

**Written Testimony of Prof. Martin Cole**

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**Before**

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**"Food and Drug Administration Globalization Act of 2009"**

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Good morning. I am Prof Martin Cole, Director of the National Center for Food Safety and Technology.

Diseases caused by foodborne pathogens constitute a worldwide public health problem and preventing them is a major goal of national governments. Microbiological foodborne diseases are typically caused by bacteria or their metabolites, parasites, viruses or toxins. Here in the US, foodborne illness outbreaks continue to make headlines and worry consumers. The Centers for Disease Control and Prevention (CDC) estimates that foodborne diseases result in 76 million illnesses, with 325,000 hospitalizations, and 5000 deaths, each year. In addition, the complexity of issues relating to food safety has also increased considerably in recent years. The rapid globalization of the food processing and retailing industries, consumer demand for more natural and more convenient products, and an overall increase in the population's susceptibility to foodborne illness are believed to be the most important factors that have led to changes in the very nature of foodborne

disease itself. In order to successfully respond to these challenges and to restore consumer confidence, the US needs to increase its emphasis on the development of a modern system for the management of microbial food safety. The elements of a modern system—risk-based preventative controls, programs to monitor their effectiveness, appropriate government oversight, and a strong program of research—will help us keep pace with emerging food safety issues, assuring safe and wholesome foods for consumers.

Managing the microbial safety of food is a complex business because microorganisms can grow and adapt to different conditions within the food supply chain. At the production and processing level, the ability to assess and manage the risk of microbial contamination is key to effective food safety control. When designing and controlling food operations this means analyzing the microbial hazards likely to be present, their ability to grow and survive in the production environment, and the best means of eliminating them. Consideration must be given to the subsequent conditions to which the food is likely to be exposed, including further processing and potential abuse during storage, distribution and preparation for use.

Regulatory efforts here in the US and internationally therefore have been focused on the use of risk assessment tools to drive food policy and standards away from prescriptive measures to outcome-based control measures. The safety of foods in international trade is governed by the World Trade Organization (WTO)/Sanitary and Phytosanitary (SPS) Agreement, which recognizes that governments have the right to reject imported foods when the health of the population is endangered. The criteria used to determine whether

a food should be considered safe should be clearly conveyed to the exporting country and should be scientifically justifiable. In order to achieve this, the term 'appropriate level of protection' has been used, which is defined as "the level of protection deemed appropriate by the Member (country) establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory". Traditionally, this has been defined in terms of having a chemical or microbial risk "as low as reasonable". This definition has caused great difficulties for a number of reasons. Although trade is becoming increasingly global, the technological capabilities of different countries, and even different companies within the same country, remain very different. Also, the idea of what is considered "reasonable" differs from country to country; acceptable risk is culturally defined.

Developments in the areas of predictive modeling and risk assessment now offer the potential to link exposure to a microbial hazard to the likely number of cases of illness in the population and are driving new risk management approaches. The approach enables the food industry to meet specific food safety objectives by the application of the principles of Good Manufacturing Practice (GMP), Hazard Analysis and Critical Control Points (HACCP) systems, performance criteria, process/product criteria and/or acceptance criteria. It provides a scientific basis that allows industry to select and implement control measures for each specific food or food operation. This approach should enable regulators to better develop and implement inspection procedures to assess the adequacy of the control measures implemented by industry and to quantify the equivalence of inspection procedures in different countries. Thus, the practical value of

using a risk based approach is that it offers flexibility of operation; it does not prescribe how an operation achieves compliance - it defines the goal.

Government oversight is an important aspect to ensuring a safe food supply, especially for unbranded goods where market disincentives for failure are less pronounced.

Regulations also allow a level playing field, ensuring that companies that do not pay for food safety controls cannot gain a cost advantage in the marketplace over companies that do make that investment. However, government oversight through regulations and inspection alone is a relatively poor means of ensuring the safety of food. The statistics of sampling means that an extremely high number of product samples are needed to detect the low level of pathogens that can cause illness. For example, if one lot of food is contaminated with Salmonella at a level of 1% and five samples are taken, there is still a 90% chance that results will be negative for Salmonella and that the lot of food will be accepted even though the lot is contaminated. This means that for pathogens with a low infective dose, where relatively low numbers can cause illness especially in children or the elderly, testing is not a good means to ensure safety. Similarly, given the volume of food traded both nationally and internationally, the amount of food that can be inspected practically is relatively low and is also therefore a poor means to ensure safety. In other words, it is not possible to test or inspect safety into foods—effective management requires risk-based preventative controls as well as government oversight.

Preventative control measures may be applied at different steps along the food chain to eliminate, prevent, or reduce a hazard to an acceptable level. Each participant along the food chain has a responsibility to apply those control measures that contribute to

providing safe foods. These control measures fall into one of two programs applied by food manufacturers: Good Manufacturing Practices (GMP) and Hazard Analysis Critical Control Point (HACCP) systems.

The first program, GMP, can be viewed as the basic sanitary conditions and practices that must be maintained to produce safe foods. It also includes certain support activities, such as raw material selection, product labeling, and coding or recall procedures.

Effective application of GMP provides the foundation upon which the second program, HACCP, is developed and implemented. The development of an effective HACCP system involves a systematic approach to the identification, evaluation, and control of food safety hazards in a food operation.

The major components of GMP include:

- Design and facilities
- Control of operation
- Maintenance and cleaning
- Personal hygiene
- Transportation
- Product information and consumer awareness
- Training

The Hazard Analysis and Critical Control Points (HACCP) system involves the following seven principles:

1. Conduct a hazard analysis
2. Determine the critical control points
3. Establish critical limits
4. Establish monitoring procedures
5. Establish corrective actions
6. Establish verification procedures
7. Establish record keeping and documentation procedures

HACCP is not implemented in lieu of GMP, and failure to maintain and implement GMP can invalidate a HACCP system and result in production of unsafe food. Effective control of a hazard in a food necessitates consideration of the components of GMP likely to have significant impact in controlling the hazard. It is necessary to consider the hazards that are most likely to occur in each particular food operation and to pay particular attention to those elements of GMP and HACCP that will contribute most to controlling those hazards. For example, in the contamination of peanut butter with Salmonella, this is usually an issue of recontamination after the roasting process, most effectively dealt with through the application of GMP measures including sanitation and separation of finished product from raw materials.

The development of an effective HACCP system involves a systematic approach to the identification, evaluation, and control of food safety hazards in a food operation. HACCP plans specify the actions to be taken in a food operation to control food safety hazards.

HACCP plans also specify records to be generated during the operation for use in verification that critical limits have been met at critical control points in production. In the event that a deviation occurs at a critical control point, the deviation should be detected in time to ensure that corrective actions will prevent unsafe food from reaching consumers. For example, the development of the Juice HACCP regulations introduced the requirement for pasteurization as a critical control measure in assuring the safety of the product.

Control measures, GMP and HACCP, must be appropriate for the hazard and are used to prevent, eliminate or reduce hazards to acceptable levels. Producing safe food requires food operators selectively to apply GMP and the principles of HACCP to develop and implement a food safety plan that will control the significant hazards in the food that is being produced. The development of regulations or guidelines relating to the use of preventative controls within a food safety plan or performance standards should be considered based on risk to public health, as well as a consideration of what is feasible and practical. For example, some microbial concerns will be better dealt with through the use of GMPs and the use of HACCP-like principles, whereas for foods where there is epidemiology linking consumption to foodborne illness it might require the articulation of specific performance standards, which might require research, especially for newly emerging issues such as fresh produce.

Recent attribution data suggests that fresh produce has emerged as the leading cause of foodborne illness in terms of number of cases in the US, with salads accounting for about

a quarter of this burden. From a global perspective, leafy green vegetables also currently represent the greatest concern in terms of microbiological hazards. Leafy greens are grown and exported in large volume, have been associated with multiple outbreaks with high numbers of illnesses in at least three regions of the world, and are grown and processed in diverse and complex ways, ranging from in-field packing and bagged product. There is currently no validated kill step in the production of leafy greens and hence food safety often relies on prevention of contamination, which is usually the weakest form of hazard control especially in a raw agricultural setting. Research is required to help validate new preventative controls measures and to determine the most effective point in the production chain for them to be applied. The example of fresh produce also illustrates the need to improve the technologies for traceability systems that are used by the industry. Traceability is essential for the effective and timely linking of foodborne illness to the source of contamination.

Given the continued globalization of the food supply and consumer trends that will continue to drive the emergence of new issues, especially in microbial food safety, it is important to establish a strong research program in order to be able to develop risk-based control measures in a proactive manner. I therefore urge this Committee and Congress to provide the means for the U.S. Food and Drug Administration (FDA) to continue the development of a modern, risk-based food safety system that requires risk-based preventative controls, programs to monitor their effectiveness, government oversight, and a strong program of research to assure the highest level of confidence for the US consumer.

