Scientific Criteria to Ensure Safe Food

Committee on the Review of the Use of Scientific Criteria and Performance Standards for Safe Food, National Research Council

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Executive Summary

GENERAL FINDINGS

The balance of progress in the reduction of certain human foodborne illnesses following implementation of the Hazard Analysis and Critical Control Point (HACCP) system in various areas of the food industry is decidedly favorable. The technical, financial, and educational efforts made by industry to implement HACCP and by the regulatory agencies to audit such implementation are commendable, but further improvements are warranted. The committee believes that the emphasis of food safety regulatory agencies must continue to be on prevention, reduction, or elimination of foodborne hazards along the food continuum.

In addition to specific issues related to each food group included in the study, several overarching issues were raised during the committee's deliberations. Despite improvements made in the area of food safety, the translation of science to practice is at best difficult in a regulatory environment. Because of the inherent deliberative nature of governmental bodies, scientific tools must be adopted and novel approaches to food safety must be sought. The need for regulatory control must be balanced with the need for regulatory flexibility and the expectation that an agency's actions reflect the most current and effective scientific methods available to protect the public health. However, the food safety community's understanding of science-based methodologies and concepts such as risk assessment or food safety objectives is limited, and much of the data needed to develop science-based strategies are often incomplete, nonexistent, or require extensive resources to generate. Furthermore, none of the scientific tools available to sup-

port the development of food safety criteria is a panacea; they all present limitations, such as gaps in research data, that need to be recognized and considered.

A second issue noted by the committee was the need to improve the management and use of food safety data to ensure that foodborne diseases are identified as early as feasible and that the origin of foodborne hazards and the most effective interventions to prevent, reduce, or eliminate them are identified. This leads the committee to conclude that there is also a need to better coordinate existing and emerging food safety information systems.

Third, the committee noted that the approach to developing, implementing, and enforcing food safety criteria, including performance standards, varies among regulatory agencies. Implementation problems, including questions about the authority of regulatory agencies to enforce performance standards, have contributed to diminishing the effectiveness of new regulatory measures aimed at controlling old and emergent foodborne hazards and have prompted many to question the effectiveness and appropriateness of the current system. As a result, implementation and enforcement activities need to be considered by regulators when developing food safety criteria.

Summary of Recommendations

Food safety regulatory agencies are applying a host of new control measures, from mandating the use of HACCP to increasing testing, with varying degrees of success, to ensure the safety of the food supply. A collective effort is needed to further improve the safety of food, and the following actions should be pursued:

- **Congress should require the development of a comprehensive national plan to harmonize the foodborne disease surveillance that is conducted by public health agencies with the monitoring of pathogens across the food production, processing, and distribution continuum that is conducted by food safety regulatory agencies.** Congress should allocate funds not only to develop and implement this plan, but also to enhance programs such as FoodNet, PulseNet, eLEXNET, foodborne outbreak reporting and data sharing, and other national foodborne disease surveillance systems conducted by public health authorities.
- **Congress should grant the regulatory agencies clear authority to establish, implement, and enforce food safety criteria, including performance standards, and the flexibility needed within the administrative process to update these criteria;** it should allocate funds to enable the regulatory agencies to undertake pilot studies and develop and maintain databases to support the development and updating of food safety criteria.

- **Food safety regulatory agencies should adopt science-based, transparent strategies to develop food safety criteria that**
  - **Clearly document the public health objective and the appropriate level of protection.**
  - **Obtain or generate the best scientific knowledge through the use of laboratory or field studies, risk assessments, and similar food safety tools.**
  - **Minimize knowledge gaps by conducting pilot programs of the proposed performance standard, by maintaining databases of critical information, or by conducting risk assessments that can be used to develop performance standards, using science-based expertise as needed.**
  - **Explicitly state the nature, limits, and extent of the scientific uncertainties.**
  - **Explicitly identify the assumptions, criteria, and expertise used to address the uncertainties in formulating the performance standard.**

- **The U.S. Department of Agriculture should take the following specific measures regarding scientific criteria, collecting data, and improving the safety of meat and poultry products:**
  - Periodically conduct baseline surveys to evaluate the microbiological status of carcass, trim, ground products, and ready-to-eat products, at processing and at retail.
  - Implement criteria for generic *Escherichia coli* levels for ground beef using the current generic *E. coli* criteria for carcasses as the model, and handle the resulting data from carcasses and ground beef through a national, anonymous database.
  - Develop a *Salmonella* performance standard for beef trim intended for grinding and reevaluate the current *Salmonella* performance standard for ground beef. Require that all beef trim for grinding be exposed to some verified pathogen reduction intervention.
  - Expand testing of *E. coli* O157:H7 to include trim destined for grinding so that contaminated trim can be diverted to further processing with verified interventions.
  - Urgently undertake research on the ecology of *E. coli* O157:H7 and other closely related serotypes in beef, from the farm through the trim, to identify appropriate control points.

  - — Until information on the ecology and mode of transmission of *E. coli* O157:H7 is available, and other effective preventive or corrective controls can be applied, only cooking to a high enough temperature or sufficient irradiation can ensure the safety of ground beef. The irradiation process does not replace the need for proper cooking. The committee urges regulatory and health authorities to (1) advise those members of the public who would prefer to minimize the risk of this product to cook irradiated and nonirradiated ground beef products to the appropriate temperature, (2) require these products to be clearly labeled with a warning of the potential for harm if not properly cooked, and (3) expand educational efforts to the public and target commercial and noncommercial food service managers and workers.
  - — Establish a research focus on intervention trials at all stages of the meat and poultry production process, from farm to table.
- **The Food and Drug Administration (FDA) should take the following specific measures regarding scientific criteria, HACCP, imported foods, and improving the safety of seafood, produce, and dairy products:**
  - — Include a process validation protocol in the *Fish and Fisheries Products Hazards and Control Guide* and appoint an advisory committee to periodically update this guide.
  - — Develop strategies to ensure the safety of imported seafood and produce by focusing on pathogen intervention strategies prior to shipment and on international harmonization of standards.
  - — Expand research on risks associated with many specific practices in the fresh produce sector, and on the potential for and significance of internalization of pathogens into fresh produce.
  - — Implement targeted educational programs to inform the public about the risks of consuming raw milk and raw milk products.
  - — Work with industry to conduct research to assess the pathogen reduction efficacy of cheese manufacturing conditions and to develop science-based performance standards for reduction of targeted pathogens in finished cheese products.
  - — Along with state authorities, consider requiring clear and concise labeling to identify cheeses manufactured from unpasteurized milk.
- **State health authorities should ban the sale of raw milk, as has already been done by FDA in interstate commerce.**

To assist the regulatory agencies in harmonizing the language in future food safety regulations, the committee developed or adopted definitions for several key terms as presented in Box ES-1.

BOX ES-1 Definitions

Public health objective: A measurable population-based target for maintaining or improving health.

Food safety objective: A statement of the maximum frequency and/or concentration of a hazard in a food at the time of consumption that is considered tolerable for consumers.

Performance standard: The degree to which a step or combination of steps in the production, processing, distribution, and/or preparation of a food must operate to achieve the required level of control over a hazard.

Microbiological criterion: A criterion that defines the acceptability of a product or food lot, based on the absence or presence or number of microorganisms, including parasites, and/or the quantity of their toxins/metabolites, per unit of mass, volume, area, or lot.

Microbiological standard: A mandatory microbiological criterion that is incorporated into a law, regulation, or ordinance.

Microbiological guideline: An advisory microbiological criterion used to inform food operators of the microbiological content that can be expected in food when best practices are applied.

KEY ISSUES

Regulatory Authority and Flexibility to Enact, Enforce, and Update Food Safety Criteria

Legal challenges to actions taken by regulatory agencies in response to violations of established food safety criteria have cast doubts on the agencies' authority to enforce criteria. While the committee did not undertake an analysis of these challenges, this situation should be promptly addressed through Congressional action.

Moreover, the current administrative process to modify food safety criteria is too cumbersome to allow appropriate and timely updating of these regulations to keep up with scientific and technological progress. To remedy this lack of flexibility, Congress should enable regulatory agencies the ability to incorporate flexibility into the administrative process so that food safety criteria can be efficiently adjusted to meet future public health goals. This flexibility includes incorporating new processing or assessment techniques and allowing the agencies the ability to change a performance standard to align it with the best contemporary scientific knowledge.

Regulatory agencies, in turn, need to be consistent in auditing and enforcing compliance with established criteria. Furthermore, because of the rapid growth of food imports, it is essential that regulatory agencies properly monitor and enforce

compliance with established performance standards and guidelines in imported foods.

Basing Food Safety Regulations on Science

A major step in advancing a science-based food safety system has been the implementation of HACCP in various sectors of the food industry. The efforts made by industry and regulators to this effect are commendable and should continue.

Regulatory agencies should follow a strategy that combines the best available data with the best expert judgment, as an appropriate, science-based means to establish food safety regulations. Scientific tools such as Microbiological Risk Assessment, Food Safety Objectives, and Statistical Process Control are available to regulators when developing and monitoring compliance with regulations. Good science-based policies should allow flexibility and encourage innovation with minimal regulatory revisions. This implies a regulatory framework that specifies results, but not the methods used to achieve these results. It also implies flexible criteria that can be efficiently changed in response to changing public health goals.

The Need to Link Food Safety Criteria to Public Health Objectives

Food safety criteria have the common objective of protecting or improving public health. Therefore, science-based food safety criteria must be clearly linked to the public health problem they are designed to address. This link, which is not always present in current regulations, would also provide a means to measure the effectiveness of new and existing regulations. To establish this link, data from foodborne disease surveillance programs and from monitoring pathogen contamination in foods must be made compatible and should be integrated.

Timely collection, analysis, and dissemination of surveillance data are essential to minimize the spread of foodborne disease outbreaks to a larger population, particularly in the light of concerns about potential intentional contamination of food. Internal sharing and comparison of compatible surveillance data, and collaboration with international surveillance systems, are also essential. However, current microbial monitoring of food in the United States is fragmented and often incompatible with foodborne disease surveillance; this reduces the effectiveness of much of the monitoring and surveillance. Efforts to standardize methodology and data reporting methods, such as PulseNet, are beginning to produce invaluable information, and their expansion is fundamental to an effective surveillance system.

Similarly, to collect data that can be compared to foodborne disease surveillance data, there is a need for periodic surveys of pathogen contamination, at various stages in the production/consumption continuum, of foods frequently

associated with foodborne illness. These data are necessary to identify the optimal locations and means for effective interventions, through appropriate criteria, that will enhance the safety of foods.

SUMMARY FINDINGS

Tools and Procedures to Establish Science-Based Food Safety Criteria

- The emphasis of food safety regulatory agencies must continue to be on the prevention, reduction, or elimination of foodborne hazards along the food production, processing, and distribution continuum, rather than on inspection of the end product.
- There is a need to define "acceptable levels" of hazard reduction at critical control points linked to public health objectives. The Food Safety Objective concept can help establish this link and define these levels, and it can also provide a theoretical framework to relate performance standards to public health objectives.
- Failure to develop HACCP plans that are appropriately specific for a given processing plant, line, and product may contribute to failure of the plan.
- There are inconsistencies in the interpretation and enforcement of HACCP regulations between and within the regulatory agencies.
- Quantitative microbial risk assessment offers the scientific tools to define the most effective solutions for lowering consumer exposure to foodborne microbial hazards.
- Statistical Process Control linked to continuous improvement must be a part of food safety regulations. The concept of "continuous improvement" is central to food safety.
- Depending on the quality of available data, food safety regulatory agencies could use controlled studies, expert opinion, or a combination thereof to develop science-based food safety criteria. Because of common gaps in available data and scientific knowledge, the combination strategy is the optimal science-based procedure to develop food safety criteria.
- Efficient and cost-effective collection of appropriate data for scientific decision-making may be facilitated through ongoing, systematic development of databases and targeted pilot studies to address specific data gaps.
- Documenting the limitations of the data and the assumptions used, and making this information available to the public, provide essential transparency to the process of developing food safety criteria.
- When appropriate data are available, a performance standard may be developed by (1) assuming that all food-processing companies are producing food of an acceptable level and setting the performance standard at a level such that the lowest compliant processor will pass, while all of the

noncompliant plants will fail, or (2) setting the performance standard at a level where only a portion of the processing plants will pass, thus enabling future adjustments to the standard.

- When zero tolerance is used as a performance standard, unique methodology issues need to be considered.
- Performance standards must be linked to a public health goal and must incorporate a measure of effectiveness in meeting the public health goal.
- Regulatory agencies need flexibility in administrative procedures to update food safety criteria to align them with the best contemporary scientific knowledge.
- It is difficult to quantify the individual costs and benefits of performance standards implemented as part of a broad regulatory change. The thesis that flexibility allows innovation, borne out in the area of environmental regulations, may be amenable to extension into the food safety regulatory environment.

Foodborne Disease Surveillance and the Monitoring of Microbial Contaminants in Food

- Foodborne disease surveillance is essential for defining trends in foodborne disease, identifying outbreaks, allocating the burden of disease among food groups, and evaluating food safety programs.
- Compatible bacterial subtype and antimicrobial resistance surveillance data from humans, animals, farms, and food products should be linked among federal agencies and state laboratories.
- Systematic sampling of animals for pathogens preslaughter and at point of slaughter to obtain a clear understanding of contamination routes is lacking. Periodic, systematic, nonregulatory microbiological surveys of food-processing plants, with sampling at various points, should be conducted to provide a basis to revise baselines on the prevalence of pathogen and indicator microorganisms for foods frequently implicated in foodborne disease outbreaks.
- Monitoring microbial pathogens in produce and seafood (domestic and imported), live animals (on farm and preslaughter), and final products, and comparison with human isolates through compatible serotyping and subtyping, would provide data to develop and evaluate food safety interventions and regulations. Without such data, it is not possible to clearly establish the contribution of current food safety criteria to improvements in public health.
- Epidemiological and food monitoring data are essential when developing quantitative microbial risk assessments for use as a basis for food safety criteria.

Safety Criteria for Meat and Poultry

- The rationale for the process control performance criteria for fecal contamination is based on the frequency and levels of contamination of beef carcasses with *E. coli* and is appropriate. However, if populations of generic *E. coli* are extremely low, other testing approaches may be necessary.
- The *E. coli* data collected by industry are not in the public domain. Collection of such data should be extended to ground beef, and all data should be handled through a national, anonymous repository.
- The *Salmonella* performance standards for carcasses and ground meat are valid criteria to reduce the levels of salmonellae in or on meat. However, if the populations or incidence of salmonellae are extremely low, other testing approaches may be necessary.
- The *Salmonella* performance standard for ground beef products may not reflect the overall quality of the grinding operation. It may instead be a reflection of the quality of incoming raw materials.
- A *Salmonella* performance standard or other appropriate criterion is needed for beef trim intended for grinding.
- All meat intended for trim for ground products, especially ground beef, and including trim from heads, should be exposed to some form of verified pathogen reduction intervention.
- Based on public health data, the zero tolerance policy for *E. coli* O157:H7 in ground beef has been insufficient to reduce the rate of human illness attributable to this microorganism. It is important to emphasize the need for testing and interventions prior to the grinding operation.
- Information on the ecology and mode of transmission of *E. coli* O157:H7 and related serotypes is urgently needed to help develop preventive measures and effective interventions.
- Currently, only cooking to a high enough temperature or sufficient irradiation can ensure the safety of ground beef. The irradiation process does not replace the need for proper cooking.
- The guidelines requiring a specific lethality for *Salmonella* as a critical control point in HACCP plans for production of cooked beef and poultry and other related products are not well justified scientifically and have resulted in an excessively conservative performance standard.
- The scientific bases for the stabilization performance standards required in the production of cooked beef and poultry and other related products are not clear; the validity of the data and assumptions is difficult to determine. These standards do not include cured meat products and should not be applied to these products.
- Development of a standard using a safety margin based on a highly conservative worst-case scenario may lead to production of overprocessed products of inferior quality, as well as to undue economic burdens for the

processor. An inadequate safety margin may lead to production of unsafe products.

- Efforts to reduce the pathogenic contamination of animals preslaughter are a key part of a farm-to-table food safety strategy.
- Substantial declines since 1996 in several bacterial foodborne diseases in the United States indicate that the collective efforts to improve food safety are achieving improvements in public health. It is likely that the Pathogen Reduction/HACCP rule has contributed to the declines in infections caused by the meat-associated pathogens *Campylobacter*, *Listeria monocytogenes,* and *Yersinia enterocolitica;* it is also likely, however, that concurrent changes in distribution, retail, and consumer behavior also played a role.
- Measuring changes in consumer behavior, as well as subtyping microbial pathogen isolates from various food sources and comparing the results with isolates from human infections, could help define a cause-and-effect relationship between performance standards and improved public health.
- Emphasizing contamination prevention rather than end-product testing to ensure the safety of meat is justified. The conclusion of previous National Academies' reports that carcass-by-carcass inspection is an ineffective food safety strategy remains valid. Meat and poultry processors and regulators should use process control techniques to ensure that performance standards for meat and poultry are met.

Safety Criteria for Seafood

- Mandatory seafood HACCP has made positive contributions to seafood safety; further benefits will depend on continuing education and technical innovation. FDA's *Fish and Fisheries Products Hazards and Control Guide* (the Guide) is both innovative and useful.
- A structured protocol for process validation that addresses criteria for qualifying "processing authorities" and for structuring sampling plans, experimental designs, and appropriate methodologies is lacking in the Guide. Similarly, a regulatory protocol is necessary to apply new, rapid analytical methodologies to process validation and routine verification.
- Appropriate control of some chemical hazards in seafood is satisfactorily achieved through restrictions on harvesting sites or by using vessel and plant records. End-product testing provides a useful verification tool for control of these hazards.
- The implementation of postharvest treatments to progressively reduce the average number of annual reported illnesses attributed to raw oysters required by the Model Ordinance is a unique, flexible approach to safety; it establishes a public health objective and requires adequate industry performance without mandating a specific process or performance standard.

- Screening limited quantities of imported seafood products at points of entry is not consistent with the preventive concept of HACCP. Prevention of safety hazards in imported seafood must place greater emphasis on pathogen intervention strategies prior to shipment. Application of the Guide to increase seafood safety in international commerce requires immediate attention.

Safety Criteria for Produce and Related Products

- Fresh produce safety is of concern because microbial pathogens introduced on fresh produce at any point may be present at the point of consumption.
- Data on risks associated with many specific practices in the fresh produce sector are lacking. Research is needed on the likelihood of internalization of pathogens into fresh produce and its underlying mechanisms.
- There are concerns about the harmonization of food safety practices for imported produce. Imported produce should follow the same or equivalent Good Agricultural Practices that are required in domestic production.
- Because the use of a D-value concept to calculate thermal processes is being challenged, the appropriateness of the 12-D process for canning low-acid foods should be scientifically reevaluated.
- Reflecting the array of products and scenarios, FDA has developed guidance documents or required standards to address produce safety. Some managing strategies that have been implemented are:
  - Good Agricultural Practices in the field and packing houses; required Good Manufacturing Practices in fresh-cut operations.
  - Implementation of HACCP in fruit and vegetable juice production. The derivation of the sampling program for generic *E. coli* in fruit juices involving surface treatment of whole fruit is an excellent example of using the combination strategy to develop a performance standard and could be used as a model when developing future food safety criteria. In contrast, the justification of the 5-D pathogen reduction process for juices lacks transparency.
  - An appropriate action level of 50 mg/kg for patulin in apple juice, apple juice concentrates, and apple juice products.
  - Issuing guidance documents on practices to be followed by sprout producers.
  - Establishing appropriate pesticide tolerances in produce.

Safety Criteria for Dairy Products

- The application of regulations within the evolving Grade A Pasteurized Milk Ordinance can be directly credited with reducing the incidence of

milk-borne disease. The development, implementation, and enforcement of the Ordinance provide a good model for an integrated strategy for food safety assurance. It involves all stakeholders, is based on science, and is appropriately transparent. This model also provides a specific structure and mechanism for a biennial review of existing regulations, which could be used in other sectors of the food industry.

- A scientifically appropriate performance standard for the reduction of a targeted pathogen in finished cheese products is needed.
- Research is needed on pathogen survival in cheese made from subpasteurized milk, and educational programs that illustrate the hazards of raw milk and raw milk-product consumption are warranted. Cheeses manufactured from subpasteurized milk should be clearly and prominently labeled as such at the point of purchase.
- State authorities should ban the sale of unpasteurized milk because of its inherent risks. Targeted educational programs that illustrate the hazards of raw milk consumption are also warranted.