NATIONAL ADVISORY COMMITTEE ON MICROBIOLOGICAL CRITERIA FOR FOODS

FINAL

RESPONSE TO THE QUESTIONS POSED BY FSIS REGARDING PERFORMANCE STANDARDS WITH PARTICULAR REFERENCE TO GROUND BEEF PRODUCTS

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Washington, D.C.

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Background

FSIS designed the *Salmonella* performance standards to verify the adequacy of HACCP systems. FSIS proposes that revising the *Salmonella* performance standards to make them more reflective of current *Salmonella* prevalence in the various raw ground product classes may be appropriate. FSIS seeks from the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) guidance on what the scientific decision points for such revisions of the existing standards might be. FSIS also seeks information on alternate methods to make improvements to the current system.

The Committee was charged with addressing the following four questions which were posed to it by the USDA/FSIS during their May 7, 2001 meeting:

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?

FSIS is also seeking review and guidance on how the current performance standards are working, whether they are helping to ensure the safety of the Nation's meat and poultry supply, and whether there are more effective alternatives to the current performance standards and if so, what these alternatives would 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 standards for ground meat and poultry. 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 USDA/FSIS to make for a more logical progression for discussion and resolution. The four 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, and 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?

The scope of this document is limited to the consideration of enteric foodborne pathogens and indicator and index organisms that are transmitted by raw meat or poultry. The principles for the development of performance standards for other pathogens, as measures for process control for other commodities, may require consideration of different factors, and as such were not considered in the current deliberations.

NACMCF has completed their responses to all questions posed by USDA/FSIS detailing the key scientific considerations that need to be attended to when developing risk assessment for application to develop performance standards.

For prioritization of the charges to NACMCF, the agency affirmed that NACMCF should: a) give priority to evaluating the data and concerns associated with question three, and completing the response to question three as soon as possible, b) address the new questions related to whether the performance standards are working and are there effective alternatives to these performance standards, c) address other ground products, and d) address other classes and categories, e.g., carcasses.

Findings

The Committee concluded that performance standards that meet the principles as outlined in this document are valuable and useful tools to define an expected level of control in one or more steps in the process.

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

General principles for deciding to conduct and develop a risk assessment have been previously described by NACMCF[1], ICMSF[2], Codex Alimentarius[3] and WHO/FAO[4]. These texts should be consulted prior to any evaluation of risk.

Performance standards define the expected level of control at one or more steps in a process. 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. The consideration of risk is needed to link the performance standard with 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. The decision to undertake a formal 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, time constraints, and the potential consequences of the decisions reached. The principles for linking public health goals to performance standards via a risk analysis process have been articulated by ICMSF and is currently under discussion internationally by Codex Alimentarius.

Conducting any risk evaluation must address uncertainty associated with factors that influence public health risk. Examples of such factors are the concentration of the pathogen present, the pathogenicity of the microorganism, the amount of food consumed, the physical and chemical characteristics of the food, and the extent to which the food is processed. The degrees of uncertainty must be considered when setting the degree of stringency required 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 overall public health risk.

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[1]National Advisory Committee on Microbiological Criteria for Foods, Principles of Risk Assessment for Illness Caused by Foodborne Biological Agents, Journal of Food Protection, Vol. 61, No. 8, 1998, Pages 1071-1074.

[2]International Commission on Microbiological Specifications for Foods Working Group on Microbial Risk Assessment, 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, 1998, Pages 1075-1086.

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

[4]Food 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.

Risk assessments should be written in a manner that allows risk managers and impacted stakeholders to understand the key factors that contribute to risk and thus influence the decision to adopt a performance standard or accept one performance standard over another.

Current Applications and Limitations

To estimate the likely impact that performance standards for *Salmonella* in ground products would have on public health, a risk evaluation conducted according to the above principles is needed. Key scientific considerations that may lead to revisions of existing *Salmonella* performance standards for ground products are:

- The risk estimate for salmonellosis from ground products prior to the imposition of the performance standard.
- The current risk estimate for salmonellosis from ground product.
- The potential of current and new technologies to achieve further reductions in the prevalence of *Salmonella.*
- The risk estimate for ground beef products with a tightened performance standard.

Conducting a risk evaluation will require sufficient information to complete an exposure assessment and a hazard characterization (i.e., dose-response relationship). The dose-response relationship that has been deduced as a result of the FAO/WHO Expert Consultation on Microbial Risk Assessment for *Salmonella*[5] would be adequate for use in such an undertaking.

As the dose-response appears to be adequately addressed, gathering information to facilitate a more accurate exposure estimate should be the focus of data development/collection. To facilitate the exposure assessment, estimates of actual numbers of *Salmonella* present in ground products need to be determined or estimated. If a quantitative risk assessment is necessary, the Committee notes that appropriately substituting prevalence data and the above referenced dose-response relationship for *Salmonella* into the "FSIS Risk Assessment for *Escherichia coli* 0157:H7 in Ground Beef" may provide a means to expedite a risk assessment model for *Salmonella* in ground beef.

FSIS can develop quantitative data in conjunction with its ongoing verification program. Data collected and appropriate sample size requirements for these risk evaluations could be approached in the following manner. Anticipating approximately 30,000 ground beef samples per year and using the *Salmonella* positive rate for the year 2000 at 3.3%, would approximate 1000 positive samples for which at least 20% or 200 (as data are collected over time, a more scientifically based number could be derived) should be handled in a manner that would allow quantitation for *Salmonella,* APC and *E. coli.* This quantitative procedure should provide sufficient data to estimate the concentration for each of these microorganisms at the time of manufacture and further would determine any correlations among these organisms. Such information would

[5]Food and Agriculture Organization of the United Nations. 2001. Risk characterization of *Salmonella* ssp. in eggs and broiler chickens and *Listeria monocytogenes* in ready-to-eat foods. Report of a Joint FAO/WHO Expert Consultation on Risk Assessment of Microbiological Hazards in Foods.

have additional value in determining initial loads of *Salmonella* in raw meat and can be used in validation of thermal processing.

The remainder of the information needed to complete an exposure assessment is the identification of factors influencing the frequency and concentrations of *Salmonella* contamination during the time interval between ground beef manufacture and consumption. Factors that may need to be considered are:

- Frequency of consumption.
- Serving sizes.
- Method and degree of cooking, including the consideration of consumer preference for under cooked beef.
- Growth kinetics models (including variability among strains).
- Inactivation kinetics models (including variability among strains).
- Temperature of storage during distribution, marketing, and in the home.
- Duration of storage, distribution, marketing, and storage in the home.

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

When risk assessments or evaluations are undertaken for different commodity ground products, they should be initiated individually to simplify the models that will have to be developed. 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.

Data Needs

- Quantitative data on *Salmonella* in meat and poultry.
- The agency should establish a mechanism to obtain epidemiological data to determine the portion of salmonellosis in the U.S. population attributed to the commodity groups for which performance standards have been established.
- Data that defines the relationship between the hazard of concern and a reduction in human health risk through the application of the performance standard.
- A benchmark value of the prevalence of *Salmonella* in meat and poultry was established through baseline studies. As reductions in the prevalence have occurred, information should be collected to identify changes made by industry to account for the lower concentrations. This information resulting from industry changes can be shared with others throughout the industry to develop best practices.
- Within USDA/FSIS there are numerous sampling programs for a variety of pathogens. These data bases should be merged to the extent that this information could be used to

determine whether relationships exist between pathogen numerical concentrations and/or prevalence and implementation of performance standards.

- *Salmonella* was selected as the target organism because it was considered to be one of the most common causes of foodborne illness associated with meat and poultry products and is present to varying degrees in all major species of livestock and poultry. Data are needed to demonstrate that the interventions targeted at reducing *Salmonella* are beneficial in reducing contamination by other enteric pathogens, as was predicted.
- To facilitate research and knowledge throughout industry and academia all data should be made available, to the extent possible, to the public suitably codified to protect proprietary information. This should lead to generation of additional data and increased knowledge of the many facets influencing control of enteric pathogens on raw meat and poultry.

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

General Principles

1. Microbiological performance standards are intended to effectuate a decrease in the presence of enteric pathogens in raw meat and poultry with the goal of improving public health.

2. Fecal contamination from slaughtered animals is a major source of enteric pathogens on raw meat and poultry.

3. Microbiological performance standards may involve the detection and/or enumeration of a microorganism that can be classified as an indicator or an index organism. These terms are defined as follows:

   - Indicator organism: indicates a state or condition
   - Index organism: the concentration or frequency of which correlates with the concentration or frequency of another microorganism of concern.

4. Attributes contributing to the scientific sufficiency in support of use of an indicator organism in lieu of a specific pathogen relative to species, carcasses, primals and trimmings and ground products derived therefrom include:

   - Similar survival and growth characteristics.
   - A shared common source for both organisms in animal gastrointestinal tracts.
   - Direct relationship between the state or condition that contributes to the presence of enteric pathogens and the indicator organism.
   - High frequency of detection when contamination of fecal origin exists.
   - Practical isolation, detection or enumeration methods.

5. One pathogen can be used as an indicator of the state or condition affecting another pathogen if it meets the basic criteria listed above.

Current Applications and Limitations

Currently both *E. coli* and *Salmonella* are being measured separately and independently as indicators of states or conditions indicating process control at slaughter facilities.

It is implied, but not explicitly stated, in the Pathogen Reduction HACCP Systems Rule that control of these two organisms will lead to the control of other enteric pathogens.

E. coli as an Indicator Organism

E. coli is currently used as a direct measure of control of fecal contamination, particularly in slaughter operations. Due to the possibility of bacterial growth between the slaughter and grinding processes, detection of the number of *E. coli* in ground product may not be as direct a measure for the concentration of fecal contamination as on carcasses immediately after slaughter. In this instance the concentrations of *E. coli* would be a measurement of fecal contamination and the duration of refrigerated storage of the meat or poultry at temperatures greater than 8-10°C.

Salmonella Performance Standards

The *Salmonella* performance standards were designed to verify process control in slaughter and ground beef operations. The rationale for this is stated in the Pathogen Reduction/HACCP Final Rule[6]. The limitations of using *Salmonella* for this purpose are discussed in the Philadelphia report[7].

The Committee points out that when HACCP systems and other prerequisite programs in ground beef operations are adequate and verified, the measurement of *Salmonella* reflects the total process control, particularly the microbial conditions of raw material. Currently, the most effective control measures for grinders are raw material selection. Purchasing specifications with microbial limits for selected microorganisms can be one control measure for raw material selection. Additionally, antimicrobial interventions have been recently approved and others are being evaluated by industry to reduce contamination. Other options are also being developed. The data from the *Salmonella* performance standard program from the year 2001 should be made public, so as to provide guidance to industry in order that commercial operations may assess their process control relative to the industry. This information would be helpful for the grinders in meeting the performance standard. Further, the HACCP verification test results should be made available to each establishment as they become available to facilitate Continuous Improvement Programs.

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[6]Food Safety and Inspection Service, USDA, Section IV, Microbiological Performance Criteria and Standards, 61 FR 38835-38836, July 25, 1996.

[7]Expert Panel's Summary Report and Recommendations, Role of Microbiological Testing in Verifying Food Safety, Scientific and Technical Conference, May 1-2, 1995, Philadelphia, PA.

Recommendations 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 that the microorganism can be used to indicate the state or condition associated with contamination by a pathogen(s) of concern. For example tests for *E. coli*, to the extent possible, could be integrated with the data in the existing *Salmonella* verification program.

2. Data should be generated which show, over time, that reductions in the indicator will lead to reductions in the pathogen in commercial operations.

3. Analytical tools should be developed which assess whether a decrease in the presence of the indicator organism leads to a decrease in foodborne human illness due to the pathogen in particular, and/or to a decrease in foodborne human illness due to enteric pathogens in general.

4. It should be determined whether a broader microbial indicator can be used as a performance standard. Examples of such broad microbial indicators would include a class of microorganisms, a microbial metabolite or specific genetic sequences.

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

Understanding variability is important in conducting risk assessments that form the basis for developing risk management strategies. Such strategies may include the development and implementation of scientifically based performance standards. Determining sources of variation will expand knowledge about such factors, particularly in relation to potential nonconformances. Understanding sources of variation are equally important to facilitate development of strategies to minimize variability and increase control over the presence of the target organism(s). The Committee considered in its deliberations that this question encompassed two distinct but integrated elements which need to be considered in order to adequately address the question dealing with:

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

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

A. A qualified, multidisciplinary team of scientists should be formed to design the study. To facilitate the process of data gathering and analysis, the Committee found it useful to view the process of producing meat or poultry products in terms of the following modules:

1. Factors that may influence the microbiological status of animals presented for slaughter.

2. Slaughter practices aimed at contamination prevention.

3. Application of interventions that reduce contamination, both pre and post slaughter.

4. Handling and holding of meat and poultry.

The Committee concludes that microbiological analyses of meat or poultry products are likely to require evaluation of the process from live animal to final product to assess the impact of factors such as regionality or seasonality. Thus, it would be ideal to be able to gather data as far "upline" as possible to optimize the possibility of determining causes/effects. The Committee also recognizes that a considerable amount of information already exists that should be useful in examining this issue. For any future studies, the Committee believes that an agreement needs to be reached as to the parameters that will be studied, standardization of sampling sites (e.g., external surfaces, trimmings, ground product), and standardization of methods of analysis. The Committee also is of the opinion that pilot studies should be commissioned to determine feasibility of the sampling scheme and to gain preliminary knowledge about variability to better define appropriate sampling plans.

The initial focus of new baseline studies should be on regionality and seasonality, with consideration given to other possible confounding factors, such as those that may be included in the list below. The study design should be sufficient to determine the estimates of variability within and between plants and whether the data are skewed in regard to the possible confounding factors.

During data gathering, the differences between species, the degree of vertical integration involved in each particular industry segment, and ensuring data are collected beyond one year are important considerations. Some of the factors to be considered are listed below by module:

1. Factors that may influence the microbiological status of animals presented for slaughter.

a) Regionality
b) Seasonality
c) Husbandry practices including grow-out, finishing, etc.
d) Weather conditions
e) Feed regimens
f) Age of animals
g) Condition of animals (health and cleanliness)
h) Transportation to slaughter
i) Holding conditions prior to slaughter

2. Slaughter practices.

    a) Sanitary dressing procedures being utilized
    b) Hygienic standards of plant and workers
    c) Line speed
    d) Size and capacity of establishment
    e) Equipment being used

3. Interventions that reduce contamination.

    a) Washing
    b) Organic acid rinses
    c) Antimicrobial compounds
    d) Hot water or steam pasteurization

4. Handling and holding of raw meat and poultry.

    a) Rapid chilling
    b) Temperature control
    c) Recontamination

    Any future studies should be designed to gain an understanding of the relationship, if any, between contamination present on the exterior of the animal, or present internally in the animal, and the contamination that is likely to result on the meat or poultry following slaughter and fabrication. Studies also should allow for discrimination between controllable and non-controllable factors affecting the frequency and/or concentration of contamination to help identify means to reduce contamination across the food chain.

B. Analysis of data should facilitate determining whether variation can be reduced through controls, e.g., intervention technologies or best practices. Ideally, it should be decided whether variation can be assigned to a cause. If an assignable variation is uncontrollable due to regionality, seasonality and other factors, consider whether the variation is significant in terms of public health consequences when developing performance standards.

    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 use of available control technologies can have a decided effect during data evaluation, and such failures should be taken into account.

Data Needs

It is recommended that the 1998-2001 HACCP verification data not be used to establish a new performance standard for ground beef or to determine either regional or seasonal variability in *Salmonella* prevalence. These sampling programs were not designed to provide statistically valid estimates of national prevalence and levels of microorganisms. For this reason and for the consideration of establishing revised raw ground product performance standards, NACMCF recommends that the agency conduct another[8] nationwide, federally inspected plant, microbiological survey for each raw ground product of interest designed to provide statistically unbiased estimates of the true prevalence of bacteria of concern. NACMCF further recommends that this survey be conducted for at least 12 consecutive months, be stratified by production volume, month and region, and the number of samples analyzed being sufficient to meet agency specified discriminatory power for comparisons of interest. Production volume is an essential factor when conducting baseline surveys. 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 and/or seasonal effects, consideration should be given to increasing the number of samples analyzed to increase the statistical sensitivity to detect significant differences.

In the case of ground beef, NACMCF recommends that an accompanying baseline survey be conducted of trimmings (the intermediate product stage between the carcasses and the ground product) which would include all source materials with additional consideration for stratification by boneless, head meat, low temperature rendered materials, advance meat recovery, lean finely textured meat, frozen, etc. Determining the microbiological profile of the trimmings will better reflect the prevalence of pathogens and other organisms in source materials for ground beef to establish performance standards if deemed necessary.

All baseline studies should, at a minimum, include an identification of the product class and product origin identified by location of manufacture and date. Such information will provide data needed to address regional and seasonal variations. Confounding factors as previously described may also need to be considered. From a practical standpoint, only a limited number of factors are likely to have a significant effect on microbial prevalence. It should not be assumed that the confounding factors will be the same for different ground products and their source materials. Additionally, the aforementioned baseline studies should include examination for not only *Salmonella*, but also for coliforms, *E. coli*, or other indicators that may have possible utility as a measurement for "cold chain management" or process control. Implicit in this is the assumption that the interventions applied to carcasses have the effect of controlling pathogens including *Salmonella*, as well as *E. coli* and coliforms. NACMCF recommends that the statistical estimation procedures used to provide prevalence estimates and their standard errors be based on the methods[9] used for the 1993/1994 raw ground product microbiological survey.

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[8]Nationwide Federal Plant Raw Ground Beef Microbiological Survey, FSIS/USDA, April 1996.

[9]Statistical Estimation Procedures for 1993 - Early 1994 Raw Ground Product Microbiological Surveys, Harry Marks and Kristen Meier, FSIS/USDA, 1 December 1995.

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? What special considerations need to be attended to in using quantitative baseline data for the development of quantitative performance standards?

Definitions

Quantitative Variable - A variable that has a numerical value, e.g., concentration (in cfu/g) 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 concentration 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 define the public health outcomes as determined through risk assessments (especially important for exposure assessment).

3. Quantitative data obtained from various points on the production line provide more specific information on pathogen reduction than qualitative data. Quantitative data can measure reductions in pathogen concentrations which may occur while qualitative data still indicate the presence of the pathogen.

4. Quantitative data can help monitor changes in the concentrations of organisms in relation to 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 quantification may be more time and resource intensive for certain pathogens.

Special Considerations and Technical Challenges for Quantitative Baseline Data

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, where appropriate, may include (but is not limited to):

- the sources of raw materials,
- date of slaughter,

- date of sampling,
- type of establishment and production volume,
- location of facility and location within the establishment where the samples are collected,
- types of interventions applied (if appropriate),
- and transportation and holding conditions prior to sampling.

The study design must also take into account normal variation (i.e., variation that exists when the process is in statistical control), and possible regional and seasonal variations, and further should determine what factors have the predominate effect on the data. The study design likely will need to be adjusted in order to accommodate differences between species and commodity sectors.

Methods used for sample collection, shipment and laboratory analyses should be developed so that the desired information can be obtained through subsequent data analysis. Under certain conditions, consideration should be given to collecting matching samples, especially in those instances where microbiological characteristics of carcasses and ground product derived from those carcasses would be of interest. Once developed, the sampling program and methods must be standardized, and the systematic documentation of appropriate implementation in the field must be provided for. 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, since it is critical that the organisms neither die nor multiply during transport. 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 determine the history of the product 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 quantitation. It is also important to note that the uncertainty (i.e., error) 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

There do not appear to be substantial scientific data relating pathogen performance standards to public health consequences. Setting a performance standard, whether based on a frequency of

occurrence of a pathogen or indicator organism, or a minimum pathogen concentration reduction, requires the establishment of a reasonable maximum frequency and required minimum reduction, respectively. Data relating pathogen performance standards to public health consequences would assist in demonstrating the impact of performance standards, on reducing public health consequences due to the presence of selected pathogens on carcasses, and in raw ground meat and poultry products.

Quantitative baseline data must be generated and also be comprehensive as described by the considerations and technical challenges discussed previously in this report. Assessment of the quantitative baseline data in preparation of quantitative performance standards should identify confounding factors, i.e., conditions or events not addressed in the original analysis that do 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 government and industry. The increased information gained from quantitative variable testing must be balanced against the increased cost of acquiring the information. While qualitative data provide less information, decreased costs allow more samples to be taken. Test methods must be standardized as well.

Application of Quantitative Performance Standards and Qualitative Performance Standards

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

Use of quantitative performance standards may also be appropriate to achieve certain public health goals. For example, reducing the concentration of a pathogen may not alter the detection of that pathogen. Further, quantitative and qualitative performance standards may be used when verifying the ability of process steps to control or reduce the concentrations 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 expensive as the most probable number (MPN) technique.

ADDITIONAL QUESTIONS POSED TO NACMCF

In their November 29, 2001-letter to the NACMCF, Dr. E. Murano and Dr. K. Wachsmuth posed two additional questions pertaining to the microbiological performance standards associated with

the 1996 Pathogen Reduction/Hazard Analysis Critical Control Point final rule. As an initial step in addressing these questions the Microbiological Performance Standards for Meat and Poultry Subcommittee carried out a lengthy discussion of the scope of the questions and the scientific issues that must be captured in developing a response.

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

As previously indicated in question 2, General Principle 1, microbiological performance standards are intended to effectuate a decrease in the presence of enteric pathogens in raw meat and poultry with the goal of improving public health. The NACMCF considers microbiological performance standards an important tool in advancing the microbiological safety of meat and poultry to articulate clearly to the industry the agency's expected level of control of the HACCP system, including sanitation SOPs.

Three criteria were considered in relation to the effectiveness of performance standards:

- Performance standards have stimulated the development and implementation of intervention technologies for reducing the levels of pathogens on meat and poultry.
- There has been a reduction in the frequency of isolations of salmonellae from verification samples by FSIS.
- Based on FoodNet data from 2001, CDC has determined that overall human salmonellosis decreased 15% (95% CI = 7% to 22% decrease) between 1996 and 2001. However, the proportion of salmonellosis linked to the meat and poultry supply cannot be determined at this time.

The NACMCF noted 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. The NACMCF considered alternate approaches on how the potential impact of the performance standards could be evaluated. The Committee observed that the only data available are the *Salmonella* verification results that clearly demonstrate a decrease in the frequency of *Salmonella*-positive samples that are collected through the agency's verification sampling program. The Committee also noted a decreased incidence of salmonellae, as reflected in the agency's verification data in raw meat or poultry has not led to a decrease in disease associated with *E. coli* 0157:H7 in ground beef.[10] In this instance the underlying assumptions of the performance standards need to be reexamined. Before new standards or approaches are adopted, alternative standards or approaches need to be examined.

[10]Morbidity and Mortality Weekly Report. 2002. Preliminary FoodNet Data on the Incidence of Foodborne Illnesses — Selected Sites, United States, 2001. Vol. 51:325-329.

Recommendation

1. FSIS should work in collaboration with CDC to measure the impact of the performance standards for raw meat and poultry on salmonellosis and other relevant enteric diseases.

2. Are there more effective alternatives to these *(Salmonella)* performance standards and if so what would they be?

The Committee noted that regardless of the approach taken to control the level of pathogenic microorganisms in raw meat and poultry, there should be either an explicit or implicit microbiological criterion underlying the approach taken. Among the alternative approaches that may be considered are:

- Use of an indicator organism in lieu of *Salmonella* standards (see the discussion relative to question 2 earlier in this report).
- Mandate pathogen control on farm or at grow-out.
- Mandate ante-mortem pathogen control (e.g., to prevent spread).
- Mandate a performance criterion for the reduction of pathogens at specific steps in the production of raw meat and poultry products.
- Mandate specific proven interventions on raw meat and poultry products (e.g., thermal treatments, use of organic acids, irradiation).
- Mandate continuous improvement criteria for plant performance within specific time periods (e.g., 10% reduction in frequency of a pathogen on an annual basis until specified criteria are met and maintained).

While NACMCF has identified some outcome-related alternatives, there is a general consensus that performance standards articulate the goals that are expected to lead to an improvement in public health. Use of performance standards generally maximizes the flexibility in relation to finding new strategies for improvement.

Recommendations

1. Sponsor an analysis to determine the steps in the food chain (i.e., farm through distribution of raw meat and poultry products) where new technologies could cause major reductions in the frequency of enteric pathogens.

2. Sponsoring agencies should provide to stakeholders a summary of the results from ongoing food safety research pertinent to this subject.

3. Request ARS, CSREES, and industry to conduct more research on the farm/feedlot level to develop effective control measures and reduce the level of enteric pathogens on live animals entering the plant.

4. Request ARS, CSREES, and industry to generate Best Management Practices (BMPs) to control pathogens from the on farm level through distribution.

5. Reevaluate the existing policy regarding the degree to which carcass surfaces can be denatured by heat or other treatments (i.e., increased denaturation on carcasses should translate into an increased kill of pathogens on the surface).

6. Support research on the use of additives that can control growth of enteric pathogens and, where possible, increase their heat sensitivity in ground products.

7. Evaluate the use of intermittent water treatments for efficacy of pathogen reductions on carcasses after hide removal.

8. Further investigate decontamination procedures (e.g., electrostatic application of diacetate, etc.) and determine if existing treatments can be further enhanced.

9. Request ARS, CSREES, and industry to enhance technology transfer of effective approved treatments from the laboratory to commercial applications.

NEXT STEPS

The Committee does not intend to work further on the two November 29, 2001 questions relative to microbiological performance standards. The Committee will continue its work on other classes of products (e.g., ground chicken, turkey, etc.). Nevertheless, if the sponsoring agencies wish otherwise the Committee should be so notified.

APPENDIX I

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

Dr. David Acheson	Dr. Anna Lammerding
Mr. Dane Bernard	Dr. Marguerite Neill
Dr. Bob Buchanan	Dr. Robert Seward
Dr. Dan Englejohn	Dr. David Theno
Mr. E. Spencer Garrett, Chair	Dr. Robert Tompkin

The MPSRMPS prepared the initial draft report for NACMCF's consideration.

COMPLETED MPSRMPS ACTIVITIES

The MPSRMPS met July 16-18, August 14-15, October 2 (Teleconference), December 4-6, 2001, January 22, August 6-8, and August 26, 2002 to address the USDA questions. A listing of documents reviewed and presentations received by the MPSRMPS during their deliberations is found in Appendix I of this draft report.

In addition to the NACMCF/MPSRMPS reading and familiarizing itself with the information and data within the cited references, they also received briefings from Dr. Al Rainosek (NOAA/ NMFS), Dr. Ricardo Molins (NAC/NRC), and Dr. Roger Cook (Ministry of Agriculture and Forestry, New Zealand). Dr. Rainosek's presentation centered on detailing the performance characteristics (operating characteristic curves) of the current FSIS Pathogen Reduction Performance Standards sampling plans for *Salmonella.* There are seven different sampling plans, one each for steers/heifers, cows/bulls, ground beef, hogs, broilers, ground chicken, and ground turkey. In particular, Dr. Rainosek contrasted the effect for one commodity (broilers) should the current performance standard of 20% be reduced based on the rationale given in the USDA/FSIS Progress Report on *Salmonella* Testing of Raw Meat and Poultry Products, 1998-2000. This progress report has been previously referenced in this interim report.

Dr. Rainosek also reviewed the use of acceptance sampling plans for appropriate understanding and application by risk managers. This presentation included Types I and II statistical sampling errors (i.e., rejection of conforming product and acceptance of nonconforming product), general information on the use of two-class and three-class attribute sampling plans, and the ten-percent rule as it applies to the relationship between sample size and lot size on the performance characteristics of sampling plans. In addition, Dr. Rainosek explained the increased chance of accepting nonconforming product when using the practice of "resampling," i.e., if the first sample indicates product rejection, take a second sample and base product disposition on results from only the second sample. Resampling should not be confused with double sampling plans which allow for possible product acceptance or rejection on the first sample or the taking of a second sample. If a second sample is taken, results from both the first and second samples are used for product disposition.

The NACMCF/MPSRMPS also was briefed by Dr. Ricardo Molins from the NAS/NRC who explained the difference between what NACMCF is doing regarding microbiological performance standards from that which the NRC will address. Dr. Cook, from the Ministry of Agriculture and Forestry New Zealand, detailed the history and principal results from his country's National Microbiological Database (NMD) HACCP Verification Programme.

DOCUMENTS REVIEWED BY THE MPSRMPS TO ADDRESS THE QUESTIONS POSED BY FSIS REGARDING PERFORMANCE STANDARDS WITH PARTICULAR REFERENCE TO GROUND BEEF PRODUCTS

1. Codex Alimentarius Commission. 1999. Principles and Guidelines for the Conduct of Microbiological Risk Assessment.

2. Codex Alimentarius Commission. 1997. Principles for the Establishment of Microbiological Criteria for Foods. Food Hygiene Supplement to Volume 1B.

3. Congressional Record/Conference Agreement Providing Funds to Have the National Research Council of the National Academy of Sciences to Conduct a Study on the "...Role of Scientifically Determined Criteria, Including Meat and Poultry Products, and a Report Including Recommendations to the Secretary to be Prepared by the National Advisory Committee on Microbiological Criteria for Foods ... Regarding Microbiological Performance Standards . . . " Congressional Record, page 114 of 146 (H9493). FY2001.

4. Expert Panel's Summary Report and Recommendations, Role of Microbiological Testing in Verifying Food Safety, Scientific and Technical Conference May 1-2, 1005, Philadelphia, PA.

5. Federal Register. February 27, 2001. USDA/FSIS 9 CFR Parts 301, 303. Performance Standards for the Production of Processed Meat and Poultry Products; Proposed Rule.

6. Federal Register. July 25, 1996. 310.25. Contamination with Microorganisms: Pathogen Reduction Performance Standards for *Salmonella.*

7. Federal Register. July 25, 1996. USDA/FSIS 9 CFR, Part 304. Pathogen Reduction: Hazard Analysis and Critical Control Point (HACCP) Systems Final Rule.

8. Federal Register. July 25, 1996. Sec. 381.94. Contamination with Microorganisms. Process control verification criteria and testing. Pathogen reduction standards.

9. Food Safety and Inspection Service, USDA. HACCP Verification Sampling Program Explanatory Notes. September 10, 2001.

10. Food Safety and Inspection Service, USDA, Section IV, Microbiological Performance Criteria and Standards, 6 FR 38835-38836, July 25, 1996.

11. Foodborne Illness Investigation - *E. coli* 0157, August 2000. Michigan Department of Community Health Communicable Disease and Immigration Division. 2001.

12. ICMSF. 1986. Micro-organisms in Foods 2 Sampling for microbiological analysis: Principles and specific applications. Meaningful Microbiological Criteria for Foods. Pages 3-11.

13. Johnston, Ralph W., et. al. 1976. *Salmonella newport* in Ground Beef Investigation 1975-1976. Presented at the Annual Meeting of the Food Research Institute, Madison, Wisconsin. May 11-12, 1976.

14. Johnston, Ralph W. 1974. The Occurrence of High Percentile *Salmonella* Incidences in Ground Beef Prepared from Cows Reared in the Southwestern United States. (Unpublished signed report supplied by Dr. R.B. Tompkin).

15. Marks, H. and Meier, K. 1995. Statistical Estimation Procedures for 1993 - Early 1994 Raw Ground Product Microbiological Surveys.

16. Mead et al. 1999. Synopses of Food Related Illness and Death in the United States. Emerging Infectious Diseases, Vol. 5, No. 5, Sept-Oct.

17. The Morbidity and Mortality Weekly Report Entitled Preliminary FoodNet Data on the Incidence of Foodborne Illnesses - Selected Sites, United States. April 6, 2001/Vol. 50/ No.13.

18. Morbidity and Mortality Weekly Report.1975. *Salmonella newport* Contamination of Hamburger. Pages 438 and 443.

19. 9CFR, Part 311. Disposal of Diseased or Otherwise Adulterated Carcasses and Parts. January 1, 2001.

20. 1999 Food Code. U.S. Public Health Services. Pages 17 (Definitions), 31-33 (Raw Animal Foods, Cooking Temperatures), 55-58 (Destruction of Organisms of Public Health Concern).

21. NRC. 1985. An Evaluation of the Role of Microbiological Criteria for Foods and Food Ingredients. Pages 85-86 (Moderate Hazards, Potentially Extensive Spread [*Salmonella*]), Pages 104-130 (Selection of Indicator Organisms and Agents as Components of Microbiological Criteria).

22. Personal communication from Al Rainosek to the NACMCF Subcommittee on Microbiological Performance Standards for Raw Meat and Poultry. June 27, 2002. Analysis of Raw Ground Beef *Salmonella* Prevalence for Sets A, B, B, D by Plant, Size and Year.

23. Personal communication from FSIS to the NACMCF Subcommittee on Microbiological Performance Standards for Raw Meat and Poultry. February 1, 2002. Explanation of the *Salmonella* PR/HACCP Testing Program - 2001.

24. Personal communication from FSIS to the NACMCF Subcommittee on Microbiological Performance Standards for Raw Meat and Poultry. 2002. Prevalence * of *Salmonella* in the PR/HACCP Verification Testing Program by Calendar Year, 1998 - 2001.

25. Personal communication from FSIS to the NACMCF Subcommittee on Microbiological Performance Standards for Raw Meat and Poultry. 2002. Tables of *Salmonella* Prevalence for Ground Beef by Region and Month.

26. Personal communication from Al Rainosek to the NACMCF Subcommittee on Microbiological Performance Standards for Raw Meat and Poultry. Example Sampling Plan for Broilers for Revised Performance Standards.

27. Rainosek, A. 2001. Performance Characteristics Associated with USDA/FSIS Microbiological Performance Standards for Broilers, Steers/Heifers, Ground Beef, etc.

28. Rainosek, A. 1997. Inherent Risks in Acceptance Sampling. *In* Fish Inspection, Quality Control and HACCP, (eds. R. Martin, R. Collette, and J. Slavin), pp. 530-537.

29. Siragusa, G.R. 2001. Is There a Relationship Between Microbial and Non-Microbial Indicators of Fecal Contamination? Presented at the International Association of Food Protection 88th Annual Meeting, Minneapolis, MN. August 5-8, 2001.

30. Siragusa, G.R., et al. 1998. Journal of Food Protection. The Incidence of *Escherichia coli* on Beef Carcasses and Its Association with Aerobic Mesophilic Plate Count Categories During the Slaughter Process. Vol. 61, No. 10, Pages 1269-1274.

31. The USDA Progress Report on *Salmonella* Testing for Raw Meat and Poultry Products 1998-2000.

32. The USDA Nationwide Federal Plant Raw Ground Beef Microbiological Survey August 1993 - March 1994.