
**NATIONAL ADVISORY COMMITTEE ON
MICROBIOLOGICAL CRITERIA FOR FOODS**

**RESPONSE TO THE QUESTIONS POSED BY FSIS
REGARDING PERFORMANCE STANDARDS
WITH PARTICULAR REFERENCE TO
RAW GROUND TURKEY**

**Adopted August 27, 2004
Atlanta, GA**

**RESPONSE TO THE QUESTIONS POSED BY FSIS
REGARDING PERFORMANCE STANDARDS WITH
PARTICULAR REFERENCE TO RAW GROUND TURKEY**

U.S. Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) designed its nationwide baseline studies to measure prevalence of various microorganisms, including *Escherichia coli* and *Salmonella*, in categories and classes of raw meat and poultry prior to the implementation of the Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems; Final Rule (PR/HACCP Rule).¹ FSIS used data from the nationwide baselines to establish *Salmonella* performance standards for categories and classes of raw meat and poultry. FSIS then used data collected through testing after implementation of HACCP and other food safety systems to verify the adequacy of control systems for individual establishments. FSIS has proposed that revising the *Salmonella* performance standards may be appropriate to make them more reflective of industry's current ability to control or reduce *Salmonella* prevalence in the various raw product classes, as determined by post-HACCP testing of individual establishments. FSIS seeks from the National Advisory Committee on Microbiological Criteria for Foods (NACMCF, or the Committee) guidance on what might be the scientific decision points for such revisions of the existing standards. FSIS also seeks information on alternate methods to make improvements to the current system. In this document, the Committee provides guidance and responds to specific questions as they relate to *Salmonella* in raw ground turkey as FSIS applies the term "raw ground turkey" in the PR/HACCP Rule. This document does not apply to mechanically separated turkey.

¹Food Safety and Inspection Service, USDA, Section IV, Microbiological Performance Criteria and Standards, 61 FR 38806-38989 (July 25, 1996).

The Committee was charged with addressing the following six questions:

1. What constitutes scientific sufficiency to support use of an indicator organism in lieu of a specific pathogen for measurement against a performance standard?
2. What constitutes scientifically appropriate methods for incorporating regional variations when developing performance standards? Seasonal variations?
3. Quantitative standards appear to have more technical challenges associated with them than do qualitative standards. What special considerations need to be attended to in the development of quantitative baseline data? What special considerations need to be attended to in using quantitative baseline data for the development of quantitative performance standards?
4. What are key scientific considerations that need to be attended to when developing risk assessment for application to the development of performance standards? What are key scientific considerations that need to be attended to when using risk assessments in the development of performance standards?
5. How are these standards working and are they helping to ensure the safety of the nation's meat and poultry supply?
6. Are there more effective alternatives to these [*Salmonella*] performance standards and if so what would they be?

The Committee recognized the dual nature of FSIS' charge, which seeks advice on both the general scientific principles for the establishment of a performance standard and the application of those principles to the possible modification of the current *Salmonella* performance standard for raw ground turkey. As a means of addressing both needs, the Agency representatives and the Committee agreed to modify and change the order of the questions submitted by FSIS to allow

for a more logical progression for discussion and resolution. The questions have been addressed in the following order:

1. What are key scientific considerations that need to be attended to when developing risk assessment for application to the development of performance standards? What are key scientific considerations that need to be attended to when using risk assessments in the development of performance standards?
2. What constitutes scientific sufficiency to support use of an indicator organism in lieu of a specific pathogen for measurement against a performance standard?
3. What constitutes scientifically appropriate methods for considering variations that may be due to regional, seasonal, or other factors when developing performance standards?
4. Quantitative standards appear to have more technical challenges associated with them than do qualitative standards. What special considerations need to be attended to in the development of quantitative baseline data? What special considerations need to be attended to in using quantitative baseline data for the development of quantitative performance standards?
5. How are these standards working and are they helping to ensure the safety of the nation's meat and poultry supply?
6. Are there more effective alternatives to these [*Salmonella*] performance standards and if so what would they be?

Findings

The Committee concludes that a performance standard based on the principles outlined in this document is a valuable and useful tool to define the expected level of control at one or more steps of a process. Furthermore, performance standards provide the flexibility for industry to develop and seek approval for new strategies for improvement. When establishing or revising a performance standard, a risk assessment (quantitative or qualitative) supported by epidemiological data should be conducted to characterize the link between the product of concern and human illness. The results of the risk assessment will estimate the public health impact of and need for the performance standard. The principles for linking public health goals to performance standards via a risk analysis process have been articulated by the International Commission on Microbiological Specifications for Foods (ICMSF)² and are currently under discussion internationally by the Codex Committee on Food Hygiene (CCFH).

Question 1. What are key scientific considerations that need to be attended to when developing risk assessment for application to the development of performance standards? What are key scientific considerations that need to be attended to when using risk assessments in the development of performance standards?

General Principles

A risk assessment is one component of the risk analysis process that consists of risk assessment, risk management, and risk communication. General principles for deciding to conduct and develop a risk assessment dealing with hazard identification, hazard characterization, exposure assessment, and risk characterization have been previously described by NACMCF³,

²International Commission on Microbiological Specifications for Foods Working Group on Microbial Risk Assessment. 1998. Potential Application of Risk Assessment Techniques to Microbiological Issues Related to International Trade in Food and Food Products. *Journal of Food Protection*, Vol. 61, No. 8, Pages 1075-1086.

³National Advisory Committee on Microbiological Criteria for Foods. 1997. Principles of Risk Assessment for Illness Caused by Foodborne Biological Agents. *Journal of Food Protection*, Vol. 60, No. 11: 1417-1419.

ICMSF⁴, Codex Alimentarius⁵, and the Food and Agriculture Organization/World Health Organization (FAO/WHO).⁶ These texts should be consulted prior to any evaluation of risk.

Performance standards, which define the expected level of control at one or more steps in a process, may be an appropriate risk management strategy. Establishing and meeting performance standards can be a means of reaching public health goals to reduce foodborne illnesses. The stringency of a performance standard should be proportional to the risk and stated public health goals. This consideration of risk may not necessitate, in all situations, an in-depth quantitative risk assessment, which requires extensive resources and time, particularly if it would unnecessarily delay timely protection of public health. Risk assessments can be quantitative or qualitative in nature, but should be adequate to facilitate the selection of risk management options. The decision to undertake a quantitative or qualitative risk assessment requires the consideration of multiple factors such as the availability and quality of data, the degree of consensus of scientific opinion, and available resources. The principles for linking public health goals to performance standards via a risk analysis process have been articulated by ICMSF⁷ and are currently under discussion internationally by the CCFH. It should be noted that while there is a risk assessment for *Salmonella* on broilers⁸, there is currently no risk assessment available for turkey carcasses, turkey parts, or ground turkey.

⁴ICMSF. 1998.

⁵Codex Alimentarius Commission. 1999. Principles and Guidelines for the Conduct of Microbiological Risk Assessment. CAC/GL-30 (1999).

⁶Food and Agriculture Organization of the United Nations. Rome. 1997. Risk Management and Food Safety - FAO Food and Nutrition Paper 65, Report of a Joint FAO/WHO Consultation.

⁷International Commission on Microbiological Specifications for Foods. 2002. Microorganisms in Foods 7 Microbiological Testing in Food Safety Management. Kluwer Academic/Plenum Publishers. New York, NY.

⁸World Health Organization/Food and Agriculture Organization of the United Nations, 2002. Risk Assessments of *Salmonella* in Eggs and Broiler Chickens: Interpretative Summary. Microbiological Risk Assessment Series No. 1.

Risk assessments must address uncertainty associated with factors that influence public health risk. Examples of such factors are the prevalence and cell numbers of the pathogen in the food during processing to the time of consumption, the virulence of the microorganism, individual consumer susceptibility, the amount of food consumed, the physical and chemical characteristics of the food, and consumer handling practices (e.g., undercooking, cross-contamination and temperature abuse). The extent of uncertainty must be considered when setting the stringency of the performance standard. Use of single-value, worst-case estimates as a means of considering uncertainty should be avoided, particularly when more than one factor contributes to the overall public health risk. This can significantly overestimate the risk and may suggest the need for interventions that may not be necessary to enhance public health. The use of distributions instead of point estimates is a preferred approach to deal with uncertainty.

Outcomes of risk assessments should be presented in a manner that allows risk managers, risk communicators, and impacted stakeholders to understand the key factors that contribute to risk and thus influence the decision to adopt or modify a performance standard or any other risk management option.

Current Applications and Limitations of Risk Assessment for Ground Turkey

To estimate the likely impact that performance standards for *Salmonella* in raw ground turkey would have on public health, a risk assessment conducted according to the aforementioned general principles is needed.

A risk assessment for *Salmonella* in ground turkey should consider the following elements:

- prevalence and cell numbers of *Salmonella* on turkey carcasses, raw ground turkey components, and raw ground turkey, because the total population on the carcass used to manufacture raw ground turkey may not reflect the total population on the individual poultry parts;

- epidemiological data for salmonellosis associated with ground turkey in the United States, including different populations at risk;
- data on the linkage of clinical strains of *Salmonella* with isolates from ground turkey;
- differences in virulence among pathogenic strains of *Salmonella* associated with ground turkey;
- time/temperature data from slaughter to consumption in relation to the multiplication of *Salmonella* (this also effects the rate of spoilage);
- frequency of consumption, serving sizes, and methods of preparation, including cooking, for ground turkey prepared at or away from home;
- nature and extent of cross-contamination of foods or food contact surfaces during preparation and storage; and
- inactivation and growth kinetic models for strains of *Salmonella*, especially those strains commonly found in ground turkey.

Some of these data may currently be available or can be extracted as a result of research and reexamining data acquisition programs that are already operational. Specific data needs will be determined by the specific risk management questions posed by the requestor. However, it is anticipated that the items identified above are among those most likely to be needed to effectively estimate the impact of performance standards on public health.

Overarching scientific considerations associated with risk assessment for purposes of modifying the performance standard for raw ground turkey are:

- a current risk estimate for salmonellosis from ground turkey in the United States;

- the potential of current and new technologies to achieve further reductions in the risk of salmonellosis from ground turkey;
- a risk estimate for salmonellosis from ground turkey subjected to different performance standards; and
- the relationship of the effectiveness of control measures employed to meet a *Salmonella* performance standard to expected changes in foodborne illnesses resulting from other enteric pathogens associated with ground turkey.

In all cases, the exposure assessments must be done in a manner that is transparent and allows both the variability and uncertainty associated with the risk estimates to be calculated. Risk assessments should be designed to allow the effective use of techniques, such as the conduct of sensitivity analyses, to identify factors that will have a major impact on the overall risk estimates.

Recommendations for Data and Research Needs

- Epidemiological data are necessary to determine the portion of salmonellosis in the U.S. population attributed to ground turkey. Epidemiological data and laboratory data of foodborne investigations could provide the most benefit if they included cell numbers in implicated products, amount of ground turkey consumed, accurate estimates of the size of the ill and exposed populations, and accurate characterization of the population, including age profiles, medical statuses, and other potential risk factors.
- Data on the extent to which cross-contamination from raw ground turkey to ready-to-eat foods is responsible for salmonellosis.
- Improvements in methods to detect and enumerate salmonellae.

- Statistically valid data on which to base unbiased estimations of prevalence and cell numbers for *Salmonella* and other enteric pathogens in ground turkey throughout the farm-to-table continuum. FSIS should consider enumerating *Salmonella* and other enteric pathogens for some of the samples in its verification sampling and testing program.
- Data that relate specific process steps to changes in prevalence and/or cell number.
- Temperature profile data for the production, handling, and distribution of raw ground turkey components.
- Temperature profile data for ground turkey from production to consumption.
- Data on the survival of *Salmonella* and other enteric pathogens in raw ground turkey under typical storage temperatures to improve the predictive microbiology component of exposure assessments.
- Characterize the impact of food handling and preparation practices as they relate to cross-contamination and survival of *Salmonella*.
- Effects of other meal components on the risk of salmonellosis.
- Existing data should be reviewed in relation to these data and research needs.

Question 2. What constitutes scientific sufficiency to support use of an indicator organism in lieu of a specific pathogen for measurement against a performance standard?

General Principles

1. The current FSIS raw ground turkey microbiological performance standard is intended to cause a reduction in the presence of enteric pathogens, with emphasis on *Salmonella*, in raw ground turkey with the goal of improving public health.
2. Microbiological performance standards may involve the detection and/or enumeration of microorganisms (or a class of microorganisms) that can be used as indicators or index organisms. These terms are defined as follows:
 - Indicator organism - indicates a state or condition
 - Index organism - the cell numbers or frequency of which correlates with the cell numbers or frequency of another microorganism of concern
3. One pathogen can be used as an indicator of the state or condition affecting another pathogen if it meets certain basic criteria. Attributes contributing to the scientific support of use of an indicator organism in lieu of a specific pathogen for raw ground turkey include:
 - similar survival and growth characteristics;
 - a shared common source for both organisms, e.g., in turkey gastrointestinal tracts;
 - direct relationship between the state or condition that contributes to the presence of enteric pathogens and the indicator organism; and
 - practical isolation, detection or enumeration methods for the potential indicator organism.

Current Applications and Limitations in the Use of Indicator and Index Organisms for Raw Ground Turkey

E. coli has been viewed by FSIS as a direct measure of control of fecal contamination and, by implication, *Salmonella* or other enteric pathogens for some meat and poultry products. There currently are no indicator or index organisms being used to assess the microbial safety of raw ground turkey. *E. coli* and *Salmonella* are being measured separately and independently as indicators of states or conditions of process control for fecal contamination at slaughter facilities for certain species. As processing continues, it becomes more difficult to use indicator organisms to measure process control for fecal contamination in raw ground products. This is because as the number and variety of processing steps increase, the number, types, frequency, and concentration of organisms become more variable and the linkages between *E. coli*, *Salmonella*, and fecal contamination become more difficult to identify.

Recommendations for Data and Research Needs

The following recommendations should be considered to assure scientific sufficiency in order to use an indicator organism in lieu of a specific pathogen for measurement against a performance standard.

1. Data should be generated to demonstrate whether the microorganism can be used to indicate the state or condition associated with contamination by a pathogen(s) of concern.
2. Data should be generated to show, over time, whether reductions in the indicator will lead to reductions in the pathogen in commercial operations.
3. Data should be generated to assess whether a decrease in the presence of an indicator organism in raw ground turkey leads to a decrease in ground turkey-associated foodborne illness.

4. Use of index organisms or broader microbial indicators (e.g., *Enterobacteriaceae*, microbial metabolites, or specific genetic sequences) should be explored for use in performance standards.

Question 3. What constitutes scientifically appropriate methods for considering variations that may be due to regional, seasonal or other factors when developing performance standards?

General Principles

1. Identifying and understanding sources of variability and uncertainty and their effects on outputs from a risk assessment are important in establishing or evaluating a performance standard.
2. Identifying or understanding the impact of sources of variability is necessary for industry to make the changes needed to exercise control over the presence of the target microorganism(s) and for FSIS to identify current limitations on control capabilities.

Recommendations for Data and Research Needs

A. Scientifically appropriate methods for the acquisition of data relating to the variations of concern

The Committee concludes that data must be gathered from production through grinding and packaging to determine sources of variation of *Salmonella* prevalence in raw ground turkey. For any future baseline studies, the Committee believes that an agreement needs to be reached within FSIS as to the parameters that will be studied and standardization of sampling procedures and methods of analysis. The Committee also is of the opinion that pilot studies should be commissioned (before the conduct of more comprehensive studies) to determine the feasibility of the sampling program and to gain preliminary knowledge about variability to better define

appropriate sampling plans. A qualified, multidisciplinary team of scientists should be formed to design the study. The main focus of new baseline studies for *Salmonella* prevalence in raw ground turkey should be on the determination of the influence of regionality, seasonality, and processing factors, as well as factors that affect turkey carcass contamination.

Specific factors related to the process that may impact the prevalence and cell numbers of *Salmonella* in raw ground turkey include:

- time and temperature history of raw materials;
- source of raw material (e.g., single or multiple plants); and
- formulation (e.g., parts, skin, additional ingredients).

To understand the impact of seasonality, data must be collected for at least one year. The study design should provide for estimates having reasonable precision (to be determined by the study design group) of variability within and among plants.

B. Scientifically appropriate methods for the evaluation of data that consider the variations of concern

Analysis of data should facilitate determining whether variation can be reduced through controls (e.g., intervention technologies, recommended best practices). Ideally, efforts should be made to assign variation to a cause. If an assignable cause of variation is uncontrollable due to regionality, seasonality, or other factors, this variation may make it more difficult for processors to comply with the performance standard and, hence meet any public health goal linked to the performance standard.

Data analysis methods include statistical process control, analysis of variance, regression analysis, or other appropriate statistical techniques. Failure to comply with general principles of food hygiene or to use available control technologies can have an effect on the data, and such failures should be taken into account during data evaluation.

Recommendations for the Use of Scientifically Appropriate Methods for Revising the Performance Standard for Raw Ground Turkey

It is recommended that the existing FSIS HACCP verification data not be used to establish a new performance standard for raw ground turkey or to determine either regional or seasonal variability or the influence of manufacturing practices or potential interventions on *Salmonella* prevalence. These sampling programs were not designed to provide statistically valid estimates of the national prevalence and cell numbers of microorganisms. For this reason and for the consideration of establishing a revised raw ground turkey performance standard, the Committee recommends that the agency conduct a new nationwide, microbiological baseline study in federal and state inspected plants. The study should be designed to provide statistically unbiased estimates of the true prevalence and cell numbers of bacteria of concern in the commodity.

The Committee further recommends that this study be conducted for at least 12 consecutive months. The results of this baseline study should be used to establish a statistically-based sampling plan for an ongoing measurement of change. Such studies should be stratified by production volume, month and region, with the numbers of samples analyzed being sufficient to meet agency specified discriminatory power for comparisons of interest. Production volume is an essential factor when conducting baseline studies. If these volumes are not available, estimates must be obtained by other means (e.g., utilization of an appropriate agreed-upon covariate for baseline studies). If there are notable regional, seasonal, and/or process-related effects, consideration should be given to increasing the number of samples analyzed to increase the statistical sensitivity to detect significant differences. The recommended baseline study

should include examination not only for *Salmonella*, but also for other pathogens and indicators that may have possible utility as a measurement for process control.

Question 4. Quantitative standards appear to have more technical challenges associated with them than do qualitative standards. What special considerations need to be attended to in the development of quantitative baseline data for the development of quantitative performance standards?

Definitions

Quantitative variable - a variable that has a numerical value, e.g., cell numbers of a microorganism.

Qualitative variable - a variable that cannot assume a numerical value but can be classified into two or more nonnumeric categories, e.g., detection (presence/absence) of a microorganism.

General Principles

1. The use of quantitative data to determine the cell numbers of a specific organism in a specific product may be more relevant to public health than the use of qualitative data.
2. Quantitative data better predict the achievement of public health outcomes as determined through risk assessments (quantitative data are especially important for exposure assessment).
3. Quantitative data obtained from various points during slaughter and further processing provide more specific information on pathogen reduction than qualitative data. Quantitative data can measure reductions in pathogen cell numbers that may occur while qualitative data still only indicate the presence of the pathogen.

4. Quantitative data can help monitor changes in the cell numbers of organisms in relation to other variables, such as the time of the year and the source of the raw material.
5. Considerations and technical challenges to the acquisition of quantitative baseline data are not substantially different from those associated with qualitative data, except that laboratory methods for quantifying certain pathogens are more time and resource-intensive. Moreover, reliable estimates of cell numbers may be difficult to obtain, particularly if the concentration is low and the organism distribution is nonuniform.

Special Considerations and Technical Challenges for Quantitative Baseline Data

Common sample preparation procedures can be used for ground products of all species (e.g., beef, pork, chicken, turkey) to obtain either a qualitative or quantitative result. *Salmonella* is rarely quantified because the traditional quantitative method is the resource-intensive most probable number (MPN) procedure. There is also a concern for the lack of precision of the MPN method. Other quantitative methods, such as direct plating, have been proposed but are not widely accepted or used. Ideally, the sampling procedure would provide results that would be most useful in predicting the impact on the public health goal established in conjunction with a performance standard.

Qualified statisticians should be consulted in designing the quantitative baseline data study and defining the data acquisition procedures, including the number of samples to be taken. Before sample collection, consideration should be given to the type of information that may be desirable in order to facilitate maximum utility of the data. Therefore, the study must include (but is not limited to) the following:

- age and geographical source of raw material;
- type of establishment and production volume;

- the point in the process or food chain where samples are collected;
- location of facility (i.e., region of the country) where the samples are collected;
- date of sample collection;
- types of interventions applied (if applicable);
- sample transportation and holding conditions prior to analysis; and
- other factors found to be significant as discussed in question 3, part A.

The study design must also take into account normal process variation (i.e., variation that exists when the process is in statistical control) and further should consider additional factors, including region and season, that may have significant effect on the variation.

Methods used for sample collection, shipment, and laboratory analyses should be standardized and validated so that the desired information can be consistently obtained through subsequent data analysis. Systematic documentation of appropriate implementation in the field must be ensured. Laboratories that are involved in the testing of samples must be appropriately accredited for these analyses. The analysts conducting the testing must be appropriately qualified to perform these tests. Prior to the conduct of a baseline study, an operational readiness review of all elements of the study should be undertaken and a pilot study should be conducted in order to ensure the proper implementation of the full study.

The conditions under which samples are transported to the laboratory must be carefully considered to minimize changes in cell numbers and physiological state of the organisms of concern. Any other changes that may occur during transport must be accounted for as well. In addition to the collection and analysis of samples, other information may be pertinent to the optimum utility of the data derived. For example, careful consideration should be given to the

specific survival and growth characteristics of the targeted organisms, particularly as differences exist in relation to the data collection or application processes. It will be important to understand the product manufacturing steps before obtaining quantitative data, since processing could have more impact on quantitative data than qualitative data.

Analyses of microorganisms that have been stressed as a result of food processing steps or other factors may require special techniques for accurate detection and quantification. It is also important to note that the uncertainty and variability associated with microbiological analyses typically increases dramatically at the lower limit of detection.

Scientific Considerations When Considering the Use of Quantitative Baseline Data to Establish Quantitative Performance Standards

The FAO/WHO Risk Assessment for Broilers⁹ is an example of how quantitative data used in a risk assessment can facilitate the evaluation of risk management options, including the use of quantitative performance standards, to achieve a desired public health outcome. In addition to assessing risk based upon prevalence, the FAO/WHO study indicated that desirable public health outcomes may be achieved by reducing cell numbers. There are insufficient scientific data in the United States to relate quantitative pathogen performance standards to public health consequences. Comprehensive quantitative baseline data must be generated as described by the considerations and technical challenges discussed previously in this report. The assessment of the quantitative baseline data in the preparation of quantitative performance standards should identify confounding factors (i.e., conditions or events not addressed in the original analysis) that provide alternative explanations for the observed effects. The assessment should consider the quantitative baseline data in relation to the shelf life of the product under study. The quantitative performance standard should be applied at the step(s) in the process where the samples were collected to establish the performance standard.

Once selected, the performance standard and acceptance criteria will determine the sampling

plans and corresponding inherent probabilities of concluding that a conforming process is nonconforming (Type I error) and a nonconforming process is conforming (Type II error). Generating quantitative data in response to quantitative performance standards will impact testing by the government and industry. The increased information gained from quantitative variable testing must be balanced against the increased cost of acquiring the information. However, public health benefits may justify the increased costs. While qualitative data provide less information, decreased costs allow more samples to be taken.

Application of Qualitative and Quantitative Performance Standards

Application of qualitative/quantitative performance standards that are supported by appropriate sampling plans and control limits should differentiate between compliant and noncompliant processes.

Use of quantitative performance standards may also be appropriate to achieve certain public health goals. For example, while reducing the cell numbers of a pathogen may not affect the detection of that pathogen, it may reduce risk from that pathogen. Further, quantitative and qualitative performance standards may be used when verifying the ability of process steps to control or reduce the cell numbers of pathogens of concern. Likewise, such performance standards can be modified to reflect changes in processing technologies, the implementation of new interventions as industry best practices, and new information regarding infectious dose. An important research need is the development of cost-effective quantitative method(s) for pathogens which are not as resource-intensive as the MPN technique.

Question 5. How are these standards working and are they helping to ensure the safety of the nation's meat and poultry supply?

⁹ WHO/FAO, Microbiological Risk Assessment Series No. 1. 2002.

As previously indicated in question 2, General Principle 1, microbiological performance standards are intended to reduce the presence of enteric pathogens in raw ground turkey with the goal of improving public health. The Committee considers microbiological performance standards an important tool to define an expected level of control at one or more steps in the process of producing raw ground turkey. However, there are no data to indicate that performance standards for raw ground turkey have had an impact on foodborne illness from enteric pathogens.

The following points were considered in relation to the effectiveness of performance standards:

1. Although not statistically based, FSIS HACCP verification data suggest that since performance standards were implemented, prevalence of *Salmonella* has been below the baseline prevalence level established as the performance standard in raw ground turkey.
2. Based on FoodNet data, the estimated incidence of human cases of salmonellosis has varied from year to year, with no significant change between 1996 and 2002.¹⁰ The addition of the 2003 data resulted in a significant decrease in salmonellosis compared to 1996, however, it is not known if this represents annual variation or the beginning of a trend.¹¹ The report also indicated that there were no substantial changes in the incidence of infection from several common *Salmonella* serotypes (Enteritidis, Newport, and Heidelberg).
3. Based on FoodNet data¹², there has been a 28% decline in campylobacteriosis from 1996-2003. However, it is not known whether this is a consequence of the *Salmonella* performance standards applied to raw meat and poultry products during this period.
4. Previous findings have shown that the most common *Salmonella* serotypes found on

¹⁰Centers for Disease Control and Prevention. 2003. Preliminary FoodNet Data on the Incidence of Foodborne Illnesses B Selected Sites, United States, 2002. MMWR Weekly, Vol. 52 (15): 340-343.

¹¹Centers for Disease Control and Prevention. 2004. Preliminary FoodNet Data on the Incidence of Infections with Pathogens Transmitted Commonly Through Food B Selected Sites, United States, 2003. Vol. 53 (16): 338-343.

animal carcasses were also the most common serotypes found in the corresponding raw ground product.¹³ However, the most common *Salmonella* serotypes found on meat and poultry products prior to the implementation of the PR/HACCP Rule did not correlate well with those found most often to cause human illness.^{14, 15}

The Committee notes that existing public health statistics make it very difficult to specifically attribute reductions in enteric diseases to the performance standards. This difficulty is due to the wide array of food safety activities underway, and confounders that affect the linkage between public health and performance standard data.

Recommendations

1. FSIS should work in collaboration with CDC to measure the impact of the performance standard for raw ground turkey on salmonellosis and infections from other enteric pathogens.
2. The relationship between serotypes of *Salmonella* isolated from turkeys, raw ground turkey, and human clinical isolates should be investigated (e.g., comparing serotypes from FSIS verification data and CDC results for clinical isolates).
3. It is recommended that food, including raw ground turkey, and clinical samples be analyzed for multiple serotypes.
4. Performance standards need to be evaluated and adjusted, as necessary, to drive continuous improvement and enhance public health.

¹²CDC. 2004.

¹³Schlosser, W., Hogue, A., Ebel, E., Rose, B., Umholtz, R., Ferris, K., and James, W. 2000. Analysis of *Salmonella* Serotypes from Selected Carcasses and Raw Ground Products Sampled Prior to Implementation of the Pathogen Reduction; Hazard Analysis and Critical Control Point Final Rule in the U.S. *International Journal of Food Microbiology*. Vol. 58:107-111.

¹⁴Schlosser, W. 2000.

¹⁵Sarwari, A., Magder, S., Levine, P., McNamara, A., Knower, S., Armstrong, G., Etzel, R., Hollingsworth, J., and Morris, J. 2001. Serotype Distribution of *Salmonella* Isolates from Food Animals after Slaughter Differs from that of Isolates Found in Humans. *Journal of Infectious Diseases*. Vol. 183:1295-1299.

Question 6. Are there more effective alternatives to these [*Salmonella*] performance standards and if so what would they be?

The Committee concludes that a performance standard based on the principles outlined in this document is a valuable and useful tool to define the expected level of control at one or more steps in a process. Furthermore, performance standards provide both the incentive and flexibility for industry to develop and seek approval for new strategies for improvement.

FSIS has proposed to revise the raw ground turkey performance standard to reflect industry's current ability to control *Salmonella* prevalence to a lower level. With respect to alternatives to the current performance standard, the Committee noted that regardless of the alternative there will be either an explicit or implicit microbiological target level underlying the approach taken. Any alternative selected should achieve the same goal (i.e., reduce human enteric disease due to the presence of pathogens in raw ground turkey) as the performance standard. Among the alternative approaches that may be considered are:

- apply one or more performance criteria at selected steps in the food chain to provide equivalent or more effective control of the pathogen(s) of concern;
- apply specific control measures at appropriate steps from farm to table; and
- Use an indicator organism in lieu of *Salmonella* (see discussion in question 2).

Any alternative to the current *Salmonella* performance standard should be linked to consumer protection. Furthermore, the alternative should encourage continuous improvement.

Recommendations for Data and Research Needs

Research to identify specific control measures or appropriate performance criteria that could apply to turkey carcasses and raw ground turkey should be conducted. Research should also be conducted to identify interventions specific to grinding, blending, extruding, forming, and packaging of raw ground turkey that can impact levels of *Salmonella* and potentially serve as control measures. Control measures or performance criteria identified through research may be effective alternatives to the *Salmonella* performance standards.

APPENDIX I

Members of the NACMCF Microbiological Performance Standards for Raw Meat and Poultry Subcommittee are:

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