NATIONAL ADVISORY COMMITTEE ON MICROBIOLOGICAL CRITERIA FOR FOODS

EXPEDITED RESPONSE TO THE QUESTIONS POSED BY THE UNITED STATES DEPARTMENT OF AGRICULTURE AGRICULTURAL MARKETING SERVICE TO SUPPORT GROUND BEEF PURCHASE FOR THE FEDERAL FOOD AND NUTRITION ASSISTANCE PROGRAMS

March 28, 2012

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EXECUTIVE SUMMARY

The Committee is on an expedited study timeline in order to provide recommendations to United States Department of Agriculture-Agricultural Marketing Service (USDA-AMS) prior to the 2012-2013 school year purchases. The current USDA-AMS microbiological criteria (*i.e.*, *Staphylococcus aureus* and *Escherichia coli* O157:H7), pathogen screen testing methodology, sampling plans, lotting and frequency of testing methodologies, and the reasons for the principle issues are addressed in this Committee's review. The Committee agreed in the overarching conclusion that, regardless of adverse speculation relative to the USDA National School Lunch Program (NSLP), its past ten-year food safety record has been exemplary.

The specific charge to the Committee was to answer the following three questions:

1. AMS is considering elimination of the requirement to test for *Staphylococcus aureus* from the Federal Purchase Ground Beef Program and AMS asks NACMCF to provide considerations and scientific discussion regarding this action with respect to public health.
2. Should AMS consider the use of alternative screening procedures beyond those stipulated in the FSIS Microbiology Laboratory Guidebook (MLG), and if so, would the AMS testing program results be comparable to FSIS' verification testing programs, and therefore useful to FSIS? What should be considered in distinguishing acceptable and unacceptable alternative screening procedures? Is it appropriate to allow alternative sample preparation procedures (portion size, enrichment broth, portion to broth ratio, enrichment time and temperature) which differed from the MLG, or which differed by AMS designated laboratory?
3. AMS asks NACMCF to evaluate boneless beef and finished product compliance program lotting and frequency of testing for pathogens and indicators of process control for both raw ground beef to be cooked on-site at schools with unknown cooking controls versus raw product destined to be cooked in a USDA inspected establishment.

The Committee makes the following recommendations:

Question 1

- The Committee has reviewed and concurred with recommendations of the National Research Council (NCR) report entitled, "An Evaluation of the Food Safety Requirements of the Federal Purchase Ground Beef Program"[2], which finds "no scientific basis for including a *S. aureus* criterion in the AMS purchase specifications" and further recommends that the "criterion be removed from the Federal Purchase Ground Beef Program."

Question 2

- AMS should consider the use of validated alternative screening methods to reduce the level of false positive results and allow for more rapid release of raw product.
- Alternative screening methods must be validated against the Microbiological Laboratory Guidebook (MLG) cultural method and must be compatible with the Food Safety and Inspection Service (FSIS)-MLG recommended confirmatory tests.
- Alternative screening methods should be: a) validated by an independent certifying organization (AOAC-Official Methods of Analysis (OMA), AOAC-Performance Tested Method (PTM), Association Françoise de Normalization (AFNOR), MicroVal, and NordVal), or b) supported by a robust validation study using the FSIS cultural method as a reference method and approved for use by AMS in consultation with FSIS, or c) those used by a regulatory body.
- After review of the current needs of AMS and due to the expedited review of the current charge, the Committee did not feel that there was sufficient time to make recommendations on alternative preparation/enrichment procedures. Therefore, the Committee recommends that AMS seek alternative screening methods to be used with the enrichment and confirmation procedures described in the MLG.
- Changes in preparation and enrichment procedures used by AMS Designated Laboratories (ADLs) could be considered by AMS in the future provided appropriate validation studies are conducted in consultation with AMS, FSIS, and, potentially, the Agriculture Research Service (ARS).

Question 3

- Maintain high standards of supplier control, HACCP implementation, carcass testing, traceability, etc. as in current program. Each plant is subjected to verification audits conducted during production activities that demonstrate their adherence to the documented program.
- With the exception of eliminating *S. aureus* testing, no changes to testing of indicator organism types are recommended at this time.
- For boneless beef trim and ground beef intended for further processing in USDA-FSIS-inspected facility using a validated cooking process with AMS oversight, testing for *E. coli* O157:H7 or *Salmonella* for disposition is unnecessary and should be discontinued.

- For product to be delivered to schools raw, boneless beef trim or ground beef lots which exceed any of the critical limits for *E. coli* O157:H7, *Salmonella*, or indicator organisms designated in Appendix B for the TRS–BB–2010 and TRS–GB–2010 will be directed to a product line for cooking at USDA-FSIS-inspected facility.
- For product to be delivered to schools raw, although the N60 sampling plan is more stringent than would be recommended when considering the documented compliance with food safety practices in the NSLP, AMS should continue N60 sampling for *E. coli* O157:H7 for boneless beef trim for two reasons. First, N60 testing is the accepted standard for USDA-FSIS sampling and commercial practices for non-intact beef. Secondly, diverting positive lots for cooking in USDA-FSIS-inspected facility using a validated cooking process with AMS oversight, will remove these lots from the product stream delivered to the school system as raw, and can serve to further reduce the risk of cross-contamination with ready-to-eat foods.
- For ground beef product destined for schools in raw form or for cooking in facilities outside AMS oversight, discontinue N8 whole-lot testing, but retain N4 for one hour sub-lots (maximum of 10,000 lbs.; N4 composited into one analytical unit). Each sub-lot found to be culture-positive for *E. coli* O157:H7, plus the "shoulder" sub-lots on either side of the positive sub-lot, will be diverted for cooking at a USDA-FSIS-inspected facility using a validated cooking process with AMS oversight for use in the AMS program.
- Continued testing of *Salmonella* (N5 for boneless beef per 2,000-lb combo bin; N4 for ground beef, one-hour sub-lot, 10,000-lb maximum; 25-g composite analytical unit) should be used to verify that intervention processes are controlled and as a factor to determine supplier eligibility; *Salmonella*-positive combo bins and sub-lots will be diverted for cooking at a USDA-FSIS-inspected facility using a validated cooking process with AMS oversight for use in the AMS program to reduce the risk of cross-contamination with ready-to-eat foods at the school level.
- Use of all data collected for SPC is suitable. FSIS should continue its analyses of the options and factors mentioned, and provide an updated report for 2013 with recommendations of scientifically supported implementations of a performance-based skip-lot sampling program and statistical process control practices as warranted.
- Regardless of sampling program, ongoing program review in consultation with FSIS and ARS should be implemented to determine if any requirements need to be strengthened in supplier eligibility, processing, etc., including use of additional or alternate intervention strategies.

I. BACKGROUND

The USDA-AMS, working with the Food Nutrition Service (FNS), the Food Safety Inspection Service (FSIS), and the Farm Service Agency (FSA), purchases ground beef and distributes same for the federal food and nutrition programs. Such programs include the NSLP, food banks, emergency feeding programs, disaster relief agencies, Indian reservations, and programs that serve the elderly.

Since the AMS program serves vulnerable populations in a wide variety of venues, it has been subjected to numerous internal and external reviews to ensure programmatic efficacy and operation adherence in accordance with sound science-based food safety principles. The latest program science review was conducted by the Food and Nutrition Board of the Institute of Medicine of the National Academy of Science (NAS) and is entitled "Review of the Use of Process Control Indicators in the FSIS Public Health Risk-based Inspection System" issued in 2009. The aforementioned NAS report contains numerous findings and recommendations. One of the findings and its recommendation was:

> "**Finding C2**: In developing its current purchase specifications for ground beef, AMS did not follow a procedure based on the scientific principles described in the National Research Council, the International Commission on Microbiological Specifications for Foods (ICMSF), and Codex Alimentarius Commission (CAC).
>
> **Recommendation C2**: AMS is encouraged to develop a systematic, transparent, and auditable system for modifying, reviewing, updating, and justifying purchasing specifications that are science-based – that is, specifications that are based on scientific principles as described in previous National Research Council, ICMSF, and CAC publications – and that state the expected public health benefits where appropriate. This would include specifying the use of pathogen detection methods that are among the most reliable available for use in related food safety programs. It may be appropriate for AMS to collaborate with ARS, FSIS, and CAC and potentially with other groups, such as NACMCF, to develop a risk-based system for assessing public health effects of purchasing specifications not just for frozen ground beef but for various products purchased by AMS for the NSLP and other programs."

As a result of the above recommendations and findings by NAS and others, the USDA-AMS requested the Committee to address three specific questions listed below. It was well recognized by the Committee that due to the complexity of the questions and the time available relative to performing an expedited study of the microbiological criteria as indicators of process control of insanitary conditions, the Committee could not completely finish the task. It was, therefore, decided that the Committee would address a set of further questions from USDA-AMS regarding the study subject.

II. CHARGE TO THE COMMITTEE

The questions to be addressed are:

1. AMS is considering elimination of the requirement to test for *Staphylococcus aureus* from the Federal Purchase Ground Beef Program and AMS asks NACMCF to provide considerations and scientific discussion regarding this action with respect to public health.
2. Should AMS consider the use of alternative screening procedures beyond those stipulated in the FSIS Microbiology Laboratory Guidebook (MLG), and if so, would the AMS testing program results be comparable to FSIS' verification testing programs, and therefore useful to FSIS? What should be considered in distinguishing acceptable and unacceptable alternative screening procedures? Is it appropriate to allow alternative sample preparation procedures (portion size, enrichment broth, portion to broth ratio, enrichment time and temperature) which differed from the MLG, or which differed by AMS designated laboratory?
3. AMS asks NACMCF to evaluate boneless beef and finished product compliance program lotting and frequency of testing for pathogens and indicators of process control for both raw ground beef to be cooked on-site at schools with unknown cooking controls versus raw product destined to be cooked in a USDA inspected establishment.

The agency representatives and the Committee agreed to change the wording in Question 3 submitted by USDA-AMS to allow for a more logical progression for discussion and resolution. The questions have been addressed in the following order below.

III. NACMCF RESPONSE TO QUESTIONS IN THE CHARGE

The responses to the questions are based on numerous discussions and the Committee's findings, conclusions, and recommendations are recorded for each question.

Question 1: AMS is considering eliminating the requirement to test for *Staphylococcus aureus* from the Federal Purchase Ground Beef Program and AMS asks NACMCF to provide considerations and scientific discussion regarding this action with respect to public health.

FINDINGS:

Although staphylococcal enterotoxins are an important public health concern, production of enterotoxins in amounts capable of causing illness does not occur until viable counts of at least 10^5 cfu/g are obtained in the food product (FDA 2009). Considering that the minimum temperatures for growth (7^o C (45^o F)) and toxin production (10^o C (50^o F)) would likely not be exceeded during processing, it is improbable that toxin production will occur in contaminated ground beef to a level capable of causing illness.[1] In fact, CODEX Alimentarius[2], "Principles for the Establishment and Application of Microbiological Criteria for Foods" (CAC/GL 21-1997) states that microbiological limits should take into consideration "the conditions under which the food is expected to be handled and consumed." Additionally, a final kill step, *i.e.*, cooking, is required before ground beef products are consumed; the organism will not reach levels necessary to produce illness-causing amounts of heat-stable enterotoxin, and therefore, is not a significant risk factor.

Current literature does not support inclusion of microbiological criteria for testing for presence of coagulase positive *S. aureus*. For example, the International Commission on Microbiological Specifications for Foods[3] (ICMSF) includes no requirement for testing ground beef for the presence or absence of coagulase-positive *S. aureus*. In addition, the National Research Council (NCR 1985) states that limits for pathogenic microorganisms in microbiological criteria for raw meats are impractical,[4] however, some companies include routine *S. aureus* testing as an indicator of insanitary processing. AMS utilizes a systems approach which controls not only acquisition of raw ingredients and processing, but also as well as AMS-FSIS conformance assessment to HACCP and other AMS eligibility processor requirements ensuring high quality and safety of the final ground product. AMS tests, for other indicator organisms such as aerobic plate count (APC), total coliforms and others, in both final product and processing environment, are sufficient to detect insanitary processing or handling conditions that could introduce contamination by *S. aureus*.

S. aureus data provided by the AMS sampling program for the period of January 2007 through December 2011 (Table 1) clearly show that the ground beef samples analyzed yielded few positive results, which were similar for the years reviewed. Further, the maximum numbers of colony forming units (cfu)/g were significantly lower than those required to produce illness-causing amounts of enterotoxin.

Table 1. Summary of Test Results for Period of January 2007 through December 2011				
Year	**Total Positive***	**Number Samples**	**% Pos**	**Maximum cfu/gm**
2007	30	1339	2.24	420
2008	28	2247	1.25	>1500***
2009	14	1161	1.21	60
2010	115	4362	2.64	1400
2011	224	11402**	1.96	410****

* Total samples positive (>10 cfu/gm) for coagulase positive *S. aureus* using Baird-Parker Plating method.
** Increased sampling in 2011 may be a response to media attention.
*** Dilutions to enumerate cfu at levels greater than 1500 were not performed.
**** Partial data sets involving one laboratory.

The issue of methicillin-resistant *Staphylococcus aureus* (MRSA) as an emerging public health concern was considered. MRSA is known for causing pyoderma and other soft tissue infections via cuts, wounds and tissue abrasions. MRSA colonizes the skin, nasopharyngeal cavities and other sites of both humans and animals possibly without evidence of infection. The Committee recognizes MRSA has been isolated from raw beef in the United States (Table 2) and Europe.[5] Although cross-contamination with antibiotic-resistant *S. aureaus* may be a pathway of concern in the future, at this time, ingestion is not a recognized pathway for MRSA infections, MRSA is not a relevant microorganism to be included in raw beef purchase specifications.

Table 2. Isolation of *S. aureus* and MRSA from retail ground beef samples.				
n	**positive, n (%)**	**MRSA positive, n (%)**	**Sampling Location**	**Reference**
156	32 (20.5)	2 (1.3)	Detroit, MI	Bhargava et al. 2011[7]
29	2 (6.9)	0	Iowa	Hanson et al. 2011[8]
198	55 (28)	0	Washington, DC	Kelman et al. 2011[6]
30	6 (20)	1 (3.3)	Baton Rouge, LA	Pu et al. 2009[9]
38	14 (37)	1 (2.6)	Chicago IL, Washington DC, Fort Lauderdale FL, Los Angeles CA, Flagstaff AZ	Waters et al. 2011[10]

CONCLUSIONS:

- Based on the above, the Committee concluded that the exclusion of *S. aureus*-specific testing will not negatively impact the safety or quality of ground beef in the NSLP.

RECOMMENDATIONS:

- The Committee has reviewed and concurred with recommendations of the NCR report entitled, "An Evaluation of the Food Safety Requirements of the Federal Purchase Ground Beef Program"[2], which finds "no scientific basis for including a

S. aureus criterion in the AMS purchase specifications" and further recommends that the "criterion be removed from the Federal Purchase Ground Beef Program."

Question 2: Should AMS consider the use of alternative screening procedures beyond those stipulated in the FSIS Microbiology Laboratory Guidebook (MLG), and if so, would the AMS testing program results be comparable to FSIS' verification testing programs, and therefore useful to FSIS? What should be considered in distinguishing acceptable and unacceptable alternative screening procedures? Is it appropriate to allow alternative sample preparation procedures (portion size, enrichment broth, portion to broth ratio, enrichment time and temperature) which differed from the MLG, or which differed by AMS designated laboratory?

FINDINGS:

The AMS, at the recommendation of FSIS currently requires AMS-designated laboratories (ADLs) contracted to conduct pathogen testing for the NSLP to adhere to the FSIS methods as described in MLG chapters 4 and 5 including the use of alternative screening methods described in MLG methods 4C and 5A. In its review of the Federal Ground Beef Purchase Program, AMS noted that the use of certain FSIS-screening methods by ADLs has resulted in a number of false-positive results[1]. For example, the ADLs reported high levels of *E. coli* O157:H7 false positives with the BAX-MP test. The occurrence of false positives resulting from incorrect implementation of the BAX-MP, improper interpretation of the BAX-MP data, or incorrect implementation of the FSIS confirmatory procedure (MLG chapter 5) has been evaluated and addressed by AMS. These types of implementation problems, alone, do not account for the high rate of false positives which have also been observed by FSIS laboratories. A high false positive rate is unacceptable when applied to 100% of lot testing as required by AMS because it takes an additional 2 to 4 days to get final confirmatory results prior to releasing raw product. Therefore, alternative screening methods may better meet the needs of the AMS-NSLP-testing program.

The performance of alternative screening procedures should be determined in a validation study, with an appropriate confirmatory method to provide a definitive result. A validation study will evaluate many aspects of screening test performance including sensitivity, specificity and recovery relative to a reference method, but also repeatability, reproducibility, precision, ruggedness, and aspects of manufacturing quality. AOAC International and ISO have published guidelines on the validation of qualitative and

[1]For the purpose of this document, a false positive is defined as screen positive/indeterminate tests which are negative by the reference confirmatory procedure for the target pathogen.

quantitative microbiological methods (Feldsine et al. 2002, ISO 2003), and recognized certifying bodies organize validation studies under contract with screening test manufacturers to validate candidate methods (also called alternative methods). Regulatory agencies, including FSIS, FDA/CFSAN, and the Canadian Food Inspection Agency (CFIA), also published guidelines for validating methods used by government or by industry (FSIS 2011, FDA/CFSAN 2011, CFIA 2011). An evaluation of alternative screening method performance should include validation of the method against the FSIS confirmation procedures as well as continued verification of the application of the method and laboratory performance (*i.e.*, stringency of validation, multiagency review, and on-site audits).

The following options were considered by the Committee as potential alternative approaches for consideration by AMS in choosing alternative methods:

Option 1 – ADLs employ an alternative enrichment and screening procedure of their choice as long as the procedure meets one of the following criteria:

a. Used by a regulatory body.

b. Validated by an independent certifying organization (AOAC-OMA, AOAC-PTM, AFNOR, MicroVal, and NordVal).

c. Supported by a robust validation study using the FSIS cultural method as a reference method and approved for use by AMS in consultation with FSIS. The FSIS confirmatory procedure would be used to confirm every screen test result. Therefore, enrichment conditions should be validated for use with respect to the appropriate FSIS confirmatory procedure, including the proper incubation period (*e.g.*, 15 to 18 hours for the *E. coli* O157:H7 method). This option would allow labs to use different procedures and could make it difficult for AMS auditors to verify the correct implementation of many different screening procedures, especially those with different enrichment conditions. For this reason, AMS may seek to limit the number of procedures that may be employed by ADLs.

Option 2 – ADLs employ an alternative screening procedure that has been validated to perform suitably under the enrichment conditions specified in the MLG. AMS would specify that the MLG enrichment conditions, which include the portion size, enrichment broth, portion to broth ratio, enrichment time and temperature, would be carried out by the ADLs. ADLs could choose screening methods that have been validated to perform acceptably under these conditions using the criteria described in option 1. AMS may seek to limit the number of screening procedures employed by ADLs to ensure that auditors can verify the correct implementation of the method(s). Methods that have been used by a regulatory body or validated by an independent certifying organization could be modified to fit the FSIS enrichment

conditions. In this case, a robust validation study could be provided to support these modifications, and the data would be reviewed by AMS and FSIS. Because the same enrichment conditions are used, the study may consist entirely of paired samples at the fractional recovery level which have been tested with both the alternative screening and confirmatory procedures. Note that many screening procedures have been validated for use after a shorter incubation period compared to FSIS. For example, some *E. coli* O157:H7 screening tests are employed after six to eight hours of incubation, in which case there could be insufficient opportunity for the target organism to grow to high enough levels to be captured by the screening test. In these cases, the reference confirmatory procedure would always be applied after an incubation period described in the MLG, not by the alternative procedure.

Option 3 – ADLs employ two screening procedures in tandem to reduce the false-positive rate. This is a common strategy used in the beef industry to reduce false-positive rates. Under this strategy, if the second procedure is negative, no further analyses would be performed. If the second procedure is positive, the ADL may carry out cultural confirmation by following the FSIS MLG procedure. Screening procedures would be chosen by the ADL, but should comply with criteria provided in Option 1. AMS may stipulate that the FSIS enrichment conditions specified in the MLG be used, and may seek to limit the number of procedures used to develop this strategy. If this option was favored by AMS, then FSIS would want assurance that the strategy would not increase the overall false-negative rate. For example, if the broths were not handled correctly, misidentified after the first test, or re-enriched from the sample, the second test may fail to detect a truly positive sample. FSIS has provided guidance to industry on this issue, see http://askfsis.custhelp.com/app/answers/detail/a_id/1375. The FSIS guidance indicates:

a. Screen positive results may be confirmed with cultural or non-cultural test methods.

b. Cultural confirmation procedures should adhere to the FSIS MLG method.

c. Non-cultural procedures should identify a different set of characteristics than the screening test (in other words, the same test used for screening, or a similar test, may not be re-used to "confirm" the screening result).

d. The second procedure should provide high sensitivity and enhanced specificity (ability to detect true negative results) compared to the screening test.

e. Both tests should be demonstrated and documented to perform acceptably under the conditions of use, which includes the enrichment conditions for

the screening test (*e.g.*, portion size, enrichment broth, portion to broth ratio, enrichment time and temperature). Acceptable performance is determined by validation, preferably through an independent organization.

Alternative methods meeting the criteria described in the above options would provide data that could continue to be useful to FSIS.

CONCLUSIONS:

- Alternative screening procedures could be used by AMS laboratories provided they are validated for intended use and compatible with FSIS-MLG confirmatory procedures.
- If alternative methods are demonstrated by validation to be equivalent to the FSIS cultural reference method then the data would be useful to FSIS and would allow:
  - AMS data to be used directly by FSIS;
  - Direct comparison of specific company results between FSIS and AMS; and
  - FSIS to assist AMS in troubleshooting laboratory issues or problems with methods and method application.
- Additional time and data are necessary for the Committee to address the appropriateness of changes to enrichment and sample preparation procedures (including portion size, enrichment broth, portion to broth ratio, enrichment time and temperature).
- Guidance is available from FSIS and from independent organizations (AOAC and ISO) on study design and procedures to evaluate/compare method performance.
- In addition to method validation, verification of the laboratory and analysts' performance verification, multiagency review and on-site audits are critical.

RECOMMENDATIONS:

- AMS should consider the use of validated alternative screening methods to reduce the level of false-positive results and allow for more rapid release of raw product.
- Alternative screening methods must be validated against the Microbiological Laboratory Guidebook (MLG) cultural method and must be compatible with

the Food Safety and Inspection Service (FSIS)-MLG recommended confirmatory tests.

- Alternative screening methods should be: a) validated by an independent certifying organization (AOAC-Official Methods of Analysis (OMA), AOAC-Performance Tested Method (PTM), Association Françoise de Normalization (AFNOR), MicroVal, and NordVal), or b) supported by a robust validation study using the FSIS cultural method as a reference method and approved for use by AMS in consultation with FSIS, or c) those used by a regulatory body.
- After review of the current needs of AMS and due to the expedited review of the current charge, the Committee did not feel that there was sufficient time to make recommendations on alternative preparation/enrichment procedures. Therefore, the Committee recommends that AMS seek alternative screening methods to be used with the enrichment and confirmation procedures described in the MLG.
- Changes in preparation and enrichment procedures used by AMS Designated Laboratories (ADLs) could be considered by AMS in the future provided appropriate validation studies are conducted in consultation with AMS, FSIS, and, potentially, the Agriculture Research Service (ARS).

DEFINITIONS:

1. *Alternative Screening Method/Procedure*: Any method, other than recognized reference method, that would provide comparable results and therefore is used to make decisions about the sample.
2. *Independent Certifying Organization*: A body that organizes validation studies based on microbiology validation guidelines published by AOAC (see Feldsine et al. 2002) or the International Standards Organization (ISO 2003). These bodies include AOAC (Official Methods of Analysis and Performance Tested Method programs), AFNOR, MicroVal, and NordVal.
3. *Reference Method*: This refers primarily to cultural methods from the FSIS MLG suitable for the analysis of meat, poultry and egg products. Methods published in the FDA-BAM and ISO methods may be appropriate on a case-by-case basis.
4. *Robust Validation Study*: A validation study which measures method performance against the appropriate FSIS reference method. The full data set and validation report would be subject to evaluation by FSIS. FSIS would use Test Kit Validation Guidelines to evaluate the study design and results. See http://www.fsis.usda.gov/PDF/Validation_Studies_Pathogen_Detection_Methods.pdf.

Question 3: AMS asks NACMCF to evaluate boneless beef and finished product compliance program lotting and frequency of testing for pathogens and indicators of process control for both raw ground beef to be cooked on-site at schools with unknown cooking controls versus raw product destined to be cooked in a USDA inspected establishment.

CLARIFIED QUESTION 3: *The Committee restructured Question 3 for ease of examination. AMS is requesting that NACMCF make recommendations on the testing of both raw material (boneless beef) and finished product (ground beef) based on intended use:*

- *finished product to be delivered to the school system (or designated facility) as a raw item and cooked within the school system or by an outside contractor but with cooking outside the oversight of AMS.*
- *finished product to be cooked at a USDA-FSIS-inspected establishment with AMS oversight and delivered as a cooked item to the school system.*

This request is a follow-up to the NAS study that found that the use of the same criteria for all applications is not consistent with CODEX principle CAC/GL 21-1997 sec 2.3 which states, "when applying a microbiological criterion for assessing products, it is essential, in order to make the best use of money and manpower, that only appropriate tests be applied (see subsection 5) to those foods and at those points in the food chain that offer maximum benefit in providing the consumer with a food that is safe and suitable for consumption."

Considering this CODEX principle, AMS requests NACMCF's recommendation concerning 1) if the current AMS program testing requirements (lotting, frequency of inspection, and sampling plans utilized for pathogens and indicators) are sufficient for product delivered to the school as a raw item for further cooking and 2), could less stringent testing requirements be employed for product delivered to the school as a cooked item?

AMS asks NACMCF to evaluate the current way AMS uses microbiological results for process capability assessment. Is it more statistically valid for AMS to rely on 1 in 5 lot sampling for boneless beef results or all lots for process capability assessment? Regarding finished product process capability assessment, should AMS rely on the whole lot results or the sub-lot results?

Comment [SVG1]: Or is this sub-lot? Just needs to be clear what the N of the 1 in 5 is… lot or sub-lot

FINDINGS:

The Committee recognizes that when the prevalence of pathogens is very low in foods, it is impractical to test sufficient number of samples to provide confidence that a given lot of food is pathogen-free. The purpose of microbiological testing in context of the products described in this charge is to verify the effectiveness of critical control procedures. These verification activities, including pathogen testing, "are more accurately conducted to verify the effectiveness of the process that will control hazards rather than to verify the safety of the food product" (BIFSCO 2010, p3).

Federal Purchase Ground Beef Program Description:

AMS contracts with eligible suppliers to deliver fresh-chilled boneless beef for further processing and with grinders to deliver coarse ground beef, frozen bulk ground beef and patties for the Federal Purchase Ground Beef Program; TRS–BB–2010 and TRS–GB–2010 describe the program. The cornerstone of this program is well-designed and implemented HACCP plans to ensure safety of the products. Among the requirements the harvest process must include at least two pathogen intervention steps. One of the intervention steps must be a critical control point (CCP) in their FSIS-recognized harvest process HACCP plan and the CCP intervention(s) must be scientifically validated to achieve a three-log reduction of enteric pathogens. Carcasses must be routinely tested for Shiga-toxigenic *Escherichia coli* (including O157:H7 and O157:Non-Motile (NM)) to verify effectiveness of interventions.

Per the 2010 requirements, lots of boneless beef are identified as 2,000-lb combo bins. For each combo bin, 60 sub-samples (N60) are randomly selected and composited to form a 325-g analytical unit for *E. coli* O157:H7 detection in accordance FSIS Directive 10,010.1 Revision 3. Five sub-samples (N5) are composited to assay for the presence of *Salmonella* (25-g enrichments) and five sub-samples (N5) are composited to assay for other indicator organisms per limits identified in Appendix B of TRS–BB–2010. Ground beef is tested using both whole-lot testing (identified as clean-up to clean-up; composite sample N8) and sub-lot testing (identified as one hour period not to exceed 10,000 lb; composite sample, N4, collected every 15 minutes; critical limits for pathogens and indicator organisms are identical to those for boneless beef. Lot definition for boneless beef (2,000-lb combo bins) and collection of ground beef samples every 15 minutes are similar to practices used by many entities in the commercial industry (BIFSCO 2010).

Comment [SVG2]: Still would clarify. Are 4 samples taken every 15 mins, or 1 sample every 15 mins, that becomes N4 after an hour… Would just make this crystal clear.

AMS provides two product streams: ground beef products sent to schools in cooked form and products sent to schools in raw form that the receiving schools either cook or contract to have cooked. AMS purchases raw beef in different pack sizes for different intended uses. The packs sized for sending to school foodservice, including 10-lb chubs of ground beef and 40-lb cases of frozen patties, are intended to be cooked by the schools. The bulk-size packs are intended for diversion to further processors for conversion into a finished end product. The State or School District diverting the product to the processor chooses the processor and finished end product. Although most of the finished end products are fully cooked, a few, such a wafer

steaks, are not. According to USDA Food and Nutrition Service regulations, "all of the processing shall be performed in plants under continuous Federal meat or poultry inspection, or continuous State meat or poultry inspection in States certified to have programs at least equal to the Federal inspection programs. ~~In addition to FSIS inspection, all donated meat and poultry processing shall be performed under AMS acceptance service grading. The cost of this service shall be borne by the processor. In the event the processor can demonstrate that grading is impractical, exemptions in the use of acceptance services shall be approved by the distributing agency prior to processing each order~~" (7 CFR 250.30, 2011). AMS also purchases a small proportion of beef for schools as a cooked product. The bulk product and the product purchased in cooked form together make up the ground beef products that are sent to schools in cooked form.

1. Ground beef (and boneless trim used to produce the ground product), which is processed in a USDA-FSIS-inspected facility using a validated cook step verified by the USDA-FSIS and sent to schools in cooked form.
    a. This product category represents about 60-80% of beef; the percentage varies depending on the year and is affected by the cost of beef, nutritional requirements and trends for products that use ground beef.
    b. A validated cooking process for ground beef conducted in a USDA-FSIS-inspected facility with oversight by AMS destroys any pathogens which may be present in the product. Testing for pathogens in the raw ingredients intended for a validated lethality step is deemed unnecessary by the scientific community (ICMSF Book 7, page 322; ICMSF Book 8, page 87-88, NRC 2010); pathogen testing in raw ingredients is not required for other commodities, *e.g.*, pasteurized milk, juice, fermented sausage, and almonds.
2. Ground beef sent as raw product to the schools will also have a validated cooking process; however, this cooking process will be conducted outside AMS oversight. The schools will cook the product themselves, have it cooked at a central kitchen or the school will contract USDA-FSIS or state-inspected facilities to cook the product.
    a. This product category represents about 20-40% of beef.
    b. A food safety plan based on HACCP principles is required by USDA for school food service. Food Code requires cooking of raw ground beef to 155°F for 15 seconds or other time/temperature combinations based on previous NACMCF opinions (2009 Food Code, Annex 3, page 399) and compliance with these requirements is very high; however, because some of this product is sent to the school raw and processed on-site, there is risk of cross-contamination and because the final lethality step is conducted without direct oversight of USDA, the microbiological testing of this product should have greater stringency.

Prevalence of Salmonella *and* E. coli *O157:H7*:

Currently, when the presence of *Salmonella* or *E. coli* O157:H7 is identified or any critical limit is exceeded for indicator microbes, FSIS and AMS are notified, and the production lot is not allowed in any USDA-AMS product. A breakdown of data for the period July 2011 through February 2012, revealed 0.93% and 0.06% of 11,454 ground beef lots were positive for *Salmonella* and *E. coli* O157:H7, respectively, whereas 0.46% and 0.02% of 54,847 boneless beef combo bins were positive for the two pathogens, respectively. Note: This is a lot positive rate based on percent-positive composite test results and not a rate of individual pieces that make up the composite. The incidence of *Salmonella* in AMS products is less than the 2.2% rate of *Salmonella* in ground beef identified in 2010 FSIS survey data and less that the 7.5% baseline rate for *Salmonella* allowed for process control (9CFR 310.25) in that commodity. The low incidence in AMS samples is attributed to the total safety system required of the suppliers and processors of product for the AMS ground beef program.

The frequency and type of sampling and testing of the boneless trim and ground beef produced for AMS should be based on whether the commodity will be subjected to a validated cook step under USDA-FSIS oversight or sent to the end user in a raw form. USDA-FSIS-inspected facilities contracted by AMS utilize a validated cook step and operate under a USDA-FSIS verifiable HACCP plan; school lunch programs are similarly required to have a HACCP program and to cook raw animal products in accordance with Food Code or to contract with state-inspected or FSIS-inspected cooking facilities themselves; however, in the latter situation, the lethality step occurs outside of AMS oversight.

The NSLP has a remarkable food safety record during the past decade. The Child Nutrition and WIC Reauthorization Act of 2004 required school food authorities to implement a food safety program based on HACCP principles for the preparation and service of school meals served to children in the school year beginning July 1, 2005 (http://www.fns.usda.gov/fns/safety/pdf/HACCPGuidance.pdf). HACCP is required in all facilities, including central kitchen, heat-and-serve, and cook-on-site kitchens. Components of HACCP include, but are not limited to, training, monitoring, corrective actions and record-keeping. With relationship to raw ground beef products, validated cooking to 155°F for 15 sec is specified by Food Code (Food Code 2009). Training and longevity of staff results in high compliance for cooking of raw animal products (beef, poultry, eggs, etc.). Although an FDA study of food handling practices in elementary schools found that noncompliance for reheating has been identified in school inspections, no violations were observed for failing to meet cooking requirements (FDA 2010).

Comment [SVG3]: Any information from the study on cross-contamination, I would mention the findings here. Especially since we mention that as an argument for why our recommendations are justified for the concerns in raw product.

Investigation of outbreaks of *E. coli* O157:H7 in schools have demonstrated no epidemiological evidence of illness associated with raw beef products since the institution of HACCP programs in schools in 2005 (CDC 2011). From 2000 through 2004, ground beef was identified as the likely contaminated food in three *E. coli* O157:H7 outbreaks which occurred in schools (two in 2000 and one in 2003), but it was "unclear whether the ground beef was obtained

through the Federal Purchase Ground Beef Program" (NAS 2010). Similarly, no confirmed *Salmonella* outbreaks in schools during 1998–2010 were associated with ground beef (CDC 2011).

Considerations for Basis of Sampling Plans:

As recommended by the NAS/NRC committee (NRC 2010), "AMS is encouraged to develop science-based approaches for proper use of raw materials that do not meet its specifications." When testing finds that a product lot does not meet AMS specifications for pathogens (*e.g.*, positive for *E. coli* O157:H7 or *Salmonella*), it should be directed into a product line with USDA-FSIS-inspected cooking, instead of removing it completely from the AMS Federal Purchase Ground Beef Program. Thus, FSIS would provide an AMS mechanism for assuring safe disposition of potentially unsafe product (NRC 2010).

Microbial testing of boneless beef trim and ground beef frequency depends on organism and product types.

Testing for indicator organisms identified in Appendix B of TRS–BB–2010 and TRS–GB–2010 is used to verify that the boneless beef and ground meat supply and processing are in control and their quality meets specifications.

Intensive testing of boneless beef trim for *E. coli* O157:H7 is designed to divert contaminated product; N60 sampling for boneless trim is in accordance with FSIS Directive 10,010.1 Revision 3 and is the currently accepted industry-wide standard.

In boneless beef, *Salmonella* is tested at a lower rate of sampling (N5) composited to provide a 25-g analytical unit. FSIS deems *Salmonella* testing as a performance standard to verify that plant HACCP systems are effective in reducing contamination with this pathogenic microorganism. Under the 1996 Pathogen Reduction/Hazard Analysis and Critical Control Point (PR/HACCP) final rule, FSIS established *Salmonella* performance standards for several raw product classes as a means of verifying that establishments control food safety hazards in fresh meat processing. FSIS verifies the performance standards by conducting the *Salmonella* verification testing program, in which FSIS samples and analyzes sets of chilled carcasses for *Salmonella.* Current FSIS Performance Standards for ground beef (9 CFR310.25) are based on an estimated national product prevalence of 7.5%, an acknowledgment that it is not feasible to eliminate the pathogen completely in raw ground beef.

Beginning in 2010, sampling/testing of ground beef for *E. coli* O157:H7 was increased from N8 whole lot (clean-up to clean-up) by adding N4 hourly sub-lot testing by sampling every 15 minutes and compositing four samples into analytical units representing one hour's production. The high degree of compliance with HACCP in the NSLP, particularly with cooking raw ground beef, and the lack of evidence that the N8 whole lot sample reduced foodborne illness in schools, suggest that continuing both the whole lot and sub-lot testing for product disposition of ground beef is not warranted. The AMS sub-lot testing plan provides greater

ability to detect contamination during an 8-hour shift than the AMS whole lot testing plan. This is because more individual samples are collected (32 versus 8 individual samples per eight-hour shift), and more 325-g composite are tested for the presence of *E. coli* O157:H7 (8 versus 1 portion per 8-hour shift). Other things being equal, a larger size of each sub-sample would be expected to have higher prevalence. For example, based on the overall AMS raw ground beef positive rate of 0.06% (and assuming contamination was Poisson- distributed), N8 sub-samples (40.6 g each) would have an apparent prevalence of 0.01% and N4 sub-samples (81.3-g each) have an apparent prevalence of 0.02%. Based on an overall capability to detect *E. coli* O157:H7 in ground beef over the course of an eight-hour shift, hourly N4 sub-lot testing offers an advantage over N8 sampling. An examination of data for the period July 2011 through February 2012 revealed that no whole lot sample was positive for *E. coli* O157:H7 (out of 1,136 samples) while 7 sub-lot samples were positive for *E. coli* O157:H7 (out of 10,318 samples).

The AMS program currently requires both whole and sub-lot testing, so a program lacking either plan would reflect less sampling than the current program; however, the incremental public health benefits of each testing program cannot be estimated with high degree of confidence on the basis of available scientific data. In the Committee's judgment, the current testing programs are redundant. Removal of the whole-lot testing plan would have minimal effect on the ability to detect contamination during the course of an eight-hour shift when compared to the removal of the sub-lot testing plan. An important difference between plans is the volume of ground beef represented by a composite test result "cleanup to cleanup" for the whole lot testing plan versus one hour's production (not to exceed 10,000 lbs) for the sub-lot plan. This means that producers confronted with a N4 sub-lot positive result may not consider all ground beef produced on the grinding equipment during a day to be adulterated and therefore diverted to cooking or other endpoints as required by the FSIS. Per AMS guidance, producers would divert three sub-lots: the sub-lot testing positive plus the sub-lots produced on the same equipment before and after the positive sub-lot.

Comment [SVG4]: Somewhere in this paragraph is where a citation (see Kerry and Gerri) is needed to explain why diverting an entire day's production (or clean-up to clean-up) is not microbiologically justified, that "hot spots" work their way out of a system and therefore helps to justify the "shoulder" diverting only….

Sampling plans have been recommended based on the potential for the risk to increase, decrease or remain the same, and the severity of pathogen consequence (ICMSF 8, Table 7.1). More stringent sampling plans are generally recommended as the potential risk increases and the severity of the hazard increases, including foods intended for sensitive populations (*e.g.*, baby food, dietetic food, hospital foods, AIDS patients, and relief foods). A point that is frequently overlooked is that ICMSF-sampling plans are intended to be used when there is limited or no information on the processes used to produce the food. Application of Good Manufacturing Practices and HACCP for process control provides more useful information for effective food safety management. Therefore, reduced sampling frequency, sample size, and sample number may be scientifically appropriate when information on the process is available, such as the program managed by AMS. Furthermore, the level of control achieved in implementation depends not only on the frequency and level of sampling, but also on the incentives for

compliance and the consequences of non-compliance. Therefore, identifying an appropriate sampling plan is not purely a statistical matter.

The Committee considered school-aged children as a "sensitive population", hence, more stringent requirements, including sampling plans, may be considered to help assure safety and public confidence; however, the cost of such programs must be weighed against the cost of buying the food needed to support the program. NACMCF will not assess this management decision; however, it will comment on the information available related to food safety. According to USDA FNS regulations, schools receiving AMS beef through NSLP must have a food safety plan based on HACCP principles that conforms to their state and local Food Code requirements (USDA/FNS 2005). The Food Code Section 3-8 prohibits serving rare meat to susceptible populations, including children (FDA 2009). An FDA (2010) study reported that for elementary schools "Management systems that were implemented to ensure foods were adequately cooked…appeared to be effective during this data collection period." This suggests that cooking in the school is reliable and sufficient to reduce hazard associated with *E. coli* O157:H7and *Salmonella* to an acceptable level, and epidemiological data (*i.e.*, lack of outbreaks associated with ground beef products in schools) support this conclusion. Therefore, the sampling that is done by AMS provides verification of effective food safety measures on the part of the supplier but AMS, in consultation with FSIS and ARS, could consider reducing sampling without compromising safety. Although the probability of detecting a defective lot is increased with greater number of random samples taken, all the sampling plans identified in this document have limitations (*i.e.*, testing cannot guarantee the absence of a pathogen).

For the purpose of testing beef trim lots, the effect of increasing sampling from N60 to N120 to detect *E. coli* O157:H7 was calculated. Based on a 325 g composite, the FSIS baseline product prevalence estimate for *E. coli* O157:H7 in beef trim was 0.68%. Assuming the concentration for *E. coli* O157:H7 in raw ground beef is Poisson distributed, this implies that for N60 sampling based on a 325 g composite, the prevalence of individual beef trim sample units (averaging 5.4 g) within lots is approximately 0.011%. The probability of detecting the pathogen at this level of contamination for N120 sampling (650 g) is 1.36%. At this low level of contamination, one would need to test 26,343 such beef trim sample units (142.69 kg) to have 95% probability of detecting the pathogen. Therefore, the impact of testing to detect *E. coli* O157:H7 is severely limited as a direct control measure. This strongly reinforces the need to focus on validated kill steps and verified HACCP process controls for the whole production system.

Use of skip-lot testing for process capability assessment:

AMS testing of product presented from contracted suppliers for sale into the NSLP currently uses both acceptance sampling and statistical process control. Across the various products, the AMS currently uses lot disposition criteria (acceptance sampling), control charts

and certain features of skip-lot sampling in different parts of their overall approach to ensuring the food is safe.

Traditional skip-lot testing is used when product is generally considered to be of consistently good quality overall (ASQ/ANSI S1-2011, ISO 2859-3). These testing plans typically have three parts: 1) Qualification: where initial requirements are met, usually by passing every-lot inspection for a specified number of lots, 2a) Skip-lot testing that starts with testing every other lot, then can change progressively to reduce testing to one in every five lots with exemplary testing results demonstrated, 2b) An increase in the frequency of testing (*i.e.*, from one-in-three lot testing to every-other-lot testing) if results do not meet the criteria to remain in the less frequent testing state, until such time as the results again warrant a reduction in the rate of testing, and 3) Disqualification from skip-lot testing that requires every-lot testing based on poor test results. Current AMS testing uses modified skip-lot testing as part of the SPC program in that every lot is tested to determine lot disposition (acceptance/rejection), but not all test results are chosen for SPC verification.

Boneless beef establishments whose tests do not meet certain parameters in the SPC plan are placed into a conditional plan, but neither the testing frequency nor the rate of inclusion in the SPC calculations are increased. That is, one test result of every five is included for SPC evaluation in the conditional period. Poor results in the conditional period then lead to exclusion from the program until such time as the establishment provides ample justification to resume. This justification is evaluated on a case-by-case basis.

The current (TRS-GB 2010) AMS approach in ground beef ignores the sample results of individual sub-lots in SPC determinations; however, sub-lot testing is used in determining disposition of some of the product in a full day's production. All product in the sub-lots that have unacceptable results, as well as both the sub-lot immediately preceding and the sub-lot immediately succeeding the unacceptable sub-lot, are excluded from the product ultimately included in the whole-lot.

This situation is, in some sense, similar to compositing samples versus using individual samples in that individual samples provide more information on separate sampling locations or projects. Composited samples save resources and represent broader definitions of "lots."; however, since no resources are saved here, the advantage of using the "whole-lot" testing is in gauging day-to-day variability while sacrificing to some extent hour-to-hour variability. Further data analysis is necessary to determine the extent of variation from hour to hour.

Statistical process control charts results over time and requires corrections to processes any time the results are outside the control limits. Typically, an individual producer or corporation would set the upper and (where applicable) lower control limits based on that company's specific production processes and capabilities. There are several instances where a uniform set of parameters are set across all producers or suppliers. Customers of FSIS-inspected establishments set up prerequisite programs with the supplying establishments to ensure supplies

meet the customer's criteria. In these instances acceptance sampling procedures, such as those found in the U.S. military's "DOD Preferred Methods for Acceptance of Product" (DOD 1996), can be used.

Since the products in question with the AMS program are distributed to school children, who have a higher proportion of vulnerable individuals than the adult population, uniform national parameters would be expected. Further data analysis is needed to guide whether the parameters established by AMS should be revised. The statistical process control used in AMS' program for ground beef consists of results from the last 20 "whole-lot" tests (*i.e.*, test results from the eight sub-samples throughout a production day). One consideration in this situation is whether it would be beneficial to conduct the SPC evaluation on these "whole-lot samples" or on the individual sub-lots. Ground beef test results provided by AMS from nine establishments showed that at least six establishments presented 13 sub-lots on at least one day between July 2011 and January 2012 (inclusive). Given this situation and the 20-lot SPC evaluation period, an establishment could conceivably test outside acceptable parameters at the beginning of a day, and then have 20 acceptable results by the end of the next day. Hourly results are useful for SPC if the results of the testing are received quickly enough to adjust production parameters. However, given the logistics of collecting, shipping, testing, and reporting the results from testing, it is several days before the results are known. Therefore, the parameters for the control charts need to incorporate several days of tests to properly gauge an establishment's process control. That is for a large producer, the 20-sample window may be too short. A given establishment could be shifting in and out of process control before it is determined whether a previous day's results were acceptable or not. Further analysis of AMS data and the statistical properties necessary for SPC are needed to set the window length and corresponding failure parameters. AMS should work with FSIS to analyze the data and to set the window length and corresponding failure parameters.

Therefore, an appropriate option is to use individual sub-lot results for SPC and expand the number of samples in the SPC window beyond 20. In cases where individual establishments produce fewer days than the SPC window length, any revised criteria would be applied to the number of lots presented. One disadvantage of this approach is that the statistical power of detecting shifts in microbial rates is reduced in the small producers. In these instances, since the individual contracts between AMS and suppliers indicate the intended amount to be produced, parameters could be developed on a case-by-case (contract) basis for contracts with fewer sub-lots than the new window length.

This option allows all data to be used in assessing statistical process control, and is preferable if the hour-to-hour variability is an essential factor. Because the time needed to move beyond a 20-sample window is relatively short and the time needed to be informed of test results is relatively long, the window should be extended beyond 20 samples and the parameters associated with the plan adjusted accordingly.

Further analysis of AMS data and the statistical properties necessary for SPC are needed to set the window length and corresponding failure parameters. NACMCF will address this area in the second phase of this charge.

For boneless beef, using only one of every five combo bins for SPC reduces the statistical power to detect a loss of process control. The choice of including all combo bin test results or a "skip-lot" approach yields options similar to those in ground beef. Further analysis of boneless beef testing is needed to more definitively inform AMS on whether a more traditional performance-based skip-lot sampling program can be used for verification testing and SPC.

The AMS has been collecting data on microorganisms in these products for years; however, some of the criteria change from year to year. These changes can make drawing comparisons across years problematic. Therefore, the analysis by NACMCF has focused primarily on the most recent data from July 2011 into January 2012. Further analysis of AMS data is needed to identify a more definitive set of options such as revising some of the testing into a more traditional skip-lot program.

The option shown above is not the only one that could be used in the AMS program. FSIS should continue the analyses mentioned above and update NACMCF as soon as practical for consideration in proposed future NACMCF charge.

CONCLUSIONS:

- The Committee concurs with NRC 2010 findings that application of the same criteria for all product streams (*i.e.*, product cooked with oversight by AMS versus sent to the school in raw form) is not consistent with Codex Principle CAC/GL 21-1997 Section 2.3. Furthermore, the Committee concurs that a validated cook process provides greater control of risk than relying on finished product testing (ICMSF 7 2002; NRS 2010).
- Boneless beef and ground beef intended for cooking in a USDA-FSIS-inspected facility using a validated process does not require pathogen testing because cooking will eliminate *E. coli* O157:H7 and *Salmonella*. Microbiological testing of indicator organisms, such as generic *E. coli* and coliforms with similar ecological niches as enteric pathogens, are useful to ensure that the process is under control, carcass decontamination is verified, and sanitation is sufficient. *Salmonella* testing for compliance with USDA Performance Standards provides an additional verification that the process is controlled.
- The 2011 microbiological testing of every lot/sub-lot, but using only select, skip-lot data for indicator organisms in SPC provides no substantive advantage with regards to product testing. Boneless beef establishments whose tests do not meet certain parameters in the SPC plan are placed into a conditional plan, but neither the testing frequency nor the rate of inclusion in the SPC calculations are increased as standard practice for skip-lot testing (ASQ/ANSI S1-2011, ISO 2859-3). Given the difficulties in managing the use of a data

sub-set, including ignoring collected results as well as seeing no advantage with skip-lot data analysis, use of all data collected is a reasonable alternative at this time.

- The current N60 sampling scheme for *E. coli* O157:H7 is consistent with the accepted standard for USDA-FSIS sampling for non-intact beef (USDA 2010) and for commercial production practices (BIFSCO 2010). Despite the excellent safety record associated with cooking conducted at the schools, the safety associated with products released to schools in raw form is less certain because the final lethality step (reduction in risk) is conducted outside oversight of AMS and FSIS and there exists a remote risk of cross-contamination of other ready-to-eat foods if the pathogen is present in the raw ground beef. Given the low pathogen prevalence in boneless beef and ground beef produced for AMS, even robust sampling plans have limited ability to detect foodborne pathogens. The Committee acknowledges the limitations of sampling but also notes that stringent *E. coli* O157:H7 testing in boneless beef and ground beef provides an extra, but small, level of probability of finding the pathogen. No change in frequency of sampling is recommended at this time for *E. coli* O157:H7 in boneless beef trim intended for grinding and subsequent direct sale to schools in raw form.

- AMS's use of *Salmonella* for product disposition is inconsistent with FSIS use of *Salmonella* as a performance standard. As with *E. coli* O157:H7, epidemiological data revealed no *Salmonella* illnesses linked to ground beef obtained through the Federal Purchase Ground Beef Program or any other source since 1998, and specifically since the inception of HACCP in the NSLP. Testing at current levels (N5 for boneless beef or N4 for ground beef) has potential merit in determining supplier eligibility (in line with FSIS *Salmonella* performance standards) as an indicator of other enteric pathogens, and to direct *Salmonella* positive lots into the product stream that includes validated cooking with AMS oversight of USDA-FSIS-inspected cooking. This approach can serve to limit potential exposure to enteric pathogens which might occur through cross-contamination at the school level.

- The high degree of compliance with the requirement for a food safety plan based on HACCP principles in the school lunch program and strong food safety practices while cooking raw ground beef, suggest that there is no apparent scientific justification for continuing the increased testing schedule (both whole lot and sub-lot testing) for product disposition of ground beef. Thus, the extra N8 sampling schedule implemented in TRS 2010 was not necessary to ensure safe food. It was concluded that eliminating N8 whole lot clean-up to clean-up testing while retaining N4 one-hour lot (maximum of 10,000-lbs) testing composited into one analytical unit per hour (or 10,000-lbs maximum) provides a scientifically valid sampling plan that is more balanced for logistics and cost of implementation.

- The safety of ground beef products served in the school lunch program, as with all foods, rely on a multifactor and integrated food safety system, including controls during production, processing, distribution, storage and any necessary lethality steps. Resources spent on enforcing HACCP controls to prevent and reduce contamination in the raw commodity result in more reliable outcomes of food safety than additional finished product testing. Microbiological sampling is a useful tool in verifying process control but is neither practical nor sufficient to provide 100% guarantee of food safety.

RECOMMENDATIONS FOR 2012 TRS:
Note: For these recommendations and further projections-these recommendations will be applicable until AMS seeks further advice from NACMCF.

- Maintain high standards of supplier control, HACCP implementation, carcass testing, traceability, etc. as in current program. Each plant is subjected to verification audits conducted during production activities that demonstrate their adherence to the documented program.
- With the exception of eliminating *S. aureus* testing, no changes to testing of indicator organism types are recommended at this time.
- For boneless beef trim and ground beef intended for further processing in USDA-FSIS-inspected facility using a validated cooking process with AMS oversight, testing for *E. coli* O157:H7 or *Salmonella* for disposition is unnecessary and should be discontinued.
- For product to be delivered to schools raw, boneless beef trim or ground beef lots which exceed any of the critical limits for *E. coli* O157:H7, *Salmonella*, or indicator organisms designated in Appendix B for the TRS–BB–2010 and TRS–GB–2010 will be directed to a product line for cooking at USDA-FSIS-inspected facility.
- For product to be delivered to schools raw, although the N60 sampling plan is more stringent than would be recommended when considering the documented compliance with food safety practices in the NSLP, AMS should continue N60 sampling for *E. coli* O157:H7 for boneless beef trim for two reasons. First, N60 testing is the accepted standard for USDA-FSIS sampling and commercial practices for non-intact beef. Secondly, diverting positive lots for cooking in USDA-FSIS-inspected facility using a validated cooking process with AMS oversight, will remove these lots from the product stream delivered to the school system as raw, and can serve to further reduce the risk of cross-contamination with ready-to-eat foods.
- For ground beef product destined for schools in raw form or for cooking in facilities outside AMS oversight, discontinue N8 whole-lot testing, but retain N4 for one hour sub-lots (maximum of 10,000 lbs.; N4 composited into one analytical unit). Each sub-lot

found to be culture-positive for *E. coli* O157:H7, plus the "shoulder" sub-lots on either side of the positive sub-lot, will be diverted for cooking at a USDA-FSIS-inspected facility using a validated cooking process with AMS oversight for use in the AMS program.

- Continued testing of *Salmonella* (N5 for boneless beef per 2,000-lb combo bin; N4 for ground beef, one-hour sub-lot, 10,000-lb maximum; 25-g composite analytical unit) should be used to verify that intervention processes are controlled and as a factor to determine supplier eligibility; *Salmonella*-positive combo bins and sub-lots will be diverted for cooking at a USDA-FSIS-inspected facility using a validated cooking process with AMS oversight for use in the AMS program to reduce the risk of cross-contamination with ready-to-eat foods at the school level.
- Use of all data collected for SPC is suitable. FSIS should continue its analyses of the options and factors mentioned, and provide an updated report for 2013 with recommendations of scientifically supported implementations of a performance-based skip-lot sampling program and statistical process control practices as warranted.
- Regardless of sampling program, ongoing program review in consultation with FSIS and ARS should be implemented to determine if any requirements need to be strengthened in supplier eligibility, processing, etc., including use of additional or alternate intervention strategies.

DEFINITIONS:

1. *Boneless Beef*: Beef manufacturing trimmings.
2. *Confidence Statements*: Confidence applies to an event after the event has occurred. For example, suppose a lot has been sampled and rejected because a pathogen has been detected in the sampled units. For that rejected lot and based on the sampling plan used, one can state with 95% confidence that, for example, 0.5% or more of the sample units in the entire lot will test positive for that pathogen. Note: This is an example of a confidence statement, not a probability statement because the lot is known to have been rejected. Table 3 in the text provides confidence statements about rejected/accepted lots, not probability statements.
3. *Contractor*: Finished product processor.
4. *Finished product*: Final ground beef product.
5. *Incidence*: Frequency that disease associated with the hazard will occur within a specified time.
6. *Prevalence*: Proportion of samples or lots containing hazard.

7. *Probability Statements*: Probability applies to an event before the event occurs. For example, suppose a lot has a 1% prevalence of a certain pathogen. It can be shown that there is a sampling plan that will detect, with 95% probability, the presence of that pathogen in that lot. Note: This is an example of a probability statement because the event of sampling and testing has not yet occurred. Frequently in practice, 95% probability is replaced with 95% confidence which technically is incorrect (see confidence statement above).

8. *Process Control/Capability*: As per TRS–GB–2010, process capability assessments are conducted on data results from each lot for microbial requirements. A process assessment involves sampling and testing of 20 consecutive lots (which always includes the last recorded result). Information from each lot will be evaluated with information from the preceding 19 lots. This has often been referred to as a 'Rolling 20'. This assessment takes into account process variations that may be attributed to product, management, sources, and time.

9. *Statistical Process Control (SPC)*: As per TRS–GB–2010, SPC is the primary analysis tool of quality improvement. The objective of any quality improvement strategy is to identify and reduce the amount of variation. SPC analyzes the variation in a process and is the applied science that assists suppliers to collect, organize and interpret microbial and fat test results on processing of ground beef destined for USDA.

10. *Supplier*: Boneless beef manufacturer.

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Question 3

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