If you haven't done it lately, take a few minutes and "surf the web." You can use the sites below as a starting point. *Inclusion of a site in this newsletter does not constitute an endorsement of the organization or its activities*. The sites are only offered as examples of the type and extent of resources available on the World Wide Web.

General Information on Risk Analysis

Society for Risk Analysis
http://www.sra.org/
Institute for Reliability and Risk Analysis
http://www.seas.gwu.edu/seas/institutes/irra/
Institute for Operations Research and
the Management Sciences
http://www.informs.org/

Risk Analysis Tools

Ecological Risk Analysis: Tools
and Applications
http://www.hsrd.ornl.gov/ecorisk/ecorisk.html
Register of Ecological Models
http://www.gsf.de/ufis/ufis/
Society for Computer Simulation International
http://www.scs.org/

Risk Calendar

The new Interagency Food Safety Risk Assessment Group (IFRAG) held its first meeting on February 11, 1998. The group will focus on pathway analysis, methods development, and information exchange for food safety risk assessment. Attendees have various interests and expertise in risk assessment and food safety and include people from various agencies, academe, and industry. The meetings will provide an opportunity for members to learn from each other and to set the stage for

doing risk assessments. Membership is open to those who have an interest and are willing to be active participants. For more information contact Dr. Jennifer Kuzma at jkuzma@oce.usda.gov or 202-720-2662.

April 1998
The ORACBA Risk Forum will be Wednesday, April 8, from 9:30-11:30 a.m. in Whitten 107-A. A panel comprised of Verel Benson (NRCS), Ron Meekhof (ORACBA), Ali Sadeghi (ARS), and Mark Tumeo (ORACBA) will discuss "The Use of Simulation Models in Ecological Risk Analysis: Modeling Manure Management Using SWAT and APEX." Please note the earlier starting time. For more information, please call (202) 720-8022.

The EPA National Health Effects and Environmental Research Laboratory will sponsor the "4th Annual Symposium on Research Advances in Risk Assessments." The meeting will take place April 27-30 in Cary, North Carolina. For further information, contact Chris Waddell at (301) 490-5500 or E-mail: cwaddell@lcgnet.com.

May 1998
The ORACBA Risk Forum will be Wednesday, May 13, from 10-11:30 a.m. in Whitten 107-A. Dr. David Heron will discuss "USDA Environmental Assessments for Genetically Engineered Plants." For more information, please call (202) 720-8022.

On May 10-13, the Maryland Department of Natural Resources will sponsor "Conference on Conservation of Biological Diversity: A Key to the Restoration of the Chesapeake Bay Ecosystem and Beyond" at the Holiday Inn in Annapolis, MD. For more information contact Rob Northrop at (410) 836-4551 or E-mail: rnorthrop@dnr.state.md.us

On May 14-15, the International Business Corporation and the National Institute of Environmental Health Sciences will be sponsoring "Characterizing Human Risk: Linking Epidemiology and Toxicology for Improved Environmental Risk Assessment." This meeting will take place in Washington, DC. For information, call (508) 481-6400.

The University of Illinois is sponsoring the 1998 World Food and Sustainable Agriculture Symposium "Pacific Rim Trade, Food Safety and Strategic Issues" May 27-28 at Urbana, IL. For information call (217) 333-5509 or visit their web site at: http://www.aces.uiuc.edu/worldfood.

June 1998
The ORACBA Risk Forum will be Wednesday, June 10, from 10-11:30 a.m. in Whitten 107-A. Notice of the speaker and topic will be distributed via e-mail. For more information, please call (202) 720-8022.

On June 15-16, the NE-165 Regional Research Committee on Public Policies and Private Strategies in the Food System, and the Farm Foundation, will host a conference on "The Economics of HACCP: New Studies of Costs and Benefits," at the Sheraton City Centre Hotel in Washington D.C. For more information and registration materials, please contact Barbara Talenda, Conference Administrator, Dept. of Resource Economics, Box 32040, U. of Massachusetts, Amherst, MA 01003-2040, at (413) 545-5732 or E-mail: talenda@resecon.umass.edu

The ***ORACBA*** *News* 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.