
NATIONAL ADVISORY COMMITTEE ON
MICROBIOLOGICAL CRITERIA FOR FOODS

NACMCF RESPONSE TO
USDA/FSIS REQUEST
FOR GUIDANCE ON
BASELINE STUDY DESIGN
AND EVALUATIONS FOR
RAW GROUND BEEF COMPONENTS

Submitted with Technical Corrections and Edits
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Washington, D.C.

**THIS REPORT WAS ADOPTED BY THE NACMCF ON
AUGUST 22, 2003**

Background

In keeping with the 1996 Pathogen Reduction: Hazard Analysis and Critical Control Point (HACCP) Systems Final Rule, and in response to a recommendation by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF, also referred to as the Committee in this report), the USDA, Food Safety and Inspection Service (FSIS) expects to receive funding for and is developing an initiative to update microbiological baseline information on raw meat and poultry products. The Agency plans to perform ongoing nationwide microbiological baseline studies on raw meat and poultry products, targeting the prevalence and levels of selected foodborne pathogens and microorganisms of potential value as indicators of process control for these commodities, and to provide data for risk assessments. The first phase of this initiative will determine the microbiological profile of raw ground beef components (RGBC).

When USDA/FSIS examined raw ground beef manufacture, various RGBCs were identified as starting materials for raw ground beef. These RGBCs were selectively grouped into five baseline studies by USDA/FSIS and chosen for testing based on associated perceived public health risk as listed below.

Five baseline studies for the RGBCs are planned (staggered over time), and are listed by USDA/FSIS in order of highest to lowest perceived associated public health risk (hazard):

1. Weasand (muscle surrounding the esophagus), Head, and Cheek Meat
2. Advanced Meat Recovery (AMR) Products
3. Low-Temperature-Rendered Products (LTRP): Partially Defatted Chopped Beef (PDCB)¹ and Lean Finely Textured Beef (LFTB), also known as Lean Beef Tissue (LBT)
4. Domestic Trim and Subprimals Destined for Ground Beef
5. Imported Frozen Beef

These initial baselines are intended to identify the contribution of several RGBC categories to the prevalence of pathogens such as *Salmonella* and *Escherichia coli* O157:H7, and to measure indicators of process control. To collect supplemental information for the development of RGBC sampling plans FSIS will conduct, through its inspection force, two questionnaire-based surveys at the beef processor level. The first survey will identify and quantify producers of each of these components. The second survey will identify how much of each component is typically used in ground beef production. The goal of these surveys is to provide information on the diversity and prevalence of the various components used in ground beef production. The results of the surveys will provide critical input to both the study design and eventual data analysis.

¹PDCB was not included in the discussion because FSIS clarified that PDCB is not allowed in ground beef or hamburger. The focus of the baseline is now on components for ground beef or hamburger and not beef patty mix, which does include PDCB as a component.

The objective of this program is to collect data that will be used to develop a general microbiological profile of all types of RGBC for selected microorganisms that represent varying degrees of public health significance. FSIS seeks to determine the contribution of each RGBC category to the prevalence of foodborne pathogens, especially *Salmonella* and *E. coli* O157:H7, in ground beef products. This information will be used for FSIS risk assessment activities and for developing regulatory strategies to reduce the prevalence of enteric pathogens in raw ground beef. Baseline data on levels of potential indicator organisms may provide a basis for FSIS guidelines on testing to verify process control.

Samples will be collected at establishments throughout the country, and the results (i.e., the prevalence and levels of selected microorganisms) will be expressed as a national average, and may be analyzed using a number of variables such as plant size, production volume, geographic location, and seasons. These analyses will enable the Agency to provide a microbiological profile of components produced under federal inspection that are destined for raw ground beef production. Furthermore, this information can be used to assist in the development of *E. coli* O157:H7 and *Salmonella* risk assessments, and for subsequent regulatory policy decisions.

Projected Outcomes

These baseline studies will provide information for the Agency's risk assessments and other scientific analyses, thereby supporting the Agency's science-based risk management programs, including possible performance standards and other regulatory options. Databases will be merged to support performance standard development and evaluation criteria, allow determinations of relationships among organisms, and also to assist in identifying industry practices which are effective in pathogen reductions. The effect of certain variables (geographic location, seasonality, plant size, production volume) on the prevalence and levels of particular bacterial pathogens will be taken into account.

Charge²

“An FSIS goal is to strive to determine the optimum study design configuration for each project, satisfying the needs of both risk assessors and policy developers. As part of this process, FSIS asks NACMCF to provide feedback on certain aspects of the proposed baseline study designs. Plans for RGBC testing are being submitted at this time and we (FSIS) would like this feedback by way of review and comments. We (FSIS) request that NACMCF specifically comment on the approach and concepts of the proposed RGBC baselines relative to the four points below. NACMCF is asked to complete this review and comment task during the meetings scheduled for the week of August 18, 2003. By close of the meetings on August 22, FSIS requests that NACMCF provide completed draft comments on the points below. Any revision to the draft comments is requested by September 12, 2003.”

² Charge for Baseline Design Evaluation, FSIS, August 19, 2003.

Specifically, FSIS asks that NACMCF provide feed back on:

1. Protocols for collecting samples of RGBCs.
2. Priority selection and grouping of RGBCs into the five distinct baseline categories chosen. Are the proposed rankings and groupings, based on perceived associated public health risks, appropriate?
3. Sampling plan design. Although the sampling plan design for RGBC baselines is incomplete (pending the results of the two surveys mentioned), what are the most important elements to consider?
4. Selected test organisms for RGBC baselines.”

The Committee recognized the dual nature of the FSIS charge which not only seeks advice on developing baseline surveys which will provide information for use in the development of regulatory strategies but for use in risk assessments as well. As a means for 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. Priority selection and grouping of RGBCs into the five distinct baseline categories chosen. Are the proposed rankings and groupings, based on perceived associated public health risks, appropriate?
2. Protocols for collecting samples of RGBCs.
3. Sampling plan design. Although the sampling plan design for RGBC baselines is incomplete (pending the results of the two surveys mentioned), what are the most important elements to consider?
4. Selected test organisms for RGBC baselines.

General Recommendations

The following narrative represents the Committee’s deliberations, comments, and general recommendations. The Committee’s specific recommendations to each individual question are denoted by bulleted items.

- A. Since the collection of the baseline survey RGBC samples and associated data are to be taken by the field inspection force, the Agency needs to ensure that sufficient resources are provided to accomplish such tasks as specified hereinafter.
- B. The Committee recommends that inspectors be given training (e.g., video, CDs) to ensure that samples are taken and shipped in an appropriate and consistent manner.
- C. As critical data needs, the following information should be collected for each sample: geographical location, age of the animal at the time of slaughter (30 months or less or over 30 months), antimicrobial interventions, processing line speed, and estimated volume produced in a 24-hour period. In addition, the source or origin of the sample

should be noted to identify if the livestock recently came from a region³ different from where the sample is being collected. FSIS should, as expeditiously as possible, determine if meaningful differences exist in the prevalence and levels of microorganisms among these factors. FSIS should evaluate these data midway through the survey period and make adjustments to the collection of critical data needs as appropriate.

- D. The Committee recommends that FSIS seek funding for appropriate baseline studies on ground beef and RGBCs in state-inspected establishments since these products contribute to the exposure component of a risk assessment.
- E. Likewise, FSIS and FDA should assess the importance of retail-produced ground beef and consider including it in a baseline study, since this product contributes to the exposure component of a risk assessment. Furthermore, FSIS and FDA should seek collaboration from the Conference of Food Protection on this recommendation.

Question 1. Priority selection and grouping of RGBCs into the five distinct baseline categories chosen. Are the proposed rankings and groupings, based on perceived associated public health risks, appropriate?

- The Committee found the categories defined by FSIS to adequately reflect possible raw ground beef components, with the addition that the imported category should include fresh components. The Committee reordered the priority ranking of the categories provided by USDA/FSIS based on volume, the perceived contribution to the risk of illness, expert opinion on the use of the components in ground beef, and processing variables such as chilling rates during production. Thus, the category of domestic trim and subprimals was identified by this Committee as representing the highest perceived risk as described below.
- The Committee recognizes that setting priority based on volume, perceived risk and other variables was compromised to some extent by a lack of data. The Committee therefore recommends that FSIS consider the use of pilot surveys to assist in prioritizing categories other than this Committee's leading category of domestic trim and subprimals.
- It is recommended that USDA reprioritize the rank order for engaging in baseline studies as follows:
 1. Domestic trim and subprimals
 2. AMR
 3. LTRP
 4. Imported frozen and fresh beef
 5. Weasand, cheek, and head meat

³For region designations, the Committee suggests that FSIS use the regions previously identified for the analyses conducted in the NACMCF Final Report of "Response to the Questions Posed by FSIS Regarding Performance Standards with Particular Reference to ground beef Products, October 8, 2002," which were based, in part, on the regions identified by Animal and Plant Health Inspection Service (APHIS).

Domestic trim and subprimals are considered by this Committee as the number one priority since these components comprise the largest volume of raw materials used in ground beef and are known to contain *E. coli* O157:H7.

AMR may be an ingredient included at levels near 10%, in nearly 50% of retail ground beef. Furthermore, AMR is manufactured under various processing conditions that could lead to differences in microbiological contamination and growth.

- The Committee recognizes that some of the LTRP production occurs at dedicated facilities, and recommends that these facilities be included in any baseline studies. Along with sampling, it is critical that a record should be made of any antimicrobial interventions.

LTRPs are believed to be a diverse category, manufactured by varying technologies under varying conditions of control. Some manufacturing processes may allow microbial growth while others may be bactericidal.

- Imported fresh and frozen beef are used in domestic ground beef production. The Committee recommends that the country of origin for the raw material must be included, and whenever possible, the interventions used during production of the raw material. Such intervention information may be available to USDA on a government to government basis from the exporting country. Sampling frequency should be related to import volume. Specifically, fresh product needs to be included in the design of the import baseline study.

The Committee recognizes that weasand, cheek, and head meat are generally not used in large quantities for ground beef production, especially by large-volume establishments. The Committee encourages FSIS to gain a better understanding of the production and disposition of these products. It may be that a single component of this category, e.g., head meat, would be a good indicator for the overall category. This would be an excellent category for which a pilot study should be undertaken before embarking on a baseline survey.

- The Committee recommends that consideration be given to the linking of samples, i.e., taking trim, subprimals, and head, cheek, and/or weasand meat from the same lot of animals. The Committee recognizes that even though this may be premature, it could provide useful information for future baseline studies.

Question 2. Protocols for collecting samples of RGBC.

- For domestic trim and subprimals, FSIS should proportionately allocate by production volume the total number of samples to three classes of trim (e.g., low fat, >90% lean; medium fat, <90% and >50%; and high fat, 50-50). Proportionality relative to production volume should be used to determine the number of samples to be taken from each selected establishment, monthly over a 12-month period and from each region, with some minimum number of samples (to be determined by FSIS) required from each month/region. Inspectors should specify estimated lean content of combo bins, when not identified by the plant, based on FSIS examples to be developed regarding subprimal cuts (knuckles, clods, chucks, rounds, skirts). Further, the Committee recommends that FSIS consider age of the animal (30 months or less or over 30 months) as an additional stratifying factor for sample collection.

- For AMR and LTRP, the Committee recommends that the samples be allocated by production volume and stratified by region and month with some minimum number to be determined by FSIS for each region/month. Further, the Committee recommends that FSIS consider age of the animal (30 months or less or over 30 months) as an additional stratifying factor for sample collection.
- For weasand, head, and cheek meat FSIS should proportionately allocate, by production volume, the total number of samples to each component based upon microbiological pilot studies and surveys. Proportionality relative to production volume should be used to determine the number of samples to be taken from each selected establishment monthly over a 12-month period and from each region, with some minimum number of samples (to be determined by FSIS) required from each month/region. Further, the Committee recommends that FSIS consider age of the animal (30 months or less or over 30 months) as an additional stratifying factor for sample collection.
- Inspectors should collect composite samples as described in Appendix 1⁴ up to a minimum of four pounds in the plant, gently mix, and divide into two portions to ship to FSIS and contract labs.

Question 3. Sampling plan design. Although sampling plan design for RGBC baselines is incomplete (pending the results of the two surveys mentioned), what are the most important elements to consider?

- The Committee recommends the use of probability sampling techniques, e.g., stratified random sampling by month, region, and possibly age of animal as indicated above to assist in obtaining representative samples for each month/region.
- For allocation of the number of samples to be taken from each plant by month/region, refer to the first three specific recommendations under Question 2.
- The Committee recommends that the Agency provide a transparent document that explains how the total number of samples was determined and identify how the number of samples are to be allocated to the establishments.

The Committee notes that FSIS plans to test approximately 2000 samples of each category for all of the listed pathogens and indicators. The need to test 2000 samples appears to be based on the expected low prevalence of *E. coli* O157:H7. The Committee noted that variation due to regionality and seasonality⁵ could be significant factors in determining the number of required samples for each component category.

⁴Draft United States Department of Agriculture, Food Safety and Inspection Service Nationwide Microbiological Baseline Data Collection Program for Raw Ground Beef Components. September 2003.

⁵ The Agency should define how seasonality will be addressed nationally as well as regionally to determine if meaningful differences in prevalences or levels of organisms, within regions, would require adjustment to how seasonality is defined.

- The Committee recommends that the statistical estimation procedures used to provide prevalence estimates and their standard errors be based on methods used by FSIS for the 1993/1994 raw ground product microbiological survey data. To increase the sensitivity of statistical hypothesis testing applications and the precision of estimates of prevalence, FSIS should also aggregate the monthly data in each region to quarterly (seasonal) groups.
- The Committee recommends that FSIS consider the collection of additional samples to account for possible high number of discards and/or non-return rates.

Question 4. Selected test organisms for RGBC baselines.

- The Committee recommends that the following organisms be selected by FSIS for the baseline studies:
 - ▶ *E. coli* O157:H7 and O157:NM Strains
 - ▶ *Salmonella*
 - ▶ Generic *E. coli*
 - ▶ Total Coliforms
 - ▶ *Enterobacteriaceae*
 - ▶ Aerobic Plate Count

The Committee suggests that FSIS should consider the development of a protocol to investigate the prevalence of non O157 shigatoxin-producing *E. coli*, particularly O111, O26, O103, O121, and O145. There may be an opportunity to incorporate such an investigation into the baseline surveys.