NATIONAL ADVISORY COMMITTEE ON MICROBIOLOGICAL CRITERIA FOR FOODS

RESPONSE TO THE QUESTIONS POSED BY FSIS REGARDING PERFORMANCE STANDARDS WITH PARTICULAR REFERENCE TO BROILERS (YOUNG CHICKENS)

Adopted February 13, 2004
Atlanta, GA

Background

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 Hazard Analysis and Critical Control Point (HACCP). 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 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, may be appropriate. 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 one class of poultry called broilers. A broiler, as currently defined by FSIS regulation, is a young chicken of either sex usually under 13 weeks of age (FSIS has proposed to reduce the age requirement to under 10 weeks).

The Committee was charged with addressing the following six questions which were posed to it by the FSIS during its June 24 - 25, 2003 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?

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 standards for broilers. 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 regionality, seasonality, 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.

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 NACMCF[1], International Commission on Microbiological Specifications for Foods (ICMSF)[2], Codex Alimentarius[3], and Food and Agriculture Organization/World Health Organization (FAO/WHO).[4] 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. 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, 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, available resources, and the potential consequences of the conclusions. The principles for linking public health goals to performance standards via a risk analysis process have been articulated by ICMSF[5] and are currently under discussion internationally by Codex Alimentarius. It should be noted that a risk assessment for *Salmonella* on broilers is available.[6]

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

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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.

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

[6]World 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.

uncertainty should be avoided, particularly when more than one factor contributes to overall public health risk. This can significantly overestimate the risk and suggests the need for interventions that may not be necessary to enhance public health.

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 or modify a performance standard or any other risk management option.

Current Applications and Limitations of Risk Assessments for Broilers

To estimate the likely impact that performance standards for *Salmonella* in broilers would have on public health, a risk assessment conducted according to the above principles is needed. The FAO/WHO has completed a risk assessment of *Salmonella* in broilers from post-slaughter through consumer handling and preparation. The risk characterization estimates the probability of infection/salmonellosis in a year due to the ingestion of *Salmonella* on fresh broiler carcasses with the skin intact, and which are cooked in the household for immediate consumption. The FAO/WHO risk assessment concluded that the existing dose response models for *Salmonella* were inadequate to characterize the dose response relationship observed in outbreak data (20 outbreaks) from Japan and the United States; thus, a new model was developed based on the outbreak data.

The FAO/WHO risk assessment can serve as an initial model that can be strengthened by consideration of current on-farm and slaughter interventions that reduce prevalence and cell numbers. The following elements should be considered in modifying this risk assessment to apply to the United States:

- Prevalence and cell numbers of *Salmonella* in U.S. broilers
- Epidemiological data for salmonellosis associated with broilers in the United States, including individual susceptibilities
- Data on the linkage of clinical strains with isolates from broilers
- Differences in virulence among pathogenic strains of *Salmonella* associated with broilers
- Time/temperature data from slaughter to consumption
- Frequency and serving sizes for broilers and broiler parts (e.g., leg, thigh, or breast portions) consumed inside and outside the home
- Nature and extent of cross contamination of foods or food contact surfaces during preparation and storage
- Methods and extent of cooking
- Inactivation and growth kinetic models for strains of *Salmonella*, especially those strains commonly found on broilers

It is important to note that some of these data may currently be available or can be deduced as a result of research and reexamining 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 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 performance standards for broilers are:

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

A risk assessment for salmonellosis from broilers is food and pathogen specific. When risk assessments or evaluations are undertaken for different poultry products (e.g., raw ground chicken), they should reflect the specific characteristics of the product and its manufacturing processes.

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 is necessary to determine the portion of salmonellosis in the U.S. population attributed to broilers. The epidemiological data would provide the most benefit if they would include cell numbers in implicated broiler products, amount of broiler product consumed, accurate estimates of the size of the ill and exposed populations, and accurate characterization of the population, including age profiles, medical status, and other potential risk factors.
- Data on the extent to which cross contamination from raw broilers to ready-to-eat foods is responsible for salmonellosis.
- Statistically valid data for unbiased estimation of prevalence and cell numbers for *Salmonella* and other enteric pathogens on broilers throughout the farm-to-table continuum. In preparation for collection of these data, FSIS should consider compatibility with data (see also recommendation on data analysis and collection in question 4) used in the exposure assessments contained in existing risk assessments.

- Improvements in methods to detect and enumerate salmonellae. FSIS should consider enumeration of *Salmonella* and other enteric pathogens for some of the samples in its verification sampling and testing program.
- Data that relates to specific process steps to changes in prevalence and/or cell number.
- Additional data on the relationship between the prevalence and cell numbers of *Salmonella* on broiler carcasses exiting the chill tank and the prevalence and cell numbers of *Salmonella* on broiler or broiler parts at retail.[7]
- Data on the survival of *Salmonella* and other enteric pathogens under chilling and freezing conditions to improve the predictive microbiology component of exposure assessments.
- Characterization of the impact of food handling and preparation practices as they relate to cross contamination and survival of *Salmonella*.
- Contribution of other foods eaten relative to the risk of salmonellosis.

Existing data should be reviewed in relation to these data and research needs.

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. Current FSIS raw broiler microbiological performance standards are intended to effectuate a decrease in the presence of enteric pathogens, with emphasis on *Salmonella,* in broilers 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 sufficiency in support of use of an indicator organism in lieu of a specific pathogen for broilers include:
   - Similar survival and growth characteristics

[7]Simmons, M., Fletcher, D.L., Cason, J.A. and Berrang, M.E. 2003. Recovery of *Salmonella* from retail broilers by a whole-carcass enrichment procedure. Journal of Food Protection, 66:446-450.

- A shared common source for both organisms in broiler 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

Current Applications and Limitations in the Use of Indicator and Index Organisms for Broilers

Escherichia coli has been viewed by FSIS as a direct measure of control of fecal contamination and, by implication, *Salmonella* or other enteric pathogens. However, recent information indicates that this may not be a valid assumption for *E. coli* in broilers. For example, in broilers, its presence may also be a result of infectious process and air sacculitis, in addition to fecal contamination.[8]

Currently, *E. coli* and *Salmonella* are being measured separately and independently as indicators of states or conditions of process control at broiler slaughter facilities; thus, they are being used as indicator organisms by definition. The rationale, implied but not stated in the Pathogen Reduction/HACCP Final Rule[9], is that control of *E. coli* and *Salmonella* will lead to the control of other enteric pathogens. The limitations of using *Salmonella* to verify process control in broiler slaughter operations are discussed in the Philadelphia report.[10] The Committee points out that when HACCP systems and prerequisite programs in poultry operations are adequate and verified, the measurement of *Salmonella* reflects the level of process control. The Committee concluded that currently there are no data that support the use of index organisms for *Salmonella* on broilers.

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 that the microorganism can be used to indicate the state or condition associated with contamination by a pathogen(s) of concern.

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[8]Gomis, S.M., Riddell, C., Potter, A.A., and Allan, B.J. Phenotypic and genotypic characterization of virulence factors *Escherichia coli* isolated from broiler chickens with simultaneous occurrence of cellulites and other colibacillosis lesions. Can J Vet Res. 2001 Jan; 65(1):1-6.

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

[10]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.

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. Data should be generated to assess whether a decrease in the presence of an indicator organism on broilers leads to a decrease in broiler-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 regionality, seasonality 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 are 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 concluded that data must be gathered from production to the step in the process where the performance standard is applied to determine sources of variation of *Salmonella* prevalence. The Committee also recognizes that a considerable amount of information already exists in the literature that should be useful in examining this issue. For any future studies, the Committee believes that an agreement needs to be reached within FSIS as to the parameters that will be studied, standardization of sampling procedures (e.g., whole broilers, parts, and ground product at appropriate steps in processing), and standardization of methods of analysis. Performance standards need to be based on product-specific baseline studies. The Committee also is of the opinion that pilot studies should be commissioned (before the conduct of more comprehensive studies) to determine 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 on broilers should be on determination of the influence of:

- preslaughter practices
- regionality
- seasonality
- climatic variations
- line speed
- volume of production
- in-plant interventions for reduction of *Salmonella* (e.g., washing, antimicrobial treatments)

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.

Additional factors that may influence the microbiological status of live broilers, and which may be better addressed through approaches such as literature reviews, industry data, or pilot studies, may include the following:

1. Pre-slaughter practices that may influence the microbiological status of live broilers presented for slaughter

    a) Generation beyond parent flock

    b) *Salmonella* control at hatcheries

    c) Growout practices that may influence the prevalence of *Salmonella* (e.g., type of house versus free range, vaccination programs, use of probiotics (competitive exclusion), prophylactic antibiotics, feed regimens, litter control, water quality and method of delivery, house temperature, lighting in house, pest control)

    d) Uniformity of weight of broilers

    e) Condition of broilers (e.g., health and cleanliness)

    f) Feed withdrawal

    g) Method of catching the broilers (e.g., manual or automated)

    h) Transportation to slaughter

    i) Holding conditions prior to slaughter

    j) Cleaning and sanitizing of cages

2. Factors associated with broiler slaughter practices
    a) Plant sanitation and personnel hygienic practices (e.g., number and type of FSIS Non-Compliance Records (NRs) per 100,000 broilers from receipt of live broilers through chilling of processed broilers)
    b) Equipment (e.g., stunning/killing, scalding, de-feathering, evisceration) being used
    c) Off-line reprocessing procedures
    d) Inspection system protocols
3. Handling and holding of raw broilers
    a) Chilling procedures
    b) Conditions that influence the prevalence of *Salmonella* during further processing and packaging
    c) Temperature control

Any future studies should be designed to gain an understanding of the relationships, if any, between contamination present on the exterior of the live broiler or present internally in the live broiler and the *Salmonella* that is likely to result on processed broilers. Studies also should allow for discrimination between controllable and non-controllable factors affecting the prevalence and/or cell number of *Salmonella* to help identify means to reduce contamination across the food chain. The approach applied by certain European countries to identify significant on-farm factors that influence the prevalence of *Salmonella* and *Campylobacter* on broilers should be considered.[11]

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[11]Angen, Ø., Skov, M.N., Chriél, M., Agger, J.F., and Bisgaard, M. 1996. A retrospective study on salmonella infection in Danish broiler flocks. Preventive Veterinary Medicine, 26:223-237.

Henken, A.M., Frankena, K., Goelema, J.O., Graat, E.A.M., and Noordhuizen, J.P.T.M. (1992) Multivariate epidemiological approach to salmonellosis in broiler breeder flocks. Poultry Science, 71:838-843.

Refrégier-Petton, J., Rose, N., Denis, M., and Salvat, G. 2001. Risk factors for *Campylobacter* spp. contamination in French broiler-chicken flocks at the end of the rearing period. Preventive Veterinary Medicine, 50:89-100.

Rose, N., Beaudeau, F., Drouin, P., Toux, J.Y., Rose, V., and Colin, P. 1999. Risk factors for *Salmonella enterica* subsp. *enterica* contamination in French broiler-chicken flocks at the end of the rearing period. Preventive Veterinary Medicine, 39:265-277.

Rose, N., Beaudeau, F., Drouin, P., Toux, J.Y., Rose, V., and Colin, P. 2000. Risk factors for *Salmonella* persistence after cleansing and disinfection in French broiler-chicken houses. Preventive Veterinary Medicine, 44:9-20

Rose, N., Mariani, J.P., Drouin, P., Toux, J.Y., Rose, V., and Colin, P. 2003. A decision-support system for *Salmonella* in broiler-chicken flocks. Preventive Veterinary Medicine, 59:27-42.

Skov, M.N., Carstensen, B., Tornøe, N., and Madsen, M. 1999a. Evaluation of sampling methods for the detection of *Salmonella* in broiler flocks. Journal of Applied Microbiology, 86:695-700.

Skov, M.N., Angen, Ø., Chriél, M., Olsen, J.E., and Bisgaard, M. 1999b. Risk factors associated with *Salmonella enterica* Serovar *typhimurium* infection in Danish broiler flocks. Poultry Science, 78:848-854.

Wedderkopp, A., Rattenborg, E., and Madsen, M. 2000. National surveillance of *Campylobacter* in broilers at slaughter in Denmark in 1998. Avian Diseases, 44:993-999.

Wedderkopp, A., Gradel, K.O., Jorgenson, J.C., and Madsen, M. 2001. Pre-harvest surveillance of *Campylobacter* and *Salmonella* in Danish broiler flocks: a 2-year study. International Journal of Food Microbiology, 68:53-59.

Wegener, H.C., Hald, T., Wong, D.L.F., Madsen, M., Korsgaard, H., Bager, F., Gerner-Smidt, P., and Mølbak, K. 2003. *Salmonella* control programs in Denmark. Emerging Infectious Diseases, 9:774-780.

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, best practices). Ideally, efforts should be made to assign variation to a cause. If an assignable variation is uncontrollable due to regionality, seasonality, or other factors, it should be considered whether this variation negatively affects the ability of the performance standard to achieve its public health goal. If significant regional or other differences are identified this could impact on a processor's ability to comply with 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 a decided 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 Broilers

It is recommended that the FSIS HACCP verification data not be used to establish a new performance standard for broilers or to determine either regional or seasonal variability or the influence of interventions in *Salmonella* prevalence. These sampling programs were not designed to provide statistically valid estimates of national prevalence and cell numbers of microorganisms. For this reason and for the consideration of establishing revised broiler performance standards, the Committee recommends that the agency conduct a new nationwide, microbiological baseline study for broilers in federal and state inspected plants designed to provide statistically unbiased estimates of the true prevalence and cell numbers of bacteria of concern in the U.S. broiler supply. 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 yearly measurement of change. Such studies should be stratified by production volume, month and region, with 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 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 intervention 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 for not only *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? 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., 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 predicts the achievement of 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 cell numbers which may occur while qualitative data still indicate the presence of the pathogen.

4. Quantitative data can help monitor changes in the cell numbers 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 will be more time and resource intensive for certain pathogens. Moreover, reliable estimates of cell numbers may be difficult to obtain.

Special Considerations and Technical Challenges for Quantitative Baseline Data

The principles and information provided in response to this question could apply to all meat and poultry products sampled at federally and state inspected facilities. However, different considerations must be addressed when developing quantitative baseline data for ground versus carcass samples. Bacteria are distributed throughout ground meat and poultry, but are limited to the surface of carcasses. When sampling carcasses it is desirable to use a procedure to recover as many of the target microorganisms as possible. Furthermore, the amount of underlying muscle that is included in a homogenized sample from the surface of a carcass will reduce or dilute the number of microorganisms detected on a per gram basis.

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. However, sampling of carcasses to obtain qualitative or quantitative results will differ among species. Factors that will result in variability of microbiological data when broiler carcasses are sampled include:

- carcass size
- non-uniform surface structure
  - external surface versus cavity microbial distribution
  - surfaces with or without skin
  - feather follicles, connective tissue, fascia
- non-uniform distribution of microbial flora on the carcass and in the cavity
- microbial cell entrapment and attachment to surface

Alternative sampling procedures to obtain microbiological data on broiler carcasses could include:

- Weighed sample (e.g., skin or muscle tissue)
- Rinse sample (e.g., whole carcass or parts)
- Swab sample (e.g., selected site(s))

All of the above sampling procedures present technical challenges when attempting to quantify *Salmonella* on broilers. Some of these technical challenges are common to all sampling procedures while some are unique to the specific method. Regardless of sampling procedure, *Salmonella* is rarely quantified in broiler samples 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. In assessing the public health impact from *Salmonella* on broilers, cross contamination of surfaces, utensils, and ready-to-eat foods should be considered.

Sponge or swab samples are neither practical nor routinely used for broilers.

When taking a weighed sample, consideration must be given to the amount and type of tissue included in the sample and the location on the carcass where the sample is taken. Data from weighed samples can be expressed as colony forming units (cfu) per gram and may be readily used in risk assessment. Weight-based samples are commonly used in official methods for quantification of indicator microorganisms worldwide, but not for quantification of *Salmonella* in broilers. Weight-based samples (neck skin) have been used in certain countries in Europe.

In 2009, the Commission of the European Communities is scheduled to adopt a microbiological standard of "*Salmonella* absence in 25 grammes" for fresh poultry meat derived from broilers.[12]

Because of the relative simplicity of the procedure, rinsing whole broilers has received wide acceptance in the United States for estimating prevalence of *Salmonella* and determining the impact of process interventions. Data from rinse samples are usually expressed as cfu (or MPN) per ml of rinse, but must be converted to a more useable format, such as number of cells per cm^2 or gram, before use in a risk assessment. Although the whole carcass is sampled, even multiple rinses do not recover all cells on the broiler carcass.[13]

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):

- 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 applicable)
- sample transportation and holding conditions prior to analysis
- other factors found to be significant as discussed in question 3, part A

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 predominant effect on the data.

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

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[12]Commission of the European Communities. 2001. Proposal for a Regulation of the European Parliament and of the Council on the control of salmonella and other food-borne zoonotic agents and amending Council Directives 64/432/EEC, 72/462/EEC and 90/539/EEC. Annex II, Section E, Council Directive 92/117/EEC.
http://europa.eu.int/eur-lex/en/com/pdf/2001/en_501PC0452_01.pdf

[13]Lillard, H.S. 1989. Incidence and Recovery of Salmonellae and Other Bacteria from Commercially Processed Poultry Carcasses at Selected Pre- and Post-Evisceration Steps. Journal of Food Protection, Vol. 52, No. 2, Pages 88-91.

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 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 (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

The FAO/WHO Risk Assessment for Broilers, 2002[14], 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. 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 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).

[14]World 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.

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. However, public health benefits may justify the increased costs. While qualitative data provide less information, decreased costs allow more samples to be taken. Test methods must be standardized as well.

Application of Qualitative and Quantitative 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, while reducing the cell numbers of a pathogen may not alter 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 expensive 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?

As previously indicated in question 2, General Principle 1, microbiological performance standards are intended to effectuate a decrease in the presence of enteric pathogens on broilers 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 broilers.

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

1. Performance standards have stimulated the development and implementation of intervention technologies for reducing the levels of pathogens on broilers.

2. There has been a reduction in the frequency of isolations of salmonellae on broilers from HACCP verification samples by FSIS.

3. Based on the FoodNet data[15] of human cases of salmonellosis, the estimated incidence of *Salmonella* did not change significantly between 1996 and 2002.

4. The lack of data on the relationship between serotypes isolated from broilers and human clinical isolates should be investigated (e.g., comparing serotypes from FSIS verification data and Centers for Disease Control and Prevention (CDC) results for clinical isolates).

The Committee 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 Committee considered alternate approaches on how the potential impact of the performance standards could be evaluated. The Committee was apprised that the FSIS has unpublished data that demonstrate a decrease in the prevalence of *Salmonella* in broilers. The Committee also noted that the decreased incidence of salmonellae, as reflected in the agency's verification data in broilers, does not appear to lead to a decrease in disease associated with salmonellosis. However, based on FoodNet data[16], there has been a 24% decline in campylobacteriosis from 1996-2002. Such a finding is supported by a CDC case control study in which it was reported that poultry is of lesser significance as a source of campylobacteriosis.[17] Before new standards or approaches are adopted, the underlying assumptions of the performance standards with respect to broilers need to be further examined.

Recommendations

1. FSIS should work in collaboration with CDC to measure the impact of the performance standards for broilers on salmonellosis and campylobacteriosis.
2. The relationship between serotypes and genotypes isolated from broilers and human clinical isolates should be investigated (e.g., comparing serotypes from FSIS verification data and CDC results for clinical isolates).
3. Performance standards need to be evaluated and adjusted, as necessary, to drive continuous improvement and enhance public health.

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

[15]Morbidity and Mortality Weekly Report. 2003. Preliminary FoodNet Data on the Incidence of Foodborne Illnesses - Selected Sites, United States, 2002. Vol. 52:342-343.

[16]Morbidity and Mortality Weekly Report. 2003. Preliminary FoodNet Data on the Incidence of Foodborne Illnesses - Selected Sites, United States, 2002. Vol. 52:342-343.

[17]2nd International Conference on Emerging Infectious Diseases. Risk Factors for Sporadic *Campylobacter* Infections in the United States: A Case-Control Study on FoodNet Sites. Atlanta, GA, July 2000.

steps in a process. Furthermore, performance standards provide the flexibility for industry to develop and seek approval for new strategies for improvement.

FSIS has proposed to revise the broiler 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 on broilers) 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.
- Use an indicator organism in lieu of *Salmonella* (see discussion in question 2).

A more effective alternative to the current broiler *Salmonella* performance standard should achieve increased consumer protection. Furthermore, a more effective alternative should incorporate continuous improvement.

Recommendations for Data and Research Needs

1. Sponsor an analysis to determine the steps from farm to table where new technologies could cause major reductions in the prevalence and cell numbers of *Salmonella* and other enteric pathogens on broilers.
2. Sponsoring agencies should provide a summary of the results from ongoing food safety research pertinent to performance standards and their alternatives to stakeholders.
3. Request USDA and industry to conduct or support more research at the on-farm/poultry house level to develop effective control measures and reduce the prevalence and cell numbers of *Salmonella, Campylobacter*, and other enteric pathogens on broilers entering the plant.
4. Request USDA and industry to generate best management practices to control *Salmonella* and other enteric pathogens on broilers from farm to table.
5. Support research on the use of feed additives or other interventions that can enhance inactivation or control growth of *Salmonella* and other enteric pathogens on broilers.
6. Evaluate the existing policy regarding the allowable degree of tissue denaturation by heat or other treatments without labeling implications. Increased denaturation on carcass surfaces could be associated with increased pathogen inactivation.
7. Evaluate the use of intermittent water treatments for efficacy of pathogen reduction on broilers after de-feathering and evisceration.
8. Request USDA and industry support technology transfer of effective FDA approved treatments from the laboratory to commercial applications.

APPENDIX I

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

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