Zero Tolerance is a Bad Strategy to Protect Food Safety**

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Summary
When promulgating regulations, government agencies tend to be unwilling to directly accept negative outcomes, including illness, as an acceptable possibility for the citizenry. This aversion reflects political reality. However, avoidance of risk thresholds can be counterproductive to public health. Of paramount importance is the development of acceptable risk levels against which to establish and scientifically evaluate quantitative food safety criteria and, thereby, to appropriately protect public health. Quantitative targets allow application of the best available technologies for modeling and monitoring hazards to effectively enhance food safety. The proposed Produce Safety Rule (PSR) under the U.S. Food and Drug Administration (FDA) Food Safety Modernization Act (FSMA) is intended to assure food safety through science-based minimum standards, or regulatory criteria. The fact that the PSR borrowed the science-based criteria for recreational water quality and applied them to irrigation water is a case example of the need for quantitative risk criteria. Without quantitative risk criteria, it is impossible to evaluate whether PSR water quality criteria are overly protective or not protective enough. Furthermore, it is impossible to test alternatives to the proposed criteria for equivalent levels of public health protection. In the broader sense of food safety, beyond irrigation water quality, risk models and other tools can be effectively used to guide policy. A short list of application examples includes the establishment of irrigation water quality targets, detection probability targets for pathogens or toxins on imported foods, and efficacy evaluation for new technologies, such as utilization of gene sequence information in the detection pipeline. Once established, the risk modeling structure allows effective communication of the scientific basis for policy decisions designed to enhance food safety, and the protective value of food safety criteria and regulations.

Current realities
Consumption of fresh produce, like any other activity, is not risk free. Recognizing this reality, food safety objectives often are stated in relative terms, as in the PSR "to minimize the risk of serious adverse health consequences or death from consumption of contaminated produce." Despite the nuanced wording of food safety objectives, public perception of food tends to be binary (e.g., fresh vegetables are safe but raw meat and eggs are not necessarily safe). Food safety programs should help producers meet the desire and obligation to deliver safe products while enabling effective communication of risk level (which is never zero). In this way the producer or retailer might assure the consumer that consumption of a fresh produce product is safe, from the perspective that the product does not carry elevated risk of illness, and that the producer, packer, and distributor have considered food safety and have implemented practices focused on preventing contamination.

In many instances, communication of risk and risk mitigation is hampered by a food safety regulatory structure that does not include numeric risk targets. Inclusion of such numeric risk targets would greatly facilitate applying science to guide regulatory, management, and policy decisions. As a case example in the U.S., the proposed PSR is intended to assure food safety through "science-based minimum standards," or regulatory criteria. Although the term science-based provides a degree of confidence in these standards, linkage of the science with the desired level of food safety is lacking in the PSR. In contrast to the criteria in the PSR, other water quality criteria, including the 2000 Beaches Environmental Assessment and Coastal Health (BEACH) Act and the Safe Drinking Water Act (SDWA), are benchmarked to numeric targets (i.e., maximum acceptable increased risk of illness). To establish these benchmarks, scientific evaluations of epidemiology and quantitative microbial risk assessment were applied to establish the

relationship between risk targets and actionable enforcement criteria. Instead, the PSR simply applied to irrigation water the science-based criteria for recreational water quality. While the logic is compelling (if it's safe enough for swimming, it should be safe enough for irrigation), the scientific basis is anecdotal rather than data driven. Lack of a target acceptable risk level greatly hinders development of science-based criteria for monitoring, such as are required by the FSMA.

The risk level that defines safe often is termed acceptable risk. In other regulatory arenas, science-based criteria are required to meet an acceptable risk criterion. Specifically, as described above, the U.S. Environmental Protection Agency (EPA) recreational water criteria in support of the BEACH Act are based on an acceptable risk level of 8 cases of gastrointestinal illness per 1,000 fresh-water swimmers or 19 in 1,000 marine-water swimmers. These values trace back to research conducted in the 1950s and historical detection limits for increased gastrointestinal illness above background gastroenteritis levels. Similarly, the acceptable risk criterion for drinking water used to support the SDWA is 1 illness in 10,000 consumers. A similar acceptable risk criterion is required to evaluate the effectiveness of criteria, such as those contained in the PSR, and to evaluate the acceptability of alternate practices, alternative standards, and variances as described in the PSR.

The language of the FSMA implies that a similar risk-backed criterion is meant to be applied to regulated activities such as irrigation of the edible portion of the crop. To evaluate alternate practices or measurements on the basis of equivalent risk to anticipated produce safety rule requirements, it is necessary that the limit must be based on a quantified acceptable risk criterion. In other words, the management or regulatory criterion (i.e., a measurable water-quality attribute, such as the density of a fecal-indicator microorganism) must be indexed to an acceptable risk level if future demonstration of equivalency is desired, as in the case of a variance request or alternate monitoring target proposal as described in the PSR. If we accept that zero risk cannot be attained, a non-zero acceptable risk level must be defined to validate or justify the irrigation water criterion. Only in this way can research be designed with measurable outcomes to show equivalency to FDA-approved management practices (the PSR).

Scientific opportunities and challenges

Food safety can be greatly enhanced by taking advantage of sophisticated risk analysis tools used in other fields, such as mitigation of terrorism risk. The Department of Homeland Security Chemical, Biological, Radiological, and Nuclear Terrorism Risk Assessment (CBRN TRA) program illustrates some opportunities and challenges. The CBRN TRA models follow the path of contaminants from the point of introduction to the point of contact. This framework effectively represents a confluence of quantitative microbial risk assessment (i.e., the calculation of the dose of microbial contaminant delivered and probability of illness as an outcome) with probabilistic risk assessment (i.e., the inclusion of probability of initiation, represented by frequency of contamination events). This framework could be a powerful tool for both calculation and communication of risk given different inputs. In particular, these calculations can be used to estimate level of input (e.g., monitoring criteria such as for irrigation water quality or sampling effort for produce coming from the field) that feed into a particular target outcome (e.g., an acceptable risk level).

Stakeholder acceptance of the CBRN TRA models has, in some cases, been challenging. In addition to realistic calculations, models can be limited by the data upon which they are based. In particular, the Food Consequence model of the Bioterrorism Risk Assessment (BTRA) carries out calculations that are directly relevant to other food safety management programs. One major challenge for development of the BTRA Food Consequence model was obtaining credible data to describe for all relevant organisms (i) the amount of contaminant introduced in the scenario, (ii) growth and/or decay characteristics, (iii) dose-response relationships in consumers, and (iv)

conditions experienced by the organisms from point of application to point of consumption. In addition, validation of risk models for a relevant scope of pathogens, product distribution systems, and regional effects are critically important to stakeholder acceptance. Failure to normalize risk across all potential "pathways" through a model can be seen as bias, or preference for one consumer group over others. Throughout the process, stakeholder education is critical to acceptance and successful implementation.

Policy issues

A well-informed, risk-focused framework for food safety is essential to establish consistent, informative regulations and criteria. The following policies and actions would result in an improved framework for food protection.

- Establish risk targets in food safety regulations. In the case of the PSR in the U.S., the FDA should establish a quantitative risk target.
- Require quantitative risk calculations as part of criteria development and formulation of rules designed to manage risk:
    - Require information gap analysis as part of the FSMA implementation in the U.S. and comparable regulations worldwide to ensure that investments are effectively directed to fulfill model data input requirements to address model information gaps. These input requirements include interactions of various environmental conditions in carrier matrices, such as food surfaces or irrigation water, and impact of background microbial communities.
    - Implement education programs to communicate results to the public in ways that are realistic. For example, by conducting mock contamination events and tracking foods, with results compared against modeled processes. This approach is similar to efforts undertaken by USDA for control of foreign animal disease spread (e.g., highly pathogenic avian influenza and foot-and-mouth disease).
- Leverage existing capabilities, similar to those developed by the DHS for CBRNE TRA, to effectively and consistently manage safety for production of fresh produce and regulation of vulnerabilities such as irrigation water quality. In this way, take advantage of existing risk management analysis tools to accurately estimate the dose delivered to consumers based on key factors including initial dose, decay processes, distribution characteristics, and consumption behavior.
- Utilize risk model results to revise the regulatory structure through what-if analysis using a range of conditions modeled in the risk model; explicitly require use of the risk model to allow variances from regulatory criteria based upon equivalent achievement of threshold risk levels.
- Implement programs to develop better detection methodologies for international trade, raw product monitoring, and monitoring at different steps of the process with criteria/sampling frequency dictated by modeled conditions.
- Formulate policies and regulations with attention to rapid development and acceptance of new measurement technologies that help to address risk-based criteria. Sampling and analysis of bulk samples by massively parallel next-generation DNA sequencing can be used to screen large pools of product for threats that are both known and unexpected (e.g., intentional contamination with biological agents that are not part of the normal public health risk suite).

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