Moving from Hazard-based to Risk-based Microbial Food Safety Systems to Promote Public Health and Foster Fair Trade Practices**

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Summary

Foods are one of the major vehicles for the transmission of a broad range of infectious diseases. The ability to prevent these diseases is becoming more complex as the world increasingly relies on global marketplaces. National governments have agreed that the best way to prevent food-related infectious diseases is through international trade that safeguards public health while ensuring fair trade practices. However, this goal has not always been realized, in part because of the highly varied approaches to food production, processing, distribution, and marketing used throughout the world. Experts have generally agreed that the framework needed is one that is science-based, risk-based, and flexible, while still ensuring verifiable levels of control.

The need to prevent foodborne infectious diseases is fostering the development of risk analysis approaches for controlling them. Great strides have been made in our ability to conduct microbial food safety risk assessments; however, equivalent gains have not been achieved in microbial food-safety risk management and risk communication. Risk management systems are in the process of moving from being hazard based to risk based, but this is hampered by our ability to define consensus international standards. Harmonization is critical both for consumer confidence and for industry, as well as for less-wealthy countries to have predictable food safety targets.

One key issue is how to take risked-based approaches and adapt them to "Hazard Analysis and Critical Control Points" (HACCP), the primary risk-management system used by the food industry. A second is how the level of stringency can be transparently related to the level of public health protection. These key issues can be overcome by food safety policies and infrastructure investments that foster transparency, improve inter-sector data exchange, develop and quantify alternative food safety approaches, harmonize international standards, and provide objective measures of the level of control currently achieved by our food safety systems.

Current realities

A predictable, adequate, affordable, and safe food supply is critical for public health, economic development, and political stability worldwide. The transmission of infectious diseases via foods is one of the key factors that erodes confidence in the food supply. While it has long been recognized that foods can be a source of pathogenic microorganisms, we have only recently appreciated the magnitude of the public-health burden. The impact is often greatest for developing countries where there is minimal food safety infrastructure, and the export of agricultural commodities and food is a primary source of hard currency.

There have been concerted international efforts to rationalize and harmonize food safety standards and guidelines, including efforts by national governments through the World Trade Organization's (WTO) Sanitary and Phytosanitary Agreement (SPS), and the UN's Codex Alimentarius Commission (CAC), as well as by industry through the Global Food Safety Initiative (GFSI). These efforts have been accelerated by the WTO's recognition of both the CAC "standards" and the importance of risk assessment. These organizations have emphasized the critical need for consensus standards that promote public health, are based on science and risk

assessment, foster fair-trade practices, and provide flexibility in the methods used to achieve the desired rigor.

Refocusing food safety standards has led to tremendous advances in microbial risk-assessment methods and food safety risk-management metrics concepts. These strengthened capabilities help identify outbreaks, attribute foodborne disease to specific foods, estimate the burden of foodborne disease, and distinguish residual food safety risks from low-frequency system failures. However, many food standards are out of date, nontransparent, poorly justified in relation to food safety risk priorities, not focused on measurable outcomes, and not translatable into actions that can be incorporated into HACCP. These food standards' shortcomings often are reflected by regulatory systems that are hazard based instead of risk based and/or an inability to communicate with stakeholders in a manner that leads to consensus in "tolerable levels of risks," while ensuring continuing improvement.

Scientific opportunities and challenges

The past decade witnessed rapid advances in our understanding of the risks related to foodborne infectious diseases. Different classes of microbial risk assessments have been developed to address diverse public health and regulatory questions (e.g., risk ranking, evaluation of risk-mitigation strategies, risk-risk trade-offs, risk-benefit trade-offs, and risk of introduction of new infectious agents). A cadre of highly capable risk assessors and subject-matter experts is emerging internationally as governments begin to use risk assessments in their regulatory deliberations. However, there are significant challenges in the other two components of risk analysis: risk management and risk communication.

Risk management is the process of determining the degree of stringency appropriate for controlling microbial food safety risks and determining which mitigation efforts can provide the desired degree of control. In general, risk managers have placed little emphasis on defining principles for effective risk management (Buchanan, 2011). However, CAC (2007) recently defined a four-step process for microbial risk management that consists of: (i) preliminary management activities, (ii) selection of risk-management options, (iii) implementation of programs, and (iv) monitoring and review. There are significant challenges within this framework such as:

- Developing a library of common metrics to objectively prioritize dissimilar risks,
- Acquiring data on contamination rates in various foods and data that associates foodborne disease with specific foods and commodities,
- Developing informatics systems for sharing data across food-industry sectors and among countries,
- Defining and maintaining "lots" for product identification,
- Distinguishing food systems' residual risks (i.e., frequency of infectious agents when the system is in control) vs. low-frequency systems' failures (i.e., incidents of loss of control), and
- Identifying effective predictors of performance.

A critical bridge in this process is the ability to link the impact of decisions and actions taken within HACCP to the expected public health protection provided by food safety systems.

Perhaps the greatest challenge to improving our food safety systems is how to achieve effective risk communication. A large and diverse group of stakeholders has deep interests in food safety, each with its own perspectives, values, and vocabulary. Communication challenges are further amplified when different countries and cultures are involved. For example, it is difficult to reach consensus on national and international food safety standards if one does not appreciate

that consumers view food safety as a binary state (i.e., safe vs. not safe), whereas food manufacturers view the degree of safety assurance as a continuum that requires a series of trade-offs in terms of public health protection, food quality, and cost of the food to consumers. The ability to achieve multidirectional communication is the foundation upon which consensus food safety standards must be developed.

Policy issues

- Advance transparent food policies which articulate the level of risk reduction that will be achieved, including relating it to frequency of risk-management monitoring and review.

- All microbiological standards should articulate the actual risk reduction likely to be achieved.

- Working through an appropriate intergovernmental organization (e.g., the Food and Agricultural Organization [FAO] and the World Health Organization [WHO]), develop and provide guidance on how to link the stringency of HACCP plans to desired public health outcomes.

- Develop policies and informatics systems that foster the inter-sector exchange of data while safeguarding the proprietary interest of the business community.

- National governments and industry should work together to pool existing data to determine baseline levels of microbial contamination in various classes of food, the variability associated with those baselines, the residual risk associated with "in control" food production and processing operations, and the incidence of systems failures.

- As per the WTO's SPS, national governments should be willing to accept international consensus food safety standards to reduce the degree of unpredictability for industry and developing countries.

- National governments and industry should look for approaches to better harmonize regulatory food safety standards and industry-purchase specifications.

- National governments, industry, and intergovernmental organizations should develop risk-based tools that allow food safety systems and approaches to be evaluated objectively, for comparability/equivalence.

- National governments should invest in developing and validating "size-appropriate" microbial food safety prevention and intervention technologies that offer approaches appropriate for small- and medium-sized producers, processors, and distributors of foods, as well as for use in less-wealthy countries.

- National governments and intergovernmental organizations should continue efforts to determine the burden of foodborne disease globally, but must couple this with equivalent information on the extent of microbial contamination in the food supply.

References

Buchanan, R. L. (2010, December/ 2011, January). Understanding and managing food safety risk. *Food Safety Magazine, 16*(6), 24–31.

CAC (Codex Alimentarius Commission). (2007). *Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM).* (CAC/GL 63–2007).

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The following summary is based on notes recorded by the ISGP staff during the not-for-attribution debate of the policy position paper prepared by Dr. Robert Buchanan (see above). Dr. Buchanan initiated the debate with a 5-minute statement of his views and then actively engaged the conference participants, including other authors, throughout the remainder of the 90-minute period. This Debate Summary represents the ISGP's best effort to accurately capture the comments offered and questions posed by all participants, as well as those responses made by Dr. Buchanan. Given the not-for-attribution format of the debate, the views comprising this summary do not necessarily represent the views of Dr. Buchanan, as evidenced by his policy position paper. Rather, it is, and should be read as, an overview of the areas of agreement and disagreement that emerged from all those participating in the critical debate.

Debate conclusions

- The food supply chain has become increasingly global. Countries currently import significant quantities of goods and products to meet their local consumption demands. Yet, food safety regulations and practices from country to country differ widely, which often leads government authorities and the public to question the safety of imported products.

- The establishment of the World Trade Organization (WTO) and Codex Alimentarius (CA) has helped ensure fair trade. However, less-wealthy countries still face significant challenges when competing in the international food market. This is primarily due to the continued technological and economic gap between wealthy and less-wealthy countries.

- To better prevent foodborne disease outbreaks, the food industry must shift from hazard-based to risk-based systems. Recent advances in risk assessment tools have provided more efficient means for addressing problems related to food safety.

- Many different food safety standards exist globally, some of which have been instituted by the private sector. The general lack of transparency in the development of private-sector standards, particularly in terms of their scientific basis and the determination of acceptable levels of risk, is problematic. Additionally, private-sector standards often place undue pressure on less-wealthy countries, where the capacity to meet them is often absent. Currently, there is no organization that has the authority to address the proliferation of private-sector standards for food trade.

- Communication of risk among all food stakeholders (i.e., intergovernmental organizations, government, the private sector, academia, and the public) must be improved. Ineffective communication leads to poor understanding and implementation of food safety practices (e.g., zero tolerance) and causes confusion related to the degrees of risk associated with food.

- Greater focus and input are needed at the policy level to ensure that food defense receives sufficient attention. Additionally, better integration of available data sources is needed so that the food industry can make informed decisions related to food defense.

Current realities

Significant discussion centered on the fact that food production, manufacture, and processing methods, as well as food safety practices, vary greatly worldwide. The contrasting methods by which peanuts are screened were presented as an illustration of these differences. In more-affluent countries, for instance, each peanut is screened by laser. In West Africa, however, the process is much more labor-intensive, with women and children examining every peanut by hand. It was further noted that the great variance in food safety practices, regulations, and standards used worldwide was one factor leading to the creation of the Sanitary and Phytosanitary (SPS) Agreement by the WTO, an international treaty establishing measures for food safety systems to facilitate safe and fair trade. The SPS operates in conjunction with CA, which is intended to protect consumers' health and ensure fair trade practices in food commerce.

The growing capacity gap (e.g., infrastructure and technology) between more-wealthy and less-wealthy countries was repeatedly highlighted. It was asserted that this divide is exacerbated by the substantial economic difficulties that less-wealthy countries routinely contend with, which impact international trade as well as their ability to meet SPS and CA measures. Both SPS and CA were instituted to improve food safety worldwide. However, it was acknowledged that difficulties in complying with the SPS and CA measures often limit the opportunities less-wealthy countries have to export food.

The food industry has been urged to move from a hazard-based (i.e., preventing identified hazards from occurring) to a risk-based (i.e., managing hazards based on acceptable levels of risk) food safety system. Recent advancements have refined risk assessment as a tool that can be applied to food safety, and have concurrently demonstrated the value of a risk-based approach. There was general agreement that this methodological shift is long overdue, and that it would benefit the food industry and public by better targeting potential problems related to food safety. However, it was noted that some stakeholders (e.g., countries and food industries) are reluctant to make this change because of the potential negative consequences for profitability.

The food safety management system called Hazard Analysis and Critical Control Points (HACCP) is a systematic preventive approach that addresses biological, chemical, and physical hazards throughout all stages of the food production and preparation processes. The HACCP system has the flexibility to function as either a hazard-based or risk-based system because it involves planning how to prevent and/or mitigate an identified hazard or risk. It was noted that HACCP is the primary risk management system used by the food industry worldwide and that it is universally accepted.

The retail food industry group has developed standards for the global trade of food products, through avenues such as the Global Food Safety Initiative (GFSI). GFSI methods have been questioned as being less than totally science-based, risk-based, and transparent.

International food-focused treaties have been jointly crafted by the United Nations' Food and Agriculture Organization (FAO) and the World Health Organization (WHO), as well as by the WTO. However, it was contended that not all treaties have been formulated with enough

involvement from the scientific community. For example, it was argued that the SPS Agreement was established with only limited input from scientific food experts.

Significant concern was expressed that both scientists and the government agencies responsible for food policies inadequately communicate levels of risk associated with food to stakeholders (e.g., to the public and each other). It was asserted that insufficient communication has undermined the degree of public confidence required for successfully ensuring food safety.

Zero tolerance is a risk communication term that has been used to express a high level of concern for safeguarding public health. In food safety policy, zero tolerance is the prohibition of a potentially threatening substance (e.g., microbiological or chemical) on or in a product, which thereby renders the product unsuitable for human consumption.

It was asserted that the food safety system is not binary (i.e., safe versus unsafe). The system is one of stringency, wherein the level of control is set based on acceptable levels of risk. Within this, varying degrees of risk are always present. Although part of government's regulatory role is to ensure that the food industry is meeting stringency standards, it was pointed out that when there is a failure within the food industry, such as an infectious disease outbreak, the government is often blamed for industry's failures or shortcomings. It was further argued that the true responsibility for food safety ultimately lies with those in the food industry because they manufacture these products.

It was noted that the top 10 food companies in the world, which are all multinational corporations, produce 90 percent of the world's food. Due to their abundant resources and research capabilities, it was widely agreed that these corporations have significant economic advantages over smaller companies as players in the world market. However, it was asserted that smaller businesses can compete in world markets in some instances, such as the orange juice market, as long as technology costs do not become prohibitive.

Scientific opportunities and challenges

Strong support was voiced for moving from hazard-based to risk-based management of food safety issues. It was contended that a risk-based approach will improve public health and food trade practices by more appropriately targeting where risks lie and accordingly mitigating these problems.

It was acknowledged that members of the food industry generally support and adopt international safety standards because regulation uniformity benefits them directly. Such standards not only decrease the burden of interfacing with individual countries' bureaucracies, but also minimize the work the food industry must invest in reconciling differing regulations in areas such as packaging and distribution. This demonstrates that opportunities exist to simultaneously promote the agendas of all stakeholders (e.g., government, food industry, and others).

Due to the high cost of certain technologies that are routinely used to protect food, small- and medium-sized farms and food manufacturers encounter disproportionate economic challenges in complying with many food standards relative to their larger counterparts. Yet, it was noted that this barrier could be overcome with the aid of research and development for lower-priced technologies. This was exemplified by the case of the orange juice industry in the United States, wherein smaller companies faced problems competing and complying with U.S. Food and Drug Administration (FDA) standards due to the high price of flash pasteurization devices

(approximately US$500,000 per device). In this instance, a research project was initiated and a more cost-effective device (approximately US$15,000) that meets FDA requirements was developed and approved.

It was contended that core communication efforts should focus on the intersection of risk and food safety. However, it was also recognized that the divergent interests of the relevant groups complicate effective communication. For example, it was noted that the public generally looks to the government and food industry for clarity on whether foods are safe — yet it is impossible for authorities and industry to promise zero risk with respect to food consumption. While it was agreed that government officials and the food industry should be honest with the public, conflicting viewpoints were voiced regarding how much the general public is capable of understanding and/or applying degrees of risk to everyday decisions. Balancing candor and clarity was accordingly perceived as an ongoing challenge.

Acceptable levels of risk are sometimes based on parameters that are not transparent. It was asserted that this lack of clarity can be problematic because ambiguity concerning the degree of risk can fuel the public's mistrust of the food safety system.

It was argued that while zero tolerance is ideal in principle, it is extremely difficult to implement such practices in real-world settings. The primary obstacle is that for zero tolerance to truly be obtained, every piece of food must be tested (as opposed to employing statistical sampling methods). This approach not only is cost prohibitive from a procedural standpoint, but also impractical given that current testing methods are often destructive to the food itself. It was argued that levels of risk therefore must be set in accordance with the ability of the food industry to effectively meet these requirements.

There was acknowledgment that the food industry needs an effective system for sharing and analyzing the various forms of data it collects on a regular basis. Multiple factors that have become barriers to data sharing were highlighted. For example, to protect themselves from economic repercussions, farmers are reluctant to divulge potentially negative information to food manufacturers or producers. Similarly, to safeguard their proprietary interests, food manufacturers are frequently hesitant to share data with competitors or regulatory agencies.

Although international food safety standards exist, not all countries require that they be adopted. For food product export, manufacturers will frequently follow only the standards necessary for their products to be accepted in a given country. Manufacturers may therefore follow different stringency standards with respect to products intended for local consumption versus those intended for consumption abroad. This is particularly true for manufacturers in less-wealthy countries who continually seek out ways to reduce costs. However, it was stated that encouraging and facilitating less-wealthy countries to export food products meeting international standards frequently motivates these countries to also adopt higher standards for their internal products. This results in safer food in all areas.

Policy issues

There was general consensus that a shift from a hazard-based to a risk-based food safety system should be promoted by encouraging the use of available risk assessment tools and increased training for stakeholders in this area (e.g., government, the food industry, and the public). It was argued that support from policy makers is necessary to facilitate the movement toward a risk-based system, including implementation of food safety risk assessments, creating and supporting data sharing mechanisms, and promoting international harmonization of food safety regulations and practices.

While it was contended that risk-based food safety systems should become the primary model implemented worldwide, it was also recognized that some food producers are already instituting scientific risk-based practices. To keep pace with these changes, policy makers must review and revise regulations and policies on both national and international levels so that existing food laws will not lag behind risk-related technological developments. It was noted that such laws currently vary widely by country, and often are outdated. In addition, it was deemed important for countries to review whether their national regulations and standards comply with the SPS agreement, and to update them where needed. Although national government agencies were tasked to review their regulations and standards after the SPS Agreement took effect, it was contended that not many countries (if any) undertook this exercise.

There was agreement that inconsistent food safety standards as well as the problems that variable standards create, particularly related to trade, must be addressed. The food safety standards that have been adopted by industry, especially by multinational food companies, often differ from standards established by intergovernmental organizations, such as the WTO. This divergence creates confusion among exporters, who are unsure of which standard to follow. It was also noted that private-sector standards prevent some smaller countries and/or manufacturers from participating in export trade, even when they are able to meet accepted standards of intergovernmental organizations. A mechanism is needed to manage the various standard-setting bodies. Additionally, to determine whether existing standards are scientifically valid, increased transparency in how standards are derived or developed is of fundamental importance.

It was noted that policies related to food safety practices must take into account the disparate capacities of small and large producers and manufacturers. While both group sizes should be held to equivalent standards, policies should allow producers and manufactures to achieve food safety standards through the creative use of effective, affordable technologies. This means that a greater focus must also be placed on applied research into developing them.

The need to improve communication among government, the food industry, and the public was widely endorsed. It was argued that the level and quality of communication related to food safety issues must be enhanced among all relevant food industry stakeholders. To move forward, communication training must be implemented and other communication mechanisms, such as multidisciplinary meetings where communication can be facilitated, should be developed and/or promoted.

Another critical aspect of communication in which improvements were suggested relates specifically to the public. There is an urgent need for the public to understand and apply levels of risk acceptance to their routine decisions. A fundamental part of a risk-based food safety system rests on decisions that accurately reflect the degree to which the public understands how regulatory agencies and the food industry establish levels of acceptable risk (e.g., the public must decide whether to consume a product, and/or how to cook it, based on decisions made by government and industry on tolerable pathogen levels). As such, the public must be provided with better risk information to make informed decisions. It was recognized, however, that public decisions will likely vary across the world due to differing perceptions of risk related to food safety (e.g., in some areas, hunger abatement may take precedence over perceived risks).

It was strongly asserted that food product testing, as part of import regulation, should occur at the point of production rather than at borders. Proponents of this change contended that point-of-production testing would be more efficacious and economical. The current emphasis on border testing is inefficient because it requires food products to be shipped in advance of testing; when problems arise, these products must then be returned to their point of origin. As such, funds are unnecessarily spent simply moving products from place to place. Additionally, it

was argued that potential problems can be addressed in a more timely and efficient manner when identified at the point of production, which would therefore make better use of the limited resources currently allocated to food testing.

It was recommended that greater attention and input at the policy level be applied to food defense (i.e., protecting the food supply from deliberate or intentional acts of contamination or tampering). For food defense to succeed, a better framework using all available data is critical. The types of data to be included for food defense can often be found in the information collected by law enforcement, regulatory agencies, and the food industry. For example, in the case of data collected by law enforcement agencies, one area of interest would be criminal activities involving the food industry. This information should be made available to agencies engaged in food safety, so it could then be used to make more informed food safety decisions.