

The Role of Quantitative Microbiological Risk Assessment in Risk Management Options Assessment

Robert L. Buchanan
U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
5100 Paint Branch Parkway
College Park, MD, USA 20740
1-301-436-2369
Robert.Buchanan@cfsan.fda.gov

The ability to use mathematical models to predict the behavior of complex systems has reached a point that it is influencing a wide array of human endeavors. A case in point is that the plane I am scheduled to take to the FAO/WHO consultation is a Boeing 777, an airplane that was completely designed and manufactured based on computer simulations and risk assessment analyses. The fact that hundreds of thousands of travelers to trust their lives to this highly complex technological achievement obviously implies that we are willing to accept the use computer modeling as an important technology when applied appropriately.

Considering the extent to which risk assessment and computer simulation techniques are being adopted in a variety of fields, it is not surprising that there is increasing use of risk assessment techniques to consider the impact of pathogenic foodborne microorganisms on the safety of foods. While there are a variety of reasons for conducting a quantitative microbial risk assessments, one of the most important and powerful applications is likely to be the evaluation of possible risk management strategies. Often referred to as a risk management options assessment, this is the process by which different options for controlling a hazard to an “acceptable level of protection” (ALOP) are evaluated and compared. This is typically done by developing a risk assessment model that establishes mathematically the various factors that contribute to the current level of risk associated with a product/pathogen pair. Once this model is established, the model is augmented with additional parameters representing the different the control strategies being considered. For example, if one were assessing the impact that a mild heat treatment has on the production of fruit juices, the product/pathogen model would be augmented with a mathematical function that would calculate the reduction in exposure that would be achieved by the heat process.

Typically, the consideration of risk reduction strategies is based on an evaluation of relative risks, comparing the impact of the introduced parameter against the initial baseline risk estimate. This focus on comparative risk reduces the need to focus of establishing the absolute risk associated with each food control strategy. This would typically involve estimating changes in the level of exposure. An exception would be if the control measure alters the susceptibility of the host (e.g., vaccination). In that instance, modification of the hazard characterization would be required. Depending of the degree of control achieved and knowledge available concerning the effectiveness of

the control measures, varying degrees of uncertainty will be introduced by the inclusion of the control measure into the risk assessment model. This uncertainty should be estimated in considering the relative risk reduction achieved by the proposed control option. One of the current challenges to estimating the effect of different control strategies is estimating the degree of compliance that is likely to be achieved by various approaches. As with any system, the more complex the process, the more likely it is to fail; however, it is currently very difficult to estimate and compare failure rates among different risk management options

Before discussing how risk assessment techniques can be used it is important to emphasize that the establishment of an ALOP is not solely a scientific question but involves the consideration of a variety of societal factors. A risk assessment will not automatically establish a “safe” level, but instead provides the risk managers and other interested parties with a means of discussing in a hopefully more objective manner the levels of safety (i.e., risk) that currently exist in a system and the level of controls that would be achieved with further reductions in the consumers’ exposure to the hazard. It is then the responsibility of the risk managers to weigh the various risks (used in its broadest sense) associated with managing a food safety system in order to achieve control of consumer exposure to a specified level.

Ideally, countries would establish their ALOP based on public health goals; i.e., there is a conscious effort to articulate the level of disease control that is expected and then translating that to a measurable parameter that can be control by food producers (e.g. food safety objective, performance standard). This provides the greatest flexibility in that the industry is given clear goals that must be achieved, but the specific approach for achieving this is left to the discretion of the manufacturer. This is consistent with the principles of HACCP and equally important the goals of both the WTO SPS Agreement and Codex Alimentarius.

However, many countries approach a risk management option assessment in a manner that I consider less than ideal manner. Instead of using a risk assessment to help the risk managers decide on an ALOP, to often the approach is to assess the current status, evaluate the impact of various risk management options, and select (and often mandate) one that is considered optimal. While this achieves the immediate goal in the short term, it is my hypothesis that this approach is actually detrimental in the long run since it reverts back to a “command and control” approach. Mandating a single risk management option negates the very risk analysis approach that is being embraced by the international food safety community. It also has an extremely detrimental effect on the ability for food manufacturer to be innovative in terms of finding new approaches to achieving food safety. For example, a risk management option mandates that milk must be heat pasteurized for a certain length of time at a certain temperature, instead of stating the performance criterion that should be achieved, virtually assures that new technologies such as high pressure processing would not be used despite the fact that it may actually process a product that is equally safe and organoleptically superior.

Some of the key questions that have to be asked when considering an optimal risk management option is to whom is it optimal and what are the criteria used to make that determination. As a hypothetical example, let's consider an instance where it is necessary to achieve a reduction of pathogens on the surface of citrus fruit. In an industrialized country where labor costs are high, the use of advanced, high-speed steam surface pasteurization technologies may be the optimal system for achieving the desired reduction. However, in a developing country where labor costs are low but capital costs are high, it may be more effective for hand wash the fruit in an appropriate sanitizing solution. Thus, if the criterion for what constitutes optimal is minimal labor cost and speed then the former is optimal whereas if the criterion were minimization of capital expenditures and full employment, then the latter would be the desired approach. "Optimal" like beauty is in the eye of the beholder. It is clear in the SPS Agreement that this is not the approach that should be taken. This implies that if one is being consistent with the goals of the WTO, the primary role of risk assessment in risk management option assessment should be to establish the equivalence or lack thereof among food control approaches.

It is my personal experience has been that risk assessment options assessments are actually a combination of the two processes. The risk managers have a general idea of the degree of public health protection they are trying to achieve. The risk assessors then examine the impacts of different control options and approaches, providing the risk managers with data that allows them to more objectively evaluate proposed options. The risk managers then provide alternative management options to be evaluated. This iterative process continues until one or more risk management option that achieves the desired level of protection is identified.

As an example of how quantitative risk assessment could be used, let's consider the recent FDA, "Draft Risk Assessment on the Public Health Impact of *Vibrio parahaemolyticus* in Raw Molluscan Shellfish," which evaluated several risk management options. Figure 1 depicts the relationship between the levels of control that would have to be achieved in the absence of risk reduction strategies in order to reduce the level of disease associated with this pathogen to varying degrees. The figure also depicted the percentage of the harvest from one region in the country if that degree of risk reduction was achieved. This is the type of information that is required by the risk managers to make a decision on the level of control necessary based on a consideration of public health goals.

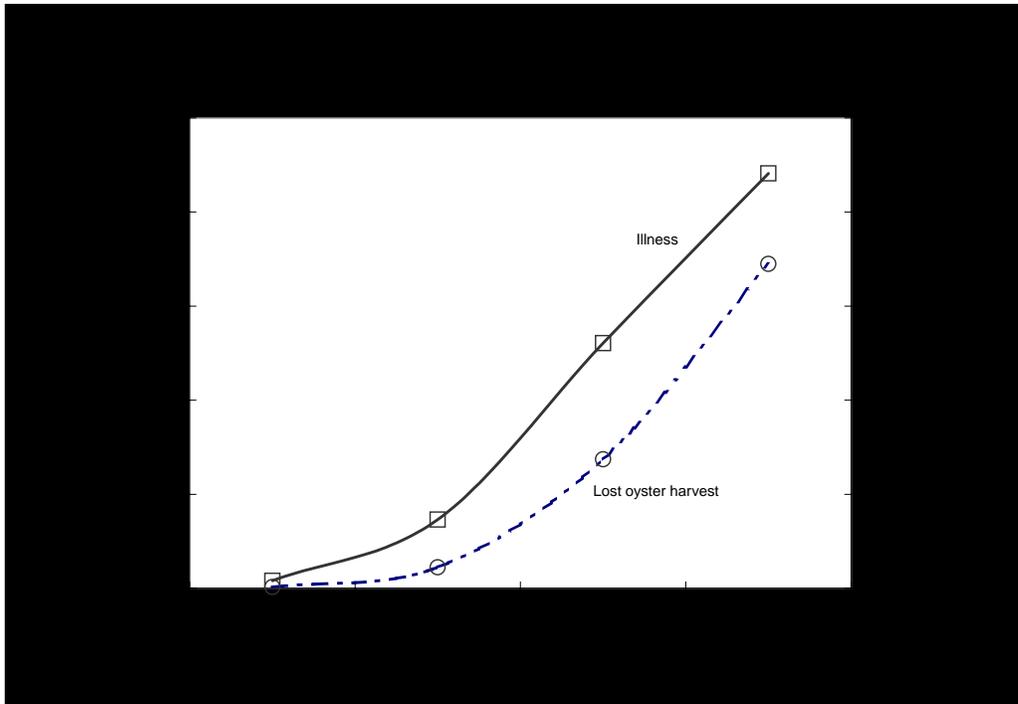


Figure 1. The predicted relationships between reductions in *V. parahaemolyticus* cases that the levels of the microorganisms in oysters.

Consideration of the scope of a risk management program may also be influenced by information acquired as a result of a risk assessment. Table 1 depicts the relative risk of risk of acquiring *V. parahaemolyticus* infections as a function of both the season and region of the country where the oysters were harvested.

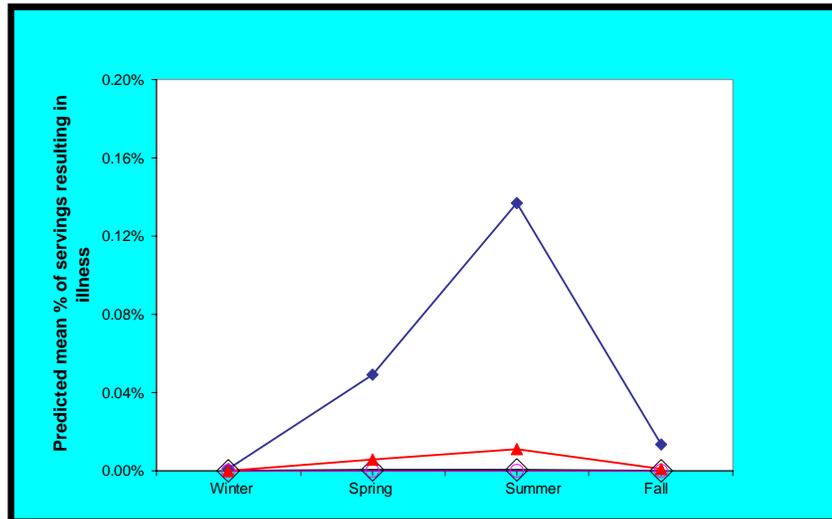
Region/Season	Fall	Winter	Spring	Summer
Gulf Coast	400	25	1200	3000
Mid-Atlantic	~0	~0	10	12
Pacific NW	~0	~0	15	50
Atlantic NE	~0	~0	12	30

Table 1. Annual sporadic cases of *V. parahaemolyticus* gastroenteritis predicted by region and season.

It is apparent that most risk is associated with specific regions and specific seasons. Thus, one risk assessment option may be to do nothing for three of the regions during the fall and winter.

This would then imply that for those regions and seasons where the ALOP for this product/pathogen pair was exceeded, an alternate approach for reducing the risk would be needed. For the purposes of this example, let's propose that the ALOP for this product pathogen pair was no more than 20 cases of illness per region during any single season. This would mean that risk reduction strategies would have to be in place for one region

during the entire year and in two regions during the summer. One approach would be to simply not allow the sale of the product in those region/season combinations that exceeded the ALOP. Alternatively, one could use alternate risk reduction strategies. The FDA risk assessment examined three possible strategies, rapid refrigeration, freezing, and mild heating. The predicted impact of these approaches for the Gulf Coast region is depicted in Figure 2.



Effect of intervention measures on the predicted risk of *V. parahaemolyticus* illnesses from Gulf Coast harvests: no mitigation (◆); freezing (△); heat treatment (●); rapid cooling (□).

It is apparent from this figure that all three risk reduction strategies would be highly effective, with freezing and mild heating being roughly equivalent and easily capable of achieving our hypothetical ALOP.

These types of evaluations do require a high degree of communication between the risk assessment team and the risk managers. In particular the expertise related to industry practices and procedures typically resides with the risk managers. However, the examples provide above required only two meetings between the groups (one early in the risk assessment and one as the assessment was being finalized) in order to determine what analyses were needed and to decide on the format that would be most effective to communicate the information needed by the risk managers. In part this reflects the fact that the risk assessment team included individuals that were experts in the shellfish industry.

In summary, risk assessment techniques provide a powerful new tool for considering the impact that different risk management reduction strategies are likely to have on public health. However, its use in support of risk management options must follow all of the principles associated with the conduct of a microbial risk assessment. In particular, the simultaneous need for functional separation and effective communication between the

risk assessors and risk managers is necessary to insure that the risk managers are making decisions that are consistent with international goals of enhancing consumer protection without arbitrarily disrupting international commerce.