Tradeoffs, the missing link in food safety risk analysis

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Food safety policy is in gridlock

Many groups, in addition to the producer and veterinarian, are now trying to direct and regulate livestock management practices. For example, in 2008 California passed a law regulating the “confineent of certain farm animals...”. The U.S. Congress recently introduced a bill restricting the use of on-farm antibiotics. Some organizations are blaming the April 2009 outbreak of swine flu on intensified pork production (Food and Water Watch, 2009). A rationale form of decision making will be needed to address these policy questions. However, for many current food safety issues indecision and stalemate are the rule of the day. Many people are saying the food safety system is in crisis, but no mutually acceptable solutions are forthcoming. salmonella standards for raw product are being lowered periodically, just “because”. The presence of some pathogens (e.g. E. coli 0157:H7, Listeria monocytogenes) are labeled as adulterants, promoting a zero risk expectation by consumers. Some countries have a zero tolerance for Salmonella on incoming product, while the exporting country is allowed to feed the same product to their own citizens. No product can be tested to one hundred percent safety, therefore, meat producers and processors are working in a constant state of uncertainty because they are only one recall away from bankruptcy.

One of the many reasons for the gridlock may be that “risk assessment is bogged down...” (NRC, 2009).

Risk assessment, however, is at a crossroads, and its credibility is being challenged .... Because it provides a primary scientific rationale for informing regulations that will have national and global impact, risk assessment is subject to considerable scientific, political, and public scrutiny. The science of risk assessment is increasingly complex; improved analytic techniques have produced more data that lead to questions about how to address issues of, for example, multiple chemical exposures, multiple risks, and susceptibility in populations.

Decision-making based on risk assessment is also bogged down. Uncertainty, an inherent property of scientific data, continues to lead to multiple interpretations and contribute to decision-making gridlock. Stakeholders—including community groups, environmental organizations, industry, and consumers—are often disengaged from the risk-assessment process at a time when risk assessment is increasingly intertwined with societal concerns. Disconnects between the available scientific data and the information needs of decision-makers hinder the use of risk assessment as a decision-making tool (NRC, 2009).

The consequences of this gridlock are varied but significant. The uncertainty of changing federal standards combined with the risk of a recall, make the meats business treacherous. Many meat packers avoid collecting or analyzing any more data than required by government regulations; taking a “don’t ask, don’t tell approach”. This shortfall causes a lost opportunity, as data analysis would aid in process control. Without the willingness to constantly monitor data, processors loose the opportunity for continuous food safety improvement.

Risk management inefficiency also leads to indecision. For example, a recent qualitative RA on cephalaxin use in food animals resulted in a “hung” decision by the FDA’s veterinary medicine advisory committee (FDA, 2006). A Salmonella enteritidis risk assessment has been ongoing since 1995. Revisions are still being requested and few decisions or new control policies have resulted (Schlosser et al. 1995; FSIS 2005).
Recommendations

The recent report by the National Research Council (2009), although applied to environmental risk assessment, has valuable suggestions on how to improve risk-based decision making. Many of the recommendations relate to improved risk management. Risk managers need a better understanding and involvement with the process. They need to insist on better scoping (defining which population and effects are of concern), better communication throughout, not just when the assessment is complete, and they need to assure better design (clarifying available control or mitigation options and alternatives).

In this last area of design (evaluating mitigation options and alternative), researchers at this SafePork 2009 congress can play a vital role. Should risk managers clarify which control options are available for consideration (e.g. carcass rinsing versus on-farm vaccination) then studies and analysis can be directed toward research and modeling both side of the option. In support of this concept, the Academy of American Society of Microbiology will soon make recommendations for global food safety. These recommendations will include an exhortation to conduct systems-based research which evaluates the risk-benefit tradeoffs for suggested interventions. This consideration may also be termed tradeoff analysis, risk-benefit, or consequence analysis. In classic medical parlance; “consider the side-effects of a proposed treatment”. A few selected food safety examples of tradeoff related research are highlighted below.

Examples of tradeoff analysis

As mentioned, intensive swine housing is being criticized by many groups. However, the alternative to intense confinement swine rearing is extensive outdoor rearing where the environment is more difficult to control. Recent research comparing outdoor and confinement reared pigs showed a higher prevalence of zoonotic pathogens in pigs raised outdoors without antibiotics (Gebreyes et al., 2008, van der Giessen et al. 2007).

Singer et al. (2007) developed a quantitative policy simulation model to evaluate potential human health risks and benefits (tradeoffs) from changes in poultry health. The model predicts the changes in human illness days (campylobacteriosis) per year caused by changes in the number of subclinically ill birds presented to slaughter. This model could be easily converted from a poultry to a pork application, with appropriate data.

The current version of the model is highly aggregate, reflecting the very high-level data that have been available to date. Equation 1 shows one of the four differential equations used to model the change in human illness days (IH) relative to changes in the quantity of subclinically ill animals (IA) presented to slaughter. The model assumes that clinically ill animals would be removed due to ante-mortem inspection.

\[ \frac{dIH}{dt} = [c + d \times IA + e \times (1 - IA)] \times (1 - IH) - h \times IH \]  

(1)

The main variables in this model are as follows:
- IH(t) = the fraction of the human population of interest that has a specified food-borne illness, such as campylobacteriosis, at any time t. (IH = “ill human” fraction.)
- IA(t) = the fraction of servings of a particular food commodity that comes from animals with a specified illness or adverse condition (e.g., airsacculitis or necrotic enteritis) that the animal treatment could help prevent, reduce, or control. (IA = “ill animal” fraction for servings from processed animals. Animals not sent to slaughter and animal carcasses removed during processing are excluded from consideration when IA is calculated, as they presumably do not affect IH.)
- c = background human illness from non-meat causes
- h = background recovery rate of human illnesses
- \( h_{\text{line}} \)
- *J'espère que tu as passé des bellesd* = proportion of human illness rate (IH) generated from the consumption of subclinically ill animals
- \( e \) = proportion of human illness rate per serving from healthy animal population

The change in human illness (\( dIH / dt \)) is modeled as a function of the proportion of the illness rate from ill animals (\( d \)) and illness rate per serving from healthy animals (\( e \)). The ratio of \( d/e \), termed the potency ratio (\( D \)) was used to represent the relative pathogen load on poultry carcasses from birds with and without airsacculitis. The parameter \( D \) was very uncertain due to dependence on only one publication (Russell, 2003). Therefore, the results were modeled across a range of \( D \) from 1 to 10, where 10 represents a 1 log increase in *Campylobacter* spp. contamination.

![Graph showing change in number of illness days (%)](image)

**Figure 1.** Changes in the total number of human illness days per year due to *Campylobacter* expressed as a percentage change from baseline. The percentage change in illness days is shown as a function of \( D \), the potency ratio between chicken servings from ill vs. healthy chickens. All other parameters are held constant at their baseline values. The model was evaluated for different values of animal illness rates (\( I_{A_{new}} \)), the prevalence of ill chickens after intervention.

As shown in Figure 1, human illness days, even with a low potency ration (\( D = 2 \)), were very sensitive to small changes in animal illness rates (\( I_{A_{new}} \)). Therefore, it is critical for decision-makers to carefully evaluate and consider the human health impact of policies affecting animal health. Clearly, additional data are needed to better estimate the magnitude of the potency ratio for poultry, beef, and pork production. A critical objective of future research could be to estimate the potency ratio (\( D \)) for salmonellosis and campylobacteriosis in the pork production.

Some work on estimating the potency ratio for pork has been conducted (Hurd et al., 2008). This study showed the prevalence of *Campylobacter* spp. on a group (~150) carcasses increased 2 to 5 times as the group prevalence of peelouts (peritoneal and pleural adhesions) increased. Additionally, a recent unpublished study, provided compelling evidence of a significant and quantifiable association between lesions and carcass contamination. It showed that investigators can readily discriminate lesioned versus non-lesioned carcasses on a busy slaughter line.

In one high-speed abattoir we collected swab samples from 358 carcasses. A lesioned carcass was identified immediately after evisceration. A photo was taken and was marked for swabbing at the end of
slaughter, just before final rinse. After another 5 to 10 carcasses passed, a non-lesioned carcass was marked and photographed. The viscera from each marked carcass were also photographed. The photos were later viewed by three board-certified pathologists, and the severity was scored. The three scores were added to obtain a pathology score, which could range from 0-7. Before taking pictures, the initial call of “lesioned” or “non-lesioned” was determined by a student data collector. For analysis purposes, the pathology score was used to redefinelesioned and non-lesioned. Every pig with a total pathology score of higher than 2 was considered lesioned, while pigs with a score of 2 or less were called non-lesioned.

Of the 187 lesioned carcasses (total pathology score >2), 23 (12.3%) were positive for Salmonella spp., 21 (11.2%) positive for Enterococcus spp., and 39 (20.9%) were contaminated either by Salmonella spp., or Enterococcus spp., or by both. The probability of Salmonella contamination in swine carcasses is 101% higher in lesioned carcasses defined by pathologist scores (Odds ratio = 2.01, 95% CI = 0.94-4.32). Using the initial call, odds ratio was 1.90 (95% CI = 0.90-3.99). The positive initial call closely matched the pathologist scores if greater than 2 (kappa value of 0.95).

Conclusion

Researchers at this SafePork 2009 congress can benefit food safety greatly if they consider how their research efforts and results can be included in quantitative risk assessments. Consider how much an intervention reduces the prevalence of a given pathogen. Consider if your research can be used to parameterize a risk model.

Society generally accepts the goal of our work is to reduce the risk of food borne illness. However, every change in the pathogen’s ecosystem or in the producer/packer’s economic system has secondary consequences or tradeoffs. Therefore interventions research should attempt to measure or evaluate what else may change in pork production with a proposed action. We must help decision makers evaluate “the risk of avoiding all risks.”

References


FDA, http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/ucm126971.htm


