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Ann Reid
Director, American Academy of Microbiology

colloquia@asmusa.org

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American Academy of Microbiology
1752 N Street, NW
Washington, DC 20036
http://academy.asm.org
Between the farm and the dinner table, there are many opportunities for disease-causing organisms and other food safety hazards to enter our food supply. Keeping food safe as it travels that path is complicated, and as our food increasingly comes from all over the world, keeping food safe is becoming even more of a challenge. As the volume of international trade expands, so too, do the opportunities for transmitting pathogens or chemical contamination from one part of the world to another.

In 2009, the American Academy of Microbiology convened a colloquium to review the current state of affairs in microbiological food safety around the world. Colloquium participants with expertise in microbiology, public health, food science, and economics discussed these matters and made several specific recommendations for improving the safety of global food supplies.

An essential take-home message is that most foodborne illness is not recognized or reported. Unless the illness is severe enough to require a visit to the doctor or hospital, it is unlikely that the source and identity of the pathogen will be determined. Only if many people are severely sickened by a single product are breaches in food safety likely to be detected. It is virtually impossible to know how many people are made sick by food, which foods are at fault, which pathogens are most widespread or dangerous, and where those pathogens entered the food production system. In such a situation, where should research, prevention and education efforts be directed? In this report, each step in our complicated food production and supply system is described, making it clear that providing safe food is a shared responsibility.

Food safety is complex, and a perfectly safe food supply is an unrealistic goal. However, as this report explains, there are opportunities for improving food safety at each step of the production and consumption process and many areas where further research could help identify and quantify risks and generate solutions. The report also identifies food safety vulnerabilities that might be addressed through investments in new technologies or more effective education.

**The Food Safety Chain has Many Links**

Food safety problems may arise at any stage from food production to consumption: on the farm, at the processing facility, at the retailer, or in the hands of consumers. The product on a grocery shelf or a restaurant plate may contain ingredients from many countries—each of which may have passed through different processing facilities, and may have been handled by wholesalers, retailers, and multiple transportation companies before finally reaching the consumer’s shelf or refrigerator. No single regulatory agency is responsible for monitoring this process. Instead, responsibility
is fragmented among multiple state and federal agencies, and, increasingly, shared with foreign governments and international organizations. Therefore, the single most important challenge in food safety may be finding a way to put in place a systems approach for managing food safety. By taking a systems approach, where each stage of food production is treated as part of a larger system of inputs, outputs, and processes, foods could be more readily tracked from their source at the farm all the way through processing and distribution. This would greatly facilitate identifying and managing potential contamination and tracking the sources of foodborne illnesses when they emerge.

**Farmers**

Farmers must approach food production as a system. Good Agricultural Practices (GAPs) have been developed to help producers minimize food safety lapses, but they need to be scientifically grounded, economically realistic, and tailored to local conditions. And, of course, they must be consistently implemented. Specific food safety issues on the farm include the use of improperly treated manure and poor-quality water. Improving food safety training for farm workers and raising standards for water quality will help alleviate some of these on-farm concerns. When food leaves the farm and enters the processing and retail system, it is important that data management systems be in place to keep track of where the food originated. Otherwise, it may be impossible to identify the ultimate source of a foodborne illness outbreak.

Sound scientific evaluation of the impact of various farm practices on food safety is not always available. Research on the following topics would be especially helpful:

- Pathogen transmission and the effectiveness of intervention strategies on farms,
- The impact of environmental factors—including interactions with local ecosystems, flooding, irrigation water, and others—on product safety, and
- The impacts of insect and wildlife vectors on product safety.

Improving the safety of food at the pre-processing stage will also require new cost-effective, sustainable, and consumer-acceptable technologies for preventing food contamination and decontaminating foods. Some of the more urgently needed technologies include:

- Means to detect water quality breaches,
- Practical water treatment devices,
- Effective vaccines for livestock and inoculants that prevent pathogen colonization,
- Pathogen-resistant varieties of plants and animals,
- Effective decontamination techniques for dry products and fresh produce and new means for preventing uptake of pathogens by produce during postharvest processing,
Improved produce harvesting equipment that reduces the risk of contamination and can be easily cleaned and sanitized on a regular basis,

Better storage structures in developing countries to prevent contamination by pests and damage resulting from inadequate climate control, and

Better means for managing potential mycotoxin contamination.

**Processors**

Processors are often reluctant to innovate or reform their practices, and aging facilities and poorly designed equipment are obstacles to processing food safely. Just as farmers have GAPs, producers are expected to implement Good Manufacturing Practices (GMPs) that are designed to prevent or minimize contamination. Like GAPs, these practices must be scientifically validated, documented, and economically realistic. Periodically, these practices need to be revisited to allow for consideration of newly emerging food safety issues. Regulatory frameworks must be in place to incentivize and ensure compliance with GMPs. Processing facilities should be repaired and upgraded on a continuous basis in order to prevent contamination and adequately inactivate foodborne pathogens. Processors in poorer countries require affordable, small-scale technologies for controlling pathogen contamination in the foods they produce.

Identifying solutions to the safety problems faced by food processors will require researchers to address several scientific needs, including gaining a better understanding of:

- the ecology and epidemiology of foodborne pathogens,
- the persistence, inactivation, and growth of pathogens in various foods that are subjected to a range of processes,
- pathogen reservoirs in food processing environments,
- the control of foodborne pathogens in ready-to-eat products and other vulnerable foods, and
- how consumers will use various products.

Processors also need new technologies that might have immediate or near-immediate benefits, including:

- technologies to prevent re-contamination between processing and packaging,
- improved post-harvest lethality treatments,
- practical application of novel processing technologies (high pressure, industrial microwaves, pulsed electric field, etc.).
more effective cleaning and sanitizing measures specifically addressed at the processing of low moisture foods,

- improved pathogen detection methods which are both more rapid and quantitative,

- real time methods of monitoring cleaning and sanitation to determine the presence of microbes, allergens, chemicals, and mycotoxins,

- mitigation technologies targeted specifically at contaminants that are difficult to control, including allergens, mycotoxins, and viruses,

- improved implementation of GMPs, and

- small-scale technologies that do not require high throughput to be cost-effective.

**Retailers**

Retailers, from grocery stores, to restaurants, food service operations in nursing homes, schools and hospitals, and vendors who sell food on the street, must cope with food contamination by workers, a problem exacerbated by constant worker turnover. Keeping food cold poses another set of problems, particularly in developing countries that often lack the necessary infrastructure. Developing cost-effective technologies to make food preparation as foolproof as possible, delivering effective training programs, and maintaining the cold chain infrastructure are the most important needs in the retail sector.

Research areas that would contribute to improved retail food safety include:

- identifying risks shared by many establishments that contribute to many sporadic cases of foodborne illness (for example, undiagnosed Norovirus infections),

- establishing science-based guidelines for regular and effective equipment cleaning,

- developing more effective education and training for retail workers,

- developing rapid and inexpensive diagnostics and effective vaccines for pathogens of highest public health risk, and

- developing effective communication between consumers and retailers to make food recalls more effective and timely.

Novel technologies that would help improve food safety in the retail sector include the following examples:

- Cost-effective cold chain equipment;

- Food service equipment that can be cleaned easily and effectively;
Technologies to make food preparation as failsafe as possible;

Systems designed to compensate for misuse by negligent or poorly trained workers; and,

Better restroom equipment and automatic hand washing equipment.

Consumers

Consumers are often unaware of, or fail to apply, safe food handling practices. New food products are constantly being introduced. Consumers can buy produce year-round from around the world and are increasingly interested in buying produce, meats, cheeses and other products directly from local farms but may not realize that even fresh food requires safe handling. Also, consumers may assume that all 'ready-to-eat' foods are risk-free and exempt from safe handling precautions.

Because most consumer-caused foodborne illnesses are not recognized as such, much less systematically reported, an important barrier to reducing their incidence is inadequate knowledge of which foods, agents, and practices pose the greatest risk. Areas for future consumer-related research include:

- determining the foodborne disease burden associated with home-prepared foods,
- quantifying the risks associated with the consumption of raw or minimally-processed foods,
- determining the impacts of proper (and improper) cooking on the risk of foodborne disease, and
- evaluating the role of cross-contamination in consumer risk.

Most critically, of all the links in the food safety chain, consumers arguably have the least understanding of their role in food safety. Therefore, research aimed at designing and disseminating effective educational resources about safe food handling practices and the risks from consuming tainted food is key to reducing the risk of foodborne illness caused at the consumer level.

An Even Longer Chain: the globalization of the food trade

In recent years, globalization has introduced a new set of challenges for food safety. Global trade is carried out amidst a complicated and spotty patchwork of food safety standards and regulations. Worldwide, food safety regulations should be reevaluated with the ultimate goal of creating a unified and harmonized global approach to food safety management. Consistent reliance on the Codex guidelines developed and maintained by the World Health Organization (WHO) and the Food and Agriculture Organization of the United Nations (FAO) provides the most promising approach upon which this effort may be based. Improving global food safety means identi-
fying the areas of greatest risk and developing practical and economical responses. Answering the following research questions would aid that process:

- What are the true costs and related benefits of food safety improvements?
- How can food safety interventions be tied to public health outcomes?
- How can we harmonize and audit inspection processes across different countries?
- How can we derive a standardized measure for “safe food”?
- To what extent do regulations actually make food safer?
- What is the impact of human behavior in food production, processing, and retail service on the safety of foods?
- How can we design cost-effective traceability systems?
- What are the effects of climate change on pathogen ecology and transmission?
- In what ways will climate change affect food safety risks?

**Risk Assessment: evaluating each link in the chain**

Finally, the report describes the process of risk assessment, which has emerged as a powerful tool for guiding food safety policy and regulation. In risk assessment, an effort is made to describe and quantify risks at each stage of a complex process. It is particularly helpful when it is difficult to measure risk directly, or when there are many real (although very low probability) risks involved. Thus, it is well-suited to the analysis of food safety, and can provide a scientific basis for decision-making for regulators, processors, farmers, and even consumers. But if it is to produce meaningful results, risk assessments must be carried out in accordance with international standards and must be focused on the correct questions. Much of the research recommended in this report would help make risk assessments more reliable and valuable. Also, the process of conducting risk assessments is expensive, time-consuming and highly technical in nature. Efforts to streamline this process would make risk assessments even more powerful.
Consumers take it for granted that their food is safe, but a quick scan of the recent news suggests that this is not always the case:

“Salmonella Outbreak Prompts Massive Egg Recall”

“Shigella Outbreak Being Investigated”

“E. coli Outbreak: All the Victims Have Same Strain”

“Hot Dogs Recalled on Listeria Fears”

These headlines point to an unpalatable truth: food carries with it the risk of foodborne illness. The WHO estimates that unsafe food sickens one in three people every year worldwide¹, but the actual incidence of foodborne illness is probably much higher. Most cases of foodborne disease go unreported, particularly in developing countries, meaning the incidence of foodborne illness may actually be 300 to 350 times greater² than reported cases would indicate.

Unless an individual's illness is severe enough to require a visit to the doctor or hospital, it is unlikely that the source and identity of the pathogen will be determined. Only if many people are severely sickened by a single product are breaches in food safety likely to be detected. This situation creates a significant public health challenge. It is virtually impossible to know how many people are made sick by food, which foods are at fault, which pathogens are most widespread or dangerous, and where those pathogens entered the food production system. In such a situation, where should research, prevention and education efforts be directed? In this report, each step in our complicated food production and supply system is described, making it clear that providing safe food is a shared responsibility.

This report describes the road that food follows from the farm to the plate. In order for that food to remain safe, everyone in the process must share the responsibility of maintaining an unbroken chain of safe practices. Along the way, the report highlights areas of research that are needed to improve food safety at each step.
The safety of food may be compromised at any point along its journey from farm to processor to retailer to consumer. The following sections identify some of the problems each of these sectors struggle with and how these problems might be addressed. Research priorities for each phase are also identified, but perhaps the most important take-home message is that failure to view, assess, and manage food safety as a system may represent the single most important and fundamental problem in modern food production. Ultimately, food safety hinges on ensuring that each link in the chain from farm to table is as strong and dependable as possible. To understand the presence of pathogens in food, one must consider the entire food production, manufacturing, and marketing system, including the complex dynamics that occur in the interaction between microbes and the environment during the production of food. Unfortunately, comprehension and consideration of the “system” as a whole is lacking.

On the Farm

Almost all food—produce, meats and poultry, and dairy—comes from farms, therefore farm practices have a profound influence on the microbiological safety of foods. Keeping foods safe until they leave the farm poses a number of challenges for growers and regulators alike, and there are research needs that must be met to overcome these challenges.

The problems

Farmers throughout the world struggle with a large number of food safety issues that arise in production agriculture. These deficiencies range from such broad fundamental problems as the failure to implement a systematic approach to maintaining food safety, to more specific contamination issues that result from the use of inadequately treated manure or tainted water. A systems approach to the farm link in the food safety chain means treating the production process on the farm as a continuous system—identifying points where contamination is possible, implementing procedures to prevent or detect breaches in food safety, and providing workers with the training, incentives and resources needed to apply those procedures consistently.

Improper use of manure or even human waste poses another safety hazard, particularly in the cultivation of fresh produce. Effectively managing farm waste to mitigate pathogen transmission is critically important. Using animal manure on fields is not necessarily unsafe, but sound management processes must be in place to prevent pathogen transmission.
Poor water quality also poses serious problems, for even in the U.S. there are no definitive regulatory standards for the quality of water used in agriculture. Outdoors, runoff water from farmland can percolate in unexpected directions and wildlife can interact with water, crops, or livestock, carrying pathogens and other unwanted materials into food and handling areas.

Other farm practices that contribute to food safety risks:

- Confined animal feeding operations and potential problems that arise from maintaining high densities of livestock, poultry, and farmed fish;
- Lack of cold storage near enough to where food is harvested to enable appropriate post-harvest handling of produce; and,
- Worker health and hygiene issues that persist due to the extensive use of an itinerant and poorly compensated migrant labor force that has little incentive to adhere to safe food handling practices.

Barriers to reducing food safety risks on the farm

Improving food safety at the farm level will not be easy. In principle, producers should implement the best known approaches to maintaining food safety. To this end, a variety of “Good Agricultural Practices” or GAPs, have been developed for many kinds of farm products. The FAO defines GAPs as “practices that address environmental, economic and social sustainability for on-farm processes, and result in safe and quality food and non-food agricultural products.” Ideally, all GAPs would be genuinely science-based, but evaluating and validating the efficacy of GAPs in mitigating food safety risks is difficult, especially when the events that the practices are meant to prevent are rare. No single set of GAPs and associated metrics will be appropriate under all circumstances. Instead, GAPs must be tailored to particular conditions or regions, and then disseminated and adopted.

Sound scientific evaluation of the impact of various farm practices on food safety is not always available. It is challenging to conduct meaningful food safety research on the farm. On-farm research is extremely complex, expensive, and difficult, and it is far from clear whether results from one farm or region are applicable to others. Furthermore, research is hampered when liability concerns prevent corporate farms from sharing food safety data. Serious knowledge gaps exist in our understanding of:

- pathogen transmission and the effectiveness of intervention strategies on farms,
- the impact of environmental factors—including interactions with local ecosystems, flooding, irrigation water, and others—on product safety, and
- the impacts of insect and wildlife vectors on product safety.

As the FAO's definition states, a good agricultural practice should be designed to be economically sustainable. However, the economic costs and benefits of food safety interventions at the farm level are difficult to measure. Food producers typically have lower profit margins than processors or vendors, making it challenging to develop
financially viable food safety measures. This reduces the incentive to produce microbiologically safe food. Proposed or recommended interventions should be evaluated economically so that producers are not asked to spend money on food safety precautions that do not appear to offer sufficient returns. Compliance by the producers is more likely if the economic benefit of proposed food safety precautions can be convincingly demonstrated.

Changes in technology and handling can lead to unanticipated changes in the microbiological ecology of food items, allowing for the emergence of new pathogens or higher incidence of known pathogens. Sometimes the risks that result from new processing or consumption habits require changes at the level of the farm. For example, Listeria monocytogenes became a problem in refrigerated, ready-to-eat foods largely after extended refrigerated storage became widespread. This pathogen is extremely widespread, but its incidence on the farm at low levels was not a major concern when conditions further along the production chain did not encourage its growth. The agent that causes bovine spongiform encephalopathy did not enter the food chain because of any changed practices at the farm level, but because changes were made in the processing of offal that resulted in contaminated cattle feed. In another example of unintended consequences, the U.S. implemented a new requirement to treat mangoes with hot water to prevent the carriage of fruit flies, and suppliers in Brazil complied. Unfortunately, the water treatment used on the mangoes contaminated the mangoes with Salmonella. Product shipped to the European Union, which did not require hot water treatment, was untainted.

Consumers can also stand in the way of implementing effective food safety measures on the farm. Negative consumer perceptions of the risks associated with biotechnology interventions, for instance, can prevent producers from using these technologies. Consumers in the European Union, for example, firmly reject genetically modified crops even if the genetic modification mitigates a food safety risk, for example by conferring resistance to the growth of mycotoxin-producing fungi.

Another barrier to improving food safety at the farm level stems from the general failure to treat food production as a continuous system. It is often difficult or impossible to identify which farm the food came from—in other words, the original source of a food product. Tracing raw food materials and the ingredients of contaminated products back to where they were produced is extremely difficult. Even basic information such as where farms are located is not readily available, therefore the original sources of small outbreaks often go unidentified, allowing contaminated food to continue to enter the production system and small problems to grow more serious. When processors pool products from many small farms, traceability becomes even more complicated.

**Improving safety on the farm**

To develop the interventions that will have the greatest impact on reducing foodborne illness, one must first identify the most pressing food safety objectives and goals. New interventions and processes need to be developed through research, then validated, implemented, and subjected to rigorous documentation and monitoring to ensure they achieve the desired objectives. Producers particularly need interventions that are both economically feasible and suitable for a broad spectrum of production environments and foods.
Food safety authorities should ensure that regulations and “good practices” are based on rigorous science. In particular, GAP standards should compel better record keeping, more thorough maintenance of the cold chain, and higher water quality standards—while remaining flexible and responsive to local practices.

High standards of water quality are essential for producing safe food. As such, it is critical to determine appropriate quality standards for water used in the production of different commodities and set correspondingly high standards for water used on the farm. This must be done with a mind to regional or economic constraints, however. For instance, it is generally recognized that groundwater is less prone to microbiological contamination than is surface water, making it a safer source for irrigation purposes. However, groundwater is not available in all regions of the world. In particularly arid regions, it may be necessary to use reclaimed water for irrigation purposes. The use of an irrigation water source with potentially higher propensity for contamination may be mitigated by choosing irrigation practices that reduce the likelihood of contamination of the edible portions of the food product. The type of irrigation method used, such as subsurface drip vs. furrow irrigation, can reduce the risk of contamination for many types of produce, particularly when using reclaimed water.

The U.S. Food and Drug Administration (FDA) has developed GAPs that recommend that farms use water with sufficiently high quality for its intended application. However, the guidance documents do not define targets for indicator organisms or limits for populations of bacteria, parasites, fungi, or viruses. By contrast, guidance documents concerning water used in the processing of food recommend water quality consistent with U.S. Environmental Protection Agency (EPA) requirements for drinking water (e.g. total coliform limit), or similar standards. Additional research is needed to identify practical and relevant microbial indicator organisms and limits for water used in farming that will have an impact in reducing incidence of contamination at the level of the farm.

The emphasis growers and consumers alike have recently begun to place on sustainability, wider availability of unprocessed and local foods, and minimization of food losses, can have implications for food safety; producers must be aware of with safety risks that may accompany new practices. Growers, for example, should not, strictly out of a desire to prevent food wastage, pass on to consumers vegetables or fruits grown under conditions that may result in pathogen contamination, such as when manure-tainted irrigation water has been used.

Improved training for farm workers is another key to addressing weaknesses in the pre-harvest food safety system. Workers should be trained in the use of fertilizers and pesticides and in basic health and hygiene practices and in GAPs. Ideally, producers would also provide their workers with immunizations for illnesses such as hepatitis A, which is currently not considered economically justified. Above all, it is crucial for producers to provide toilets and hand washing facilities on-site for their workers and to assure appropriate and routine use of these facilities.

Research and technology priorities

There are a number of priorities for research to improve food safety on the farm, starting with the need for better sampling methods. Appropriate sampling and
sample preparation is necessary for pathogen detection, but routine sampling can be insufficient because contamination frequently occurs sporadically and at low levels. Consequently, routine testing of foods will reveal only persistent or widespread contamination, with smaller scale incidents going unnoticed despite the fact that they, too, can result in disease. For this reason, end-product testing, which cannot readily identify the source of contamination, may need to be supplemented by more frequent testing earlier in the food production chain.

To reduce the likelihood of pathogen contamination of food on the farm, researchers must know where and when in the food production pathway the pathogen is likely to be found, and at what concentration. For example, identification of the rates of fecal shedding of pathogens by food animals, and the likelihood of pathogen transmission between animals held in high density would be beneficial. These sorts of findings then need to be directly related to the likelihood of human exposure, a process that can be facilitated by the use of various risk assessment tools (see page X). However, answering these questions is tricky. A great many disease-causing agents are found at low levels nearly everywhere, or are found only sporadically. Furthermore, the dose needed to make someone sick can vary widely between different populations. Very young children and the elderly, for example, often are made ill by a much smaller number of pathogenic agents than other populations. Therefore, linking pathogen levels on the farm to public health risk is extremely challenging. Nonetheless, it is the gathering of this sort of information that will make it possible to identify those monitoring and intervention strategies with the greatest possible impact on reducing foodborne illness.

In addition to further research, improving the safety of food at the pre-processing stage will require new cost-effective, sustainable, and consumer-acceptable technologies for preventing food contamination and for decontaminating foods. Some of the more urgently needed technologies include:

- means to detect water quality breaches,
- practical water treatment devices,
- effective vaccines for livestock and inoculants that prevent pathogen colonization,
- pathogen-resistant varieties of plants and animals,
- effective decontamination techniques for dry products and fresh produce and new means for preventing uptake of pathogens by produce during postharvest processing,
- improved produce harvesting equipment that reduces the risk of contamination and can be easily cleaned and sanitized on a regular basis,
- better storage structures with climate control where necessary, and
- better means for managing potential mycotoxin contamination, including the development of grains that are resistant to colonization with toxin-producing molds and technologies to remediate mycotoxin contamination of grain.
Processors

Food processors take farm products and transform them in any of a number of ways into the items we find on grocery store shelves. It is these foods—boxed, bagged, bottled, frozen, dried, or canned—that make up the bulk of what we eat in the developed world. One goal of food processing is to kill, inhibit, or remove pathogens from foods, but some processing conditions can facilitate pathogen growth, so that pathogen levels in the processed product are higher than in the raw ingredients.

The problems

To produce microbiologically safe foods, processors must take into consideration both the inputs they receive from producers and the equipment and procedures they use to process them.

In recent years, we have seen erosion in research and development efforts at food companies and a reluctance to innovate or reform practices. Moreover, aging facilities and equipment that lack good sanitary design are obstacles to processing food safely. Too often, low profit margins mean that innovation and repairs are only undertaken after major outbreaks of foodborne illness. Often, capital improvements are not made routinely and systematically, but only in response to emergencies. From a public health point of view, this is clearly a flawed model; processing facilities should be repaired and upgraded on a continuous basis to prevent outbreaks of foodborne illness.

Unrecognized or newly emerging hazards may also result in foodborne illnesses. Sometimes hazards are detected only when epidemiologic data suggest an association between a particular food and a particular pathogen or illness. Examples abound here. For example, recent outbreaks of salmonellosis associated with contaminated peanut butter came as a surprise, because Salmonella cannot grow in low-moisture food and there was little previous evidence to indicate consuming peanut butter was a risk for contracting salmonellosis. It is unlikely that this is a "new" issue. However, improved ability to detect and analyze outbreaks and improved understanding of the resilience of this microbe in what were thought to be low risk foods has made this a critical emerging food safety concern.

Technology can play a key role in reducing the risks that have grown with the increasing complexity of the food distribution system. After an outbreak of E. coli O157:H7 sickened more than 500 people, the CDC initiated a program called PulseNet that uses DNA testing to compare the genetic fingerprints of pathogenic bacteria from patients and suspect foods. The fingerprints are loaded into a database where they can be compared and indistinguishable fingerprints detected. The system allows outbreaks to be detected even when cases are widely dispersed; in a 2006 outbreak of E. coli O157:H7 infection traced to fresh spinach, there were 199 cases in 26 states and only three states had more than 15 cases. As food distribution becomes increasingly global, linking other national and regional networks similar to PulseNet can allow rapid detection of even more highly dispersed incidents. For example, in 2007, outbreaks of shigellosis in Denmark and Australia were both linked to baby corn imported from Thailand.
PulseNet has been tremendously helpful in identifying outbreaks, but the time to produce and analyze fingerprint data has resulted in delays in the identification and initiation of subsequent control measures. Smaller foodborne disease outbreaks are investigated by state and local health or agriculture departments, the resources for which vary widely among the localities. Although a database of CDC outbreak investigations is available electronically, along with the source food (if identified), similar databases are not provided by the states and municipalities. This means that a large portion of outbreak data that could be used to direct policy is unavailable in a readily usable form. Epidemiologic systems need to be harmonized and more importantly, the databases maintained by the different food safety agencies (FDA, CDC, USDA-Food Safety Inspection Service (FSIS), states and locals) must be compatible and shared, so that the efforts of all groups with responsibility for food safety can be coordinated. To mitigate future large-scale outbreaks, public health systems need to use improved questionnaires and more aggressive investigations to collect better exposure data.

### Barriers to reducing food safety risks at the processing stage

The absence of adequate guidance is sometimes a problem for processors. Just as farmers are expected to follow Good Agricultural Practices, processors are required to develop and implement Good Manufacturing Practices (GMPs) to minimize risk of contamination. GMPs complement and support the Hazard Analysis and Critical Control Points (HACCP) system of food safety management. HACCP represent a systems approach to food processing, including identification of hazards, monitoring, verification and record-keeping. To be effective, GMPs and HACCP must have full buy-in from processors, which means in part that they must be economically realistic. Furthermore, they must be clear and reasonably easy to implement. And ideally, of course, they should be continuously updated as new information becomes available. In reality, GMPs are frequently not fully implemented. In other instances, there may be confusion over terms. For example, a distinction between the terms “control point” and “critical control point” may be confusing to processors trying to implement a HACCP plan correctly. The HACCP concept is currently ripe for reexamination and the principles may need to be revisited and updated to reflect four decades worth of experience with HACCP.

Small- and large-scale food processors have specific food safety problems that may be unique to their size. Small-scale food processors, because they are on the losing end of the economies of scale, may have fewer cost-effective intervention technologies at their disposal and less overall resources. Large processors, on the other hand, may find that there are communication barriers between management and the workforce or tension between the interests of the food safety or quality assurance staff and the production and marketing staff. All processors could improve their compliance with GMPs (where available) and safe practices in general by providing adequate food safety training programs for workers. Regulatory bodies could improve compliance and encourage more sampling by offering incentives, but should also follow up with frequent inspections and fines for noncompliance.

Just as consumers are reluctant to accept some safety measures available for use on the farm, they also occasionally reject the use of certain processing technologies, such as irradiation, despite their proven ability to make food safer. In the 1980s,
the International Atomic Energy Agency (IAEA), the WHO, and the FAO concluded that food irradiation is safe up to a specified dose. Some countries allow irradiation for a few products, such as spices and herbs, but have encountered resistance to applying it to other products. Even safe and effective techniques cannot be used if consumers do not support them.

Finally, monitoring compliance with GMPs and HACCP is expensive. Requirements that processors hire third-party auditors to inspect plants and verify safe practices add to processing costs, but do not always achieve their intended goal. Auditors may miss important safety lapses or be reluctant to antagonize their clients with negative reports, and processors may be unable or unwilling to address the problems identified in the audits.

We cannot “inspect” safety into foods, and even the best inspection system will not completely eliminate contamination with foodborne pathogens. However, the differences in food inspection practices among countries can contribute to food safety issues at the international level. Even within a single country like the United States, inspection practices are inconsistent from place to place and food to food. Specifically, for all but a few products, inspection at the farm level is not done. Processing facilities under USDA-FSIS jurisdiction (including meat, poultry and processed eggs) have near constant inspection, whereas facilities under FDA jurisdiction (which include those handling seafood, fruits and vegetables, cheese, and bakery products) are inspected infrequently. In fact, a recent report by the Inspector General of the Department of Health and Human Services revealed that fewer than half of the over 51,000 facilities regulated by the FDA were inspected between 2004 and 2008.9 Inspection of retail and institutional establishments is the responsibility of states, and frequency and rigor vary. Inspection resources for imported food products are particularly scant. The rather haphazard U.S. food inspection system functions neither optimally nor equitably and hence provides piecemeal protection to the food supply.

Research priorities

Identifying solutions to the safety problems faced by food processors will require researchers to address several scientific needs, including:

- gaining a better understanding of:
  - the ecology and epidemiology of foodborne disease pathogens,
  - the persistence, inactivation, and growth of pathogens in various foods subjected to various processes,
  - pathogen reservoirs in food processing environments,
  - the control of foodborne pathogens in ready-to-eat products and other vulnerable foods, and
  - consumer use of various products,

- determining if interventions can be managed as CCPs in a HACCP plan,

- developing and validating appropriate sampling methods (size, location, number) for various commodities, and
Even the most stringent safety practices at the food processing phase will not achieve the impossible goal of eliminating pathogens.

- conducting adequate research to validate the safety of new processes and new product formulations.

**Needed technologies**

Processors also need new processing technologies that might have immediate or near-immediate benefits, including:

- technologies to prevent re-contamination between processing and packaging,
- improved post-harvest lethality treatments,
- practical application of novel processing technologies (high pressure, industrial microwave, pulsed electric field, etc.) including specific guidelines for process validation,
- more effective cleaning and sanitizing measures addressed specifically at the processing of low moisture foods,
- improved pathogen detection methods which are both more rapid and quantitative,
- real time methods to monitor cleaning and sanitation to determine the presence of microbes, allergens, chemicals and mycotoxins,
- mitigation technologies targeted specifically at difficult to control contaminants, including allergens, mycotoxins, and viruses,
- improved implementation of GMPs, pre-requisite programs, and HACCP, including the implementation of mandatory education, training, and certification programs for audits/producers (Global Food Safety Initiative model), and
- small-scale technologies that do not require high throughput to be cost-effective. As with farming, new processing technologies are often driven by the needs and budgets of large-scale operations.

Almost all regulatory food safety measures are aimed at the processing, not the production, phase of the farm-to-fork continuum, but even the most stringent safety practices at the food processing phase will not achieve the impossible goal of eliminating pathogens. The efficacy of any treatment is dependent on the initial numbers of pathogens in the food and the type of food, so prevention or reduction of contamination at the farm stage remains necessary.
Retailers

Food retailers include all kinds of businesses—grocery stores, restaurants, institutional food service operations in nursing homes, schools and hospitals, and vendors who sell food on the street.

The problems

Because the food retail sector is so diverse, food safety challenges vary widely depending on the scale and type of operation. But there are two sources of food safety problems that face all retailers: unsafe food handling practices and inadequate infrastructure.

In retail food sales, as in processing and farming, there is always the risk workers may contaminate the product. Contamination by food handlers is a major problem at the retail level, especially for multi-ingredient foods. Noroviruses are of particular concern. The virus is highly infectious, many infections are asymptomatic, and the virus is shed at very high levels and for many days or weeks after symptoms have disappeared. Low pay leads to high turnover in food service workers, which exacerbates food safety problems because training in safe food handling practices and hygiene must be constantly reiterated to reach new workers. Poorly paid workers may also have little incentive to maximize food safety – for example, staying home when they are ill is likely to create real economic hardship. In developing countries, contamination by workers is a particular problem in street food, since vendor carts lack easy access to clean water, toilets, and hand washing facilities. Group feeding environments like schools, hospitals and nursing homes present a particularly important challenge. In many cases, the consumers in such food service environments are especially vulnerable to infection, and food preparation in large batches increases the risk that many susceptible people will be exposed if noroviruses or other highly infectious agents are present.

Keeping foods cold at all stages of the distribution chain represents another set of problems for retailers—particularly in developing countries, which often lack the necessary infrastructure to accomplish this.

Addressing these and other problems in retail food safety is challenging. Cultural differences in handling practices, for one, are difficult to change, and may continue to cause food safety problems despite the best efforts of regulators. In addition, implementing continuous refrigeration and other preservation measures is prohibitively expensive in many parts of the world and may not be realistic for years to come.

Research and technology priorities

Identifying new food safety risks as the retail landscape changes is challenging, as is disseminating information about new risks and about innovations in the science and technology of food safety. It will never be possible to eliminate pathogen contamination at the retail level, but there are areas of research and technology development that would help to minimize occurrence.
Research areas that would contribute to improved food safety at retail include:

- identification of risks shared by many establishments that contribute to many sporadic cases of foodborne illness (for example, undiagnosed Norovirus infections); such research could provide economic justification for such interventions as mandatory hepatitis A vaccination for food workers;

- establishment of science-based guidelines for regular and effective cleaning and disinfection of retail food preparation and food service equipment, along with effective training to maximize compliance;

- development of effective education and training approaches for retail workers—especially deli workers and meat, dairy, and produce managers—that emphasize prevention of cross-contamination, the importance of hand washing compliance, and avoidance of bare hand contact with food;

- development of rapid and inexpensive diagnostics, and effective vaccines, for pathogens of highest public health risk; and,

- development of effective communication practices between consumers and retailers to make food recalls more effective and timely.

Novel technologies that would help improve food safety in the retail sector include the following examples:

- Cost-effective cold chain equipment;

- Food service equipment that can be cleaned easily and effectively;

- Technologies to make food preparation as failsafe as possible and systems designed to compensate for misuse by negligent or poorly trained workers; and,

- Better bathroom equipment and automatic hand washing equipment, for example, tap-mounted antimicrobial treatments for waterspouts, sanitizers and hand sanitizers effective in eliminating non-enveloped viruses (such as human noroviruses).

An international body called the Codex Alimentarius (see page X) works to establish food standards that protect consumers without inhibiting international trade. Rapid change in the retail sector and constantly emerging information about food safety makes it difficult for Codex to continuously keep standards up to date and widely disseminated. Because disconnects between regulation, science, and the marketplace often create confusion and uncertainty, some retail establishments simply adhere to private criteria for food safety, which may be based more on economic concerns and the needs of the retailer than on science or safety. There is a need to address retail-specific food safety hazards around the world, including the development and implementation of controls and regulations that are realistic and achievable by all sectors, regardless of national boundaries. Regulators need to speed up the process of developing and implementing regulations or adopting food safety criteria developed by the private sector so that safe practices become the norm for retail food providers.
Consumers

The last link in the food safety chain is the consumer. Food preparation at the consumer level is enormously varied, sometimes relying on every modern convenience (including refrigeration, microwave ovens, hot and cold running water, etc.) and sometimes making do with nothing but a coal stove and improvised cooking gear. Despite the diversity in food preparation and consumption practices, there are unifying problems associated with consumer food safety, and chief among them is a lack of awareness about the basic tenets of food safety.

The problems

Food safety concerns at the consumer level include risks of contamination that originate with (or at least are perpetuated by) consumers themselves as well as risks that arise from circumstances over which consumers have little or no control. Many consumers, particularly those in developing countries, may not be aware that foods can make them sick if not properly handled, prepared, and stored. In developed countries, consumers are more aware of the risk of foodborne illness but often assume that processing takes care of contamination and that the food they purchase is safe. Either way, few consumers fully understand that the food they buy can sicken them and that they must play a role in protecting the safety of their own food. Even if consumers do know that their food can make them sick, they often do not know enough about safe food handling practices and the possibility of cross-contamination. And some consumers eat raw shellfish, raw eggs or raw milk even when they are aware of these foods’ safety risks.

Sometimes food packaging can present problems for consumers. In some cases, it is difficult to tell the difference between products that need to be cooked further and those that do not, since some raw products look just like those that are highly processed and hence safe for direct consumption. What’s more, many consumers do not realize that once a package containing perishable foods is opened, the safety of the food inside can be compromised. Written instructions are not necessarily effective, since many consumers are illiterate, and even literate consumers often neglect to read directions.

There is evidence that consumers are increasingly using microwave ovens instead of standard ovens. This switch has safety implications because microwave heating of foods is not always uniform and consumers frequently do not microwave foods to a high enough temperature to kill harmful microbes.

Many consumers, particularly young ones, not only lack an understanding of safe food handling practices, but often lack basic cooking skills altogether. These consumers often expect to pull food off the shelf and serve it right away, a practice that can put them at risk if the food is not intended to be ready to eat. Poor temperature control in household refrigerators may be responsible for accelerated food wastage and increased risk of pathogen growth in refrigerated food in the home. This can result in small familial outbreaks of foodborne illness that are typically unreported and unlikely to be traced by the family back to inadequate refrigeration.
There is an increasing demand for high-value agricultural commodities that are consumed raw or partially cooked, and for which there is no “kill” step intended to reduce or eliminate potential pathogen contamination. Raw produce items such as these have been the source of a number of major outbreaks in the past 15 years. As the trend toward more convenient, more varied, and less processed food grows, new food safety challenges arise. Street foods in periurban slum areas in developing countries, for example, can present a particular hazard to consumers.

**Barriers to reducing risk**

In many parts of the world, consumers lack a safe water supply for cleaning and preparing foods. Inadequate sewage treatment and hand washing facilities in these areas result in widespread fecal contamination that can easily spread to food and cause illness if consumers are not especially vigilant and knowledgeable about safe food preparation.

In the developing world, just having enough food—food security—often takes precedence over food safety. When food security in this sense is a primary concern, food safety inevitably takes a back seat. Income is the primary deciding factor between whether a community is focused on food safety or food security; only after an adequate supply of food is available can individuals shift their focus to the safety of that food supply. Food security can also mean protecting the food supply from intentional contamination. Many of the approaches to detecting and preventing unintentional contamination also contribute to increasing this kind of food security.

When consumers get food preparation wrong, there is usually no follow-up or mending of ways. The adverse effects of improper handling by consumers are usually limited in scope, resulting in sporadic cases of illness that are never traced back to a particular bad habit or event. Moreover, because the incubation period between ingesting foodborne pathogens and illness can be days, or even weeks, as in the case of *Listeria monocytogenes*, consumers are even less likely to link their illness to its cause. Thus, these incidents do not provide the much-needed opportunities for food safety professionals to provide consumer guidance aimed at promoting change.

Governments and public health bodies recognize that although they can make food safety information widely available, they cannot control consumer behavior in general. Consumer education must take into account that many consumers may not be scientifically literate enough to appreciate the scientific basis for safe food handling and they may be unable to evaluate the relative risks and benefits of different foods and preparation methods. This places a greater burden on the processor to provide perfectly safe foods—an unachievable and unrealistic goal.
Research Needs

Because most consumer-caused foodborne illness is not recognized as such, much less systematically reported, an important barrier to reducing its incidence is inadequate knowledge of which foods, agents, and practices pose the greatest risk. Areas for future consumer-related research include:

- determining the foodborne disease burden associated with home-prepared foods,
- identifying the principal causes of foodborne illness in developing countries,
- quantifying the risks associated with consumption of raw or minimally-processed foods,
- determining the impacts of proper (and improper) cooking and food handling on the risk of foodborne disease, and
- evaluating the role of cross-contamination in consumer risk.

Of all of the stakeholders along the pathway from farm to table, consumers arguably have the least understanding of their role in food safety. Thus, research aimed at designing and disseminating effective educational resources about safe food handling practices and the risks from consuming tainted food is the key to reducing the risk of foodborne illness caused at the consumer level. Public health officials and professionals involved in food safety research need the tools to do a better job communicating food safety and risk assessment information to consumers and risk managers. Because of the fundamental importance of safe food, messages to the public—from youth onward—must be carefully constructed, including simple, consistent information about the basic scientific principles behind food protection. To make good choices, consumers need to know the most basic food safety messages: cook, chill, clean, and separate.

Public health initiatives should place greater emphasis on developing targeted food safety for school-based programs, particularly in elementary and middle schools. Exposing consumers to educational programs that instill the fundamentals of safe food handling early on, before they are old enough to develop bad habits, could amend the general lack of consumer education in food safety. Starting food safety education at a young age presents an effective long-range strategy to bring the message to the next generation of consumers. Safe food handling programs should be mandated components of school curricula, from elementary school through high school in health, home economics, and science classes. Games that incorporate messages about safe food handling practices could also be effective tools for reaching young audiences. Whatever the approach, educational efforts for children should be responsive to their needs and understanding, whether they are from a rural or urban setting, or are influenced by particular ethnic or cultural food preferences and practices.
Food safety messages for children must be concise and consistent, and the fundamental importance of hand washing should be a central lesson. The FightBac program (www.fightbac.org), which emphasizes hand hygiene and the importance of food storage conditions, is one example of a successful education program for children.

Outlets that may be suitable for delivering food safety messages to adult consumers include:

- magazines,
- talk shows and cooking shows,
- social networking tools like Facebook,
- YouTube videos,
- churches,
- day care centers,
- health care providers
- children’s television shows, like Sesame Street,
- local health departments,
- senior centers and Meals On Wheels programs,
- store displays, and
- food banks and soup kitchens.

Warning labels have not proven to be very effective means of conveying food safety messages. As they tend to be small and overly detailed, they are frequently disregarded by consumers. In addition, while messages conveyed during a food safety crisis may find a receptive and motivated audience, for public health reasons it would be far preferable to convey the message effectively beforehand so that crises can be prevented.

Messages for consumers should be appropriate to the language and culture of the target audience and accommodate cultural differences in food handling practices. For example, in Mexico, public health authorities have used murals to convey safe food handling practices, and efforts in other parts of the world have employed pictographs to convey these messages. However, in general, research has shown that pictographs, especially if they are abstract, may be difficult to understand. More research is needed on the effectiveness of warning labels and pictographs for food safety.
For the sake of future education efforts, we need to understand factors that influence the adoption of effective food handling practices. Like all messages, consumers and other stakeholders will more readily accept information about food safety if they grasp why it is important. In designing public education programs, social psychologists could be consulted to pass on what they know about human behavior with respect to food handling and how best to tailor messages to change that behavior. Public-private partnerships would greatly facilitate effective consumer education programs. Further, after delivering messages, it is critical to follow up to assure that such communications have actually resulted in measurable and long-term changes in behavior.

**Technology Needs**

In addition to consumer education efforts, changes in food packaging and labeling may also be in order. To better protect consumers from food handling misconceptions and mistakes, processors should include clear, validated handling instructions on their products and label foods that are potentially hazardous. However, the food industry has limited incentives to place warning labels on their products voluntarily, as they increase costs and may make consumers reluctant to buy. Processors could also reformulate refrigerated and ready-to-eat foods or introduce technologies that make foods safer or more shelf-stable to reduce the risk of illness from consumer ignorance or carelessness.

Consumer appliances, including refrigerators, ovens, and microwaves, can incorporate smart designs to assist consumers in preparing foods safely. Refrigerators, for example, should be equipped with built-in thermometers and door alarms to alert the user when the door is left open. Manufacturers must always keep the consumer in mind when developing new food safety technologies and consider whether the user will understand, accept, and properly implement the innovation.

To better protect consumers from food handling misconceptions and mistakes, processors should include clear, validated handling instructions on their products and label foods that are potentially hazardous.
Before routine long-distance shipping and widespread international trade, especially of unprocessed food, consumers either grew most of their food themselves or purchased it from local small producers. Although the effects are difficult to quantify, the growth of international trade (often referred to as globalization), long-distance travel, and migration of populations have not only profoundly influenced the kinds of foods available to consumers, but have also presented new challenges for regulating food production and enforcing food safety standards. Climate change, like many environmental problems, also has impacts that transcend political and regional boundaries, posing new and unique problems for food safety.

The Impacts of Global Trade on Food Safety

Historically, geographical separation has been a key barrier to the spread of disease, but international trade and travel are reducing this barrier, allowing diseases to move fluidly between regions and continents. Foodborne disease is no exception; fifty years ago, it was prohibitively expensive to transport produce and other perishable foods over great distances. Today these foods can be transported halfway around the world, allowing consumers to enjoy a variety of fresh products year-round. While rapid enough to bring foods to consumers before spoiling, long-distance shipping tends to increase the amount of handling and the time between farm and consumer, which can give pathogens on the food more time to multiply, potentially amplifying the hazard for the consumer.

In the U.S., as in many countries, imported foods occupy a larger and larger share of the market. For example, about 50% of nuts, 50% of fruits, and 80% of seafood now come from abroad, and produce imports are expected to continue to grow. What’s more, according to the World Bank, an increasing proportion of exported foods come from poorer countries that have fewer resources for food safety management. For example, the share of the U.S. food imports (by value) coming from China increased from about 2% in the 1990s to 5.8% in 2008. Recent outbreaks suggest that the global trade of food items, especially those originating in developing countries, has resulted in some significant food safety problems.

Increased demand for produce, exotic products, and high value, ready-to-eat food has shifted the risk profile, making formerly safe foods more prone to contamination problems. Changes in food processing that are necessary to enable these products to be transported over long distances may have unintended consequences for their microbial ecology. Often these foods are consumed raw or with little or no further processing, further heightening the risks. High-value products are shipped around the globe to be reprocessed and repackaged. Some high-value fruits, for instance,
are grown and preserved in large cans in California, then shipped to China to be repackaged in single-servings. There has not been sufficient research to know how this practice, or other food trends in response to consumer preferences—like “fair trade” foods—will affect food safety.

The relatively new practice of moving foods over long distances has developed faster than efforts to create a tracking system. When suppliers purchase ingredients on the spot market instead of having direct relationships with particular producers, product chain control is lost, making it difficult, if not impossible, to identify the original sources of the various ingredients in a particular food item.

Regulatory systems in many countries, including the U.S., are not designed to manage global trade adequately. Currently, the private sector takes considerable responsibility for ensuring the safety of food. In general, government regulations represent minimum standards, while other factors, including consumer preferences and requirements imposed by retailers, are more complicated and demanding.

Clearly increased global trade has the potential to allow pathogens to move around the world, makes it more difficult to trace the origin of foods, and calls into sharp focus the problem of differing regulatory standards around the world. But the impact of globalization on the overall incidence of foodborne illness is not known. Recent improvements in surveillance may facilitate outbreak identification, but when dealing with foodborne disease on a global scale, incompatible epidemiologic surveillance systems may complicate matters.

Differences in Food Safety Practices and Perceptions Between Nations

Country-to-country differences in risk perception, surveillance, regulations, production systems, and other factors present other problems for ensuring the safety of food.

Citizens of different countries often perceive risks differently, a fact that can create disparities in regulatory standards and deep misunderstandings in trade. Economic disparities also lead to differences in the extent of regulatory infrastructure and the level of reporting and investigation of contamination incidents and outbreaks of foodborne illness. Nations that do not have the infrastructure to investigate foodborne disease may not be aware of its prevalence in their populations. Regulatory standards can even vary within a country; for instance, each province of Canada maintains a different set of regulations.

Individual countries also conduct different testing on foods: some countries conduct microbiological testing only, whereas other countries (including the U.S. and countries in the European Union) also test for the presence of pesticides, mycotoxins and heavy metals. To supplement testing, governments can also require certification, either by the government or third-party entities, to ensure safe practices. For example, Chinese authorities try to improve the safety of exported food by certifying exporters and the farms that supply them.

The level of sophistication of food production and processing technologies, and the associated degree of control of foodborne hazards, vary from country to country.
Economics and technical capabilities dictate the approaches a country will take, with poorer countries inevitably mustering less technical ability. For example, South Africa is currently wrestling with AIDS and other imminent public health threats and not focusing on foodborne illness.

Concern for food safety is a privilege of the wealthy. In parts of the developing world, where 1.25 billion people live on 1 to 2 dollars per day, achieving an adequate food supply takes precedence over food safety. In these places, food safety is a luxury. When there is not even adequate safe drinking water, the quality of water used for agriculture must be given lower priority, compromising food safety. Exporters in developing countries are disproportionately affected by stringent international standards governing water quality and animal waste management. Statistics are hard to come by, but foodborne illness is likely a greater public health burden in developing countries than in countries like the U.S., which has greater resources to identify and track cases of disease. The need to focus on food security rather than food safety in the poorer nations of the world results in safety lapses, contributing to substantial disease. In some cases, for example, food that has been rejected for export to the developed world based on the grounds of quality or safety is given to the poor in the developing world.

Differences in cultural habits can also dictate risk perception and may even drive regulation. In Mexico, for example, few people eat undercooked meats, so the exposure to pathogens in meat and the epidemiology of foodborne illness is different from that in many other countries. Combine this with the fact that outbreaks of E. coli O157:H7 may be underreported in Mexico, and it is likely that Mexico's regulators do not view pathogens in meat to be as hazardous as other countries perceive them to be. Since the North American Free Trade Agreement took effect in 1994, there has been an increase in the rate of outbreaks of foodborne illness in the U.S., possibly because of the different production practices in other countries in the alliance. This seems to be a greater issue with produce than with other foods, perhaps because it is minimally processed and increasingly popular.12

Disease Surveillance

Global trade, travel, migration, and climate change are transforming food safety from a community-scale concern to a global public health problem. In order to track cases of disease and improve the safety of foods worldwide, scientists, industry, and public health officials need access to robust disease surveillance data, and although the various systems different countries have established for the surveillance of foodborne illness are loosely compatible, they do not function in an integrated manner. Ideally, we need open and timely sharing of information, harmonized global data sharing systems and a systematic strategy for collecting data so that results from different countries are compatible.

Foodborne disease occurs both sporadically and in outbreaks. In the U.S., the Foodborne Diseases Active Surveillance Network, also called FoodNet, is the primary source of data on the incidence of foodborne disease. As such, it is not intended to be an outbreak investigation system but rather focuses on characterizing the total burden of foodborne disease. Although FoodNet has gathered important data upon which public health prioritization has been based, it does not
adequately address the issue of attribution, or identification of the source (mode of transmission or specific food source) responsible for any one culture-confirmed case reported through the FoodNet system.

As mentioned earlier (see page 15), PulseNet, a national network of state and federal laboratories coordinated by the Centers for Disease Control and Prevention (CDC) and with participation of FDA, USDA FSIS and APHIS, performs standardized molecular sub-typing of foodborne bacterial pathogens and brings these data together in a single database to enable the identification and tracking of outbreaks. PulseNet is becoming an international initiative; the last continent to join, Africa, goes online in 2010. However, there is still room for improvement. Variability in laboratory capacity poses a considerable problem, since many countries lack the resources to culture isolates, and disparities in cost and availability of reagents between labs in the northern and southern hemispheres can prevent labs from using standardized protocols. In addition, PulseNet principally focuses on a few diarrheal diseases; however, in developing countries, diarrheal illness often results from a variety of pathogens associated with contaminated water, not food. There is as yet no global standardization of the molecular typing used by PulseNet although this may become less important as declining DNA sequencing costs allow direct determination of pathogen DNA sequence to replace the indirect, molecular subtyping techniques used today.

**Inspection and Monitoring**

Inspection systems and criteria need to be standardized and harmonized so that, across countries and industries, results from one inspection are comparable to results from another. Currently, the 1995 World Trade Organization’s (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures, called the “SPS Agreement,” grants countries the right to choose a measure that differs from the international standard to achieve an appropriate level of protection as long as it complies with the other rules of the Agreement. This recognizes that individual nations may be unwilling to subscribe to uniform measures for all hazards.

The most rigorous food safety systems will not ensure the safety of the food supply if they are not properly implemented and managed. Failure in these systems frequently results from failures, on the part of management, to provide proper resources (training, education, equipment), or to detect and correct human error that occurs during food production, processing, or preparation. The regulatory system is not set up to penalize management when it is responsible for food safety failure.

Tracking management effectiveness will require comprehensive databases that document the prevalence of pathogens in foods and environmental samples. Data sharing issues abound, as industry rarely shares its data with regulatory agencies because of concerns about confidentiality and potential regulatory ramifications. This reluctance is compounded internationally by concern about triggering import restrictions. Incentives may garner more effective partnerships with industry and encourage data sharing and better communication. Companies also need improved methods for early detection of pathogens in foods, especially with regard to improved sampling and identification of contaminants before products reach the market.
Migration and Food Safety

As the world becomes increasingly interconnected, migration and international travel are also increasing, and these phenomena have the potential to create problems in food safety, particularly where communications are strained by language and cultural barriers.

Migrating populations can bring their own particular expectations about the safety, handling, and preparation of foods that may not meet the standards of the receiving culture. In general, people want familiar foods when they move into new areas, and the food preferences that migrating populations bring with them (including exotic meats or food processing styles) also have the potential to introduce new risks to an area. People who move to new countries often work in food production, food processing, or food service, where their customary standards might be applied without the knowledge of management.

Travelers and immigrants may also carry pathogens with them, such as hepatitis A virus, noroviruses, V. cholerae, or parasites that can be spread by food. Again, this can pose a particular problem when immigrants work in food production, processing, or retail environments.

Impacts of Global Climate Change

The impacts of climate change are beginning to be felt around the world, and as the climate changes, so, too, will the microbiological quality and safety of foods. Although there is not an abundance of definitive research on specific changes in food safety (and it is likely that the effects for most farm products will be minimal), any change in the environment where food is produced has the potential to change food safety risks. Many of the consequences of climate change, including changes in water availability, extreme weather events, changes in pest prevalence, and increases in the incidence of harmful algal blooms, may well have important effects on the microbiological safety of food. The FAO recently published a comprehensive assessment of the food safety hazards that may result from global climate change.13

Water makes up about 60% of most fresh foods by weight and is an indispensable element of food processing. Therefore, supplying sufficient safe water for food production and processing will probably be one of the greatest issues facing agriculture in the future. Water supplies will almost certainly not keep up with demand in many parts of the world in the coming decades, making irrigation and reclaimed water usage—both practices that can introduce microbiological hazards to foods—more common. New precipitation and seasonal temperature profiles will also have profound impacts on where and how foods are grown. Crops that now grow only in warm, equatorial regions are beginning to move poleward into formerly unsuitable climates. If livestock farming follows the shifting location of feed crops, the geographic incidence of foodborne illness from E. coli O157:H7 may also change.

Extreme weather conditions are expected to become more common, and may increase risks. For example, drought has historically been associated with increases in aflatoxin production. Flooding and hurricanes also have the potential to change the microbiology of crops. El Niño, a recurring pattern of warm water currents that
occurs periodically in the Pacific Ocean, may provide a glimpse of the potential impact of extreme weather. For example, during El Niño of 1998, California garlic and onion crops were heavily damaged by fungal infections (see Box A).

In locations where the weather becomes warmer and the winters no longer bring a hard freeze, an increase in the numbers of insect pests is expected. This could lead to greater pesticide use, potentially affecting food safety. The spread of animal diseases into new areas is also possible, increasing the risk of disease spread from wildlife to farms.

The pathogen *Vibrio parahaemolyticus* has begun to appear in waters previously too cold to support its growth. Temperature increases in coastal waters are also associated with more frequent algal blooms, likely resulting in an increased incidence of seafood-associated foodborne disease.

The potential negative effects of climate change may be greater for countries that lack the resources for cold storage, which increases the potential for the growth of foodborne pathogens on contaminated foods.

Growers and food processors need novel, practical and effective strategies for water purification and disinfection to minimize the increased pressure that climate change will place on water supplies. Other approaches to reducing the amount of water used in food production, like irradiation or other effective physical antimicrobial treatments, could help preserve clean water for other uses. However, they must be affordable for small producers and acceptable to consumers.

**At the global level, who is responsible for food safety?**

From a legal perspective, manufacturers and processors currently bear most of the responsibility for keeping food safe. The job of ensuring that industry meets this responsibility lies with national and state governments. However, food safety will be maximized if all stakeholders involved in the production and consumption of food, including everyone in the chain from growers to consumers, shares the responsibility for ensuring the safety of foods.

As in many countries, the U.S. legal system provides two approaches to ensuring food safety: regulation and access to the civil court system. As discussed above, the regulatory system in the U.S. has not yet adapted to the needs and challenges of global trade. The result of this, in some instances, is food manufacturers taking matters into their own hands, setting their own food safety standards, and ensuring that they are met. Every major purchaser of ingredients develops its own specifications, and international companies often monitor and educate suppliers in best practices and conduct audits on site. Some large US retailers that play major roles in international trade, have been especially active in establishing food safety standards, demonstrating how retailers can influence global food safety.

The relative role of consumers in assuring food safety varies globally. In developed countries, consumers tend to assume that food is safe and do not recognize their own role in food safety—placing full responsibility for safety on producers, retailers and regulators. In developing countries, consumers may be more likely to assume

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**Box A: Rust disease shrinks garlic crop**

1998 was an ‘El Niño’ year; ocean surface temperatures in the equatorial region of the Pacific Ocean were unusually warm. El Niño conditions affect weather on the West Coast of the United States and weather changes can have important agricultural consequences. In 1998, the wet, rainy spring caused by El Niño caused hundreds of thousands of dollars of damage to onion and garlic crops. Rust disease, encouraged by the warm, wet spring, infested most garlic and onion fields, sometimes infecting every single plant. Overall crop yields were reduced by 75%.

International trade in food is often politicized. Import bans can be used as a measure of tit-for-tat diplomacy, sometimes with food safety as the nominal rationale. This practice can create unnecessary trade barriers and make it difficult to develop science-based international food safety standards and regulations.

The FDA and others have begun addressing the matter of ensuring the safety of foods imported into the U.S. by setting up satellite offices in countries around the globe. Its first overseas office was opened in China in November 2008. In response, other nations have launched food safety offices in the U.S., resulting in an inefficient and sometimes antagonistic constellation of offices and standards. Instead of establishing satellite offices and piecemeal systems like these, the overarching goal should be to build relationships with other countries to establish equivalent production, processing, distribution, and inspection regulatory systems.

In international food trade, responsibility for establishing requirements for food safety, education, coordination, training, and port control lies with the national government of the importing country. Differing requirements can act as barriers to trade, so during the Uruguay round of trade negotiations, participating countries established the “Sanitary and Phytosanitary Measures” (SPS) and the “Technical Barriers to Trade” (TBT) agreements. These agreements allow countries to restrict imports to protect human, animal, or plant health, so long as they do so in a manner that restricts trade as little as possible. An importing country can require a higher level of SPS protection than the international standard if it can provide scientific justification for the measure or can establish an “Appropriate Level of Protection” based on assessed risk. If the exporting country believes that the import requirement is unjustified, the SPS Agreement requires the importing country to provide the reasons for the measure. These procedures have tended to focus food trade discussions on scientific evidence and assessment of risk.

It is not always straightforward to determine whether differing standards are due to genuinely different perceptions of risk or to a desire to protect domestic producers. For example, the European Union allows concentrations of *Listeria monocytogenes* of up to 100 colony-forming-units/gram of some foods, whereas, until recently, the United States had a zero tolerance criterion for the same pathogen. Considerable negotiation and input from scientific experts has been aimed at harmonization of these standards. But when there is a lack of agreement on the scientific basis for limits, and economic and political interests are at stake, reaching consistent international standards is difficult in the absence of a neutral mediator.

The SPS and TBT Agreements require member nations to base their import regulations on the internationally agreed standards established by the Codex Alimentarius, a set of food standards and codes of practice initiated in 1962 by a group assembled by the FAO and the WHO. Codex standards are currently applied on a voluntary basis and different countries and companies apply the standards to varying degrees. Codex is considered the minimum set of standards for food in international commerce. The goal...
of the World Trade Organization, as implemented through Codex, is to establish an international risk management framework that:

- is systems-based,
- deals with alternative mitigation strategies,
- increases the use of risk-based standards and other metrics,
- is based on distinguishing inherent versus catastrophic risks, and
- is based on validation and verification.

U.S. regulatory agencies (USDA-FSIS and FDA) mandate the use of Hazard Analysis and Critical Control Points (HACCP) management systems for several types of foods, such as seafood, meat and poultry. The HACCP approach is advocated by Codex, providing a common approach to food safety that is internationally recognized. Full adoption across the board by industry could be a way to standardize food safety programs internationally. The process of developing agreed-upon standards through Codex is very slow and is not always able to address emerging agents and situations rapidly, so reliance on Codex-based standards may not always be practical, at least in the short term.

The current system for ensuring the safety of foods for export and import is a complicated and spotty patchwork of standards and regulations. Worldwide, food safety regulations should be reevaluated with the ultimate goal of creating a unified and harmonized global approach to food safety management. Consistent reliance on Codex guidelines is the most promising approach upon which this effort may be based, especially if efforts are made to ensure that Codex-based standards are continuously updated in an iterative, timely and responsive manner.

At the global level, just as at the national level, if one link in the food production chain breaks and compromises the microbial safety of a food item, tainted food may make it all the way to a consumer's table. Ultimately, reaching the goal of safe food will require consistent application of best practices all along the food chain both nationally and internationally.

**Research Needs**

The complications of global trade, differences in food safety practices between nations, effects of climate change, and movement of people by travel and migration, all pose challenges for ensuring a safe global food supply. Overcoming these hurdles will require researchers, public health authorities, and others to address some fundamental questions, including:

- **What are the true costs and related benefits of food safety improvements?** Of particular concern is managing the cost of ensuring the safety of foods exported by developing countries. How much expense is justified to reduce any particular risk, and what is a reasonable amount
of risk to accept? For example, what would be the cost and trade implications for exporting countries of reducing aflatoxin in foods?

- **How can food safety interventions be tied to public health outcomes?** If investments in food safety are to be prioritized, we need to know their public health impact. However, at present, we lack a systematic means to tie food safety interventions to public health outcomes. This is partly because it is so difficult to determine the number and source of foodborne illnesses, making it difficult to determine whether an intervention has made a difference. The success of an intervention should be evaluated on impact, namely, the numbers of cases of illness which can be (or are) prevented as a consequence of the intervention.

- **How can we harmonize audit and inspection processes across different countries?**

- **How can we derive a standardized measure for “safe food”?** Should food be deemed safe based on the number of specific pathogens, outbreaks, or incidence of disease? Currently, it is difficult to measure the success of food safety programs. Moreover, public health outcomes are a moving target.

- **To what extent do regulations actually make food safer?** Do regulations make a difference or do they impose costs without really improving safety?

- **What is the role of human behavior in food production, processing, and service on the safety of foods?** Do producers, processors, and retailers actually understand the reasons for regulations and the public health consequences of falling short? Are consumers willing to accept higher prices for safer food?

- **How can we design cost-effective traceability systems?** There are data management issues at many different levels, but traceability poses a particular problem. Solutions for small-scale operations are especially needed.

- **What are the effects of climate change on foodborne pathogen ecology and transmission?**

- **In what ways will climate change affect food safety risks?** We need improved models to gain a better understanding of complex global food safety issues.
The process of moving food from the farm to the table is complicated. There are many different steps where contamination can be introduced, perfect monitoring is impossible, and the likelihood of any particular person becoming sick is hard to measure. And yet, safeguarding public health requires making decisions about what steps of the process are most vulnerable, how much contamination is acceptable, and where investments in food safety will have the greatest impact. Increasingly, under such circumstances, the process of risk analysis is used to help make decisions. A 2001 Institute of Medicine report defined risk assessment as follows:

“Risk assessment is the process through which information on risks is identified, organized, and analyzed in a systematic way to get a clear, consistent presentation of the data available for practical decision-making. It is not a formula, but an analytical framework that defines the types of data and methodologies that are to be used to analyze a risk, and explains why, and also details the uncertainties and problems associated with particular assessments.”

The report went on to explain why risk assessment is so important:

“The risk assessment and management processes were developed for two major reasons. One of the most important reasons is that, in almost all cases, it is beyond current technological capabilities to directly measure risks to large populations from chemical agents, pathogens, and other hazards. Without going through the risk assessment process, there is no scientific basis for regulatory decision-making.”

Risk assessment requires an effort to quantify risks at each stage in a process. Therefore, assessments are critically dependent on underlying scientific evidence. The process of carrying out a risk assessment can help identify where additional research would be most imperative for quantifying risk.

The risk assessment process consists of four steps:

- Hazard identification, or identification of the pathogen and its significance to foodborne disease.

- Hazard Characterization, or determination of how much of the pathogen will make a person ill.

- Exposure Assessment, or estimation of how much of the agent a person is likely to encounter; and
Risk Characterization, or determination of the risk of illness given the likely degree and route of exposure.

The clear utility of the process of risk analysis is evidenced by its increasingly widespread use in food safety decision-making. For example, an executive order now requires an economic analysis, which includes risk assessments and cost-benefit analyses, for all federal regulations with an estimated economic impact of over $100 million\(^\text{15}\). Adoption of risk analysis has varied by country. At present, risk analyses are predominantly conducted by developed countries; they are increasingly being applied by developing countries, but often under the direction of developed countries due to their high cost, data-intensive nature and need for specialized expertise.

In the U.S., risk assessments have been successfully applied to critical pathogen-commodity combinations such as \textit{E. coli} O157:H7 in ground beef, \textit{Salmonella enterica} serovar Enteritidis in eggs, and \textit{Listeria monocytogenes} in refrigerated, ready-to-eat foods. The information gathered in risk assessments has been used to develop some very effective risk management plans, as evidenced by reduced prevalence of pathogen contamination and disease incidence. The process has been praised for its transparency and strong scientific basis. Risk assessments can only be effective if they ask the right questions, and are conducted in an appropriate manner. In one case, a risk assessment of \textit{Listeria} in foods, assessors asked, “How do we reduce the number of positive test results?” The risk assessment was effective to this end, but it was not effective in reducing cases of listeriosis. A better question would have been to ask, “How do we reduce the number of cases of listeriosis?” A risk assessment that is based on the wrong question is of limited value in the end. Regulatory agencies are making risk assessments more useful for policy purposes by specifying in advance the questions and interventions to be considered in the assessment. Additionally, it is important to consider the potential for secondary and unintended consequences, and risk-risk trade-offs in risk assessments. For example, it would be appropriate to evaluate both the benefits and the risks that may result from eliminating the use of antibiotics as growth promoters in livestock feed.

Despite the demonstrated utility of some risk assessments, consumer groups have criticized regulatory agencies for relying on them too heavily, since taking time to “study the problem” can seem like a stalling tactic to those pressing for change. As they are currently conducted, most risk assessments are indeed expensive, time-consuming and highly technical. USDA-FSIS has now developed a handbook for conducting risk assessments, but the guidelines do not specify how to use the collected data—leaving risk managers, communicators, and consumers with concerns about how to interpret the results of the assessments.

The process of risk assessment is complex, and it is a challenge to translate the information and findings in a way that promotes understanding by the public and other stakeholders. This step is nonetheless essential and is one of the objectives of risk communication. It is critical that stakeholder involvement be sought early in the risk assessment process, rather than only after the assessment is completed. This practice promotes transparency and encourages the sharing of data and information that might not otherwise be accessible to the agency conducting the risk assessment. Furthermore, each risk assessment team should have risk communication specialists who can tailor messages about the findings to specific stakeholders.
We need more people who are trained in the principles and practice of microbiological risk assessment as applied to food safety—particularly individuals with expertise in mathematics who also have an understanding of microbiology and food and agricultural systems. Such individuals must also be able to work as part of a multidisciplinary team.

Implementing the findings of risk assessment, or risk management, has received considerable attention in the past ten years. However, the subtle ways in which risk assessment, management and communication interact, and the specific roles for risk assessors, managers, and communicators, are still evolving. For example, risk managers must be able to understand the intricacies of risk modeling, because choosing one model over another may have a significant impact on risk estimates. Risk analysts should have training in the underlying biology and ecology of the system they are modeling, and in how to make their results understandable to risk managers. Risk communicators then provide the “glue” to communicate results and their significance to all stakeholders. Consumers may lose confidence in risk assessments when improbable events do, in fact, occur if the limitations of the risk assessment process are not clearly communicated.

Additionally, risk managers need to state more clearly the potential interventions being considered in a risk assessment and the outcome of concern to be modeled, e.g., human cases, deaths, illness days, etc.

To be most effective, the three functions of risk analysis, i.e., risk assessment, risk management, and risk communication, should be fully integrated. Complicating matters are differences between research, assessment, and management timelines. Risk management often requires quick decisions, while risk assessors need adequate time to complete their complex modeling tasks. It is also critical to understand that models are only a representation of reality, and an imperfect one at that. Some risk assessment parameters are based on solid data, and some are—by necessity—based on assumptions, because adequate data do not exist. For example, compliance and behavioral adoption issues are not always included in models, but if they are, the values are often based on imperfect data.

Developing effective food safety management systems requires users to identify priorities so that they may target where to make changes. USDA-FSIS is currently working on risk ranking to determine the appropriate distribution of inspection resources in meat, poultry, and egg processing. Similar risk ranking efforts targeting food safety management systems are underway at FDA. It may be time to evaluate formally the role of risk assessment as a food safety management tool. This would provide information to direct future risk assessment efforts, help focus research on collecting the information needed to fill data gaps, and aid in moving the field forward. It may be time to include such emerging methods as geographic information systems (GIS), microbial source tracking (MST), and advanced molecular typing methods in future risk assessment efforts, providing additional data and increasing the predictive power of future models.
The concept of “zero tolerance” may be a worthy goal, but it is an impossible and even misleading standard.

Setting a tolerable level of risk.

Eating will never be a risk-free endeavor. The concept of “zero tolerance” may be a worthy goal, but it is an impossible and even misleading standard. Like it or not, risk managers will eventually have to pose the question “what is safe enough?” Unlike risk assessment—a scientific/mathematical endeavor based to the greatest degree possible on data—determining how much risk is acceptable is not a scientific question, but instead includes societal, political, and economic considerations that can cause tension between stakeholders (including the public) and risk managers.

Risk managers consider a number of factors when determining a tolerable level of risk:

- The severity of the hazard—how sick will people get?
- The affected population—how many, and which people will get sick?
- The extent of consumption—how many people may be exposed to the risk?
- Avoidability—how easy is it to avoid the risk?
- The potential for control—how practical are interventions that would reduce the risk?
- The availability of alternative foods and other factors—could a safer and equally nutritious product be substituted?
- Secondary or unintended consequences of the management strategy—will reducing the risk make the product more expensive, frighten consumers, or reduce their acceptance of regulatory intervention?

Needed risk assessment tools and data gaps

Though already extremely useful, food safety risk assessment is still evolving. Risk assessors need more advanced, multidisciplinary modeling tools that can be integrated with molecular typing, geographic information systems, and other data sources. Full access to data (some of which may be unavailable due to industry concerns about confidentiality) would be most helpful. Integration of risk ranking and prioritization within the risk analysis framework would be useful. Results of risk assessments should be used to help risk managers direct resources to the highest priority food safety problems, ensure these resources are used judiciously, and determine the most effective interventions.
Some of the other tools needed to improve food safety risk assessment include:

- benchmarking tools for assessing progress toward improving the safety of the food supply,
- tools for relating international microbial risk management metrics to HACCP and other U.S. food safety risk management systems, and
- tools in more languages for use in non-English speaking countries.

Some of the current data gaps or scientific needs assessors face when conducting food safety risk assessments include:

- lack of quantitative data on epidemiological attribution (linking the presence and numbers of a particular pathogen in a specific food with actual illnesses caused in a human population),
- lack of food consumption data on specific products of interest,
- lack of good information about food handling practices at the consumer and retail levels,
- reliable dose-response data for individual pathogens, considering diversity of pathogenicity, survival and growth characteristics, and other factors among strains within a group of foodborne pathogens (e.g., not all \( L. \) monocytogenes strains are equally virulent) and in all populations, including those at increased risk,
- lack of quantitative data on pathogen load in products at risk for contamination,
- inability to reliably measure the relationship between mitigation and positive public health outcomes, and
- lack of an acceptable manner by which industry, government, and academia can share data to provide more robust estimates of risk.
Recommendations

Use a Systems Approach to Manage Food Safety.

A systems approach should be applied so that each stage of food production, processing, sale and preparation is treated as part of a larger system of inputs, outputs, and processes, and so that foods are tracked from their source to their final destination.

Harmonize Global Food Safety Management Systems.

National governments should continue to invest in harmonization of international food safety management systems and standards, including microbiological criteria, guidelines, and educational materials. Consistent reliance on Codex guidelines provides the most promising approach upon which this effort may be based.

Develop New Sampling and Testing Methods.

Sampling and testing provide the basis for pathogen detection, but scientists currently have few methods that are rapid and sufficiently sensitive at their disposal. We must develop improved sampling methods and alternative detection techniques in an effort to make real-time detection a reality.

Develop Innovative Food Safety Interventions.

Increased investment and research commitment is needed to develop, validate, and apply innovative food safety interventions and to validate the effectiveness of interventions already in use. There is an urgent need for new and improved food safety interventions for many critical points in the food chain and for all scales of food production and processing. Cost-effective interventions are particularly needed.

Target Food Safety Messages to the Consumer.

Exposing consumers to educational programs that instill the fundamentals of safe food handling early on, before they are old enough to develop bad habits in the kitchen, could amend the general lack of consumer knowledge in food safety. Public health programs should place greater emphasis on developing targeted school-based food safety education programs, particularly for children in elementary school and middle school. These messages should be focused, concise, consistent, and provided by a trustworthy source.


