Review of Use of Process Control Indicators in the FSIS Public Health Risk-Based Inspection System: Letter Report

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Review of the Use of Process Control Indicators in the FSIS Public Health Risk-Based Inspection System

A Letter Report

Committee on Review of the
Use of Process Control Indicators in the FSIS Public
Health Risk-Based Inspection System

Food and Nutrition Board

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Willing is not enough; we must do."
—Goethe

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This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the National Research Council's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process. We wish to thank the following individuals for their review of this report:

Russ Flowers, Silliker Corp.
Randy Huffman, Maple Leaf Foods
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Dale L. Morse, New York State Department of Health
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Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations nor did they see the final draft of the report before its release. The review of this report was overseen by **Jim E. Riviere,** Center for Chemical Toxicology Research and Pharmacokinetics, College of Veterinary Medicine at North Carolina State University, and **Harley W. Moon,** Department of Veterinary Pathology, Professor Emeritus, Iowa State University. Appointed by the National Research Council and the Institute of Medicine, they were responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the authoring committee and the institution.

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March 13, 2009

Carol Maczka, Ph.D.
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Dear Dr. Maczka,

At the request of the Food Safety and Inspection Service (FSIS), the Institute of Medicine (IOM)—under the auspices of the Standing Committee on the Use of Public Health Data in FSIS Food Safety Programs—established the Committee on Review of the Use of Process Control Indicators in the FSIS Public Health Risk-Based Inspection System to review criteria developed by FSIS for ranking establishments based on relative risk. The body of this letter report provides the committee's findings and recommendations regarding whether FSIS has adequately defined and identified indicators of process control that will be used to rank establishments and allocate agency inspection resources to protect public health. Specifically, the committee has evaluated how FSIS is proposing to use its available data to develop risk-based criteria for ranking establishments, as described in the technical report *Public Health Risk-Based Inspection System for Processing and Slaughter* (*PHRBIS*; FSIS, 2008b).

SUMMARY

Overall, the committee finds FSIS's commitment to developing a risk-based inspection system commendable and agrees with the general concept of using process control indicators as part of an algorithm to rank establishments in different levels of inspection. The committee also encourages FSIS to continue to provide the rationale and scientific evi-

dence serving as the basis for the proposed system and praises FSIS for its resilience as it improves the proposal with public comments. In general, the committee found it a challenge to evaluate the adequacy of indicators of process control to rank establishments and allocate agency inspection resources without a clear understanding of the rationale for the general approach. The committee's deliberations, based on its review of the report *PHRBIS,* open meetings, and personal communications with FSIS, resulted in the following findings:

- The proposed inspection system consists of two components: one based on process control indicators and a second based on public health impact. The committee was tasked to review only the first component, but found it difficult to completely exclude deliberations on indicators of public health impact.
- The report *PHRBIS* lacks details that are crucial to its evaluation. For example, the description of the algorithm, the scientific basis for the algorithm, the scientific basis for the use of the process indicators, the description and analysis of data, and the use of the process control indicator algorithm as it is integrated into the overall inspection system are not clearly articulated in the FSIS technical report.
- The specific activities assigned to the three levels of inspection are not explicated. Likewise, the process of decision making to transfer a plant into a different level of inspection (LOI) (e.g., from LOI 2 to LOI 1) is not well defined. Further, it is not clear for how long or how frequently a plant in category LOI 2 or LOI 3 will be subject to an in-depth inspection or how these LOI designations relate to current regulatory requirements.
- Key terms of the algorithm, such as "process control indicators," are not well defined. In addition, the proposed algorithm assigns the same weight to all process indicators, even though they vary in their ability to predict loss of process control. For example, some indicators may predict future loss of control (e.g., the rate of health-related noncompliance records [NRs]), but others might only reflect past loss of control (e.g., recalls). For some foods, no adequate process control indicator is proposed.
- The statistical analysis that was conducted to find associations between proposed process control indicators—lift analysis—is a data-mining tool appropriate for use in finding initial associations among events that occur infrequently. However, the identi-

fication of process control indicators to properly categorize plants based on risk to public health requires more complex statistical analysis as well as data that have been collected for the purpose of identifying such indicators.

- Although there are limitations on the use of pathogenic organisms or *Salmonella* verification testing results as indicators of process control (e.g., infrequency of events), the committee concludes that the use of such testing to categorize plants in different levels of inspection is appropriate, if the recommendations stated in this report are followed.
- FSIS currently tests each product class for different microorganisms, for different purposes, and with different underlying assumptions. The applicability of these data to the FSIS algorithm is dependent on the specific protocols, assumptions, and statistical characteristics of each testing program. The FSIS technical report did not provide in-depth consideration of the statistics that underlie the specific microbiological testing protocols employed and the assumptions made when using such data (e.g., the magnitude of type I and type II errors).
- The use of the rate of NR receipt as an indicator of process control is promising but presents limitations based on the nature of the NRs (e.g., they document failure to comply with a regulation but are not always associated with a loss of process control or a public health hazard; NRs are subjective in nature; statistical analysis was conducted by aggregating data from all facilities, which might have biased the results).
- Other proposed process control indicators also present limitations. The use of public health-related recalls, enforcement actions, and outbreaks to rank establishments in different levels of inspection has been justified based on potential direct public health risk, a valid risk-management decision criterion. However, the initial data analysis has not provided scientific support for these decision criteria as predictive of a loss of process control or for their association with other indicators.

The deliberations of the committee resulted in recommendations for improvement in the areas listed below that should be followed prior to implementing this algorithm:

- Definition of key terms used in developing the algorithm, specifically, pointing out the limitations and consequences of using such terms in the context of the proposal;
- Design of the algorithm, by conducting a risk-ranking activity to better identify process control indicators and their relative importance;
- Collection or retrieval of additional data for the purpose of confirming the current process control indicators as well as exploring the use of new potential process control indicators to improve the sensitivity of the algorithm; and
- Development of procedures to validate the algorithm.

CHARGE TO THE COMMITTEE

Responding to the request of the Food Safety and Inspection Service of the U.S. Department of Agriculture (USDA), the Institute of Medicine of the National Academies appointed the nine-member ad hoc Committee on Review of the Use of Process Control Indicators in the FSIS Public Health Risk-Based Inspection System. Committee members provided expertise in meat and poultry microbiology, molecular biology methods, design and operation of processing establishments, risk analysis and decision-making tools, meat and poultry inspection, and foodborne disease epidemiology and public health. The committee met three times during the course of its work. The first meeting (Appendix A: Meeting Agendas) was held on November 6-7, 2008, in conjunction with a public data-gathering session with FSIS representatives, who provided program background and an in-depth description of the committee's task (Box 1). The committee's second meeting on December 17-18, 2008, also included Dr. Artur Dubrawski, of Carnegie Mellon University, and Dr. Marc Huckabee and Dr. Curtis Travis, consultants to FSIS from Science Applications International Corporation, who conducted the statistical analysis. During an open session of that meeting, these invitees responded to the committee's questions about the statistical analysis of the data on process control indicators that were used by FSIS to establish the proposed risk-based algorithm. In addition to discussions with FSIS representatives and consultants, the committee formally requested data and information from FSIS through the Freedom of Information Act, as suggested by FSIS representatives. The committee deliberated on the following process control indicators and the data analysis approaches used by FSIS to evaluate their potential inclusion in the algorithm:

- *Salmonella* verification testing in raw meat and poultry
- Pathogen testing in ready-to-eat (RTE) meat and poultry (*Salmonella enterica*, *Listeria monocytogenes*, and *Escherichia coli* O157:H7) and raw ground beef and its components (*E. coli* O157:H7)
- Noncompliance records
- Enforcement actions
- Class I and II recalls
- Pulsed field gel electrophoresis (PFGE) patterns of *Salmonella* serovars of particular human health concern for isolates derived from the raw meat and poultry *Salmonella* verification testing program
- System for Tracking *E. coli* O157:H7 Positive Suppliers (STEPS)

The committee also discussed the potential use of other indicators that were not included in the FSIS proposal. Findings and recommendations were drafted. A third committee meeting was held on January 13-14, 2009, in Washington, DC, to finalize its findings and recommendations and to prepare the report for external review.

The committee reviewed the data and statistical analysis (Appendixes D and E of the technical report *Public Health Risk-Based Inspection System for Processing and Slaughter* [FSIS, 2008b]) provided for the proposed indicators listed above. Appendix D of that report includes a description of the data used; Appendix E describes the data analysis that was conducted and the conclusions derived thus far. Appendix D and E also include limitations of the data and analysis and the rationale for the design of the algorithm.

At the request of FSIS and because another National Academy of Sciences (NAS) committee (Committee on Review of the Food Safety and Inspection Service [FSIS] Risk-Based Approach to Public Health Attribution) was assigned the task, data on volume and food attribution were not reviewed by this committee. FSIS noted that this algorithm would undergo improvements during the committee's deliberation and, therefore, the proposal should be considered preliminary; since the publication of its technical report, FSIS has slightly modified the selection of process indicators. The committee based its deliberations on the updated version of the algorithm that was presented at its meeting on November 6-7, 2008 (see the indicators of process control and levels of inspection

in Appendix B of this report). The committee additionally reviewed several other FSIS reports, such as the 2008 technical report on poultry slaughter provided to the National Advisory Committee on Meat and Poultry Inspection (NACMPI) (FSIS, 2008a), to better understand the evolution of the FSIS algorithm.

This letter report begins with a background description of the FSIS initiative of a risk-based inspection system. Overall recommendations and findings are followed by recommendations for each specific process control indicator reviewed. The agenda of the workshop held on November 6-7, 2008, and the agenda for the open session of the second meeting are provided in Appendix A. Appendix B lists the indicators of process control corresponding to each level of inspection. Appendixes C and D contain a list of acronyms and a glossary, respectively. Appendix E lists the committee members' biosketches.

BOX-1
Statement of Task

An ad hoc committee will review whether the Food Safety and Inspection Service (FSIS) has adequately defined and identified indicators of process control to protect public health that will be used to rank establishments and allocate agency inspection resources. Specifically, the committee will evaluate how FSIS is proposing to use its available data to develop a relative risk ranking of establishments described in the technical report *Public Health Risk-Based Inspection System for Processing and Slaughter*, publicly posted at http://www.fsis.usda.gov/Regulations_&_Policies/National_Advisory_Committee_on_Meat_&_Poultry/index.asp.

BACKGROUND

Public Health Risk-Based Inspection System for Processing and Slaughter

The Food Safety and Inspection Service, the USDA agency responsible for ensuring the safety of meat, poultry, and egg products, has examined a number of strategies to develop a risk-based food safety system. Examples include the development and implementation of the Pathogen Reduction; Hazard Analysis and Critical Control Point (PR/HACCP) Systems; Final Rule in 1996 (FSIS, 1996), the development of microbiological performance standards (FSIS, 1999), and requirements for pathogen testing of ready-to-eat foods (Requirements for specific classes of product. 2008. 9 CFR Part 430).

In January 1997, President Clinton announced a Food Safety Initiative to reduce the incidence of foodborne disease in the United States. Among other changes, government agencies in charge of ensuring food safety were directed to improve inspections and enforce HACCP compliance in establishments that process meat and poultry (FDA-USDA-EPA-CDC, 1997). It was anticipated that implementation of the HACCP system would be accompanied by concurrent changes in inspection procedures. In 2003, the IOM Committee on Review of the Use of Scientific Criteria and Performance Standards for Safe Food found that the inspection of FSIS-regulated establishments relied largely on visual and organoleptic observations rather than on risk to public health (IOM, 2003). Although these are important and necessary elements of a plant survey, an improved, risk-based inspection system would assign levels of inspection to establishments according to the magnitude of their product's risk to the public's health. Other organizations, including the National Academies (NRC, 1987; IOM, 1990) and the Government Accountability Office (GAO, 1992), have previously emphasized the need for a risk-based inspection system for meat and poultry products.

In 2006, FSIS initiated the development of a risk-based inspection system. In its technical report *Public Health Risk-Based Inspection System for Processing and Slaughter* (hereafter referred to as *PHRBIS*) (FSIS, 2008b), FSIS proposes a decision-making tool to rank establishments according to their risk to public health by categorizing them first acccording to their level of process control and then by the impact on public health of the food produced. In addition, FSIS intends to upgrade several other elements of the proposed inspection system. For example, FSIS plans to strengthen its information technology system to enable inspection personnel to enter data on hazard analysis and make subsequent decisions in a more integrated and objective manner (FSIS, 2008b). FSIS also plans to train its inspection force (inspectors and supervisors) in effective use of the proposed inspection system tools. For example, in addition to continuing routine inspection training, a group of in-plant inspectors will receive training to enhance their understanding of establishment food safety systems, including HACCP plans or sanitary requirements. Supervisors will also be trained to use a more streamlined inspection review process (E. Dreyling, FSIS, personal communication, December 13, 2008).

As FSIS describes in its technical report *PHRBIS*, the proposed tool has evolved with input from stakeholder groups as well as the USDA's National Advisory Committee for Meat and Poultry Inspection. An important innovation of this current proposal is to rely, where possible, on

data collected in conjunction with FSIS's regulatory programs (FSIS, 2008b). The ultimate aim is the production of an effective tool for achieving the Healthy People 2010 goals of reducing foodborne disease caused by *Salmonella*, *Escherichia coli* O157:H7, and *Listeria monocytogenes* (HHS, 2000). FSIS concludes that to protect public health most effectively, inspection resources have to be allocated based on the degree of risk to public health presented by each processing plant. Therefore, a key element of the risk-based inspection system is an algorithm for categorizing slaughter and processing plants according to risk so that inspection efforts are focused on those establishments having the greatest impact on public health (FSIS, 2008b). The algorithm consists of two consecutive steps to rank an establishment's risk: a first component to determine the establishment's level of process control (i.e., identifying attributes that indicate whether the establishment is maintaining control) and a second component to quantify public health impact (i.e., the volume of the commodity produced at the establishment together with public health attribution of the food produced) (FSIS, 2008b). The committee was charged with reviewing the scientific basis of and rationale for the first component of the algorithm—the data and data analysis that were used by FSIS to identify indicators for categorizing establishments according to their level of process control. A second NAS ad hoc committee (Committee on Review of the Food Safety and Inspection Service [FSIS] Risk-Based Approach to Public Health Attribution) was charged with reviewing the second component, the public health attribution system. Because the two components are closely related (e.g., the volume of production in an establishment influences the sampling plans for pathogen testing programs that FSIS proposes to use to indicate process control) and included in an overall inspection system, this committee found it difficult to completely exclude deliberations on indicators of public health impact.

OVERALL FINDINGS AND RECOMMENDATIONS

This section of the report provides overall findings and recommendations related to strengthening the proposed FSIS risk-based decision tools for ranking establishments. It is followed by a section that provides more specific recommendations for each proposed indicator. Prior to implementing the algorithm, the recommendations in this report should be followed.

General Approach

The committee concurs that a risk-based approach to inspection is essential and commends FSIS for undertaking such a daunting and controversial endeavor. The committee found that the development and use of a model (algorithm) to categorize establishments based on risk can ultimately be a systematic approach to realizing and implementing decision criteria in a transparent, predictable manner. However, the committee found it challenging to comprehend the framework, concepts, and rationale that FSIS applied in several segments of the proposed model. The descriptions of the algorithm, the scientific basis for the selection of the proposed process indicators, the analysis of data, and the use of the process control indicator algorithm as it is integrated in the overall inspection system were not clearly stated in the technical report *PHRBIS* that was provided to the committee. For example, FSIS uses the term "algorithm" to describe its decision-making tool to categorize plants into levels of inspection. As shown in Table 1, there are various definitions of the term algorithm.

However, in the context of a risk-based system, the term algorithm implies a mathematical model. Since FSIS did not construct a mathematical model, it would be more precise to use the designation decision tool or framework. To avoid confusion for the reader, the committee decided to retain the term algorithm for the purposes of this report.

TABLE 1 Definitions of Algorithm

Definition	Source
A set of rules for solving a problem in a finite number of steps, (e.g., finding the greatest common divisor)	http://dictionary.reference.com/
A procedure for solving a mathematical problem (e.g., finding the greatest common divisor) in a finite number of steps that frequently involves repetition of an operation; *broadly*: a step-by-step procedure for solving a problem or accomplishing some end especially by computer	http://www.merriam-webster.com/
A precise rule (or set of rules) specifying how to solve some problem	http://www.websters-online-dictionary.org/

Continued

Table 1 continued

Mathematics. A process, or set of rules, usually expressed in algebraic notation, now used especially in computing, machine translation, and linguistics *Medicine.* A step-by-step procedure for reaching a clinical decision or diagnosis, often set out in the form of a flow chart, in which the answer to each question determines the next question to be asked	Oxford English Dictionary, 2nd edition, 1982
Any special method of solving a certain kind of problem; specifically, the repetitive calculations used in finding the greatest common divisor of two numbers	Webster's New World Dictionary, 2nd college edition, 1982

Finding 1: *Although the use of a model to categorize plants in levels of inspection is appropriate, the descriptions of the algorithm, the scientific basis for the use of the process indicators, the description and analysis of data, and the use of the process control indicator algorithm as it is integrated into the overall inspection system are not clearly articulated in the FSIS technical report.*

RECOMMENDATION 1: The committee recommends that in addition to the improvements in data collection and analysis presented below, FSIS revise its proposal to improve the transparency and clarity of the description of the overall inspection system—in particular, the process control indicator algorithm, its scientific basis, and the type and analysis of data used. Further, FSIS should consider tailoring the proposal to its target audiences (e.g., plant managers, FSIS inspectors and supervisors, FSIS managers and scientists, outside expert panels) and providing them with supplemental information or reports.

Definitions of Process Control and Process Control Indicators

The FSIS (2008b) report does not adequately define various terms that are key to evaluating the proposed inspection system (e.g., algorithm, process control, process control indicator). The ambiguous use of these terms hampered the ability of the committee to understand the use of data and could result in misinterpretations and unnecessary disputes in the future. To avoid confusing the reader and for the purposes of this report, however, the committee opted to retain the terms *process control* and *process control indicators* while also pointing out the ambiguity of their usage.

The committee offers more clearly defined key terms and explains its interpretation of those terms for the purposes of this report. The concept of process control, which applies to all manufacturing companies and can be used broadly to address both quality and safety issues, is used in the context of the current report as a means to quantify how well an establishment is employing control measures to minimize pathogen contamination. Examples of definitions of process control are shown in Table 2.

TABLE 2 Definitions of Process Control

Definition	Source
At certain points in the processing of a food, control measures can be applied to prevent an unacceptable increase in a hazard, eliminate it, or reduce it to an acceptable level	*Scientific Criteria to Ensure Safe Food* (IOM, 2003, p. 94)
Activities involved in ensuring a process is predictable, stable, and consistently operating at the target level of performance with only normal variation	BusinessDictionary.com (http://www.businessdictionary.com/)
The inspection of work-in-progress to provide feedback on, and correct, a production process. First developed as a mechanical feedback mechanism, process control is now widely used to monitor and maintain the quality of output	bnet.com (http://www.bnet.com/)
Method by which the input flow of processing plants is automatically controlled and regulated by various output sensor measurements. Process control can also describe the method of keeping processes within specified boundaries and minimizing variation within a process	Chemicals-technology.com (http://www.chemicals-technology.com/glossary/)
The active changing of a process based on the results of process monitoring. Once the process monitoring tools have detected an out-of-control situation, the person responsible for the process makes a change to bring the process back into control	NIST/SEMATECH e-Handbook of Statistical Methods (http://www.itl.nist.gov/div898/handbook/pmc/section1/pmc13.htm)
The automated control of a process. Process control is used extensively in oil refining, chemical processing, electrical generation, and the food and beverage industries where the creation of a product is based on a continuous series of processes being applied to raw materials	PCMag.com (http://www.pcmag.com/encyclopedia_term/0,2542,t=process+control&i=49753,00.asp)

In its 2003 report *Scientific Criteria to Ensure Safe Food*, IOM evaluated the use of scientific criteria and standards in food safety regulations (IOM, 2003). That report defines various terms used in food

safety and refers to process control in various contexts. For example, the report refers to control measures as those measures that "can be applied at certain points in the processing of a food to prevent an unacceptable increase in a hazard, eliminate it, or reduce it to an acceptable level." The report also states that "process control is based on four premises: (1) product quality or product safety must be built into the manufacturing process, (2) the manufacturing process must be monitored and the data must be analyzed using appropriate measurement and statistical techniques, (3) the process must be managed to ensure its variation remains stable and predictable, and (4) the process is capable of delivering product that meets the performance standard" (IOM, 2003). Manufacturing processes inherently possess some degree of variation that is acceptable and considered within the limits as long as it is predictable and stable, as described in *Scientific Criteria to Ensure Safe Food* (IOM, 2003). Thus, the concepts of validation and verification against one or more articulated performance metrics form an integral part of any process control system.

The committee adopted the following definition of process control for the purpose of this review:

> *A process is in control when, within the limits of a stable and predictable process variation, all hazards are controlled to an acceptable level.*

This definition assumes that the process variation is known. It also assumes that there is active monitoring of the process using appropriate metrics, which ideally would allow corrective actions to be taken before a critical safety limit is surpassed.

Using this general definition of process control, the committee defined a process control indicator for the purpose of this review as:

> *A measurable attribute that indicates whether a process maintains or surpasses an acceptable degree of risk or hazard control.*

An adequate indicator is an attribute that can be measured with objectivity and for which limits that indicate a need for corrective action can be established. It should be noted that such limits require consideration of both the scientific basis for the metric being employed and the societal considerations that were implicit in establishing the performance criterion used for decision making.

In the proposed algorithm, FSIS utilizes the term "indicator of

process control"; however, no definition is provided. Furthermore, FSIS's selection of certain process control indicators that are based on a limit of detection or the single occurrence of a process deviation may reduce the primary strength of process control approaches (i.e., signaling the need to take corrective action before a critical limit is exceeded). An ideal indicator of process control is one that can predict future outcomes with some level of certainty. Such indicators allow establishments to take corrective actions before a loss of control represents a threat to public health, thereby advancing FSIS's goal of reducing the number of high-risk establishments. In the absence of ideal indicators, it is acceptable to select others, as long as their limitations are fully recognized. Among the indicators of process control being proposed by FSIS as part of its algorithm are two basic types: those that may predict a future loss of control (e.g., exceeding a specific rate of NRs) and those that are outcomes of a past loss of control (e.g., finding a pathogen in an RTE food product, recall of a product for safety reasons). Although predictors of future loss of control are better indicators because triggering an in-depth inspection and corrective action could prevent future risk to public health, it is reasonable to conclude, in the absence of any contradictory information, that a plant that has produced contaminated products in the past may not have implemented adequate corrective actions and may therefore need a more comprehensive inspection program until its production process is shown to be in control. Such events are not true indicators of process control; rather, they demonstrate prior failures. This distinction is vital to understanding the algorithm, and therefore future improvements to it, and should be stated clearly along with the definition of process control indicator.

Another fundamental limitation of the FSIS proposal is the fact that food process attributes inherently vary; the mere presence of an indicator organism could therefore simply reflect process variation within a threshold and not necessarily demonstrate that a process is out of control. During the open meeting discussions, FSIS staff acknowledged that none of the proposed indicators do, in fact, indicate that process control has been lost; instead, they alert FSIS that a more in-depth inspection is needed. This is a subtle but important distinction to disclose in order to avoid misinterpretations of a plant's categorization. Indeed, the proposal does not adequately describe how the inspectors will address cases where an in-depth inspection reveals that the system is still under control and following regulatory requirements, but the process repeatedly fails in one indicator.

Process control indicators provide variable levels of predictability. Identifying and ranking process control indicators that are very different in nature may be challenging, but this should not preclude FSIS from implementing a risk-based inspection system. Statistical and risk-ranking analysis methodologies (e.g., multivariate analysis) can help in determining the relative importance of different predictors by commodity, and these results should be taken into consideration when developing the algorithm. Other decision-making tools such as decision trees can help in categorizing plants at different levels of inspection. An evaluation plan to review the validity of the algorithm and to update it as new information becomes available is warranted.

Finding 2: *The committee finds that the technical report* PHRBIS *does not adequately define various terms that are key to a clear understanding of the proposed inspection system—specifically, process control and process control indicators.*

RECOMMENDATION 2: Prior to analyzing the available data and selecting the indicators to develop a risk-based inspection system, the committee recommends that FSIS clearly define the terms (and their limitations) that are critical to the development of the inspection system proposed in the technical report *PHRBIS*, such as algorithm, process control, and process control indicator. FSIS should seek external advice from experts, especially on risk and risk-ranking, on the reliability and accuracy of various attributes to predict public health hazards, but also from experts on the subject matter; this information should be used to evaluate the utility of potential indicators of process control. Further, FSIS should distinguish which indicators are suitable for different classes of meat and poultry products. Once a suitable decision-making tool (e.g., a decision tree) has been adopted, it should be validated for its purpose.

Levels of Inspection

The system proposed by FSIS (FSIS, 2008b) integrates nine process control indicators in a three-tier algorithm (system) that classifies processing and slaughtering establishments into one of three levels of inspection (LOI 1, 2, or 3), with LOI 3 representing the strictest level of inspection (Appendix B). Subcategorization of LOI 1 and LOI 2 plants will be done according to their impact on public health (based on volume and food product public health attribution). Although the nature of the inspections prescribed for the three different levels is not described explic-

itly in the proposal, it was clear from discussions with FSIS representatives that the categories will be used to identify establishments to receive near-term for-cause Food Safety Assessments (FSAs), to prioritize routine FSAs that are conducted in all establishments at least once every four years, and to schedule routine hazard assessment verification (HAV).[1] Those establishments designated LOI 1 or LOI 2 facilities will undergo routine inspection procedures or more in-depth inspections, such as more frequent FSAs than are routinely done (every four years) and HAV inspections. Those plants with a suspected loss of process control (those in LOI 3) will receive an immediate for-cause FSA (C. Travis, Science Applications International Corporation, personal communication, December 13, 2008).

Although the committee was not specifically asked to comment on the number or thoroughness of the levels of inspection proposed, evaluation of FSIS's use of its available data as process control indicators to rank establishments required that the committee fully understand the details of the concepts and procedures associated with the proposed algorithm and decision criteria leading to the various levels of inspection. The committee experienced some confusion over the use of three levels of inspection, specifically the inclusion of an intermediate level, LOI 2, in which an establishment appears to be considered neither in nor out of control. It is the understanding of the committee that LOI 2 is reserved for establishments that have recently been classified as LOI 3 but are implementing corrective actions, clearing an enforcement action, or being inspected through an HAV or FSA. It was not clear to the committee for what length of time or how frequently an LOI 2 establishment will be subject to HAV inspection, or whether this will be decided on a case-by-case basis or by using a decision-making framework. For example, if a slaughtering establishment has failed the *Salmonella* verification testing percentile cut point, *Salmonella* verification testing results must remain below that cut point for at least 120 days for an establishment to be reclassified as LOI 1 (FSIS, 2008b). In that case, the committee questions what the frequency of HAV inspections would be, who would make decisions about the course of action to take, which process steps would be inspected, and the rationale for the length of time before the plant is eligible to be reclassified as LOI 1 (120 days). Furthermore, it is unclear

[1] HAV is a proposed inspection activity in which FSIS in-plant inspectors review certain components of the facility's process controls (e.g., HACCP monitoring and verification activities). HAV is considered an intensified routine inspection activity to be conducted by specifically trained in-plant inspectors.

how these level-of-inspection designations relate to the current regulatory requirements for *Salmonella* verification testing associated with different product classes. For example, for ground turkey, 15 positive samples are allowed in a single 53-day window, whereas beef carcasses can have only one positive sample in a single 83-day window. In both cases (a ground turkey processor having up to 15 positive samples in a single 53-day window and a beef processor having one positive sample in a single 83-day window), the establishments would be in compliance with FSIS process control regulations, and it would be difficult to classify them as being out of control. Similarly, if a Class I recall has occurred during the preceding 120 days and the affected plant receives an HAV inspection, the committee questions by whom and when the adequacy of the process will be confirmed and the decision made to reclassify the establishment to LOI 1.

Finding 3: *Specific procedures assigned to the three levels of inspection are not clearly described.*

RECOMMENDATION 3: The committee recommends that FSIS clearly describe in its proposal the nature of the inspection for each different level, the decision-making process that would result in a change in inspection level, and the relationship between level-of-inspection designation and the state of process control as specified by current FSIS regulations. The FSIS personnel responsible for making such decisions and their expertise should also be designated in the proposal. If the system is completely automatic (e.g., input from an inspector automatically results in a specific LOI decision, involving no subjective judgment on the part of the inspector), the committee recommends that studies be carried out to ensure that the model includes all possible scenarios.

Data Collection and Analysis of Proposed and New Indicators of Process Control

FSIS used various statistical analyses to correlate proposed process control indicators with recognized process control indicators now in use (e.g., results of *Salmonella* verification testing) or with other proposed indicators that, based on FSIS regulatory definitions, record the presence of adulterants and therefore imply a failure of control in the system. Based on the data presented, except for the *Salmonella* verification testing results and NRs, the proposed indicators of process control measure a problem that has occurred in the past (they demonstrate an outcome), but

they are not statistically associated with other process control indicators (e.g., *Salmonella* verification testing results). Furthermore, the design of the data collection and analysis to justify the selection and use of the proposed indicators was not based on any specific definition of process control and process control indicators.

Some current predictors of process control may no longer be useful in the future. For example, the tendency and purpose of *Salmonella* verification testing is reduction in the frequency of contamination of raw meat and poultry products with *Salmonella* (i.e., fewer *Salmonella*-positive samples will be found over time). If the standard is successful, then *Salmonella* positives might become so infrequent in the future that the test will lose its utility as a predictor of process control.

The committee commends the effort to develop a data-driven risk-based inspection system and provides some comments for consideration to improve future acquisition or analysis of the data.

Collection of Data

Given the importance of establishing risk-based inspections to the overall effectiveness of FSIS programs, the identification of process control indicators to categorize establishments based on their risk to public health would best be achieved through a data collection approach specifically designed for that purpose. FSIS has used lift analysis, a data-mining method that determines associations between two variables that occur separately in time (i.e., predictability), to identify indicators of process control (see below). While this is a defensible approach, the system could be improved substantially if a more complete statistical analysis was performed and additional data for proposed or new predictors were collected. Also, the proposed algorithm does not currently include an adequate process control indicator for some products (e.g., RTE foods). Microorganisms that are more likely to be found in the environment or the product, such as generic *Escherichia coli,* may be a better indicator of process control than a microorganism that is normally present only in low numbers. Information on process control deviations collected by inspectors should be tested to determine their usability as predictors of process control; similarly, the FSIS-Agricultural Research Service (ARS) study on poultry slaughter (*Technical Report on Improvements for Poultry Slaughter Inspection*, including Appendix H, "Data Analyses Supporting Proposed Performance Standards") (FSIS, 2008a) should continue and be expanded.

The committee finds that retrieving data already collected by industry or others could help identify other potential indicators of process control. For example, data on generic *E. coli* that are collected by industry should be analyzed to determine their usefulness in predicting process control. The committee recognizes that there are challenges in acquiring data from industry or others, but it encourages FSIS to act promptly to collect these data and analyze their potential as indicators of process control. At least in the case of poultry slaughter, the FSIS-ARS study suggests that FSIS found enough evidence to use generic *E. coli* as an additional performance standard for process control (FSIS, 2008a). It is also worth noting that the study employed many of the data analysis approaches that are recommended below.

For the indicators proposed in FSIS's technical report (FSIS, 2008b) and potential new indicators, detailed findings and recommendations for data collection and analysis are provided in the following sections.

Use of Lift Analysis

Lift analysis is a data-mining tool that can identify associations between two variables separated in time. It is the central statistical analysis used by FSIS to estimate the predictability of loss of process control and is explained in detail in Appendix E of the technical report *PHRBIS* (FSIS, 2008b). Lift is a measure of how much prediction results are improved by use of a model over those obtained by chance. Lift indicates how well the model improved the predictions over a random selection, given actual results, and allows a user to infer how a model will perform on new data. It works by converting input and output data accumulated over time into binary streams.

Lift analysis is generally considered a relatively imprecise, preliminary data-mining tool that would typically be followed up with more rigorous evaluation. However, it is appropriate for the analysis of some data sets. For example, it works well as a metric of increased risk, the purpose of the process indicators analyzed here. The use of lift analysis also conforms to the predictive nature of the modeling task for at least some of the predictors that were evaluated. Multiple combinations of evidence and outcome window sizes were used to empirically select promising configurations. FSIS indicated that the time windows (the length of time separating the two variables) selected were multiples of seven days, to eliminate the strong day-of-the-week effect observed in data. However, this may also have led to a misinterpretation of the data for certain tests as discussed below. Although other alternatives (e.g., logistic regression)

could have been employed, this simplified statistical analysis appears useful in the context of the low frequency of occurrence of several of the attributes that FSIS proposes to use for its algorithm. Lift analysis seems to tolerate rare event data better than the alternative, more sophisticated, univariate regression analysis, which might not detect a correlation (even if it existed) due to the rare occurrence of the outcome. FSIS conducted lift analyses forward; that is, they were designed to detect the likelihood that a future outcome would occur, given the occurrence of a particular event in the past. For example, lift analysis was used to evaluate the ability of NRs to predict that an establishment producing raw meat or poultry would fail *Salmonella* verification testing, which in turn is used by FSIS to determine whether an operation is out of process control. When sufficient data were available, FSIS conducted regression analyses among variables.

Because of the rare occurrence of some of the proposed indicators, the committee supports the use of lift analysis described in Appendix E of *PHRBIS* (FSIS, 2008b) for initial identification of relationships. The analysis aggregates data from all establishments to increase statistical power. For example, the *Salmonella* verification data were aggregated across establishments for the analysis. Aggregating data is a valid approach as an initial assessment of raw data. However, it may produce a biased estimate of association, so further confirmatory analysis with more sophisticated statistical tools is warranted.

In conducting the lift analysis, it would seem particularly important to ensure that associations between attributes that are predictive be used in a manner that is consistent with their current use. It is not surprising that the *Salmonella* verification testing program was among the most effective indicators of process control examined by FSIS, since it is one of the few metrics evaluated that was specifically designed as a process control indicator (i.e., control of fecal contamination). However, what is not adequately stated in the report is that the verification testing program does not regard *Salmonella* as an adulterant in these products. This seems to have led to substantial confusion in the report, particularly with regard to the time window that should be employed between the issuance of an NR and when the presence of a positive *Salmonella* finding is indicative of a loss of process control. In the *Salmonella* verification testing program, each raw meat and poultry product has its own unique criterion for the level of control deemed acceptable. This led to the committee's being unclear about the basis of the lift analyses for these commodities. The technical report *PHRBIS* (FSIS, 2008b) indicates that the lift analysis was based on the occurrence of the first positive *Salmonella* sample dur-

ing various 7- to 84-day windows following the occurrence of an NR. However, the presence of a single positive sample is not consistent with the way the *Salmonella* verification testing program is conducted—it examines whether the number of *Salmonella*-positive samples in the specified moving window exceeds the current standard for that specific commodity. Thus, it would not be surprising to see a positive sample after an NR for ground turkey, a product class with a baseline frequency of *Salmonella* occurrence of approximately 50 percent; however, this would not be indicative of a process that is out of control. Conversely, one would not expect to see a positive *Salmonella* sample from a beef carcass, a commodity that has a baseline frequency of 1 percent; in this case, the occurrence of a positive result might be predictive of a loss of process control. It is also worth noting that the original lift analyses did not take into account the variance in the *Salmonella* verification testing regime or the confidence levels associated with this microbiological criterion. The current performance standards for *Salmonella* verification testing in raw products are based on an 80 percent confidence interval, that is, a 20 percent probability that failing a *Salmonella* verification set occurred by chance; therefore, even if an attribute correlated with a failure to meet the *Salmonella* process control standard, that relationship may have occurred by chance alone. Not until an establishment has failed three consecutive *Salmonella* verification testing sets is it considered, from a regulatory standpoint, to be out of process control.

Finding 4: *Lift analysis is a data-mining tool that is appropriate to use for finding initial associations among events that occur infrequently. However, the identification of process control indicators requires more complex statistical analysis as well as data that have been collected for the purpose of identifying such indicators. The committee emphasizes that although mining or extracting data from currently existing data sets to design the inspection system is commendable and the use of lift statistics for data mining is justified, the system could be significantly improved if more complete statistical analyses were conducted in addition to the lift analysis and if additional data were collected for more useful predictors. Also, the proposed algorithm does not currently include an adequate process control indicator for some foods (e.g., RTE foods).*

RECOMMENDATION 4: The committee recommends that FSIS perform further statistical analysis for the purpose of validating proposed indicators of process control as well as exploring the utility of new process control indicators through new studies, expert consultation, and lit-

erature review. In some instances, FSIS should take advantage of data for other potential process indicators generated by industry or others. After a preliminary association with an outcome is established (predictability is demonstrated statistically), FSIS should conduct further analysis to confirm the utility of product-based process indicators and ultimately conclude the analysis with a multivariate model or similar method. FSIS should then modify the algorithm as new predictors are identified and test the adequacy of its current (and future) algorithm.

Microbiological Testing

Several of the process control indicators included in the proposed algorithm are based on the results of microbiological testing programs. As discussed above, *Salmonella* verification testing appears to be particularly well suited as a predictor of loss of process control and an alert to take corrective actions prior to exceeding a public health limit. However, its application within the algorithm needs to be consistent with its current use in the FSIS regulatory framework and should take into account the statistical characteristics associated with sampling programs and the operational assumptions made when establishing microbiological performance standards. For the sake of transparency and to confirm the scientific basis of an attribute that is being used to categorize an establishment based on risk, FSIS should ensure that it has fully articulated the statistical operating characteristics of its *Salmonella* verification testing when it is being used in a framework other than the current regulatory framework. FSIS should also identify, to the degree feasible, the sources of type I and type II errors associated with the testing regime and the relative sensitivities of the analytical methods. There is also a need throughout the technical report and in its accompanying analysis to carefully differentiate the assumptions in the *Salmonella* verification testing program, where it serves as an indicator of control of fecal contamination in raw products, from its detection during the testing of RTE foods, where it is considered a pathogen whose presence indicates that the process has already failed.

In addition to the *Salmonella* verification testing of raw products, the results of microbiological testing of ground beef for *E. coli* O157:H7 and RTE foods for *L. monocytogenes*, *Salmonella*, and *E. coli* O157:H7 were examined as potential indicators of process control. For these microbiological testing activities, detection of a positive sample is considered by definition an indication of loss of process control (i.e., there is "zero tolerance"). However, these testing programs are based on an evaluation of

individual lots of product and are not specifically designed to measure process control (ICMSF, 2002). The decision criteria for the assignment of establishments based on these testing results have operationalized the lot-by-lot sampling program by effectively assuming there are no type II errors (false positive results). While this is a practical risk-management approach for the implementation of regulatory programs, its application in the algorithm suggests that FSIS has not fully considered the general concepts underlying process control indicators and the statistical basis for microbiological testing. This could be corrected by FSIS's articulating its underlying assumptions regarding the interpretation of microbiological testing programs. The FSIS technical report could benefit greatly from a more in-depth consideration of the statistics that underlie microbiological testing and the assumptions made in using such data as decision criteria in the FSIS algorithm.

For greater transparency of the statistical basis for FSIS's interpretation of the testing programs in which detection of a microorganism is assumed to represent a loss of process control, FSIS should include a discussion of type I errors (the incidence of false negative results). As pointed out by the International Commission on Microbiological Specifications for Foods (ICMSF, 2002), the probability of detecting a pathogen in a food depends on the concentration (mean and variance) of the pathogen in the food, the assumed distribution, the number and size of the samples examined, and the sensitivity of the analytical method. Thus, the absence of a positive result does not necessarily indicate that a food is free of the pathogen of concern and that the process is therefore in control. For example, the current protocol of examining a 25-g sample effectively provides 95 percent confidence that a contaminated lot would be detected if the mean concentration is 1 CFU (colony forming unit)/3 g. However, if a ground beef lot had an *E. coli* O157:H7 concentration of approximately 3 CFU/100 g, there is 50 percent likelihood that the contamination would not be detected using the current protocol for this pathogen. Transparency in the role of microbiological sampling programs as process control metrics requires information on the confidence that a positive sample will be detected, based on the mean concentration and standard deviation that were assumed in designing the sampling protocols included in the report *PHRBIS*.

Finding 5: *FSIS currently tests different classes of products for different microorganisms, for different purposes, and with different underlying assumptions. The applicability of these data to the FSIS algorithm is dependent on the specific protocols, assumptions, and statistical character-*

istics of each testing program. The FSIS technical report did not provide in-depth consideration of the statistics that underlie the specific microbiological testing protocols used and the assumptions made when using such data (e.g., the magnitude of type I and type II errors, assumed pathogen concentration means and standard deviations, confidence intervals, the specificity and sensitivity of the microbiological protocols).

RECOMMENDATION 5: The FSIS technical report should describe the characteristics of the microbiological criteria being used as determinants of loss of process control. These characteristics include in-depth consideration of the statistics underlying the specific microbiological testing protocols used and the assumptions that are made in using such data (e.g., the magnitude of type I and type II errors; assumed pathogen concentration means and standard deviations). As recommended in the following sections, FSIS should also consider investing in research to find and validate alternative microbiological indicator tests whose target microorganism occurs at a substantially greater frequency than those currently in use. If successful, this would provide FSIS with a better process control indicator that could be used to analyze trends and to take actions (e.g., perform an in-depth inspection) before public health limits are exceeded.

FINDINGS AND RECOMMENDATIONS ON SPECIFIC PROCESS INDICATORS

Salmonella Testing Results

Use and Scientific Evidence

In accordance with the PR/HACCP rule, FSIS has set *Salmonella* testing standards to be met by establishments producing certain raw products. As introduced above, the standards were derived from national estimates of prevalence by product and were calculated so that an establishment operating at the national baseline *Salmonella* prevalence has an 80 percent probability of meeting the standard. To assess compliance with the standards, FSIS implemented the *Salmonella* verification testing program in 1998, in which establishments are monitored by testing sampling sets for *Salmonella* at a specific frequency and comparing them with performance criteria based on product class (FSIS, 2008b). The time

required to complete a sampling set ranges from two months to one year. FSIS monitors eight classes of raw meat and poultry products, and test data are available for about 80 percent of establishments. The sampling protocol is described in Appendix D of the technical report *PHRBIS* (FSIS, 2008b). In the current *Salmonella* verification program, FSIS categorizes establishments producing those eight product classes into three categories by comparing their *Salmonella* verification results to the *Salmonella* prevalence rates within each class of product:

- ***Category I***—Establishment achieved *Salmonella* prevalence rates <50 percent of the performance standard (based on the national estimate baseline for a given product) in the two most recent *Salmonella* sets.
- ***Category II***—Combinations of results for two most recent sets do not qualify as Category I, but establishment has not failed the most recent *Salmonella* set.
- ***Category III***—Establishment failed most recent *Salmonella* set.

Table 3 shows the national prevalence rates, number of samples per set, and number of positives to be categorized as Category I, II, or III. Based on 2006 results, only 3 percent of establishments were in Category III.

TABLE 3 Cut Points of Set Results Defining *Salmonella* Verification Categories by Product Class

Product	Baseline Prevalence (%)	Number of Samples per Set	Number of Positives Relative to Standard		
			≤50%	>50%	Exceeds
Steers, heifers	1.0	82	0	1	2 or more
Cows, bulls	2.7	58	1 or fewer	2	3 or more
Ground beef	7.5	53	3 or fewer	4-5	6 or more
Market hogs	8.7	55	3 or fewer	4-6	7 or more
Broilers	20.0	51	6 or fewer	7-12	13 or more
Ground chicken	44.6	53	13 or fewer	14-26	27 or more
Ground turkey	49.9	53	15 or fewer	16-29	30 or more
Young turkeys	19.6	56	7 or fewer	8-13	14 or more

SOURCE: Pathogen Reduction; Hazard Analysis and Critical Control Point (PR/HACCP) Systems; Final Rule, Section 310.25 (b) 2 (meat), Section 381.94 (b) 2 (poultry).

Although a decrease in the incidence of foodborne infections is often cited as evidence that the *Salmonella* verification testing program is an effective process control indicator, various factors may confound the value of that association. The ability to relate these results to improvement in public health is limited by the lack of a good food attribution model that can directly connect cases of salmonellosis to specific food products. However, in the absence of direct measures of attributable public health outcomes, the data available on the exposure of the public to raw meat and poultry products containing *Salmonella* provide a reasonable measure of the relative risk reduction associated with those products. One factor limiting the utility of the data is that although FSIS has published *Salmonella* results since 1996, because of changes in sampling designs and the segments of the industry being reviewed, data are not always comparable from year to year. Progress was clearly evident when FSIS tracked the percentage of *Salmonella* positives in verification sam-

ples by product class. For example, in 2006, 100 percent of the sample sets submitted by ground turkey establishments, 88.6 percent of those from broiler establishments, 94.5 percent of those from market hog establishments, 91.2 percent of those from cow or bull establishments, and 93.9 percent of those from steer or heifer establishments passed the *Salmonella* standard (Category I or II). By the end of 2007, 100 percent of ground turkey establishments, 97.2 percent of broiler establishments, 97.3 percent of market hog establishments, 95.2 percent of cow or bull establishments, and 94.7 percent of steer or heifer establishments passed the standard (FSIS, 2008c).

The FSIS proposes the use of establishment categorization based on *Salmonella* testing as an indicator of process control (FSIS, 2008b; E. Dreyling, FSIS, personal communication, February 18, 2009). The level of inspection to which an establishment would be assigned would depend on its *Salmonella* testing results:

- LOI 1: Establishment was below the *Salmonella* percent positive LOI 1 percentile cut point on most recent sample set, unannounced sampling, or other *Salmonella* testing programs
- LOI 2: Establishment was above the *Salmonella* percent positive LOI 1 percentile cut point on most recent sample set, unannounced sampling, or other *Salmonella* testing programs and not in *Salmonella* Category III
- LOI 3: Establishment is in *Salmonella* Category III

FSIS proposes to determine the percentile cut point for the three levels by analyzing the number of *Salmonella* verification positive results for each specific class of product (e.g., broilers, ground beef) and finding the inflection points in the curve representing the number of establishments versus the rate of positive *Salmonella* verification testing results over a period of three months. An example given by FSIS for ground beef is shown in Figure 1.

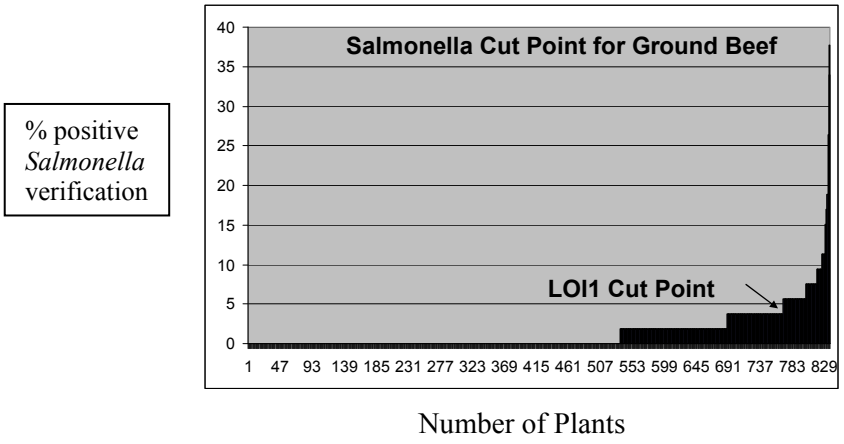

FIGURE 1 Inflection points in the *Salmonella* verification testing data used to determine cut points in the proposed algorithm for ground beef. SOURCE: E. Dreyling, FSIS, personal communication, December 13, 2008.

Committee's Discussion

Salmonella verification testing was designed to be a process control indicator in raw products, so its use in the algorithm is appropriate, as long as positive *Salmonella* test results occur with sufficient frequency and at high enough levels. As the prevalence of *Salmonella* decreases, alternatives to *Salmonella* testing should be sought. Also, the number of products for which *Salmonella* testing is an indicator (i.e., there are currently only eight raw meat and poultry product classes in the program) is appropriately limited, so alternative indicators based on an objective measurement (e.g., other microbiological testing approaches) will have to be identified for RTE foods. The current use of discrete testing sets decreases the overall power of the testing program as an indicator of process control compared to the daily testing required by the generic *E. coli* testing program.

As mentioned above, there does appear to be a fundamental problem in the way the association of these data with other indicators was evaluated using lift analysis. FSIS would also benefit from an analysis of how the results of the first *Salmonella* verification testing set relate to the potential use of this metric as an enforcement tool (i.e., the failure of three *Salmonella* verification testing sets). Additional explanations related to

the method for differentiating Category I from Category II should be provided—for example, whether the 50 percent frequency cut point is better determined by halving the number of positive samples or by shortening the length of the sampling window. FSIS also needs to provide a better explanation of the utility of these data as an indicator of process control when the frequency of *Salmonella* detection falls below approximately 10 percent. Alternatively, FSIS should explore whether the *Salmonella* verification testing data would provide greater discriminatory power if they were quantitative instead of qualitative.

Finding 6: *The use of* Salmonella *verification testing results to rank establishments in different levels of inspection is justified, but could be enhanced by additional explanation and characterization.*

RECOMMENDATION 6: The committee recommends that FSIS provide a more detailed analysis of how it will employ the results of the *Salmonella* verification testing program, including a consideration of the underlying statistics of its application. FSIS would also benefit from the following data collection and research activities to alleviate some of the limitations of *Salmonella* verification testing as an indicator of process control:

- Sponsor research programs to develop and validate faster, quantitative testing methodologies for *Salmonella.* Inclusion of newer, molecular-based methods for typing and subtyping *Salmonella* isolates may also help distinguish the underlying reasons for loss of process control (see also below).
- Continue to develop a process- and commodity-specific national baseline for *Salmonella* levels to verify the effectiveness of FSIS efforts to ensure food safety.
- Collect data on *Salmonella* serotypes by raw product and at different steps throughout the process, including the incoming step. *Salmonella* serotype data could help determine whether a loss of control has occurred within an establishment. It could provide evidence of the source of contamination (by traceback investigations) and a contamination pattern in an establishment. In addition to their potential value in foodborne disease attribution (i.e., determining which products are more likely to be associated with foodborne disease), FSIS should evaluate the use of *Salmonella* serotype data as a potential indicator of process control.

- Explore the use of prevalence and load of *Salmonella* in the incoming raw material as an indicator of process control.
- FSIS should provide a more in-depth description of the sampling and testing statistics that are the basis for the *Salmonella* verification testing program, as well as how these characteristics and assumptions influence the use and interpretation of the data for categorizing establishments. This should include consideration of the magnitude of type I and type II errors, assumed pathogen concentration means and standard deviations, specificity and sensitivity of the microbiological protocols, and so forth.

Listeria monocytogenes Testing Results for RTE Products

Use and Scientific Evidence

FSIS considers the presence of a pathogen in a ready-to-eat food product an indicator of a public health risk; therefore by definition, it indicates a potential loss of process control. The levels of inspection proposed by FSIS relating to *Listeria monocytogenes* (Dreyling, 2008; FSIS, 2008b; E. Dreyling, FSIS, personal communication, February 18, 2009) are as follows:

- LOI 1: Establishment has not had a positive FSIS test result for *L. monocytogenes* in RTE products or a positive *L. monocytogenes* food contact surface sample; or if it has, any related FSA and follow-up sampling has been completed more than 120 days previously, all related enforcement actions are closed, and establishment meets all other LOI 1 criteria.
- LOI 2: For an establishment that has had an FSIS positive *L. monocytogenes* test result in an RTE product or an *L. monocytogenes*-positive food contact surface sample, any related FSA and follow-up sampling has been completed in the previous 120 days and all related enforcement actions are deferred or in abeyance.
- LOI 3: Establishment has had an FSIS positive *L. monocytogenes* test result in an RTE product or an *L. monocytogenes*-positive food contact surface sample.

The relative rates of *L. monocytogenes* infection in 2007 (CDC, 2008) were 42 percent lower than in 1996-1998, which might be interpreted as a success for plant hygiene and sanitation controls and regulations. However, there was no change in the 2007 incidence compared to rates reported in 2004-2006. There were continuing reductions in the rate of *L. monocytogenes* contamination in RTE meat products during 1990-2007 (FSIS, 2008d).

Any finding of this pathogen in an RTE food immediately places the establishment into LOI 3, requiring an in-depth inspection (FSIS, 2008b). As part of its RTE regulatory sampling, FSIS has four *L. monocytogenes* testing programs: ALLRTE, RTE001, Routine *L. monocytogenes* (RLm), and Intensified Verification Testing (IVT). Under the ALLRTE program, inspectors sample products at random (except for products that do not support the growth of *L. monocytogenes,* such as fats and oils, dried soup mixes, and popped pork skins). RTE001 is a risk-based program in which establishments are selected for testing based on risk factors identified in FSIS's *L. monocytogenes* risk assessment. Products identified as presenting a higher risk are sampled more often than products considered to be less risky. Four variables are used to determine relative risk: product type; production volume; alternative 1, 2, or 3 and the processing plant's history of *L. monocytogenes* testing results (E. Dreyling, FSIS, personal communication, December 13, 2008).

Committee's Discussion

FSIS considers the presence of *L. monocytogenes* in a finished product or on a food contact surface after the posttreatment process an indication of a loss of process control. Comments about this basic assumption and others related to the use of microbiological testing as a means of verifying process control have been made earlier in the section on microbiological testing. As indicated above, this metric is primarily an outcome but is being used as a predictor of loss of process control in the proposed FSIS algorithm. Furthermore, as observed in the lift analysis, the low incidence of positive *L. monocytogenes* samples makes it difficult to establish a significant association with other potential predictors of loss of process control (see FSIS, 2008b; Appendix E). FSIS's decision, based on public health concerns, to operationalize its testing programs to identify any isolation of *L. monocytogenes* from RTE foods as a loss of process control is a valid risk-management decision; however, FSIS should fully explore the rationale for and impact of that decision in terms of the achieved risk reduction and the assignment of establish-

ments to risk categories. It is also worth noting that several risk assessments of RTE foods have indicated that the risk of listeriosis in such products is highly dependent on whether the product supports the growth of *L. monocytogenes* (WHO-FAO, 2004). FSIS has not indicated how this risk factor was considered in the designation of establishments based on the results of the *L. monocytogenes* testing programs or what percentage of RTE food products whose positive tests resulted in source establishments being categorized as LOI 3 were foods that supported growth of the pathogen.

As with other pathogens, not all meat and poultry product processors are tested for *L. monocytogenes*, only those producing RTE foods (FSIS, 2008d). The incidence of listeriosis decreased during the decade between 1996-1998 and 2007 (CDC, 2009), presumably due in part to the various preventive controls applied to meat and poultry processing plants. The current low frequency of events (for example, only 0.37 percent of 2,963 ALLRTE samples in 2007 tested positive for *L. monocytogenes*; E. Dreyling, FSIS, personal communication, December 13, 2008) presents a challenge to using the presence of a pathogen as an indicator of process control, since there may be no detectable correlation with loss of process control because of the low number of positives. As mentioned above, the testing protocol for *L. monocytogenes* is restricted in sample size and frequency, limiting the ability to directly relate the presence of the pathogen to ongoing processing—that is, absence of the pathogen does not necessarily indicate that the process is in control, and vice versa.

Finding 7: *The use of* L. monocytogenes *testing results in RTE foods to rank establishments in different levels of inspection has been justified based on the potential direct health risk of the pathogen, a valid risk-management decision criterion, particularly for specific production lots. However, the initial data analysis has not provided scientific support for use of this decision criterion to predict loss of process control or for its association with other indicators. As previously mentioned, FSIS has not discussed the sampling and related statistics that should be considered when using any microbiological sampling program to verify process control. The FSIS algorithm does not consider that all RTE products do not present the same level of risk to public health.*

RECOMMENDATION 7: Given the limitations of the use of *L. monocytogenes* testing results as a process indicator, the committee recommends that FSIS do the following:

- Consider redesigning the testing protocols by prioritizing inspection of RTE products according to product risk, that is, with consideration of a product's ability to support the growth of *L. monocytogenes* (e.g., the food's acidity level, the use of preservatives). This risk-based approach is being adopted by others (e.g., the Codex Alimentarius Commission) and merits consideration by FSIS.
- Consider analyzing industry data on *L. monocytogenes* or *Listeria* spp. in the environment and/or *Listeria* spp. on food contact surfaces or in the final product to determine whether these data could serve as a useful indicator of process control. For example, FSIS could use data collected more frequently for routine sampling of processing environments that may be reservoirs of *L. monocytogenes.* Although unpublished results of PFGE analyses of *L. monocytogenes* isolates from samples taken from 127 plants suggested that contamination of product or contact surfaces did not originate in the plant environment (E. Dreyling, FSIS, personal communication, December 13, 2008), further analysis is needed to confirm or refute this finding due to the small sample size. This is particularly important when considering that the scientific literature is replete with examples suggesting that controlling harborage sites in the processing environment is critical to managing this foodborne pathogen (Giovannacci et al., 1999; Lundén et al., 2003; Peccio et al., 2003; Thévenot et el., 2006; Keto-Timonen et al., 2007).
- Conduct lift analysis and other appropriate analyses by product class to determine whether there is a correlation between *L. monocytogenes* and specific NRs for products with inherently high public health risks. This will allow comparisons with statistical analyses already conducted for all products.
- Sponsor research programs to develop and validate improved and quantitative testing methodologies for *L. monocytogenes* as a potential means of increasing the discriminatory power of this indicator. Improved sampling and testing methods might increase the confidence in the methodologies and decrease the number of false positives and false negatives. Rapid methodologies will decrease the temporal gap between the loss of control and the inspection, and therefore it is more likely that the associated problem (and the solutions) could be found. These kinds of improvements will enhance the reliability of the algorithm.

- FSIS should provide a more in-depth description of the sampling and testing statistics that are the basis for *L. monocytogenes* regulatory testing programs, as well as how the characteristics and assumptions of the sampling and testing statistics influence the use and interpretation of these data for categorizing establishments based on this metric. This should include consideration of the magnitude of type I and type II errors, assumed pathogen concentration means and standard deviations, specificity and sensitivity of the microbiological protocols, and so forth.

E. coli O157:H7 Testing Results in Raw Ground Beef or Its Components

Use and Scientific Evidence

The testing programs for *E. coli* O157:H7 are targeted primarily at raw ground beef and, more recently, the trim used in this raw product. Testing of trim and/or finished product is used extensively by industry as a control measure for diverting contaminated meat to other uses that have a lethal treatment step. The following criteria for *E. coli* O157:H7 have been proposed by FSIS (Dreyling, 2008; FSIS, 2008b; E. Dreyling, FSIS, personal communication, February 18, 2009) to define the level of inspection categories:

- LOI 1: Establishment has not had a positive FSIS *E. coli* O157:H7 verification result; or if it has, any related FSA and follow-up sampling has been completed more than 120 days previously, any related enforcement actions are closed, and establishment meets all other criteria for LOI 1.
- LOI 2: Establishment had an FSIS positive test for *E. coli* O157:H7 in RTE products or ground beef or components, and any related FSA and follow-up sampling has been completed in the previous 120 days and all related enforcement actions are deferred or in abeyance.
- LOI 3: Establishment has had an FSIS positive test for *E. coli* O157:H7 in RTE products or ground beef or components.

As mentioned above, major declines in the incidence of certain foodborne diseases occurred between 1996 and 2004, including Shiga toxin-

producing *E. coli* O157 (STEC O157) (CDC, 2008). For STEC O157, there has been no significant decline in cases since 2004, despite interventions to reduce ground beef contamination (CDC, 2008).

No statistical analysis was performed by FSIS to correlate the presence of the pathogen with process control. Lift statistics were conducted by FSIS between *E. coli* O157:H7 and consumer complaints, NRs, recalls, and enforcement actions. The only suggestive results for predictors of the presence of *E. coli* were obtained for NRs and enforcement actions restricted to a 14-day time window (see FSIS, 2008b; Appendix E).

In the case of ground beef, *E. coli* O157:H7 is by regulation considered a pathogen even if the product is intended to be further processed or cooked by the consumer. FSIS's rationale for including this pathogen in the algorithm is that any level of *E. coli* O157:H7 presents a high risk to the public.

Committee's Discussion

The limitations of this indicator are similar to those that apply to the use of other pathogens as indicators of process control. Prior comments on the interpretation of microbiological results for pathogens with a zero tolerance as defined by a standardized testing program are valid for the testing of raw ground beef for *E. coli* O157:H7. While the occasional detection of a positive sample cannot definitively establish a loss of process control, the use of testing results for *E. coli* O157:H7 for this purpose is a valid risk-management decision to operationalize the decision criterion for the testing program and to safeguard the public from a pathogen that is capable of infecting individuals at a low dose. However, FSIS should be prepared for instances in which the subsequent FSA findings cannot document a loss of process control, particularly given the potential for *E. coli* O157:H7 to be spread in grinding operations.

The low frequency of contamination events is a major challenge, particularly in establishing an association with other potential indicators of a loss of process control. As noted for *L. monocytogenes*, because of these sampling limitations, a failure to detect *E. coli* O157:H7 does not necessarily demonstrate that a process is in control.

As mentioned above, many producers of raw ground beef routinely test incoming raw ingredients for *E. coli* O157:H7 as a control measure to reduce the potential presence of the pathogen in the final product. However, because of the probabilistic nature of microbiological testing, there is a distinct possibility that the raw ingredients could test negative for *E. coli* O157:H7, but samples of the final product would be positive.

Again, this reflects the characteristics and limitations of sampling and its dependence on the random nature of the contamination. To address the possibility that contaminated trim may not be detected, FSIS includes in the LOI 3 category those establishments that appeared in the STEPS database more than once in the preceding 120 days (FSIS, 2008b). However, it is not clear that including the grinding establishment in the LOI 3 category and therefore increasing its inspection would solve the loss of process control. The basis for the number of times that a trim provider is listed in the STEPS database (i.e., why two instead of one or three) or the duration of time (i.e., 120 days) selected as a criterion for inclusion in the database is also not clear.

It is not evident to the committee whether the algorithm considers instances in which a ground beef product has been found by the grinding facility to be adulterated by *E. coli* O157:H7, but subsequently sent for further processing and pathogen elimination. In this case, the grinding establishment would not be in loss of process control if it appropriately diverts product that has tested positive for the pathogen.

Finding 8: *The use of* E. coli *O157:H7 testing results for ground beef and its components to rank establishments in different levels of inspection has been justified based on the potential direct health risk of the pathogen; this is a valid risk-management decision criterion, particularly for specific production lots. However, the initial data analysis has not provided scientific support for the ability of this decision criterion to predict loss of process control or for its association with other indicators. As previously mentioned, FSIS has not discussed the use of this indicator in relation to the sampling and related statistics that should be considered when using any microbiological sampling program to verify process control.*

RECOMMENDATION 8: The committee recommends improving the use of the presence of *E. coli* O157:H7 as an indicator of process control in raw ground beef by the following measures:

- Provide a more in-depth description of the sampling and testing statistics that are the basis for the *E. coli* O157:H7 regulatory testing program and of how the characteristics and assumptions of the sampling and testing statistics influence the use and interpretation of the data for categorizing establishments based on this metric. This should include consideration of the magnitude

of type I and type II errors, assumed pathogen concentration means and standard deviations, specificity and sensitivity of the microbiological protocols, and so forth.

- Assess the association of the practice of trim testing with the frequency of *E. coli* O157:H7 in final product to evaluate the use of trim testing as a risk determinant. This can be done by using appropriate study designs to address potential confounders and interactions. If such an association is found, incorporate this into the algorithm as applied to ground beef as a simple predictive criterion based on whether an establishment tests incoming trim to a sufficient degree.
- Because of the low frequency of *E. coli* O157:H7 isolations in ground beef, evaluate data on other potential indicators of fecal contamination such as generic *E. coli* (see below).
- Support research to develop and validate improved sampling and testing methodologies for *E. coli* O157:H7. Improved sampling and testing might increase confidence in the methodologies and decrease the number of false positives and false negatives. Rapid methodologies will decrease the temporal gap between the loss of control and the inspection, and therefore it is more likely that the associated problem (and the solutions) could be found. These kinds of improvements will enhance the reliability of the algorithm.

E. coli O157:H7 and *Salmonella* Testing Results for RTE Products

Use and Scientific Evidence

In addition to testing raw ground beef, FSIS also tests specific RTE foods for the presence of *E. coli* O157:H7 and *Salmonella*. The following criteria for *Salmonella* and *E. coli* O157:H7 (Dreyling, 2008; FSIS, 20008b; E. Dreyling, FSIS, personal communication, February 18, 2009) define the level of inspection categories:

- LOI 1: Establishment has not had a positive FSIS test result for *Salmonella* or *E. coli* O157:H7 in RTE products; or if it has, any related FSA and follow-up sampling has been completed more than 120 days previously, any related enforcement actions are closed, and establishment meets all other criteria for LOI.

- LOI 2: For an establishment that has had a positive FSIS test for *Salmonella* or *E. coli* O157:H7 in RTE products, any related FSA and follow-up sampling has been completed in the previous 120 days and all related enforcement actions are deferred or in abeyance.
- LOI 3: Establishment had an FSIS positive test for *Salmonella* or *E. coli* O157:H7 in a RTE product.

Unlike the *Salmonella* verification testing program for raw meat and poultry products where it is used as an indicator of fecal contamination, *Salmonella* in RTE products is considered an adulterant.

In summary, RTE foods are intended to be consumed without further processing, so any level of *Salmonella* or *E. coli* O157:H7 contamination is regarded as a risk to consumers, especially those that are more vulnerable. FSIS considers RTE products adulterated if either of these pathogens is detected and therefore infers a loss of process control.

Committee's Discussion

The presence of *Salmonella* or *E. coli* O157:H7 in an RTE product that has undergone a lethal treatment step (e.g., cooking) that substantially reduces levels of both pathogens is indicative of posttreatment recontamination and thus a loss of process control. In other RTE products that receive a less stringent treatment (e.g., semidry fermented sausage), the effectiveness of the treatment depends on a number of factors, including ensuring a low level of contamination in raw ingredients. In these products, there is a small likelihood that a positive sample might be detected when the process was under control, but such a finding would more likely indicate either a loss of control or an inadequately validated process. While the occasional detection of a positive sample cannot scientifically be stated as a definitive loss of process control, using this detection as an indicator of process control is a valid risk-management decision to operationalize the decision criterion for the testing program and to safeguard the public from a pathogen capable of infecting individuals at a low dose. However, FSIS should be prepared for instances in which subsequent FSA findings cannot document a loss of process control, particularly for RTE foods that have less stringent inactivation treatments.

As with *E. coli* O157:H7 in ground beef and *L. monocytogenes* in RTE meats and poultry, testing for *Salmonella* or *E. coli* O157:H7 in RTE foods has all the advantages and limitations discussed earlier in the

general section on the use of microbiological testing. They include the possibility that products that test negative are not under control, as well as difficulties in demonstrating statistically significant associations with other predictive indicators due to the rarity of detecting these pathogens in RTE foods.

Finding 9: *The use of* Salmonella *and* E. coli *O157:H7 testing results in RTE foods to rank establishments in different levels of inspection has been justified based on the potential direct health risk of these pathogens; this is a valid risk-management decision criterion, particularly for specific production lots. However, the initial data analysis has not provided scientific support for use of this decision criterion to predict loss of process control or for its association with other indicators. As previously mentioned, FSIS has not discussed the sampling and related statistics that should be considered when using any microbiological sampling program to verify process control. The current use of these data to determine the risk associated with establishments producing RTE foods does not take into account the inherent differences in risk associated with the different classes of meat and poultry products that fall within the broad designation of RTE foods.*

RECOMMENDATION 9: The committee recommends improving the use of the presence of *Salmonella* and *E. coli* O157:H7 as an indicator of process control in RTE products by the following measures:

- Provide a more in-depth description of the sampling and testing statistics that are the basis for the *Salmonella* and *E. coli* O157:H7 testing programs in RTE foods as well as how the characteristics and assumptions of the sampling and testing statistics influence the use and interpretation of these data for categorizing establishments based on this metric. This should include consideration of the magnitude of type I and type II errors, assumed pathogen concentration means and standard deviations, specificity and sensitivity of the microbiological protocols, and so forth.
- Because of differences in the inherent risk of various subcategories of RTE products, the product classes should be subdivided to determine whether better predictors can be identified for specific products.

- Because of the low frequency of *Salmonella* and *E. coli* O157:H7 isolations in RTE products, evaluate data on other potential indicators of process control. For example, and in conformance with the committee's recommendation below, deviations from control point limits in an RTE HACCP plan may be better suited as indicators of process control.
- Support research to develop and validate improved sampling and testing methodologies for *Salmonella* and *E. coli* O157:H7. Improved sampling and testing methods might increase the confidence in the methodologies and decrease the number of false positives and false negatives. Rapid methodologies will decrease the temporal gap between the loss of control and the inspection, and therefore it is more likely that the associated problem (and the solutions) could be found. These kinds of improvements will enhance the reliability of the algorithm.

Noncompliance Records

Use and Scientific Evidence

FSIS personnel perform thousands of inspection procedures each day in federally inspected slaughter and processing establishments to determine whether the plants are in compliance with regulatory requirements. An NR is written to document noncompliance, and the establishment is notified so that it takes action to remedy the situation and prevent future recurrence. The issuance of an NR is prompted by any one of more than 500 citation violations, all of which relate to adherence to regulatory requirements (FSIS, 2008b). A committee review of NRs selected by FSIS and industry representatives reveals that some, but not all, NRs address public health risks. Because many NRs are not related to food safety or public health, FSIS performed the statistical analysis using the totality of NRs and also using exclusively health-related NRs to determine any improvement of predictability with use of only the selected NRs. Two sets of health-related NRs were created and analyzed separately: a group of nine FSIS experts with diverse backgrounds in the regulation of meat, poultry, and egg products assigned each NR a weight of 3, 2, 1, or 0 indicating the degree of loss of process control it represented, and the median score of each was used to identify those with a weight of three (W3NR). A second set of health-related NRs was identified by an industry coalition.

FSIS proposes to categorize plants according to the level of inspection needed (LOI 1, LOI 2, or LOI 3) (Dreyling, 2008; FSIS, 2008b; E. Dreyling, FSIS, personal communication, February 18, 2009) in response to their NR rates in the following way:

- LOI 1: An establishment whose public health NR rate (over a rolling three-month average) is less than the LOI 1 percentile cut point, when all other indicators suggest that the process is in control.
- LOI 2: An establishment whose public health NR rate (over a rolling three-month average) is greater than the LOI 1 percentile cut point but less than the LOI 3 percentile cut point.
- LOI 3: An establishment with health-related NR rates (over a rolling three-month average) higher than the highest percentile of health-related NR rates (e.g., those citing specified risk material [SRM], insanitary dressing, zero tolerance, residue).

FSIS included a statistical analysis to justify the use of NRs as predictors of loss of process control in Appendix E of the technical report *PHRBIS* (FSIS, 2008b). FSIS proposes to determine the percentile cut point for the three levels by analyzing the number of health-related NRs (W3NRs, as identified by FSIS) issued to each specific type of establishment (e.g., broiler processing, beef slaughter, beef grinding) and finding the inflection points in the curve representing the number of establishments versus the percentage of NRs over a period of three months. An example for beef slaughter establishments given by FSIS is shown in Figure 2.

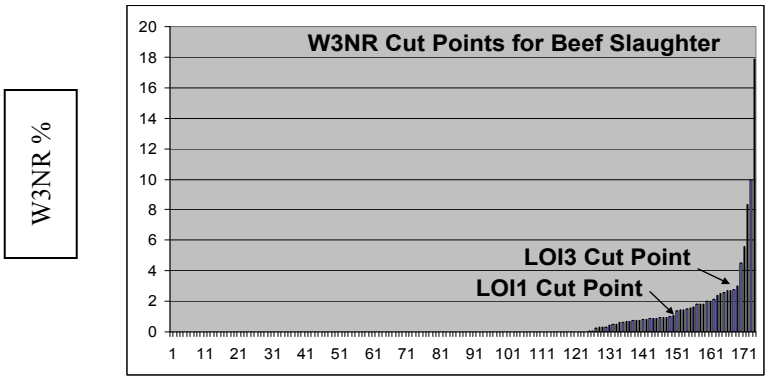

FIGURE 2 Inflection points in the W3NR data used to determine cut points in the proposed algorithm for beef slaughter establishments.
SOURCE: E. Dreyling, FSIS, personal communication, December 13, 2008.

Once the NRs were selected, FSIS performed a lift analysis of the various sets of NRs (i.e., W3NRs and those selected by an industry coalition as described above) to estimate their power to predict the loss of process control. The lift analysis was performed using aggregated data, that is, data from all types of establishments, against the following variables: pathogen test results, consumer complaints, food safety recalls, enforcement actions, and RTE *L. monocytogenes* alternatives (FSIS, 2008b). Results from the lift analysis indicate that the rate of W3NRs received by an establishment could be used to predict positive *Salmonella* verification test results. As an example, the lift analysis showed that receipt of one W3NR within the previous seven days correlated with a threefold increase in the likelihood of recording a positive test result for *Salmonella* within the following two weeks. Different periods of time, or time windows, were used and a decrease in lift (or predictability) was noted with an increase in time window. The lift was greatest if the W3NR group was used for the analysis rather than either the aggregated NRs or the industry-proposed NRs. Therefore, W3NRs may be predictive of loss of process control and of an unsafe product. None of the analyses with other outcome variables found a significant lift, suggesting that health-related NRs would not necessarily be a good predictor of consumer complaints, food safety recalls, enforcement actions, RTE *L.*

monocytogenes alternatives, or future product contamination with *E. coli* O157:H7 or *L. monocytogenes*. The significant association between NRs and *Salmonella* verification testing was the FSIS's basis for using selected health-related NRs as an indicator of process control and therefore including this indicator in the FSIS proposed algorithm.

Lift analysis was also performed using only those individual NRs that were issued most frequently (more than 1,000 times over seven days), and the results were reviewed by the committee (FSIS, 2008b). This analysis showed that some of the NRs clearly contribute to the predictive ability of W3NRs much more than others. These promising results show that an even more limited number of NRs may be identified as significantly predictive. For example, an NR issued due to visible fecal material entering the chiller in a poultry operation is 4.8 times more likely to be followed by a positive test for *Salmonella*, with a highly significant association ($p < 0.001$; 95 percent CI: 4.251-5.513), compared to an NR resulting from lack of compliance with general rules, which had a nonsignificant likelihood of association of 2.4 ($p < 0.075$; 95 percent CI: 0.671-4.364). These values were for an evidence and outcome window of seven days.

Committee's Discussion

Several limitations could affect the ability of NR data to predict loss of process control. These relate to the subjective nature and purpose of NRs and the statistical analysis used to determine their predictive accuracy, as well as human factors.

NRs were developed not to indicate a loss of process control but rather to document failure to comply with USDA regulations. It appears that many of the current public health-related NRs are not aligned with the HACCP plan, the food safety system required in FSIS-inspected establishments. For example, some critical control points are not referenced in the current NRs. In selecting the public health-related NRs (i.e., W3NRs), FSIS assigned them equal weight in the assessment and the algorithm. It is likely that some of these NRs are more closely associated with public health risk than others, as evidenced by data presented by FSIS (E. Dreyling, FSIS, personal communication, December 13, 2008). Some of the regulations underpinning the issuance of NRs are nonspecific (e.g., section 416.4[d] accounts for more than 50 percent of the NRs written during all of 2006, three months in 2007, and one month in 2005, according to data provided by FSIS [E. Dreyling, FSIS, personal communication, December 13, 2008]) and aggregate failures that may not be

related to health. In addition, some current NRs document outcomes of control failure so they are already used independently to classify levels of inspection. For example, NRs issued due to a positive result for *E. coli* O157:H7 or *L. monocytogenes* in RTE foods do not predict future loss of control but are instead an outcome of past loss of control and therefore, by definition, put an establishment in LOI 3. To address these current limitations, a more focused, commodity-based analysis excluding those NRs that are already used independently to classify levels of inspection would help identify true predictors of process control. Also, future public health-related NRs should be closely aligned to the pertinent HACCP plan, especially the critical control points.

Another limitation derives from the subjective nature of some NRs. There are two types of cause for writing an NR: (1) visual and organoleptic evidence that a regulatory requirement is not being met, as observed by inspection personnel, and (2) laboratory findings (microbiological data, product composition, etc.) demonstrating that a regulatory requirement is not being met. The decision to issue an NR is not always based on quantitative data, but often relies on observation and is therefore a subjective decision on the part of inspection personnel. It is important to note that the levels of technical experience and training of the inspection personnel who write NRs are very diverse. It is the committee's observation that significant variation can be expected in the interpretation of regulations and in individual inspector's criteria for justification of a specific NR. Supervisory review by the inspector-in-charge may likewise be variable or subject to bias and, therefore, unreliable. As part of the in-plant performance system (IPPS), supervisors are to assess the quality of the NRs written by inspectors at least once in a rating year (E. Dreyling, FSIS, personal communication, December 13, 2008). The districts also randomly select a number of NRs every month to review for quality and to provide feedback to supervisors. FSIS has indicated that the quality assessment it currently uses does not focus on the factual accuracy of the NR, but rather on whether it includes all of the administrative elements required (e.g., regulation violated, type of product and process, corrective action taken) (E. Dreyling, FSIS, personal communication, December 13, 2008). The results of the IPPS and the district assessments are captured in AssuranceNet, but they focus on the proficiency of the employee, not the quality and substance of individual NRs.

The lift analysis performed by FSIS suggests that the likelihood of a positive *Salmonella* verification test is higher when specific NRs have previously been written for an establishment. The lift analysis shows only preliminary associations and will obviously be applicable only to

commodities for which *Salmonella* verification testing is required. For example, the analysis provides no justification for the use of NR rates to categorize RTE establishments where *Salmonella* verification testing is not conducted. In addition, the data used for the analysis were not segregated by type of commodity; instead, the data were aggregated across all commodities, which increased the statistical power but possibly generated a bias in the association. That is, because *Salmonella* is more likely to occur in a poultry-processing establishment than in a beef operation, data from raw poultry may drive the analysis. NRs for an establishment that processes raw chicken might be different from or less frequently generated than NRs for a plant that processes ground beef or RTE meat. More accurate use of these data would require the selection of NRs that reflect a loss of process control for each type of product.

Another limitation is what appears to be an arbitrary selection of threshold points to classify an establishment as LOI 1, LOI 2, or LOI 3. FSIS proposes to use the inflection points of the curve of the number of plants with a specific NR rate, which might not be related to a particular risk differential between establishments, as the threshold point to assign establishments to a level of inspection (Figure 2). This may be especially problematic for commodities with a small positive sample size. There are also numerous ways of determining inflection; to evaluate the scientific adequacy of the determination method, FSIS should describe it in the technical report *PHRBIS.*

Finally, the committee concludes that the data indicate that reliance on use of the rate of NRs as a measure of process control might present a logistical and economic disadvantage for small plants, which may lack the legal or financial resources to appeal an NR and whose rate of NR receipt may therefore appear misleadingly high. For example, during 2008, the rate of NRs was higher in small and very small plants than in large plants (E. Dreyling, FSIS, personal communication, December 13, 2008). The committee questions this difference and recommends that it be investigated because it could distort a plant's NR rate and consequent categorization into an LOI.

Finding 10: *The use of selected NRs as process control indicators in a risk-based inspection system offers potential. However, because current NRs are written to document failure to comply with regulations, not all of them are predictors of loss of process control. The subjective nature of the issuance of NRs also limits their use as process control indicators. The description of the association between NRs and other measures of process control would benefit from a more effective communication of*

which NRs are employed for specific commodities and which ones are pertinent to all meat and poultry products.

RECOMMENDATION 10: The committee strongly recommends that FSIS conduct the following activities to improve the scientific basis for using NRs as process control indicators:

- Stratify lift statistics on *Salmonella* verification test results and NRs by plant size and commodity.
- Perform further appropriate statistical analysis to identify and rank which public health-related NRs among the 66 W3NRs have the greatest predictive value for various product classes.
- Convene a panel of qualified external scientific experts to review the results of these analyses and other potential factors; this panel would also make recommendations on weighting factors for the different product classes.
- Validate the use of NRs as predictors of positive *Salmonella* verification test results by conducting a pilot test to ensure that positives are not occurring simply as a result of the expected baseline load of *Salmonella* in the products or the variability of *Salmonella* load.
- Investigate the utility of surrogate indicators (e.g., generic *E. coli* or others) to identify noncompliance records that might be predictors of public health risk and loss of process control.

RECOMMENDATION 11: In concurrence with previous NAS reports (NRC, 1987; IOM, 1990, 1998, 2003), the committee recommends focusing on those inspection activities that foster the implementation of and compliance with HACCP systems and sanitary requirements. The committee strongly recommends that additional NRs be developed to reflect indicators of process control, instead of relying entirely on NRs that were created for purposes of regulatory compliance. The committee recommends that FSIS identify, validate, and adopt those NRs that are truly predictive of future contamination problems—for example, those being triggered by process deviations from HACCP plan critical control point limits. This exercise should be conducted under the guidance of a non-FSIS expert panel.

RECOMMENDATION 12: To reduce the subjectivity implicit in current NRs, the committee recommends supporting the improvement of the

inspection force (inspectors and supervisors) by strengthening oversight of the writing of NRs to determine not only that the appropriate information is provided on regulatory citations, but that the information is both factual and properly documented to support the noncompliance; and improving the training and testing of inspection personnel themselves, with special emphasis on the quality and consistency of NRs and on any new NRs to be developed.

Enforcement Actions

Use and Scientific Evidence

Enforcement actions are taken by FSIS against an establishment that fails to comply with regulatory requirements. As with NRs, not every enforcement action is related to a food safety problem; some may be issued in response to regulatory requirements of a different nature (e.g., nutritional labeling). FSIS Rules of Practice define the type of administrative enforcement action that FSIS takes under a given condition and the procedures to follow. The administrative actions include regulatory control action, withholding action, and suspension. When there is an imminent threat to public health, FSIS takes immediate action. In other situations, FSIS provides prior notification of intended enforcement action to the establishment. FSIS may defer an enforcement decision based on corrections submitted by the establishment, or it may place a suspension action in abeyance if an establishment presents and puts into effect corrective and preventive action. Examples of food safety-related reasons for enforcement action are failure of the establishment to comply with its HACCP plan or with regulatory requirements for generic *E. coli* testing. Enforcement actions are typically initiated by the Enforcement Investigations and Analysis Officer (EIAO) during an FSA and after a lack of effective corrective action leads to repeated NRs, indicating that the problem has not been adequately addressed, or after a severe violation (FSIS, 2008b). For the most severe violations, enforcement actions may not be preceded by an NR.

FSIS proposes to use enforcement actions as indicators of loss of process control in cases when enforcement actions remain open (LOI 3) or are deferred or in abeyance as a result of a process control failure (LOI 2) (E. Dreyling, FSIS, personal communication, February 18, 2009). If an enforcement action is taken as the result of an FSA in an LOI 3 estab-

lishment, the establishment cannot be recategorized to LOI 2 until an enforcement action is deferred or in abeyance. If an enforcement action is taken for a reason other than an FSA, the establishment will also be placed into LOI 3.

A lift analysis was performed between enforcement actions and NRs. As presented in Appendix E of the technical report *PHRBIS* (FSIS, 2008b), the results suggest that NRs are not predictive of future enforcement actions. The ability of enforcement actions to predict future pathogen contamination was also statistically analyzed. The lift calculations show that enforcement actions do not appear to be good predictors of process control (Appendix E of *PHRBIS*).

Nevertheless, FSIS justifies the use of enforcement actions as process control indicators because by definition they arise from a failure to abide by regulations, some of which are related to food safety (FSIS, 2008b). FSIS proposes to use those enforcement actions that are related to food safety issues as indicators of loss of process control.

Committee's Discussion

Based on the statistical analysis and due to the potential time lag between a process control failure and the consequent enforcement action (several weeks may pass before an action is initiated), enforcement actions are likely not to be predictive but instead only indicative of past problems.

Enforcement actions are, in fact, reactive processes. In addition, some enforcement actions are further delayed to ensure that sufficient legal evidence has been collected to substantiate an action related to a public health concern, possibly further decreasing their value as predictors. An enforcement action is an outcome of failure, that is, it may indicate that the process is already out of control, but not necessarily predict future loss of control.

If the NRs were weighted and specific outcome-based NRs were removed, there might be a correlation with enforcement actions. However, enforcement actions occur at a low frequency (e.g., 222, 217, and 308 enforcement actions were issued in 2006, 2007, and 2008, respectively (E. Dreyling, FSIS, personal communication, December 13, 2008), so finding a statistical correlation with other indicators of loss of process control might not be possible. In fact, results of the lift analysis performed by FSIS did not suggest any likelihood that enforcement actions are related to other process control indicators, such as pathogen or indicator organism test results (FSIS, 2008b). Therefore, as the technical re-

port *PHRBIS* indicates, it is not statistically justifiable to use enforcement actions as a predictor of process control.

As indicated above, differences in the ability to appeal NRs might predispose certain plants to receive enforcement actions, thereby introducing a facility size-based bias to this algorithm.

Finding 11: *The use of enforcement actions to rank establishments in different levels of inspection has been justified based on their suggesting a past loss of control, a valid risk-management decision criterion. However, the initial data analysis has not provided scientific support for use of this decision criterion to predict a loss of process control or for its association with other indicators. Enforcement actions currently prompt regulatory action, so they already result in categorization in LOI 3.*

RECOMMENDATION 13: The committee recommends using the enforcement actions that result from a failure of process control to categorize establishments in levels of inspection, not as predictive indicators of loss of process control.

Recalls

Use and Scientific Evidence

There are three types of recalls that an establishment voluntarily conducts in response to detection of a problem in a food product that has already reached the market (FSIS, 2008b):

- Class I recall: Prompted by a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death
- Class II recall: Prompted by a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences, or where the probability of serious adverse health consequences is remote
- Class III recall: Prompted by a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences

The FSIS proposes to use recalls to categorize plants by level of inspection (Dreyling, 2008; FSIS, 2008b; E. Dreyling, FSIS, personal communication, February 18, 2009) as follows:

- LOI 1: Establishment has not shipped adulterated or misbranded product (includes recalls related to human illness); or if it has, any related FSA and follow-up sampling was completed more than 120 days previously, any related enforcement actions are closed, and establishment meets all other criteria for LOI 1.
- LOI 2: For an establishment that has shipped adulterated or misbranded product (includes recalls related to human illness), any related FSA and follow-up sampling was completed in the previous 120 days, and all related enforcement action (e.g., Notice of Intended Enforcement [NOIE]) is deferred or in abeyance.
- LOI 3: Establishment has shipped adulterated or misbranded product or is undergoing enforcement action (e.g., NOIE) that is not the result of an FSA.

As with other indicators of loss of process control, not every recall is prompted by public health concerns; by definition, Class I and II recalls are (or might be) related to public health, whereas Class III recalls are not. FSIS conducted lift statistics to determine whether the occurrence of a public health recall could be used to assess NRs as predictors of loss of control. It also assessed whether recalls could predict enforcement actions or pathogen test results (FSIS, 2008b). In general, except for an association of Class I and II recalls with the finding of *L. monocytogenes* in RTE products, the results of these analyses were not statistically significant (see FSIS, 2008b; Appendix E).

According to FSIS, those recalls related to issues affecting public health (e.g., linked to product failure due to the presence of microbial pathogens) would be, by definition, indicative of a potential process control failure and therefore already identify the need for in-depth inspection at the offending establishment (FSIS, 2008b).

Committee's Discussion

One limitation shared with other indicators of process control is the low frequency of occurrence of recalls. For example, FSIS reports that the total number of recalls in 2008 was 48 (there were 39 Class I recalls, 9 Class II recalls, and no Class III recalls) (FSIS, 2008e). The utility of

recalls is further limited by their lack of specificity as well as their lack of timeliness (they may occur too late to identify issues in food processing); their use is reactive to a past food safety problem, not necessarily predictive of a future problem.

As FSIS states, the statistical analysis that estimates the ability of recalls to predict a loss of process control should allow for differentiation between recalls that have a public health impact and those that do not. A public health-related recall is often based on a laboratory test result—that is, the result of a microbiological test. Because of the limitations of sampling (size, frequency, etc.) and the sporadic nature of contamination, the isolation of a foodborne pathogen may not indicate a breakdown in process control. In some situations, especially related to *E. coli* O157:H7 in ground beef, a recall is based on failure to hold a product that has been tested for a pathogen, not a failure of the control process.

Finding 12: *The use of public health-related recalls to rank establishments in different levels of inspection has been justified based on potential direct public health risk, a valid risk-management decision criterion. However, the initial data analysis has not provided scientific support for this decision criterion as being predictive of a loss of process control or for its association with other indicators.*

RECOMMENDATION 14: Only health-related product recalls should be included in the model for ranking public health risks and assigning inspection resources. FSIS should continue to conduct assessments and take regulatory enforcement actions in plants following a recall.

STEPS Database

Use and Scientific Evidence

The System for Tracking *E. coli* O157:H7 Positive Suppliers database identifies suppliers of trim to grinding operations whose ground beef product tests positive for *E. coli* O157:H7. FSIS proposes to use this database to categorize LOIs for supplier establishments in the following manner (Dreyling, 2008; FSIS, 2008b; E. Dreyling, FSIS, personal communication, February 18, 2009):

- LOI 1: Establishment has not been cited in the STEPS database more than once; or if it has, any related FSA and follow-up sampling has been completed more than 120 days previously, any related enforcement actions are closed, and establishment meets all other criteria for LOI 1.
- LOI 2: For an establishment in the STEPS database more than once, any related FSA and follow-up sampling has been completed in the previous 120 days, and all related enforcement actions are deferred or in abeyance.
- LOI 3: Establishment was in the STEPS database more than once within the previous 120 days.

The justification for using the STEPS database is that grinding operations lacking an *E. coli* O157:H7 intervention step that would decrease the likelihood of the presence of pathogens need a process control step to ensure that incoming trim products are not already contaminated with pathogens.

Committee's Discussion

The committee recognizes the potential benefits of this approach and would be interested in seeing the details and data supporting it. As discussed above in relation to testing ground beef for *E. coli* O157:H7, FSIS should assess the role of testing trim for *E. coli* O157:H7 as a risk determinant.

Foodborne Disease Outbreaks

A foodborne outbreak is the occurrence of two or more cases of a similar illness resulting from the ingestion of a common food. FSIS proposes to use foodborne disease outbreaks to categorize establishments in levels of inspections as follows (Dreyling, 2008; FSIS, 2008b; E. Dreyling, FSIS, personal communication, December 13, 2008):

- LOI 1: An establishment has not been linked to an outbreak; or if it has, any related FSA and follow-up sampling has been completed more than 120 days previously, any related enforcement actions are closed, and establishment meets all other criteria for LOI 1.

- LOI 2: For an establishment that was linked to an outbreak, any related FSA and follow-up sampling has been completed in the previous 120 days, and all related enforcement actions are deferred or in abeyance.
- LOI 3: Human illness was linked to an FSIS-regulated product from the establishment.

Finding 13: *The use of foodborne disease outbreaks to rank establishments in different levels of inspection has been justified based on their potential direct public health risk, a valid risk-management decision criterion. However, the initial data analysis has not provided scientific support for use of this decision criterion to predict loss of process control or for its association with other indicators.*

RECOMMENDATION 15: The committee recommends including foodborne disease outbreaks in the algorithm to categorize plants in levels of inspection. The committee also strongly recommends that FSIS systematically work with other appropriate federal and state agencies to routinely disseminate public reports of the results of the investigations into the plant and process failures associated with these outbreaks.

Salmonella Serotypes of Human Health Concern

If FSIS is planning to use specific serotypes as indicators of process control, serotypes not often linked to human health should also be considered. Since the potential application of serotype evaluation to the designation of facilities as LOI 1, 2, or 3 is dependent on establishing a clear relationship between individual serotypes and disease attribution, any recommendations by this ad hoc committee await the findings of the NAS Committee on Review of the Food Safety and Inspection Service (FSIS) Risk-Based Approach to Public Health Attribution.

Consumer Complaints

The use of consumer complaints as a potential indicator of process control was analyzed by FSIS and then dismissed due to the challenge of overcoming its limitations (FSIS, 2008b). The committee agrees that the process currently employed to collect and analyze consumer complaints is not appropriate for use as an indicator of an establishment's need for a

higher level of inspection. In addition to having no significant associations with other potential indicators (see Appendix E in FSIS, 2008b), consumer complaints may often incorrectly associate a food with an adverse health effect.

OTHER POTENTIAL INDICATORS OF PROCESS CONTROL

Microbial Test Results

The primary goal of process control for raw meat and poultry products is to limit the presence of fecal contamination, the source of enteric pathogenic microorganisms. Both *Salmonella* and generic *E. coli* are indicators of fecal contamination and, as such, indicators of loss of process control, and both were targeted by FSIS in the pathogen reduction HACCP regulation. The ideal process indicator is one that is present at sufficient levels and frequency to be measured on a routine basis. For some commodities (e.g., beef carcasses), *Salmonella* is currently found so rarely that its usefulness as an indicator is limited. It is envisioned that for other commodities where it is currently useful, *Salmonella* could become equally rare in the future. FSIS would benefit from identifying alternative microbial indicators that could augment current indicators of fecal contamination on a commodity-specific basis.

Data on generic *E. coli* are collected by individual plants on a regular basis, but are not used by FSIS. Establishments are not required to send such data to FSIS, only to make them available if requested. According to FSIS, there are two limitations to the collection of data on generic *E. coli* that prevent FSIS from using them as indicators (C. Travis, Science Applications International Corporation, personal communication, December 13, 2008). One is FSIS's concern about the comparability of data resulting from a variety of different testing methods. Although the PR/HACCP regulation states that validated methods of testing should be used, there is no required single standard testing methodology or sampling procedure. It would appear that this could readily be corrected if FSIS articulated the specific methodological requirements (e.g., sensitivity, specificity, reproducibility, repeatability) of its current standard methods and its expectation that similar performance would be achieved by alternative validated methods. The second limitation is that the agency does not currently have the information technology capability to

retrieve and process such data efficiently. It is worth noting that in its May 2008 technical report to the NACMPI on poultry slaughter, FSIS presented convincing evidence of the potential utility of generic *E. coli* as a process control indicator and suggested that it was considering a new performance standard based on its use (FSIS, 2008a). These findings were based on a detailed study of various potential indicators of process control performed by FSIS and ARS. FSIS indicated that it has analyzed a 2006-2008 generic *E. coli* data set from its baseline program, but because this data set is small, the results were inconclusive (FSIS, 2008a).

Indicator organisms in RTE foods are used not as indicators of fecal contamination but rather as indicators of other control measures, such as the adequacy of the microbicidal step, prevention of recontamination, and maintenance of proper storage conditions (e.g., refrigeration). The FSIS algorithm does not currently include the use of any indicator microorganism for assessing process control in RTE foods. Given the low frequency of *L. monocytogenes* or other pathogens, FSIS would benefit from identifying appropriate alternative microbial indicators that could be used to assess applicable process controls in RTE foods. Although generic *E. coli* might not be an indicator of fecal contamination in RTE products, it is still a valuable indicator of general sanitation, recontamination problems, and temperature abuse.

Finding 14: *Microbes currently used as process control indicators are only rarely found in some commodities and are therefore of limited usefulness (e.g.,* Salmonella *in ground beef). It is anticipated that in the future,* Salmonella *will be even less frequent and therefore less valuable as an indicator. Furthermore, in the proposed algorithm, there are no identified process control indicators for RTE foods.*

RECOMMENDATION 16: FSIS should investigate the potential utility of industry data on generic *E. coli* as an indicator of process control. The committee recognizes the challenges of this approach, but encourages FSIS to act promptly to complete the analysis of the data it has already acquired, collect additional data as necessary, and analyze them for their predictive ability as potential indicators of process control.

Use of the HACCP System

A HACCP plan is developed by identifying steps in a specific meat and poultry process that are critical to ensuring food safety and is meant

to include the application of corrective actions when those critical control points are not met. Critical control points in HACCP plans were regarded as points in a process in need of specific interventions that, if failed, might result in an end product with risks to public health. If a commodity that was produced under a process deviation leaves the plant without corrective action, this constitutes a loss of control. By regulation, the control point limits are to be validated and verified by the establishments (*Hazard Analysis and Critical Control Point [HACCP] Systems. Validation, Verification, Reassessment*. 2008. 9 CFR § 417.4). Therefore, it may be appropriate for FSIS to study the feasibility of a system in which deviations from control point limits are incorporated as NRs and used to categorize plants according to the inspection level required. In fact, for most HACCP plans, critical control points and limits should be similar in nature for all facilities processing the same commodity. The committee acknowledges that for the processing of raw product, defining the control points is challenging; in these cases, more weight could be allocated to pathogen contamination as a control indicator.

RECOMMENDATION 17: The committee recommends that FSIS consider using specific critical control point deviations as indicators of process control. Process deviations should be integrated into an algorithm to categorize plants according to the level of inspection needed. Because of inherent problems in the use of NRs described above, the committee recommends redefining public health-related NRs and creating new ones where appropriate so that they reflect the current view of HACCP as a food safety control approach. This approach should identify true science-based indicators of process control. This concept should be included in inspection training programs. USDA should conduct a pilot study in a few plants to determine if the new NRs based on HACCP critical control point adherence are valid and useful parameters to be considered as predictors of loss of process control. This should be followed by longitudinal studies designed to validate the new NRs.

Value of Real-Time In-Plant Data Acquisition

The committee supports FSIS's efforts to explore options for rapid collection and reporting of real-time data that indicate potential failures of process control. The real-time data should focus on objective measures of control (e.g., critical control points) for the process and take advantage of electronic data-capturing tools.

The committee agrees that FSIS should use in-plant inspection personnel to collect real-time data. They would provide immediate input into the algorithm indicating a potential failure of process control. To be effective, objective process performance measures should be defined. For example, real-time tracking of repetitive instances of noncompliance that are related to food safety and that affect process control would be reported and used as indicators of process control. Also, whenever feasible, performance measures should allow action to be taken before the process fails. The committee supports FSIS's current activities to develop such a system and urges that it do so concurrently with carefully designed training of its inspection and supervisory personnel.

CONCLUSION

The committee recognizes the magnitude of the task of designing a risk-based system to rank meat and poultry slaughtering and processing establishments based on their impact on public health. The committee notes that at the request of FSIS, only the data on and analysis of indicators of process control were reviewed. Other components of the algorithm (e.g., volume) vital to determining its applicability were not. FSIS should include as part of the proposed inspection system a specific plan for when and how it will evaluate the system. Scientific verification and validation are essential to evaluate the success or failure of the new program.

The committee agrees with the general concept of using process control indicators as part of an algorithm to rank establishments in different levels of inspection. The committee recommends that FSIS continue the collection and analysis of data and, in consultation with stakeholders and expert panels, continue to improve its proposed risk-based inspection system so that it more effectively allocates inspection resources according to risk. Prior to implementing this algorithm, the recommendations in this report should be followed. Specifically, the committee emphasizes the need to align the process control indicators of a risk-based inspection system with HACCP, a framework required throughout the meat and poultry slaughtering and processing industry that serves to minimize the risk of foodborne illness.

The committee also recommends that FSIS improve the clarity and transparency of the algorithm so that its intent, scientific basis, and implementation are clearly articulated and understood by all stakeholders. One option for FSIS to communicate effectively with stakeholders would

be to produce supplemental informative documents targeted to specific audiences (e.g., inspectors, plant managers), in addition to a technical report. Also, because this new algorithm would bring about changes in inspection procedures, a parallel training program for the inspection force would likewise be necessary.

The Committee on Review of the Use of Process Control Indicators in the FSIS Public Health Risk-Based Inspection System thanks FSIS for the opportunity to review the technical report *Public Health Risk-Based Inspection System for Processing and Slaughter* and hopes that its findings and recommendations are useful. The committee will be available to FSIS for any clarifications regarding this letter.

Sanford Miller, *Chair*
Committee on Review of the Use of Process Control Indicators in the FSIS Public Health Risk-Based Inspection System

Attachments

Appendix A	Meeting Agendas
Appendix B	Levels of Inspection
Appendix C	Acronyms
Appendix D	Glossary
Appendix E	Biographical Sketches of Committee Members

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Appendix A

Meeting Agendas

Committee on Review of the Use of Process Control Indicators in FSIS Public Health Risk-Based Inspection System

November 6-7, 2008
Keck Center, Room 100
500 Fifth Street, N.W., Washington, DC 20001

Thursday, November 6, 2008—Room 100

OPEN SESSION

8:15 a.m. Welcome, Introductions, Plans for the Two Days, Statement of Task
Committee chair and NRC staff

9:00 a.m. Food Safety and Inspection Service (FSIS) Overview
Carol Maczka (Assistant Administrator, Office of Food Defense and Emergency Response)

9:10 a.m. U.S. Department of Agriculture (USDA) Perspective on Charge to Committee
Scott Hurd (Deputy Under Secretary of the Office of Food Safety)

9:25 a.m. How FSIS Does Inspection
William Shaw (Senior Food Technologist, Office of Food Defense and Emergency Response)

9:55 a.m.	FSIS Public Health Risk Ranking Algorithm *Erin Dreyling* (Data Analyst, Data Analysis and Integration Group, Office of Food Defense and Emergency Response) Handout: Technical Report ("Public Health Risk-Based Inspection System for Processing and Slaughter")
11:00 a.m.	Information on FSIS Risk-Based Approach to Public Health Attribution *Curtis Travis* (Consultant) *Erin Dreyling* *Lynda Kelley* (Science Adviser, Office of Food Defense and Emergency Response) Handout: Appendix A of Technical Report ("Public Health Attribution and Performance Measures Methods")
1:35 p.m.	Proposed Methodology for Risk-Based Regulation of In-Commerce Activities *Don Anderson* (Staff Officer, Program Evaluation and Improvement Staff, Office of Program Evaluation, Enforcement and Review)
2:25 p.m.	Public Comment Period
3:15 p.m.	End of Open Session

Friday, November 7, 2008—Room 202

OPEN SESSION

10:30 a.m.	Meeting with FSIS representatives *Erin Dreyling*, FSIS *Curtis Travis*, FSIS

December 17, 2008
National Academy of Sciences Building, Room 180
2100 Constitution Avenue, N.W., Washington, DC 20418

OPEN SESSION

9:30 a.m. Meeting with FSIS Representatives
Artur Dubrawski, Carnegie Mellon University
Mark Huckabee, Science Applications International Corporation (SAIC)
Curtis Travis, SAIC
Erin Dreyling, FSIS

10:30 a.m. Break

10:45 a.m. Meeting with FSIS Representatives (*continued*)

Appendix B

Levels of Inspection

LOI 1 Criteria

LOI 1—Establishment must meet ALL of the criteria below, when applicable:
Establishment has not had a positive Food Safety and Inspection Service (FSIS) *Escherichia coli* O157:H7 verification result; or if it has, any related Food Safety Assessment (FSA) and follow-up sampling has been completed more than 120 days previously, any related enforcement actions are closed, and establishment meets all other criteria for LOI 1[a]
Establishment has not had a positive FSIS test result for *Listeria monocytogenes* in ready-to-eat (RTE) products or a positive *L. monocytogenes* food contact surface sample; or if it has, any related FSA and follow-up sampling has been completed more than 120 days previously, all related enforcement actions are closed, and establishment meets all other LOI 1 criteria[a]
Establishment has not had a positive FSIS test result for *Salmonella* or *E. coli* O157:H7 in RTE products; or if it has, any related FSA and follow-up sampling has been completed more than 120 days previously, any related enforcement actions are closed, and establishment meets all other criteria for LOI
Establishment has not shipped adulterated or misbranded product (includes recalls related to human illness); or if it has, any related FSA and follow-up sampling was completed more than 120 days previously, any related enforcement actions are closed, and establishment meets all other criteria for LOI 1

Establishment was below the *Salmonella* percent positive LOI 1 percentile cut point on most recent sample set, unannounced sampling, or other *Salmonella* testing programs
LOI 1: Establishment has not been cited in the STEPS[b] database more than once; or if it has, any related FSA and follow-up sampling has been completed more than 120 days previously, any related enforcement actions are closed, and establishment meets all other criteria for LOI 1
Establishment was below the LOI 1 percentile cut point for *Salmonella* serotypes of human health concern or pulsed field gel electrophoresis (PFGE) matches[c]
An establishment has not been linked to an outbreak; or if it has, any related FSA and follow-up sampling has been completed more than 120 days previously, any related enforcement actions are closed, and establishment meets all other criteria for LOI 1
An establishment whose public health noncompliance record (NR) rate (over a rolling three-month average) is less than the LOI 1 percentile cut point, when all other indicators suggest the process is in control[d]

[a] Could be expanded to include other federal, state, local, foreign government, or industry positive samples once data are available and can be analyzed.
[b] System for Tracking *E. coli* O157:H7 Positive Suppliers.
[c] Future criteria to be implemented when data analysis is complete.
[d] Percentile cut point to be determined via data analysis.

LOI 2 Criteria

LOI 2—Establishment meets ONE or MORE of the criteria below:
Establishment had an FSIS positive test for *E. coli* O157:H7 in RTE products or ground beef or components, and any related FSA and follow-up sampling has been completed in the previous 120 days and all related enforcement actions are deferred or in abeyance [a]
For an establishment that has had an FSIS positive *L. monocytogenes* test result in an RTE product or an *L. monocytogenes*-positive food contact surface sample, any related FSA and follow-up sampling has been completed in the previous 120 days and all related enforcement actions are deferred or in abeyance [a]
For an establishment that has had a positive FSIS test for *Salmonella* or *E. coli* O157:H7 in RTE products, any related FSA and follow-up sampling has been completed in the previous 120 days and all related enforcement actions are deferred or in abeyance
For an establishment that has shipped adulterated or misbranded product (includes recalls related to human illness), any related FSA and follow- up sampling has been completed in the previous 120 days, and all related enforcement action (e.g., Notice of Intended Enforcement [NOIE]) is deferred or in abeyance
Establishment was above the *Salmonella* percent positive LOI 1 percentile cut point on most recent sample set, unannounced sampling, or other *Salmonella* testing programs and not in *Salmonella* Category III
For an establishment in the STEPS[b] database more than once, any related FSA and follow-up sampling has been completed in the previous 120 days, and all related enforcement actions are deferred or in abeyance
Establishment was above the LOI 1 percentile cut point for *Salmonella* serotypes of human health concern or PFGE matches[c]
For an establishment that was linked to an outbreak, any related FSA and follow-up sampling has been completed in the previous 120 days, and all related enforcement actions are deferred or in abeyance

An establishment whose public health NR rate (over a rolling three-month average) is greater than the LOI 1 percentile cut point but less than the LOI 3 percentile cut point[d]

[a] Could be expanded to include other federal, state, local, foreign government, or industry positive samples once data are available and can be analyzed.
[b] System for Tracking *E. coli* O157:H7 Positive Suppliers.
[c] Future criteria to be implemented when data analysis is complete.
[d] Percentile cut point to be determined via data analysis.

LOI 3 Criteria

LOI 3—Establishment must meet ONE or MORE of the criteria below:
Establishment has had a FSIS positive test for *E. coli* O157:H7 in RTE products, or ground beef or components[a]
Establishment has had an FSIS positive *L. monocytogenes* test result in an RTE product or an *L. monocytogenes*-positive food contact surface sample[a]
Establishment had a FSIS positive test for *Salmonella* or *E. coli* O157:H7 in an RTE product
Establishment has shipped adulterated or misbranded product or is undergoing enforcement action (e.g., NOIE) that is not the result of an FSA
Establishment is in *Salmonella* Category III
Establishment has been in STEPS[b] database more than once within the previous 120 days
Establishment has had repetitive *Salmonella* serotypes of human health concern or PFGE matches[c]
Human illness was linked to an FSIS-regulated product from the establishment
Establishment has health-related NR rates (over a rolling three-month average) higher than the highest percentile of health-related NR rates (e.g., those citing specified risk material [SRM], insanitary dressing, zero tolerance, residue)[d]
Establishment has sustained structural damage

[a] Could be expanded to include other federal, state, local, foreign government, or industry positive samples once data are available and can be analyzed.
[b] System for Tracking *E. coli* O157:H7 Positive Suppliers.
[c] Future criteria to be implemented when data analysis is complete.
[d] Percentile cut point to be determined via data analysis.

Appendix C

Acronyms

ARS	Agricultural Research Service
CDC	Centers for Disease Control and Prevention
CFU	colony forming unit
EIAO	Enforcement Investigations and Analysis Officer
FSA	Food Safety Assessment
FSIS	Food Safety and Inspection Service
HACCP	Hazard Analysis and Critical Control Point
HAV	hazard assessment verification
ICMSF	International Commission on Microbiological Specifications for Foods
IOM	Institute of Medicine
IPPS	in-plant performance system
IVT	Intensified Verification Testing
LOI	level of inspection
NACMPI	National Advisory Committee on Meat and Poultry Inspection
NARMS	National Antimicrobial Resistance Monitoring System
NOIE	Notice of Intended Enforcement
NR	noncompliance record
PCR	polymerase chain reaction
PFGE	pulsed field gel electrophoresis
PHRBIS	Public Health Risk-Based Inspection System
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point
RLm	Routine *Listeria monocytogenes*
RTE	ready-to-eat
SRM	specified risk material
STEC	shiga toxin-producing *Escherichia coli*

STEPS	System for Tracking *E. coli* O157:H7 Positive Suppliers
USDA	U.S. Department of Agriculture
W3NR	public health-related noncompliance record as identified by FSIS

APPENDIX D

Glossary

Abeyance	Temporary inactivity, cessation, or suspension.
Adulterant	Any substance that lessens the purity or effectiveness of another substance.
ALLRTE	Food Safety and Inspection Service (FSIS) testing program for *Listeria monocytogenes* in which inspectors sample products at random.
AssuranceNet	FSIS web-based system that monitors field activities and helps ensure that its enforcement actions are consistent nationwide.
Enforcement action	Measure of an establishment's ability to implement and maintain corrective action once a noncompliance is observed and documented. FSIS can take a variety of enforcement actions (e.g., notice of intended enforcement [NOIE], suspension, and inspection under consent order) against establishments that fail to comply sufficiently with applicable requirements.

Escherichia coli O157:H7	An enterohemorrhagic strain of *E. coli* that produces large quantities of toxins that cause severe damage to the lining of the intestine. It is the most commonly identified Shiga toxin-producing *E. coli* (STEC) in North America. As a bacterial pathogen, *E. coli* O157:H7 is capable of causing foodborne infections in humans.
Food Safety Assessment	Assessment conducted by FSIS to analyze an establishment's control of its food safety systems. FSAs assess all aspects of an establishment's food safety system in accordance with FSIS Directive 5100.1. While performing an FSA, Enforcement, Investigations, and Analysis Officers (EIAOs) assess whether meat and poultry establishments have designed their food safety systems to control, and thereby minimize, the presence of *Salmonella, E. coli* O157:H7, and *L. monocy-togenes.*
Foodborne disease	Disease caused by the consumption of contaminated foods or beverages. Many different disease-causing pathogens can contaminate foods, resulting in many different foodborne infections. The most commonly recognized foodborne infections are those caused by the bacteria *Salmonella*, *E. coli* O157:H7, and *Campylobacter* and by a group of viruses known as the Norwalk and Norwalk-like viruses.
For-cause FSA	As part of FSIS's new information technology system, a for-cause procedure is generated when a prompt threshold is reached. An inspector

	will be instructed to assess the presence and implementation of controls by answering questions regarding vulnerable points. Inspectors will record answers to questions about vulnerable points and will decide if further regulatory actions are appropriate.
Generic E. coli	A normal bacterial inhabitant of the intestines of all animals, including humans. Normally *E. coli* serves a useful function in the body by suppressing the growth of harmful bacterial species and by synthesizing appreciable amounts of vitamins. It is not typically a foodborne pathogen.
Hazard Analysis Critical Control Point (HACCP)	A process control system that identifies where hazards might occur in the food production process and puts into place stringent actions to prevent the hazards from occurring. By strictly monitoring and controlling each step of the process, there is less chance for hazards to occur.
Hazard Assessment Verification (HAV)	A proposed inspection activity in which FSIS in-plant inspectors review certain components of the facility's process controls (e.g., HACCP monitoring and verification activities). HAV is considered an intensified routine inspection activity that is conducted by specifically trained in-plant inspectors.
Indicator of process control	A measurable attribute that indicates whether a process maintains or surpasses an acceptable degree of risk or hazard control. An adequate

	indicator is an attribute that can be measured with objectivity and for which limits that define the need for corrective actions can be determined.
Intensified Verification Testing (IVT)	Follow-up verification testing done by FSIS when a product sample from any operation involving any ready-to-eat 90RTE meat or poultry product is found to be positive for *L. monocytogenes*. This intensified verification testing is done after the establishment has taken corrective and preventive actions. IVT could occur because of a history of having produced adulterated product, for investigative purposes, or because there is a concern that the establishment may not be properly controlling for pathogens.
Kill step	When referring to a food process, the step in the production process (e.g., heat treatment) that will reduce the pathogen level in the product to an undetectable level.
Lift analysis	A data mining tool that can identify associations between two variables separated in time. A "lift" is a measure of how much better prediction results are using a model than could be obtained by chance. Since lift is computed using a data table with actual outcomes, lift compares how well a model performs with respect to the data on predicted outcomes. Lift indicates how well the model improved the predictions over a random selection, given actual results. Lift allows a user to infer how a model will perform on new data. It works by

	binarizing the input and the output data streams and aggregating binary observations accumulated over time in a 2-by-2 contingency table.
Listeria monocytogenes	A Gram-positive bacterium that has been found in at least 37 mammalian species, both domestic and feral, as well as at least 17 species of birds and possibly some species of fish and shellfish. It can be isolated from soil, silage, and other environmental sources. *L. monocytogenes* is quite hardy and resists the deleterious effects of freezing, drying, and heat remarkably well for a bacterium that does not form spores. Most *L. monocytogenes* are pathogenic to some degree.
Listeria spp.	Species of *Listeria*, a Gram-positive bacteria, found as single short rods or chains approximately 0.5 micron wide and 1 micron long. *Listeria* may swim with 1-5 flagella to invade human cells.
Microorganism	An organism (bacterium or protozoan) of microscopic or ultramicroscopic size.
Noncompliance report (NR)	A record completed by FSIS inspection program personnel each time they determine that an establishment is not in compliance with regulatory requirements. The NR explains the nature of the regulatory action and informs the establishment's management of the noncompliance. Once issued, an establishment must

	take action to remedy the situation and should take measures to prevent its recurrence.
Notice of Intended Enforcement	Type of enforcement action taken by FSIS against establishments that fail to comply sufficiently with applicable regulatory requirements.
Organoleptic	Any sensory properties of a product, involving taste, color, odor, and feel. Organoleptic testing involves inspection through visual examination, feeling, and smelling of products.
Outbreak	With reference to food, the occurrence of two or more cases of a similar illness resulting from ingestion of a common food.
Pathogen	An agent of disease. The term pathogen most commonly is used to refer to infectious organisms such aas include bacteria, viruses, and fungi. Less commonly, pathogen refers to a noninfectious agent of disease such as a chemical.
Performance standard	According to FSIS, a standard prescribing the objectives or levels of performance (e.g., pathogen reduction standard for a raw product) that an establishment must achieve.
Process control	Within the limits of a stable and predictable process variation, a hazard is controlled to an acceptable level. This variation needs to be defined and the process must be monitored so that corrective actions are implemented before limits are surpassed.

Pulsed field gel electrophoresis	A molecular method that identifies organisms by their genotypes. It is an electrophoretic technique in which the gel is subjected to electrical fields alternating between different angles, allowing very large DNA fragments to snake through the gel and, hence, permitting efficient separation of mixtures of such large fragments. The resulting electrophoretic patterns are highly specific for strains from a variety of organisms and provide an opportunity to examine multiple variations throughout the genome of the organism so as to identify specific strains and accurately link them with disease outbreaks.
Ready-to-eat (RTE) foods	Products that have received a lethality treatment. The lethality treatment, generally a cooking procedure, must be designed to eliminate pathogens or harmful bacteria. This lethality treatment makes the product safe to eat without additional preparation by the consumer to achieve food safety.
Recall	Withdrawing of a product (e.g., food) from the marketplace in response to detection of a problem. Reasons for a recall may be the potential for the product to be hazardous to health but might also include a labeling error that would have no health consequences.
Relative risk ranking	Prioritization of items based on the level of risk to which they will expose the population.

Risk-based inspection system	Inspection methods that are based on the risks inherent in processing and slaughter operations.
RTE *L. monocytogenes* alternatives 1, 2, or 3	One of several options that establishments producing *L. monocytogenes*-exposed RTE meat and poultry products are required by regulation to adopt for those products that have been exposed to the environment after a lethality step (i.e., post-lethality). The *L. monocytogenes* alternative categories are as follows: **Alternative 1**—Establishments that apply both a post-lethality treatment to an RTE product to reduce or eliminate microorganisms on the product *and* the use of an antimicrobial agent or process as part of the product formulation. **Alternative 2**—Establishments that apply either Alternative 2A—A post-lethality treatment to limit the growth of *L. monocytogenes* on the product, or Alternative 2B—An antimicrobial agent or process as part of the formulation. **Alternative 3**—Establishments that rely only on testing and sanitation measures.
RTE001	Risk-based FSIS testing program for *L. monocytogenes* in which establishments are selected for testing based on risk factors identified in its peer-reviewed *L. monocytogenes* risk assessment.

Salmonella	Any of various gram-negative, rod-shaped bacteria of the genus *Salmonella* that are pathogenic in humans and animals.
Salmonella verification testing	An FSIS program launched in 1998 to monitor the effectiveness of its PR/HACCP rule on *Salmonella* performance standards for slaughter establishments and establishments that produce raw ground meat product. This program assesses process control in individual establishments. The program also provides feedback to stimulate industry action to reduce human exposure to *Salmonella* in raw meat and poultry. Eight product classes are subject to sampling: three ground products (beef, chicken, and turkey), and five carcass classes (young chickens; young turkeys; market hogs; steers or heifers; and cows or bulls).
Serotype	A group of closely related micro-organisms distinguished by a characteristic set of antigens.
Shiga toxin-producing *E. coli* (STEC)	A group of *E. coli* that cause disease by producing Shiga toxin. The most commonly identified STEC in North America is *E. coli* O157:H7.
STEPS (System for Tracking *E. coli* Positive Suppliers) Database	A database developed by FSIS that identifies suppliers of trim to grinding operations whose ground beef product is positive for *E. coli* O157:H7.
W3NR	The noncompliance reports (i.e., regulatory requirements) that were

	considered by an FSIS panel to be most strongly related to public health and, thus, indicative of a definite loss of process control. About 12 percent of all possible NRs were identified as W3NRs.
Zero tolerance	FSIS policy that has been established for *E. coli* O157:H7 in non-intact raw beef products and for *Salmonella*, *L. monocytogenes,* and *E. coli* O157:H7 in RTE meat and poultry products. Contamination of those products with these microorganisms is considered adulteration by FSIS; therefore, regulatory action is taken if these pathogens are present in those products.

Appendix E

Biographical Sketches of Committee Members

Sanford A. Miller, Ph.D., *Chair*, is a senior fellow at the Joint Institute for Food Safety and Applied Nutrition at the University of Maryland, College Park. In December 2000, he was named professor and dean emeritus of the Graduate School of Biomedical Sciences at the University of Texas Health Science Center at San Antonio, where he was the dean of the Graduate School of Biomedical Sciences and professor in the Departments of Biochemistry and Medicine from 1987 to 2000. He is the former director of the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration (FDA). Previously, he was a professor of nutritional biochemistry at the Massachusetts Institute of Technology. Dr. Miller has served on many national and international government and professional society advisory committees, including as chair of the Joint Food and Agriculture Organization-World Health Organization (FAO-WHO) Expert Consultation on the Application of Risk Analysis to Food Standards Issues. His honors include the Conrad A. Elvehjem Award of the American Institute of Nutrition, the Babcock-Hart Award of the Institute of Food Technology, the Esther Peterson Consumer Service Award from the Food Marketing Institute, the Sterling B. Hendricks Award from the U.S. Department of Agriculture, and election to fellow of the American Society for Nutrition. In June 2000, he was the recipient of the FDA's Distinguished Alumni Award. He has been a member of many National Academy of Sciences committees, including the Food and Nutrition Board's Standing Committee on the Scientific Evaluation of Dietary Reference Intakes, Subcommittee on Upper Reference Levels of Nutrients, and Panel on Macronutrients. He was named a national associate of the National Academies in 2002. He is author or coauthor of more than 200 original scientific publications. Dr.

Miller received a B.S. in chemistry from the City College of New York, and an M.S. and a Ph.D. from Rutgers University in physiology and biochemistry.

Gary R. Acuff, M.S., Ph.D., is a professor of food microbiology and the head of the Department of Animal Science at Texas A&M University. He is also a member of the faculty of Food Science and the Graduate Faculty. His professional memberships include the American Society for Microbiology, the Society for Applied Microbiology, and the International Association for Food Protection (IAFP). He serves on several advising and planning committees for the above professional organizations and served as president of IAFP in 2007-2008. He was a member of the Editorial Committee for the fourth edition of the *Compendium of Methods for the Microbiological Examination of Foods*, published in 2001, and served as a member of the U.S. Department of Agriculture (USDA) National Advisory Committee on Microbiological Criteria for Foods from 1992 to 1997. He received his B.S. in biology from Abilene Christian University, and his M.S. and Ph.D. in food science and technology from Texas A&M University.

Robert L. Buchanan, Ph.D., is the director of the University of Maryland's Center for Food Safety and Security Systems. He has 30 years of experience in teaching, conducting research in food safety, and working at the interface between science and public health policy, first in academia, then in government service in both USDA and FDA, and most recently at the University of Maryland. His scientific interests include extensive experience in predictive microbiology, quantitative microbial risk assessment, microbial physiology, mycotoxicology, and HACCP (Hazard Analysis and Critical Control Point) systems. He has published on a broad range of subjects related to food safety and is one of the codevelopers of the widely used USDA Pathogen Modeling Program. Dr. Buchanan has served on numerous national and international advisory bodies, including serving as a permanent member of the International Commission on Microbiological Specification for Foods, the U.S. delegate to the Codex Alimentarius Committee on Food Hygiene for 10 years, a six-term member of the USDA National Advisory Committee on Microbiological Criteria for Foods, and the Institute of Medicine (IOM) Committee on Emerging Threats to Public Health. As a member of ConAgra's Food Safety Advisory Council, he provides scientific advice on HACCP and other food safety systems. He received his B.S., M.S., M.Phil., and Ph.D. in food science from Rutgers

University, and postdoctoral training in mycotoxicology at the University of Georgia.

Michael P. Doyle, Ph.D., is regents professor of food microbiology and director of the University of Georgia Center for Food Safety. Previously, he was distinguished professor of food microbiology and toxicology at the University of Wisconsin. Dr. Doyle's research program promotes collaboration among the food industry, the university, and federal and state agencies. His research focuses on developing methods to detect and control foodborne bacterial pathogens at all levels of the food continuum, from the farm to the table. He is internationally acknowledged as a leading authority on foodborne pathogens, especially *Escherichia coli* O157:H7, and consults widely on the topic. As a member of ConAgra's Food Safety Advisory Council, he provides scientific advice on food safety. His National Academies service includes chairmanship of the Committee on the Review of the USDA *Escherichia coli* 0157:H7 Farm-to-Table Process Risk Assessment and participation in the 2004 and 2007 U.S.-Iranian Workshop on Food Safety, the National Research Council (NRC) Committee on National Needs for Research in Veterinary Science, and the IOM-NRC Committee to Ensure Safe Food from Production to Consumption. Dr. Doyle is a graduate of the University of Wisconsin-Madison, where he received his B.S. in bacteriology, and his M.S. and Ph.D. in food microbiology. He is currently vice chair of the Food and Nutrition Board (FNB) and chairs the FNB Food Forum. He was elected to the IOM in 2003.

John J. Maurer, Ph.D., is a professor in the Department of Population Health and the Poultry Diagnostic and Research Center, and a member of the Center for Food Safety, at the University of Georgia. He is a member of the American Association of Avian Pathologists and the American Society for Microbiology, for which he has served as president of the Southeastern Branch. He was the recipient of the Pfizer Award for Research Excellence and the John Bowen Award for Excellence in Research. His research interests include the development, validation, and implementation of molecular tools into on-farm surveillance programs for foodborne pathogens; molecular epidemiology and population genetics of veterinary and zoonotic pathogens; and the ecology of antibiotic resistance and foodborne pathogens in the food production environment. Dr. Maurer has a B.S. in microbiology from Purdue University and a Ph.D. in microbiology from the University of Texas Health Science Center at San Antonio.

Craig A. Reed, D.V.M., is a visiting professor, Large Animal Clinical Sciences, at the Virginia-Maryland (VA-MD) Regional College of Veterinary Medicine. He also serves as vice chair of the Virginia Board of Health. He has worked with the U.S. Department of Agriculture, where he crafted policy and delivered food safety programs involving meat, poultry and egg products, fruits, and vegetables. He served as the administrator of the Animal and Plant Health Inspection Service and associate administrator of the Food Safety and Inspection Service (FSIS) and as the director of the Food, Nutrition and Health Institute at Virginia Tech from 2001 to 2003. He has designed and implemented programs such as HACCP in meat, poultry, and egg products and the Pesticide Data Program in fruits and vegetables. Dr. Reed received his B.S. and D.V.M. from Michigan State University.

Steven C. Ricke, M.S., Ph.D., is a professor in the Departments of Food Science and Poultry Science at the University of Arkansas. He also serves as the Donald "Buddy" Wray Chair in Food Safety and the director of the Center for Food Safety in the Institute of Food Science and Engineering. Dr. Ricke is a member of the American Association for the Advancement of Science, the American Chemical Society, the American Society for Microbiology, the International Association for Food Protection, the Poultry Science Association, and the Society for Industrial Microbiology. His research interests include food safety; *Salmonella* pathogenesis, genetics, and physiology; food fermentations; and gastrointestinal microbiology. Dr. Ricke received his B.S. and M.S. from the University of Illinois at Urbana-Champaign and his Ph.D. from the University of Wisconsin.

Juliana M. Ruzante, D.V.M., M.P.V.M., Ph.D., is the risk analysis manager for the Joint Institute for Food Safety and Applied Nutrition in College Park, Maryland. She worked for the University of Guelph and the Public Health Agency of Canada developing and operationalizing a multifactorial framework to rank foodborne risks using multicriteria decision analysis (MCDA), and at the Western Institute for Food Safety and Security developing training material on animal health and food safety. She also worked as a quality assurance specialist for one of the largest pork and poultry processing companies in Brazil. She was a member of the Food Safety Research Consortium and has served as an expert on the meeting organized by the Food and Agriculture Organization of the United Nations and the World Health Organization

on the risks associated with *Enterobacter sakazakii*. Dr. Ruzante received her D.V.M. from the University of São Paulo and her master's in preventive veterinary medicine and Ph.D. in comparative pathology from the University of California, Davis.

Robert Tauxe, M.D., M.P.H., is deputy director of the Division of Foodborne, Bacterial and Mycotic Diseases at the Centers for Disease Control and Prevention. His division is charged with prevention and control of foodborne and zoonotic bacterial infections and mycotic diseases. His faculty appointments include the Department of Global Health and the Department of Biology, both at Emory University. Dr. Tauxe's interests include bacterial enteric diseases, epidemiology and pathogenesis of infectious diseases, epidemiologic and clinical consequences of bacterial genetic exchange, antimicrobial use and resistance to antimicrobial agents, and teaching epidemiologic methods. Dr. Tauxe's memberships include the American Epidemiology Society, the American Society for Microbiology, and the American Academy of Microbiology; he is a fellow of the Infectious Diseases Society of America. Dr. Tauxe has served internationally in Belgium, Mali, Rwanda, Peru, and Guatemala and has supervised numerous overseas epidemiologic investigations. Dr. Tauxe has authored or coauthored 242 journal articles, letters, and book chapters. Dr. Tauxe received his B.S. from Yale University, his M.D. from Vanderbilt Medical School, and his M.P.H. from Yale University.

Consultant

Kerri Harris, Ph.D., is an associate professor in the Department of Animal Science at Texas A&M University, serves as director of the Center for Food Safety, and is president and CEO of the International HACCP Alliance. Prior to becoming the president and CEO of the HACCP Alliance, she served as associate director and helped standardize HACCP training programs, assisted with the development of the train-the-trainer course and the accreditation program for HACCP training providers. At Texas A&M University, Dr. Harris team-teaches a HACCP course for graduate/undergraduate students and coordinates various HACCP and food safety industry training programs. She has worked closely with the food industry to provide valuable assistance in implementing HACCP programs. Dr. Harris has published multiple refereed journal articles and other publications, co-authored two book chapters, and presented at multiple national meetings. She is an active

member in the American Meat Science Association, the American Dietetic Association, and the Institute of Food Technologists. Awards include the Department of Animal Science "Outstanding Service Award" in 1993 for her contributions to the nutrition and meat science programs and the Vice Chancellor's Award in Excellence for Industry-Agency-Association Partnerships in December 2000. Dr Harris received her B.S. in food science, M.S. in nutrition, and doctorate in nutrition from Texas A&M University.