An Evaluation of the Food Safety Requirements of the Federal Purchase Ground Beef Program

ISBN
978-0-309-17709-2

44 pages
8 1/2 x 11
PAPERBACK (2010)

Committee on an Evaluation of the Food Safety Requirements of the Federal Purchase Ground Beef Program; National Research Council

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Board on Agriculture and Natural Resources

Division on Earth and Life Studies

NATIONAL RESEARCH COUNCIL
OF THE NATIONAL ACADEMIES

THE NATIONAL ACADEMIES PRESS
Washington, DC
www.nap.edu

THE NATIONAL ACADEMIES PRESS 500 Fifth Street, NW, Washington, DC 20001

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This study was funded by the U.S. Department of Agriculture Food Safety and Inspection Service, Contract No. AG-3A94-C-08-0018/ AG-3A94-D-10-0082. Any opinions, findings, conclusions, or recommendations expressed in this publication are those of the authors and do not necessarily reflect the views of the organizations or agencies that provided support for the project.

International Standard Book Number-13: 978-0-309-17709-2

International Standard Book Number-10: 0-309-17709-X

Additional copies of this report are available from the National Academies Press, 500 Fifth Street NW, Lockbox 285, Washington, DC 20055; (800) 624-6242 or (202) 334-3313 (in the Washington metropolitan area); Internet, http://www.nap.edu.

Suggested Citation: National Research Council. 2010. An Evaluation of the Food Safety Requirements of the Federal Purchase Ground Beef Program. Washington, DC: The National Academies Press.

Printed in the United States of America.

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Acknowledgments

This report has been reviewed in draft form by persons chosen for their diverse perspectives and technical expertise in accordance with procedures approved by the National Research Council Report Review Committee. The purpose of the independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards of objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process. We wish to thank the following for their review of the report:

Robert L. Buchanan, University of Maryland
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Douglas A. Powell, Kansas State University
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Angela L. Siemens, Cargill, Inc.

Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations, nor did they see the final draft of the report before its release. The review of the report was overseen by Drs. Kristine M. Gebbie, City University of New York, and Michael P. Doyle, University of Georgia. Appointed by the National Research Council, they were responsible for making certain that an independent examination of the report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of the report rests with the author committee and the institution.

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November 29, 2010

Ms. Rayne Pegg
Administrator
Agricultural Marketing Service
U.S. Department of Agriculture
1400 Independence Ave. SW
Washington, DC 20250

Mr. Alfred Almanza
Administrator
Food Safety and Inspection Service
U.S. Department of Agriculture
1400 Independence Ave. SW
Washington, DC 20250

Dear Ms. Pegg and Mr. Almanza,

In response to the request of the U.S. Department of Agriculture (USDA) and the Food Safety and Inspection Service (FSIS), the National Research Council of the National Academies created an ad hoc Committee on An Evaluation of the Food Safety Requirements of the Federal Purchase Ground Beef Program of the USDA Agricultural Marketing Service (AMS). The committee's charge is to evaluate the scientific basis of the current food safety requirements and prepare a report of its findings.

The committee (see Appendix A for membership and biographies) had two meetings in Washington, DC: on July 14–15 and on August 10–11, 2010. In the first meeting, the committee had the opportunity to hear from two industry experts about their companies' food safety program. In the second meeting, the committee met with representatives of the Agricultural Research Service (ARS) and FSIS who have provided technical advice to the Federal Purchase Ground Beef Program. The committee also spent part of the second meeting on report preparation in closed session. The AMS representatives attended open sessions of both meetings and entertained questions and requests for any additional documents that the committee needed for its study.

Throughout its deliberations and meetings since the beginning of this study, the committee has benefitted from open and frank discussion with USDA representatives—including those of AMS, ARS, and FSIS—and representatives of the meat processing industry. The committee expresses gratitude to them for their assistance in gathering information. The committee also commends AMS for placing a high priority on food safety issues and for seeking advice and input from ARS, FSIS, industry, and the National Research Council in establishing and reviewing its current specifications. In addition, this report reflects countless hours of research, writing, and editing by the committee and National Research Council staff, and the chair expresses sincere appreciation for their dedication and work.

The product of this fast-track study is the attached report. The report contains the committee's findings and recommendations for AMS's consideration as it continues to procure and provide safe

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ground beef products to the National School Lunch Program and other federal food and nutrition programs.

Sincerely,

Gary R. Acuff, Chair

Committee on An Evaluation of the Food Safety Requirements of the Federal Purchase Ground Beef Program

SUMMARY

The U.S. Department of Agriculture (USDA) Agricultural Marketing Service (AMS) purchases and distributes food for various federal food and nutrition programs, which include the National School Lunch Program (NSLP), food banks, emergency feeding programs, Indian reservations, programs that serve the elderly, disaster-relief agencies, and a variety of other institutions that serve the food-insecure. Thus, the AMS commodity program serves members of society who may be most vulnerable to foodborne illness and its consequences, including children, the elderly, and the immunocompromised.

As part of its Federal Purchase Ground Beef Program, AMS buys ground beef from more than 15 suppliers that are required to meet specifications (food safety requirements) that exceed those mandated by the USDA Food Safety and Inspection Service (FSIS) for all federally inspected meat processing plants, such as those which supply meat to retail stores and restaurants. However, in December 2009, a news article in *USA Today* suggested that some large-scale purchasers of ground beef in the corporate sector have more stringent requirements than AMS. That and other news stories and a letter from U.S. Senator Kirsten Gillibrand (D-NY) to Secretary of Agriculture Tom Vilsack about perceived deficiencies in the Federal Purchase Ground Beef Program led to a review of the AMS ground beef purchase specifications by the Agricultural Research Service (ARS) and FSIS concurrent with the USDA Office of the Inspector General (OIG) audit that was being conducted at that time; the revision—based on recommendations from ARS, FSIS, and OIG—of the AMS ground beef purchase specifications that are found in the *Technical Requirements Schedule* for ground beef; and a request for an independent body (the National Research Council) to review the current Federal Purchase Ground Beef Program.

In response to this request, the National Research Council of the National Academies created an ad hoc Committee on An Evaluation of the Food Safety Requirements of the Federal Purchase Ground Beef Program. On the basis of the statement of task that AMS provided to the National Research Council, the committee considered its charge to be to evaluate the scientific basis of the AMS technical documents that describe the food safety requirements for beef suppliers (July 2010 *Technical Requirements Schedule* for ground beef) and testing procedures for AMS-accredited laboratories (June 2010 *Statement of Work* for AMS-accredited laboratories), to examine how the AMS safety requirements compare with those used by large retail and commercial food service purchasers of ground beef, and to provide recommendations to AMS for conducting periodic evaluations of the Federal Purchase Ground Beef Program.

The AMS purchase specifications for frozen ground beef specifically include limits on the pathogens *Escherichia coli* O157:H7 and *Salmonella,* which are recognized hazards in raw ground beef products (ICMSF, 2005). To assess the extent of the risk to schoolchildren posed by the presence of those pathogens in AMS purchased ground beef, the committee reviewed foodborne-illness outbreaks that occurred in schools and were associated with ground beef and products containing ground beef. Although most foodborne illnesses do not occur as part of recognized outbreaks, in school settings large groups of students may be exposed to a contaminated food item simultaneously. Because clustering of cases in a school makes it more likely that a common source of exposure would be recognized, outbreak data constitute a useful tool for evaluating the presence of *E. coli* O157:H7 and *Salmonella* associated with ground beef in schools.

The Centers for Disease Control and Prevention (CDC) received reports of 263 confirmed foodborne outbreaks of *E. coli* O157:H7 infection in the United States from 1998 to 2007. Ground beef was identified as the likely contaminated food in 69 (26%) of the reported outbreaks, of which three were found to have occurred in schools (two in 2000 and one in 2003). Two of those three *may* have involved ground beef that was purchased by the schools through the Federal Purchase Ground Beef Program. In one, in 2000, students at a private school in Minnesota became ill after eating apparently undercooked ground beef in a baked casserole known as hot dish that was prepared at the school. A review of ground beef handling procedures at the school indicated that thawing, cooking, and cooling of the ground beef may have been inadequate. However, the packing plant of origin and the packing date for the ground beef

used in the hot dish could not be conclusively identified, so it is unclear whether the ground beef was obtained through the Federal Purchase Ground Beef Program. The other outbreak, in 2003, involved beef burritos that were distributed in restaurants and schools in Nebraska. On the basis of the details of those incidents and the institutions involved, the committee thought it unlikely that the two outbreaks involved AMS purchased ground beef and did not consider them relevant to the discussion of the safety of ground beef in the Federal Purchase Ground Beef Program.

An outbreak in 1998 was entered into the CDC database with the location "other", and no food vehicle was identified. However, investigation of the outbreak revealed that students became ill apparently after eating undercooked ground beef in tacos prepared in a school in Washington state. The ground beef was obtained through the NSLP, and this was the only confirmed outbreak of *E. coli* O157:H7 infection linked to the Federal Purchase Ground Beef Program.

It is noteworthy that the two *E. coli* O157:H7 outbreaks (in 1998 in Washington state and in 2000 in Minnesota) occurred because undercooked ground beef was served to students and before FSIS issued a requirement that establishments reassess their Hazard Analysis and Critical Control Point (HACCP)[1] plans in 2002 (USDA-FSIS, 2002). Successful implementation of HACCP plans in the industry has been widely credited with substantially improving the quality and safety of ground beef.

CDC also received reports of 1,152 confirmed foodborne outbreaks of *Salmonella* infection in the United States from 1998 to 2007. Ground beef and products containing ground beef were identified as the likely contaminated foods in 36 (3.1%) of the outbreaks. Of the 36, one outbreak was associated with beef lasagna that was prepared at home and eaten in a school; the other outbreaks were not associated with schools. The CDC database indicates that the key ingredient in the lasagna that contributed to the outbreak was eggs, and ground beef was not the likely source of the *Salmonella Enteritidis* contamination. Hence, no confirmed *Salmonella* outbreaks in schools during 1998–2007 were associated with ground beef obtained through the Federal Purchase Ground Beef Program or any other source.

The finding that no outbreaks of either *Salmonella* or *E. coli* O157:H7 associated with AMS-purchased ground beef have been recorded in more than a decade strongly suggests that existing AMS purchase specifications have been protective of public health. It is possible that sporadic cases and small outbreaks have gone unrecognized. However, the attention given to *E. coli* O157:H7 infections and school food safety since 2000 makes it unlikely that any sizable outbreaks have occurred. Prevention of such outbreaks depends on continuing to ensure the low likelihood that ground beef is contaminated by pathogens during its production and continuing to ensure that it is properly handled, stored, and cooked before being served.

Food safety requires a system of multiple interventions and controls throughout production and processing. Even when producers and processors minimize or reduce contamination, thorough cooking of ground beef is essential to protect the health of students served by the AMS program regardless of the stringency of purchase specifications.

In response to its charge, the committee detailed several findings and recommendations regarding the AMS Federal Purchase Ground Beef Program. The major findings and recommendations are presented below.

- The scientific basis of the current purchase specifications for ground beef is unclear. Some specifications were based on industry practices, but the scientific basis of the industry practices cannot be ascertained by the committee. Other specifications appear to have been based on information that was gathered through informal, ad hoc expert consultation. **The Agricultural Marketing Service is encouraged to develop a systematic, transparent, and auditable system for modifying, reviewing, updating, and justifying science-based purchasing specifications.**

[1]HACCP—a system designed to manage safety of food through the analysis and control of biological, chemical, and physical hazards.

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- In developing the current purchase specifications for ground beef, the AMS procedure did not follow the scientific principles for establishment and implementation of microbiological criteria described by the National Research Council, the International Commission on Microbiological Specifications of Foods, and the Codex Alimentarius Commission. **It is recommended that future revisions of the specifications be based on such principles.**
- The recent update of the AMS purchase specifications relied heavily on informal ad hoc expert opinion, which the committee determined to be the least preferred form of evidence. **To strengthen the scientific basis of the Agricultural Marketing Service purchase specifications, it is recommended that the Agricultural Marketing Service use resources that yield more reliable evidence (such as the use of reports based on data, internal reports based on Agricultural Marketing Service data, formal expert consultation, and peer-reviewed reports and risk assessments) and that are consistent with the entire context of the service's need to develop a cohesive program.**
- As part of its program to ensure the safety of the ground beef that it purchases (that is, compliance with FSIS and AMS requirements), AMS routinely collects microbiological testing data from its suppliers. **The committee recommends that the Agricultural Marketing Service look into appropriate methods of analyzing these data because they could be useful for process control and improvement and could enable the service to evaluate and guide future revisions of the ground beef purchase program specifications.**
- The July 2010 *Technical Requirements Schedule* for ground beef (*TRS-GB*) contains specifications that increase the testing requirements for ground beef. However, increased testing might not increase the safety of the product. Process control is a well-established method for improving food safety and is the basis of HACCP. **The Agricultural Marketing Service should ensure that suppliers in its purchase program are responsible for the safety of their products and for the management, performance, and improvement of their processes**. **It is recommended that the Agricultural Marketing Service develop a strong supplier evaluation program that is based on statistical process control techniques and that encourages suppliers to improve both process and product performance.**
- The committee examined and found considerable variations in the microbiological standards set by 24 large purchasers of ground beef in the corporate sector. Substantial differences were found among the specifications of the corporate purchasers in criteria for aerobic plate counts, coliforms, generic *E. coli*, *Staphylococcus aureus*, *Salmonella*, *Listeria monocytogenes*, and *E. coli* O157:H7. The committee believes that the intended use of the ground beef is a likely factor in the variations. For example, although all raw AMS-purchased ground beef is distributed in frozen form, distributors of fresh products may require different standards designed to improve shelf-life. In addition, little information was available to the committee on the scientific (or any other) basis of the corporate specifications. The committee was therefore unable to compare AMS specifications with those of the corporate purchasers directly.
- The July 2010 *TRS-GB* specifications apply to all ground beef purchased by AMS. Ground beef not compliant with these specifications may not be made into cooked products eligible for purchase by the AMS, even if they are handled and cooked according to FSIS guidelines in a USDA-inspected facility. Yet, proper cooking kills pathogens in ground beef, making those products safe to eat. Moreover, USDA food and nutrition program participants may purchase commercially available cooked ground beef products outside of the AMS procurement system. While these products must meet all FSIS requirements, their source materials do not necessarily have to meet AMS ground beef specifications. As a result, there is no apparent health benefit supported by the current AMS policy, especially since indications of unwholesomeness are always grounds for rejection of both raw and cooked

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products. **Therefore, the committee recommends that Agricultural Marketing Service consider permitting July 2010 *TRS-GB* noncompliant products to be used in cooked meat products purchased through USDA food and nutrition programs if they meet FSIS requirements.**

- The overall procedures in the June 2010 *Statement of Work* for the testing of supplier samples by AMS-accredited laboratories appear to be appropriate. However, the committee found one inconsistency involving the reporting of *E. coli* O157:H7 between procedures in the AMS June 2010 *Statement of Work* for AMS-accredited laboratories and the USDA FSIS *Microbiological Laboratory Guidebook,* which it referenced. **The committee recommends that the Agricultural Marketing Service address that inconsistency.**
- **The committee recommends that the Agricultural Marketing Service—through partnerships with the Agricultural Research Service, the Food Safety and Inspection Service, and the Centers for Disease Control and Prevention—follow developments associated with pathogens of current concern and other emerging pathogens to develop strategies for the protection of vulnerable consumers (such as schoolchildren and the elderly). The Agricultural Marketing Service outreach for advice should continue and be expanded by considering the use of existing advisory committees, such as the National Advisory Committee on Microbiological Criteria for Foods.**

BACKGROUND

The U.S. Department of Agriculture (USDA), through its Agricultural Marketing Service (AMS), purchases and distributes food for the federal food and nutrition programs. One of those programs is the National School Lunch Program (NSLP), which has been receiving ground beef purchased by AMS for more than 60 years. The AMS ground beef purchase program, which is referred to as the Federal Purchase Ground Beef Program, also provides ground beef and other commodities to food banks, emergency feeding programs, Indian reservations, programs that serve the elderly, disaster relief agencies, and a variety of other institutions. Thus, although the NSLP is a primary beneficiary of the Federal Purchase Ground Beef Program, the program serves many of the most vulnerable Americans of all ages and backgrounds.

AMS buys ground beef from more than 15 suppliers that are required to comply with federal regulations and guidelines and to adhere to strict nutritional, food safety, and food quality requirements. Specifications for the Federal Purchase Ground Beef Program exceed those mandated by the USDA Food Safety and Inspection Service (FSIS) for all federally inspected meat processing plants. Since 2003, more than 15 companies have participated constantly in the program. The number of companies that supply ground beef varies from time to time because of changes in eligibility status.

In the late 1990s, the AMS specifications for ground beef and boneless beef were spelled out in *Technical Data Supplement 136 (TDS-136)*. *TDS-136* required that suppliers meet FSIS regulatory requirements for sanitation and Hazard Analysis and Critical Control Point (HACCP) plans, have one antimicrobial intervention step that is a critical control point in their HACCP plans, and comply with FSIS good manufacturing practices. In 2001–2002, requirements were added to the *TDS-136* specifications; among these were having one additional antimicrobial intervention step, testing carcasses for *E. coli* O157:H7, and having a quality control program that meets the microbiological upper specification limits for indicator microorganisms (for grinders that perform extra trimming).

In 2003, the first *Technical Requirements Schedule* for ground beef (*TRS-GB*) was implemented, and suppliers were required to submit a technical proposal. According to the *TRS-GB*, which supersedes *TDS-136*, AMS would buy ground beef only from suppliers that successfully document their process (by submitting a technical proposal) and undergo an on-site assessment that ensures that all AMS specifications are met before any contract award. The *TRS-GB* required a contracted supplier to use statistical process control methods (statistical techniques for monitoring and controlling a process to ensure that it is able to produce a conforming product) and to test for *Salmonella* and *E. coli* O157:H7 (in raw materials and finished ground products). Samples that tested positive for *Salmonella* or *E. coli* O157:H7 would be rejected by AMS, and the supplier in question would be required to conduct a cause–effect analysis to prevent recurrence. Processors that have numerous instances of positive results for those organisms would be deemed ineligible to contract with the Federal Purchase Ground Beef Program. In 2004, AMS established contracts with outside laboratories to perform microbial testing on all suppliers' samples.

In December 2009, a news report in *USA Today* suggested that some large-scale purchasers of ground beef in the corporate sector have more stringent requirements for their suppliers than does USDA. That and other articles and a letter from U.S. Senator Kirsten Gillibrand (D-NY) to Secretary of Agriculture Tom Vilsack about perceived deficiencies in the Federal Purchase Ground Beef Program, led to a technical review of the AMS ground beef purchase standards by the USDA Agricultural Research Service (ARS) and FSIS concurrent with the USDA Office of the Inspector General (OIG) audit that was being conducted at that time.

AMS also held discussions with large commercial beef suppliers and purchasers to learn about their food safety approaches and to hear their comments on the July 2010 *TRS-GB*. In February 2010, USDA announced new food safety initiatives, which included revision of the AMS *TRS-GB* based on new recommendations from ARS, FSIS and OIG. The announcement of the new initiatives was followed in

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April 2010 by a request from USDA for an assessment of the AMS ground beef safety requirements by an independent body. The National Research Council was asked to perform the assessment and to provide a report to AMS and FSIS.

COMMITTEE'S STUDY APPROACH

The committee's statement of task is as follows:

> An NRC-appointed committee will evaluate the scientific basis of current food safety requirements of the Federal Purchase Ground Beef Program and prepare a letter report of its findings. In the course of its study, the committee will examine technical and other documents that describe food safety measures required of suppliers of ground beef to the Program. Such measures include food safety requirements in the process of manufacturing ground beef items and the testing of materials (including laboratory accreditation and procedures established by those laboratories for selection, delivery, analysis, and reporting of findings of samples) throughout the process, from slaughter to delivery of product to the recipient. The study will also examine how USDA standards, methods, and requirements compare to those used in the large purchasing programs of industry leaders who supply ground beef products directly to the consumer through retail sales or food service operations. The committee will seek input from suppliers, food safety experts, and other entities involved in purchasing ground beef on a large scale.
>
> The committee's report will present the committee's evaluation of the scientific validity of USDA's current technical requirements and methods and a benchmark of USDA processes and methods relative to those in recognized industry-leader programs. The report will also provide recommendations to USDA on how to perform future periodic evaluations relative to recognized best practices.

On the basis of the statement of task, the committee considered the following as its charge: to evaluate the scientific basis of the AMS technical documents that describe food safety requirements for suppliers to the Federal Purchase Ground Beef Program and procedures for testing laboratories, to examine how the AMS standards, methods, and requirements compare with those used in large purchasing programs of industry leaders that supply ground beef products directly to consumers through retail sales or food service operations, and to provide recommendations to AMS for conducting periodic evaluations of the Federal Purchase Ground Beef Program.

The committee examined the scientific basis of the AMS July 2010 *TRS-GB* (USDA-AMS, 2010a) and of the June 2010 Statement of Work (SOW) for AMS-accredited laboratories (USDA-AMS, 2010b), and it considered ARS and FSIS representatives' answers to questions posed by the committee during its second meeting. To address the second task, the committee requested, through a representative of an industry association (Scott Goltry, American Meat Institute), microbiological specifications for retail and commercial food service entities that purchase ground beef directly from meat companies or indirectly from purchasers or suppliers. The committee used the combined knowledge that it gained in addressing the first and second tasks and its own collective expertise and judgment to address the third task—to provide recommendations to AMS for evaluating its program.

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THE SCIENTIFIC BASIS OF THE AGRICULTURAL MARKETING SERVICEFEDERAL PURCHASE GROUND BEEF PROGRAM SPECIFICATIONS

To address the scientific basis of the AMS ground beef purchase specifications, the committee evaluated and considered the following:

- Data available on *Salmonella* and *E. coli* O157:H7 outbreaks associated with beef in schools.
- Recognized principles for establishment of microbiological criteria.
- Indicator microorganisms as potential predictors of food safety.
- AMS specific requirements.
- Statistical process capability.
- The June 2010 Statement of Work for AMS-accredited laboratories.

Outbreaks Associated with Ground Beef in Schools

The AMS purchase specifications for frozen ground beef include criteria for the pathogens *Salmonella* and *E. coli* O157:H7, which are recognized hazards in raw ground beef products (ICMSF, 2005). To assess the extent of the risk to schoolchildren posed by the presence of the pathogens in AMS purchased ground beef, the committee reviewed foodborne-illness outbreaks in schools associated with ground beef and products containing ground beef. An outbreak is defined as the development of a similar illness in two or more persons after consumption of the same food (CDC, 2010a). The Centers for Disease Control and Prevention (CDC) coordinates national surveillance of foodborne diseases in the United States. Although responsibility for foodborne-disease surveillance and outbreak investigation resides in the jurisdictions of local and state health departments, information about confirmed and suspected foodborne outbreaks is reported to CDC. Since 1998, CDC has collected a standardized set of data on each reported outbreak that include state, date, and location of occurrence; etiology; numbers of ill, hospitalized, and deaths; and associated food (vehicle) if identified (CDC, 2010b). Most cases of foodborne illness do not occur as parts of recognized outbreaks, but information from outbreak investigations is extremely important in determining the safety of specific food items or commodities. That is particularly true for school settings, where large groups of students may be exposed to a contaminated food item simultaneously. Clustering of cases in a school makes it more likely that a common source of exposure would be recognized than if a similar food item were distributed through grocery stores or restaurants. Furthermore, school-aged children are more likely to be medically evaluated for illnesses involving bloody diarrhea or fever. Thus, outbreak data constitute a useful tool for evaluating the risk of *E. coli* O157:H7 and *Salmonella* associated with ground beef in schools.

From 1998 to 2007, 492 confirmed foodborne-disease outbreaks in schools were reported to CDC. The number of reported outbreaks per year ranged from 31 in 2007 to 70 in 2000. Norovirus accounted for 164 (33%) outbreaks; 160 (33%) had an unknown etiology, but many of these were probably due to norovirus. The number of school-associated outbreaks has been declining since the publication of a U.S. General Accounting Office report that was published in 2000 (GAO, 2000). Information on school outbreaks due to *E. coli* O157:H7 and *Salmonella* are summarized below.

E. coli O157:H7

From 1998 to 2007, CDC received reports of 263 confirmed foodborne outbreaks of *E. coli* O157:H7 infection in the United States. Ground beef (or products containing ground beef, such as

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meatballs, lasagna, and tacos) was identified as a vehicle in 69 (26%) of the outbreaks. Schools were identified as a location of three of the ground beef outbreaks—two in 2000 and one in 2003. An additional outbreak of *E. coli* O157:H7 infection associated with a school lunch in Washington state occurred in 1998 but was not so identified in the CDC database. Hence, a total of four ground beef outbreaks in schools have been reported in the United States since 1998. One of the 2000 outbreaks occurred in a private elementary school in Minnesota, and the other occurred at the State University of New York (SUNY), Albany. The 2003 outbreak involved beef burritos that were distributed in restaurants and schools in Nebraska. Because the Federal Purchase Ground Beef Program supports food assistance programs, such as the NSLP, the committee thought it unlikely that the 2000 SUNY outbreak and the 2003 restaurant–schools outbreak involved AMS-purchased ground beef and therefore did not consider them relevant to the discussion of the safety of ground beef in the Federal Purchase Ground Beef Program. Thus, from 1998 to 2007 there were two primary school lunch outbreaks associated with ground beef contaminated by *E. coli* O157:H7 that *may* have involved ground beef purchased by AMS (S. A. Seys, Office of Public Health Science, FSIS, USDA, Minneapolis, MN, personal communication, Aug. 2, 2010).

In the 1998 Washington state outbreak, students in Finley Elementary School became ill after eating apparently undercooked ground beef in tacos prepared in the school. About 3% of children who ate the tacos became ill, and the odds ratio of 4.2 had a very wide 95% confidence interval (0.4–108.2), which may have affected how information about the outbreak was entered into the CDC database. The ground beef was obtained through the NSLP, and this was the only outbreak confirmed and linked to the Federal Purchase Ground Beef Program. At least 11 children became infected. The outbreak led to a $4.6 million award as a result of litigation (GAO, 2003). In the 2000 Minnesota outbreak, at least 18 students (11% of those interviewed) in a Catholic grade school in Minneapolis became ill after eating apparently undercooked ground beef in a baked casserole (called hot dish) prepared in the school. A review of ground beef handling procedures in the school indicated that thawing, cooking, and cooling of the ground beef may have been inadequate. However, the plant of origin and the packing date of the ground beef used in the hot dish could not be conclusively identified.

Both those outbreaks occurred before FSIS issued the October 7, 2002, *Federal Register* notice (USDA-FSIS, 2002) that required establishments to "reassess their HACCP plans to determine whether *E. coli* O157:H7 contamination is a hazard reasonably likely to occur in their production process". Successful implementation of HACCP plans throughout the beef industry has been widely credited with improving the quality and safety of ground beef. From 1998 to 2000, a mean of 9.0 ground beef–associated outbreaks of *E. coli* O157:H7 infection occurred each year. From 2001 to 2004, only 4.8 ground beef–associated outbreaks per year were reported. From 2005 to 2007, a mean of 7.7 outbreaks per year were reported, and 12 were reported in 2007. However, no additional school lunch–associated outbreaks were associated with ground beef after the reassessment was required. Those results suggest that when *E. coli* O157:H7 control practices are not followed, outbreaks can occur. However, such outbreaks appear to be uncommon; one confirmed outbreak was attributed to AMS-purchased ground beef in a 10-year period. Both adherence to proper food handling practices and the low likelihood of ground beef contamination (about 0.13% according to data provided by AMS) contribute to the primary prevention of school-associated outbreaks. However, the relative importance of adherence to the practices and the low likelihood of contamination has not been determined.

Salmonella

From 1998 to 2007, CDC received reports of 1,152 confirmed outbreaks of foodborne *Salmonella* infection. Ground beef (or products containing ground beef, such as meatballs, lasagna, and tacos) was identified as a vehicle in 36 (3.1%) of the outbreaks. A school was identified as a location of only one of the outbreaks, which was associated with beef lasagna that was prepared at home and eaten in a school.

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The CDC database indicates that the key ingredient in the lasagna that contributed to the outbreak was eggs, and ground beef was not the likely source of the *Salmonella Enteritidis* contamination. Hence, no confirmed *Salmonella* outbreaks in schools during 1998–2007 were associated with ground beef obtained through the Federal Purchase Ground Beef Program or any other source.

Principles for Establishing Microbiological Criteria

Internationally recognized bodies—such as the National Research Council (NRC, 1985), the Institute of Medicine (IOM,2009), the International Commission on Microbiological Specifications for Foods (ICMSF,2002), and the Codex Alimentarius Commission (CAC,1997)—have developed principles and procedures based on scientific knowledge, statistical rules, and epidemiological information to determine when establishment of microbiological criteria and testing should be expected to make a contribution to public health. They all emphasize the use of a systematic approach for process control, such as HACCP, as the primary and most effective means of managing microbial hazards to protect public health. They also point out that appropriate microbiological testing can serve a useful role in assessing the adequacy of food safety programs. However, no matter how extensive it might be, microbiological testing alone cannot ensure the safety of the food supply. Following the principles outlined by the National Research Council, ICMSF, and CAC would provide a more transparent and systematic process that is based on scientific principles for establishing specifications.

The National Research Council has discussed the role of microbiological criteria for foods in a detailed report (NRC, 1985). The more recent general principles described by CAC (1997) are consistent with the 1985 National Research Council conclusions. The CAC (1997) principles are used as an example in this report because they are more recently published and internationally recognized principles that have been fully vetted through CAC and are cited as the guiding principles for establishment of microbiological criteria by other authoritative groups (for example, ICMSF, 2002).The CAC principles are intended to apply to both regulatory authorities and food business operators. Some sections of the principles are particularly relevant to the present discussion in that they address basic guidelines for developing criteria and potential actions that can be taken when criteria are not met. Some portions of *Principles for the Establishment and Application of Microbiological Criteria for Foods* that are useful for AMS to consider are discussed below with examples of how they may apply to the Federal Purchase Ground Beef Program.

Application of Appropriate Tests

CAC/GL 21-1997 Section 2.3:

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 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.

On the basis of scientific principles, the National Research Council (NRC, 1985, p. 3) reached a similar conclusion and stated that "microbiological criteria should be established and implemented only when there is a need and when the criterion can be shown to be effective and practical". Public or social considerations may also attempt to influence development of criteria; however, the present committee concurs in the previous conclusions (NRC, 1985; CAC, 1997) that resources should be applied to science-based criteria.

One example of a test that may not be scientifically appropriate in the Federal Purchase Ground Beef Program is the one for *Staphylococcus aureus*. The rationale follows, using information from ICMSF (1996, 2005) as supporting evidence. *S. aureus* is naturally associated with mucous membranes and skin of warm-blooded animals, so its presence does not necessarily indicate inappropriate conditions in raw product. The minimum and optimum temperatures for growth are 7°C and 37°C (45°F and 99°F), respectively; and the minimum and optimum temperatures for toxin production are 10°C and 40–45°C (50°F and 104–113°F), respectively, under otherwise optimum conditions. Growth and toxin production are inhibited by the presence of other microorganisms. Inasmuch as toxin production requires a *S. aureus* population of at least 10^6colony forming units (CFU) per gram (ICMSF, 2005, p. 35), which is ten times greater than the AMS upper specification limit (USL)[2] for aerobic plate count (APC, a method of determining the total number of aerobic bacteria in food), this hazard is not likely to occur. The low temperatures (below 7°C) used for ground beef processing also inhibit *S. aureus* growth. Some may consider *S. aureus* as an indicator of process control, but other measures—such as APC, coliforms, and *E. coli*—serve the same purpose. The APC may also be a more useful indicator because the diversity of the population present may include organisms that have higher growth rates at lower temperature.

Documentation of analysis in a manner similar to that conducted for *S. aureus* would provide AMS with transparent justification of how science and principles for establishing criteria were applied in the establishment of other microbiological criteria. AMS provided no such documentation for the present committee to review; if such analysis is conducted, changes in other criteria may be justified. Recommendations related to *Salmonella* are also discussed below in Finding A5.

Finding A1: The committee finds no scientific basis for including *S. aureus* criterion in the AMS purchase specifications. It does not present a public health issue in this product, its presence does not indicate inappropriate handling or conditions, and other tests provide more useful information on process control. Testing for *S. aureus* does not add value.
Recommendation A1: The committee recommends that the criterion for *S. aureus* be removed from the Federal Purchase Ground Beef Program and that similar analyses be conducted and documented for other criteria to provide transparency and a scientific basis for the criteria specified.

Dependence of Appropriateness of Criteria on Intended Use

CAC/GL 21-1997 Section 3.1.1 Application by regulatory authorities, paragraph 3:

In situations of non-compliance with microbiological criteria, depending on the assessment of the risk to the consumer, the point in the food chain and the product-type specified, the regulatory control actions may be sorting, reprocessing, rejection or destruction of product, and/or further investigation to determine appropriate actions to be taken.

The National Research Council (NRC, 1985, pp. 27–28) reached a similar conclusion for both regulators and processors. The present committee concurs in the previous conclusions of the National Research Council and CAC. AMS excludes noncompliant raw ground beef products from *all* USDA food and nutrition programs. The committee concludes that the AMS criteria for pathogens are not relevant for product that is intended to be fully cooked, especially when it is under such controls as those in a USDA-inspected establishment. For example, if a sample of a lot of ground beef trim tests positive for *E. coli* O157:H7, the lot is classified as containing the pathogen. The meat processor cannot use the lot to manufacture uncooked ground beef patties. However, under FSIS regulations, the meat processor can ship

[2]Expressed as CFU/g for each indicator organism; USL is factored into the determination of a supplier's process capability or capability to supply a product that conforms to AMS specifications.

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the product to a further processor, and the further processor can use the trim in a product that will be cooked. The cooking process must be sufficient to destroy *E. coli* O157:H7. After cooking, the meat product is considered to be safe to eat. There is substantial scientific justification for stating that validated cooking processes provide greater assurance of safety than testing (for example, ICMSF, 2002). In light of statistical implications associated with sampling plans, testing cannot guarantee the absence of pathogens (ICMSF, 2002). In addition, slight deviations above the concentrations of microbial indicators specified in the July 2010 *TRS-GB* (USDA-AMS, 2010a) do not necessarily indicate the unwholesomeness of product (that is, that it is not fit for consumption and is possibly injurious to health) (see the next section of this report, on indicator microorganisms). That is not to suggest that grossly contaminated product (that is, having substantially more contamination than should be present if good manufacturing practices are applied) or spoiled product should be accepted for further processing.

Finding A2: The current AMS testing requirements apply to ground beef that may be used in a variety of forms, including frozen ground beef patties (which are likely to be cooked in that state by the end user), coarse ground beef (which AMS indicated is likely to be fully cooked in a USDA-inspected facility), and other products, such as products that are irradiated. Application of the same criteria for all applications is not consistent with Codex Principle CAC/GL 21-1997 Section 2.3. When the ultimate use of a product cannot be determined, it is reasonable to use conservative specifications. However, during a public meeting with AMS on July 15, 2010, the committee learned that for some products, such as coarse ground beef, further processing in USDA-inspected facilities is expected.
Recommendation A2: The committee recommends that AMS consider conducting a more thorough review of criteria for different product types through a national advisory committee designated to provide impartial scientific advice on microbiological criteria to federal food safety agencies, such as the National Advisory Committee on Microbiological Criteria for Food (NACMCF). The representation of academic, industry, and government experience on NACMCF, or a similar group, can provide a balanced study of specific science-based applications. Considerable time and relevant data are necessary to provide a thorough analysis of the specific criteria recommended for different applications. Some criteria may not be relevant for products intended to be fully cooked in USDA-inspected facilities.
Finding A3: There is no public health benefit of removing all noncompliant products from all other AMS programs if they are to be cooked later according to FSIS guidelines in a USDA-inspected facility. However, indications of unwholesomeness are always grounds for rejection of product.
Recommendation A3: The committee recommends that AMS consider permitting July 2010 *TRS-GB* noncompliant products to be used in cooked meat products purchased through USDA food and nutrition programs if they meet FSIS requirements.

Identification of Appropriate and Technically Feasible Criteria to Protect Public Health

CAC/GL 21-1997 Section 4 General Considerations Concerning Principles for Establishing and Applying Microbiological Criteria:

4.1 A microbiological criterion should be established and applied only where there is a definite need and where its application is practical. Such need is demonstrated, for example, by epidemiological evidence that the food under consideration may represent a public health risk and that a criterion is meaningful for consumer protection, or as the result of a risk assessment. The criterion should be technically attainable by applying Good Manufacturing Practices CAC/GL 21 (Codes of Practice).

4.2 To fulfill the purposes of a microbiological criterion, consideration should be given to:

- the evidence of actual or potential hazards to health;
- the microbiological status of the raw material(s);

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- the effect of processing on the microbiological status of the food;
- the likelihood and consequences of microbial contamination and/or growth during subsequent handling;
- storage and use;
- the category/categories of consumers concerned;
- the cost/benefit ratio associated with the application of the criterion; and
- the intended use of the food.

The National Research Council (NRC, 1985, p. 17) identified similar considerations for foods for which criteria are appropriate, and the present committee concurs in the previous conclusions of the National Research Council and CAC. AMS has identified the most relevant pathogens for raw ground beef—*Salmonella* and *E. coli* O157:H7—and efforts to minimize such contamination are appropriate. AMS has also taken a precautionary approach to establishing criteria for frozen ground beef and assumes that all products they consider for purchase will not be further processed. As previously discussed, that is not the case: AMS indicates that as much as 80% of the product will be fully cooked in a USDA-inspected establishment. Furthermore, the committee's analysis of outbreaks associated with ground beef in schools suggests that outbreaks were rare even *before* the AMS and FSIS requirements became more stringent. That suggests that controls in place before AMS modified its requirements were appropriate for protecting public health. Furthermore, current FSIS Performance Standards for ground beef (9 CFR 310.25) consider *Salmonella* as an indicator and therefore allow its presence in up to 7.5% of samples collected in an establishment, an acknowledgment that it is not feasible to eliminate the pathogen in raw ground beef. Therefore, the AMS standard for ground beef free of *Salmonella* is inconsistent with recognized principles for establishment of specifications.

Finding A4: The application of more stringent microbiological criteria by AMS for the 2010 Federal Purchase Ground Beef Program is inconsistent with CAC/GL 21-1997 principle 4 in that previous requirements appeared adequate to protect public health.
Recommendation A4: As previously recommended, AMS should consider conducting a more thorough review of criteria for different product types through existing national advisory committees or organizations.
Finding A5: FSIS policies acknowledge that *Salmonella* may be present in raw frozen ground beef that is produced under the Food and Drug Administration's Good Manufacturing Practices. Cooking requirements for both food processing (in USDA-inspected facilities) and food service (state and local food-code requirements) are designed to eliminate that hazard, and procedures to control cross-contamination are mandated in both settings. Frozen storage and distribution do not allow growth of the organism. Thus, the AMS-implied zero tolerance for *Salmonella* (actually, absence in 25 g) is inconsistent with established principles for developing microbiological criteria and with current FSIS requirements. The committee emphasizes that a standard that requires the absence of a pathogen in some quantity of food is not actually a true zero tolerance. For example, a sampling plan that requires testing of only a single 25-g sample of food has a 63% chance of accepting a lot that contains *Salmonella* at a concentration of 1 CFU/100g, with a standard deviation of 1 log CFU/g (which means that the concentration varies from 1 CFU/1,000 g to 1 CFU/10 g). A sampling plan that reduces the chance of accepting that same lot to less than 5% requires at least seven negative samples of 25 g each (ICMSF, 2009).
Recommendation A5: AMS should consider using *Salmonella* as an indicator in a manner similar to FSIS. One approach is a moving window, in which results are evaluated over time and old results are eliminated as new results are added. Recurring positive results may be appropriate for product rejection or supplier ineligibility, but total absence is not currently feasible. The assistance of existing national advisory committees or organizations may be useful in addressing this issue.

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Indicator Microorganisms as Potential Predictors of Food Safety

Samples of foods and surfaces may be analyzed for the presence of *E. coli*, Enterobacteriaceae, coliforms, fecal coliforms, or APC as indicators of sanitary conditions, hygiene, adherence to good manufacturing practices, proper or adequate processing, post-processing contamination, and storage time or temperature abuse. That enteric pathogens originate in the intestinal tract of animals and humans supports the biological rationale for using particular microbial indicators, especially *E. coli*, as indicators of potential contamination of food with fecal material except when possible growth has occurred because of poor cold chain management[3]. Although the probability that a pathogen is present may increase with under-processing, post-processing contamination, or manufacture under unsanitary conditions, the presence of an indicator is no guarantee that a pathogen is also present. There is no specific relationship between indicator and pathogen concentration, but it can generally be assumed that a reduction in the concentration of an indicator organism will produce a similar reduction in the concentration of the associated pathogen (Brown et al., 2000). For a microbial indicator to be an effective predictor of the presence of an enteric pathogen in a particular food, there is a need to establish a statistical association for the specific situation under consideration. Establishing an association between an indicator and a pathogen can be problematic because pathogens are generally present sporadically and in low numbers; therefore, a very large number of samples (thousands, tens of thousands, or more) is required to assess potential associations.

To ensure compliance with AMS purchase standards, AMS periodically conducts inspections and collects and analyzes samples from production combo lots (each lot is approximately 2,000 pounds [907 kg] of boneless beef) to determine compliance with the *TRS-GB*. Aerobic (standard) plate count, total coliforms, generic *E. coli*, coagulase-positive *Staphylococcus*, *Salmonella,* and *E. coli* O157:H7 tests are performed in AMS-accredited laboratories, and the resulting data are accumulated. The data are used to make decisions regarding specific combo lots and to evaluate contractor performance with a moving window approach.

Finding A6: The committee finds that AMS is in possession of potentially valuable datasets that can be used to study the strength of the statistical correlation between indicator organisms and foodborne pathogens in ground beef.

Recommendation A6: The committee recommends that AMS investigate its own microbiological data to assess their utility in providing a scientific basis for the use of indicators in setting purchase specifications that reduce risk.

Agricultural Marketing Service Microbiological Requirements

As a technical requirement document for AMS purchase of ground beef items, the committee found the July 2010 *TRS-GB* (USDA-AMS, 2010a) to have little information on the scientific basis of the selection and adoption of the safety requirements for boneless beef and ground beef. Hence, to evaluate the scientific basis of the purchase requirements adopted by AMS, the committee relied on the information provided by AMS, and the ARS and FSIS representatives who attended the two committee meetings. They based their comments on personal knowledge, current legislation, and information that they received from a pool of industry representatives who were willing to discuss their criteria confidentially.

[3]Maintenance of proper temperature control throughout the process of delivering the food to the end-user, from production, through processing and handling, transport and distribution.

The information given to the committee indicated that the AMS specifications were based primarily on expert opinion and industry practices and that AMS did not use the multiple years of microbiological data that it had collected from contractors' samples. In one specific instance, AMS made a decision (the requirement for a minimum of two interventions with Critical Control Points to attain a 3-log or 99.9% reduction) on the basis of one retailer's practices (M. E. O'Connor, USDA-AMS, Washington, DC, personal communication, Aug. 11, 2010). In some instances, requirements were made by using a "conservative or a precautionary approach" that was based not necessarily on existing data but instead on informal expert consultation.

Finding A7: The scientific basis of the AMS technical requirements for the purchase of ground beef is questionable and might not reflect the best evidence available (see the section "Weight of Evidence and Role of Expert Opinion in Developing Science-Based Food Safety Requirements"). In addition, expert consultation was conducted in an informal, ad hoc, and nontransparent manner. Current industry practices were also used by AMS in establishing its purchase criteria, but the scientific basis of the industry practices cannot be ascertained by the committee.

Recommendation A7: Expert consultation and industry practices can be helpful in making informed decisions in setting specifications and purchase criteria. However, the committee recommends that the solicitation and use of expert advice and industry practices be conducted in a structured, systematic, and transparent manner. In addition, the committee recommends that AMS consider examining the analysis of microbiological data collected from contractors' samples to determine whether the data can provide an empirical basis for determining and evaluating purchase specifications (see Recommendation A6 above).

Finding A8: No statistical assumptions, such as on the prevalence of pathogens or confidence levels, were used by AMS in defining sampling strategies and lot sizes (see discussion on sampling in the section "Heuristic vs Science-Based Approach to Developing Specifications and a Food Safety Assurance System").

Recommendation A8: Sample and lot sizes should be determined with statistical methods. Modeling techniques can also help in making decisions on lot sizes and can provide valuable information on the likelihood of accepting or rejecting a contaminated lot, which is directly related to public health risk. Criteria or requirements can be more readily justified if they are derived through statistical calculations and modeling techniques.

Statistical Process Capability

According to the July 2010 *TRS-GB* (USDA-AMS, 2010a), AMS will evaluate contractor performance through a statistical process capability assessment that is based on a moving window of 20 consecutive lots. The capability assessment method proposed in the July 2010 *TRS-GB* should be able to detect the increase in the frequency of positives for all contractors that had *E. coli* O157:H7–positive samples and should be able to trigger the mechanisms that would deem these contractors ineligible. Once ineligible, a contractor is excluded from the purchase program, at least temporarily, until it can provide AMS its plan for corrective actions. The plan for corrective actions is evaluated by an on-site assessment audit performed by AMS personnel. If approved, the contractor can re-enter the program in conditional status. In conditional status, the contractor has to have 20 consecutive results that meet "process-capable" criteria. That requirement has to be met within 60 calendar days or in accordance with the production schedule approved by the contracting officer.

Finding A9: The AMS statistical process capability assessment for evaluating a contractor's performance seems to be effective but is limited to a particular timeframe and does not consider the contractor's performance over time.

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Recommendation A9: AMS should attempt to identify risk factors for the presence of *E. coli* O157:H7 by using longitudinal analysis of historical data—using not only microbiological data but inspection scores, seasons, establishments' characteristics, and other available information relevant to identifying risk factors for *E. coli* O157:H7 in ground beef. The process would probably assist in selecting contractors that are less likely to have ground beef contaminated with *E. coli* O157:H7.
Finding A10: The July 2010 *TRS-GB* contains specifications that increase the testing requirements for ground beef. However, increased testing might not increase the safety of the product. Process control is a well-established method for improving food safety and is the basis of HACCP.
Recommendation A10: AMS should ensure that suppliers of boneless beef and ground beef grinders are responsible for the safety of their products and for the management, performance, and improvement of their processes. Data on the product that are obtained by the food processors and the service need to be analyzed for *TRS* compliance, process stability, and process capability with appropriate statistical methods. It is recommended that AMS develop a strong supplier evaluation program that is based on statistical process control techniques and that encourages suppliers to improve both process and product performance.

Evaluation of the Statement of Work for Agricultural Marketing Service–Accredited Laboratories

The committee reviewed the June 2010 Statement of Work (SOW) (USDA-AMS, 2010b), which provides the requirements for laboratories seeking to enter into a service contract with AMS to collect samples, conduct required microbiological and fat tests, analyze the data, and report the results for suppliers participating in AMS's Product Certification Service.

Finding A11: The overall procedures for laboratory accreditation appear to be appropriate. According to the June 2010 SOW, the laboratory will be required to test for the presence of "Shiga-toxigenic *E. coli* O157 (including O157:H7 and O157:Non-Motile (NM), referred to in this document as *E. coli* O157:H7)". The SOW also states that screening tests detailed in the FSIS *Microbiology Laboratory Guidebook (MLG),* Chapter 5A.01 (USDA-FSIS, 2008a), can be used for *E. coli* O157:H7 testing. However, *MLG* Chapter 5.04 (USDA-FSIS, 2008b) indicates the following definition for reporting *E. coli* O157:H7:

Confirmed Positive—a biochemically identified *Escherichia coli* isolate that is serologically (i.e., based on antigen-antibody characteristics) or genetically determined to be "O157" that meets at least one of the following criteria:

1. Positive for Shiga toxin (ST) production
2. Positive for Shiga toxin gene(s) (stx)
3. Genetically determined to be "H7"

Hence, the definitions in the June 2010 SOW and *MLG* Chapter 5.04 seem to be inconsistent, inasmuch as a Shiga toxin–negative *E. coli* O157:H7 would be considered positive for *E. coli* O157:H7 by *MLG* Chapter 5.04 but not by the definition in the SOW. The SOW also did not provide details of how laboratories are expected to detect or identify O157: nonmotile.
Recommendation A11: The committee suggests that AMS provide further clarification of the procedures that the laboratories are expected to use to detect and identify *E. coli* O157:H7 and that AMS clarify specifically how these methods are related to the methods and definitions detailed in the relevant *MLG*

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chapter. AMS should also clarify how laboratories are expected to detect or identify O157: nonmotile (for example, with phenotypic or genetic tests).

COMPARISON OF THE AGRICULTURAL MARKETING SERVICE SPECIFICATIONS WITH THOSE OF LARGE INDUSTRY PURCHASERS OF GROUND BEEF

Current AMS specifications in the July 2010 *TRS-GB* (USDA-AMS, 2010a) for the Federal Purchase Ground Beef Program were extracted, summarized, and presented in tabular format (see Table 1). Microbiological specifications for retail and commercial or food service purchasers of ground beef were obtained through direct requests to companies or indirectly from requests to purchasers or suppliers through a representative industry association. Because of proprietary concerns raised by the companies that agreed to share their specifications through the American Meat Institute (AMI), the company names were removed from documents by AMI before their submission of the specifications to the committee. Each company was assigned a letter designation (A through X, as shown in Table 1). The committee is uncertain of the extent of the scientific evidence, if any, that supports the microbiological specifications provided by industry, either singly or combined into a program. No information was provided on the sampling plan (number of samples analyzed, analytical-unit size, and action taken if limits were exceeded), so calculation of the stringency of sampling plans was not possible. Moreover, different users may consider some measures as food safety specifications, as quality indicators, as tools for assessing process control, or as evidence of supply chain management. As a measure to protect public health, therefore, the comparison is of little value, or even of little purpose, because the scientific underpinnings of the specifications, excluding *E. coli* O157:H7 contamination, cannot be determined.

Finding B1: Substantial variation in the data is evident. The reasons for the variation are uncertain; however, one factor that may account for at least some of it is the intended use of the product. For instance, product that is to be distributed fresh to a food service may require a lower specification limit if a longer shelf-life is required. As a consequence, comparisons of specifications have little meaning unless the basis of the specifications and the intended use of each product are known.

Finding B2: The committee recognizes that AMS expected its specifications to be compared with or benchmarked against industry specifications. However, meeting that expectation relied heavily on the amount of information that the committee was allowed to access. It appears on the surface that AMS specifications are comparable with or even more demanding than those of the commercial companies, but the lack of information on intended use, sample size, sample number, or actions taken when specifications were exceeded renders comparison of AMS specifications with those of other companies inappropriate and scientifically invalid.

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Table 1 Microbiological Specifications of Various Companies A Through X and Upper Specification and Critical Limits of AMS[a, b]

	Microbiological Characteristic Measured Qualitatively or Quantitatively						
Company	**APC (CFU/g)**	**Total Coliforms (CFU/g)**	***E. coli* (CFU/g)**	***S. aureus* (CFU/g)**	***Salmonella***	***L. monocytogenes***	***E. coli* O157:H7**
A	100,000	1,000	240	N/A	N/A	N/A	
B	<50,000	<500	<10	<100	Min	Min	Neg
C	750,000	1,100	240	<1,500	Min	N/A	
D	250,000	N/A	110		Min	Min	
E	1,000,000	5,000	—	240	Min	Min	
F	—	—	—	—	Min	Min	
G	500,000	1,000	250	250	Min	Min	
H	500,000	1,000	100	500	N/A	N/A	
I	500,000	500	240	100	Min	Min	
J	<100,000	<500	<110	250	Min	N/A	
K	—	—	—	—	—	—	
L	500,000	1,000	250	500	Min	—	
M	500,000	1,100	100	—	Min	Min	
N	—	—	—	—	—	—	
O	—	—	—	N/A	—	—	
P	250,000	240	100	<500			
Q	<500,000	<1,100	N/A	Neg			
R	<1,000,000	<10	<3	110	Neg	Min	
S	100,000	500	150	—	Min	Min	
T	—	—	—	250	—	—	
U	750,000	5,000	—	<110	Min	Min	
V	<100,000	<500	<150		—	—	
W	500,000	500					Neg
X	<100,000		<110				Neg
AMS upper specification limit[c]	50,000	100	100	500			
AMS critical limit[d]	100,000	1,000	500		Neg		Neg

[a]APC = aerobic plate count; dash = company's default specification, not shown, used as company's specification; empty cell = company does not include as a requirement in its specification; N/A = company does not require testing for organism as part of its specification; Min = minimizes occurrence of positives through Good Manufacturing Practices; Neg = negative.

[b]Exceeding these specified limits typically results in rejection by companies A through V of the out-of-specification production unit; the same is probably true for companies W and X, but this was not confirmed. Disposition of product varies with microbial nonconformity; if positive for *E. coli* O157:H7, product may be rendered or sold for thermal processing; if other specifications are exceeded, product may be reprocessed or sold into secondary markets.

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[c]For boneless and ground beef; used for evaluation of process capability. If process is deemed out of control by AMS, the company becomes ineligible as a supplier. *S. aureus* for ground beef only; if initial and backup ground beef samples exceed the *S. aureus* upper specification limit, production lot is rejected.
[d]For boneless and ground beef; used to reject lot-by-lot data (whole-lot = "cleanup to cleanup" or sub-lot plus "shoulders" depending on positive sample, that is, if whole-lot sample or sub lot sample results in nonconforming test).

RECOMMENDATIONS ON HOW TO PERFORM FUTURE EVALUATIONS RELATIVE TO RECOGNIZED BEST PRACTICES

Heuristic vs Science-Based Approach to Developing Specifications and a Food Safety Assurance System

Specification writers may use a *heuristic approach* to develop specifications, which focuses on using experience to develop specification and is based on the following assumptions:

- The food safety assurance system has worked in the past.
- The company has not shipped product that has caused a food safety incident.
- Therefore, the system will work in the future.

That approach assumes that the past conditions and "context" (dotted box in Figure 1) have not changed and will not change. However, if the "context" changes, the food safety assurance system may or may not be adequate to ensure shipment of safe food.

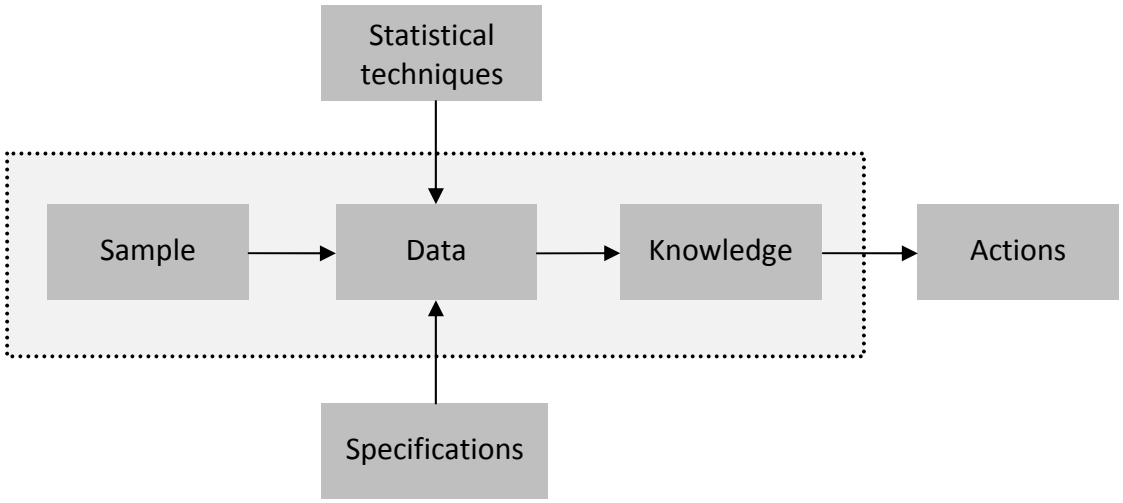

Figure 1 Food safety assurance process to take appropriate action on a process or product lot. Context and conditions used to collect and analyze data are shown in dotted box.

An alternative method of developing a food safety assurance system is to use a process-controlled *science-based approach*. This would be based on the idea that a properly designed system is statistically stable—that is, values obtained will fall between a set of mathematically defined limits—and capable of meeting specifications. It uses the tools of statistical process control to assess process stability

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and process capability. Statistical process control is a powerful tool. It can be used by purchasers to monitor supplier performance: they can rank supplier performance, determine whether suppliers are continually improving their performance, and obtain quantitative knowledge of whether specifications are being met.

A number of questions can be asked to determine whether an organization uses a *science-based approach* to develop a specification, including the following:

- *Was the level of risk for a food pathogen considered in developing the specification?* This includes the potential concentration of the pathogen in the food, the infective dose of the pathogen, and the consequence of an illness.
- *Did the organization consider what may go wrong with the product and the process?* When this question is asked, the organization needs to take action to minimize the occurrence of the hazard in the product or develop a testing procedure that identifies the presence of the hazard. In addition, the supplier should provide a plan to AMS describing how it will meet the specifications.
- In developing a product compliance-sampling program, were proper statistical procedures used to ensure that the pathogen can be detected with a specific level of confidence? The number of samples analyzed should be determined in a manner that provides the organization with a specific level of confidence that a hazard is being controlled. For example, the sampling scheme could provide 95% confidence (or another level) that a specific amount of beef trim does not contain *E. coli* O157:H7. No practical sampling scheme can guarantee total absence of a microorganism (Table 2).

For example, if the contamination rate of *E. coli* O157:H7 in lots of AMS ground beef is 0.13%, the proportion rate of *E. coli* O157:H7 in a lot of ground beef is 0.0013. Using that value, if AMS wants a 95% confidence level that a combo or lot of ground beef does not contain *E. coli* O157:H7, 3,000 samples need to be collected from the combo, and all the samples must test negative for the pathogen. In addition, the samples must be randomly collected from the meat trim that is present in the combo so that each piece of meat has an equal chance of being selected for testing. That level of sampling is not realistic for production of foods.

HACCP has achieved its success by designing food safety into the manufacturing process. Thus, the only rational means of achieving continual reduction in pathogens is to control the process of manufacture of ground beef from harvesting to packaging of the frozen patty and use statistical process control tools to monitor the process, and use continual improvement techniques to improve process and process performance.

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Table 2 Relationship of Number of Units Sampled and Portion of Lot That Contains a Pathogen for 95% Confidence in Detection

Proportion of Lot Contaminated with Hazard	No. Samples That Must Be Tested for Detection
0.001	3,000
0.005	600
0.010	300
0.020	150
0.030	100
0.040	75
0.050	60

SOURCE: ICMSF (2002) and ASQ (2008).
NOTE: Sampling plan assumes that no samples are positive (c=0).

- *If the testing system indicates that something has gone wrong, does the organization use root-cause analysis to try to determine a reason for the problem and then take effective action to prevent the cause in the future?* This analysis will not always determine a specific root cause of a problem.
- *Are proper testing and sampling methods used to gather and test the samples?* The methods will be based on a proper level of precision and accuracy to ensure that the proper actions are taken. In some cases, tests may involve measurements of physical characteristics (such as time, temperature, and pH) rather than microbiological tests.
- *Does the food safety assurance program focus on prevention or on detection of the hazard?* The most effective food safety assurance program is based on preventing the occurrence of a food safety hazard rather than detecting the hazard in an ingredient or the final product.

The focus of the *science-based approach* is to understand the context of the food safety assurance system (Figure 1). Once the "context" is understood, a food safety assurance system can be developed to ensure the shipment of product that meets defined food safety requirements

Weight of Evidence and Role of Expert Opinion in Developing Science-Based Food Safety Requirements

The committee spent considerable time in discussing what *science-based* means for food safety requirements in the Federal Purchase Ground Beef Program. Ultimately, it implies evidence obtained through the use of the scientific method to formulate and test hypotheses, using rigorous means of data collection, analysis, and interpretation so that the results of an investigation (or series of investigations) may be judged as valid and reliable through a process of peer review and replication. However, the committee recognizes that such scientific evidence is not always available to serve as the basis of decision-making, especially in response to rapidly changing circumstances. Thus, decisions inevitably will be made under conditions of uncertainty and using the best available evidence. As part its deliberations, the committee discussed what might constitute superior evidence and found the hierarchy proposed by Roudebush et al. (2004) to be helpful. The committee proposes a diagram for classifying science-based food safety requirements by AMS. Figure 2 shows the hierarchy that the committee would like AMS to consider. The committee notes that several of the components of the diagram may have

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equivalent rankings in usefulness, so to some extent the rankings are somewhat artificial. Nevertheless, the committee believes that AMS should consider some sort of hierarchy in evaluating science-based requirements.

At the bottom level of the diagram is informal ad hoc expert opinion (discussions with individual experts). Expert opinion may be the only option in some cases, and AMS should consider it an evidence option of last resort. In specific instances in which AMS has used expert opinion, it should seek to validate it by collecting data and preparing an internal report. If the findings of the report contradict the expert opinion, AMS should stop following it. One example regarding apparently conflicting expert advice involved the risk posed by use of XF trim (beef fat with visible lean) as a stand-alone source for grinding. It appears that some experts consulted by AMS suggested that XF trim represented an increased risk of *E. coli* O157:H7 contamination, whereas experts (those invited to speak at the meetings) consulted by the committee suggested that there is no evidence that XF trim has an increased risk of this contamination. That conflict of opinion requires data to resolve, and the results of a carefully executed study could help to inform AMS and industry practices.

Figure 2 Hierarchy of science-based food safety evidence. Weight of evidence increases as it approaches the top of the list.

At the second level are industry standards and best practices. These are more useful than ad hoc expert opinion because they may reflect a broader consensus among multiple experts. However, the committee cautions that it would be problematic to adopt multiple practices from a variety of sources and simply add them to existing AMS requirements. First, the committee notes that a particular best practice may be specific to a given company and that all the other programs may influence the practice that the company has in place; thus, its performance in another context may be different. Second, the committee notes that if AMS continues to add requirements without evaluating its existing requirements, the system that results may be needlessly complex and not provide the food safety assurance of a simpler system. For example, a requirement for a 3-log reduction in interventions at slaughter operations, which was based on a similar requirement recently announced by one retailer (Gabbett, 2010), was added to an existing AMS requirement that slaughter operations use two interventions with Critical Control Points. The new requirement added complexity in not specifying how a 3-log (99.9%) reduction in two combined interventions should be validated. Treatment A may result in a 1-log (90%) reduction and treatment B in a 2-log (99%) reduction on the basis of independent laboratory studies. Combining the treatments may indeed lead to a 3-log reduction, but they might not be additive, for example, because of cross-protection. Furthermore, two slaughter operations that start with different levels of contamination will necessarily achieve different levels of protection when a consistent 3-log reduction is applied. The outcome of the

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interventions has greater relevance to food safety management than does the level of reduction at one stage for the complex food system involved in production and processing of ground beef.

At the third level are reports based on confidential data that are not peer-reviewed. The committee notes that some data are usually better than no data, but confidential data that are not subject to peer review or even AMS internal review warrant skepticism. AMS should seek ways to encourage the review and sharing of data in a manner that promotes the needs of AMS, advances science, and protects confidentiality to the greatest degree possible. In addition, it is important to review the objectives and procedures of data collection by different sources, inasmuch as they may vary and influence the data collected, their value, and their interpretation.

At the fourth level are internal reports based on relevant AMS data. As noted above, in specific instances in which AMS uses expert opinion (such as the case of XF trim use), it is appropriate to validate it by collecting data and publishing an internal report. Such analysis will give AMS a stronger scientific base on which to justify its requirements. A report that outlines the assumptions and rationale for AMS specifications will be useful when questions arise on the origin and suitability of the requirements.

At the fifth level is formal expert consultation (for example, with NACMCF). Unlike ad hoc expert opinion, formal consultation with a diverse group of experts who have different backgrounds and different constituencies can provide more confidence in decision-making. The committee assumes that formal expert consultation provides an opportunity for different experts to debate varied points of view and to reach consensus through the use of the array of evidence listed in Figure 2. Moreover, a carefully designed expert consultation process permits consideration of the entire context of a situation within which individual factors can differentially affect food safety outcomes. In contrast, ad hoc expert opinion might address only one aspect of a program and not consider other elements or unintended consequences that may affect an entire food safety program.

At the top level of the diagram are peer-reviewed reports and risk assessments. An expert consultation that is subjected to peer review may fall into this category. The committee notes that such a high standard may be difficult to achieve regularly, but it is nevertheless a goal. AMS has a unique opportunity to establish itself as a food safety leader by taking all possible steps to base its specifications on the highest standards.

Finding C1: In the recent update of the AMS purchase specifications, there was a heavy reliance on informal ad hoc expert opinion, which the committee determined to be the least-preferred form of evidence. Elements of the program appear to have been gathered from multiple sources (such as log-reduction requirements, concentrations of indicators, and actions taken if positives are found) with no evidence of a process that considered the entire context of a situation to develop a unified and cohesive program. The scientific basis of the AMS purchase specifications would be strengthened by the use of resources that yield more reliable evidence and that are consistent with the entire context of AMS's need to develop a cohesive program. Recommendations relevant to this finding are offered later.

Other Considerations

As a large purchaser of ground beef for distribution to the school lunch program, emergency feeding programs, food banks, protective shelters, disaster-relief programs, reservations, and other eligible programs that serve the food-insecure, AMS serves members of society who may be most vulnerable to foodborne illness and its consequences, including children, the elderly, and the immunocompromised. It is essential that the specifications set by the USDA Federal Purchase Ground Beef Program are based on the best available science and have as goals protecting public health and ensuring that the ground beef products purchased in the program are safe, nutritious, wholesome, and of high quality.

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The American public and elected representatives must have confidence that the specifications established by AMS for its purchase of ground beef will accomplish those goals. As the result of a series of highly publicized food recalls and illness outbreaks involving foodborne pathogens, the American public and the mass media have become particularly sensitized to issues of food safety. Most Americans say that they have heard of a recent food recall and that they are familiar with recent recalls of ground beef (Hallman et al., 2009). Recent surveys suggest that American consumers rank the healthfulness and safety of food high on their list of concerns (Deloitte, 2010). Moreover, a recent study indicates that the public believes that the most important food safety issues today are "foodborne illnesses from bacteria", followed closely by "chemicals in food", and that most consumers believe that food safety is the responsibility primarily of the government and industry (IFICF, 2010).

Maintaining the confidence of Americans in the safety, wholesomeness, quality, and nutritional value of the products that they purchase is especially important because of the nature of the AMS commodity program and its clientele. In particular, the NSLP serves more than 31 million children a day. Children who are eligible for the NSLP typically come from low-income and food-insecure families and so have little choice but to eat what is provided by the program. As a consequence, real or perceived problems with the safety of the foods provided by the NSLP may be seen by the public as leading to involuntary exposure of particularly vulnerable children to unnecessary risks. In that respect, AMS may be seen as a proxy for American parents and others in society who want to safeguard children by having them served only safe, wholesome, high-quality, nutritious foods. Loss of confidence in the NSLP "brand" might lead parents to advise their children to avoid eating school lunches that are provided through the program, and this is likely to lead to the consumption of less healthy alternatives. It might also lead to a lack of support for the program among taxpayers and their representatives, which could result in a reduced ability of the NSLP to meet the needs of eligible children.

AMS may find it reasonable to adopt and implement conservative standards and requirements that are protective of public health and can easily be understood by the public as providing the highest degree of food safety, quality, wholesomeness, and nutrition. Continuing efforts to benchmark AMS specifications against specifications that are maintained by industry leaders and are science-based may help in that regard.

However, AMS also needs to consider carefully the potential unintended consequences of increased testing and product requirements. Additional testing requirements are likely to increase costs to producers. If those costs seriously affect the purchase price of ground beef available through the commodity program, schools may decide to buy their ground beef on the open market at a lower cost and to reserve their available commodity credits to purchase other items. In effect, if AMS opts to set specifications far above industry practices that are based on scientific principles, the added costs of meeting the specifications might lead to the increased consumption of ground beef produced under much lower standards. The effect of the AMS corrective action procedures (rejecting of all product in a lot for all USDA food and nutrition programs) vs those of industry (such as identifying and correcting causes, using data in a moving window, and isolating specific product for alternative processing or rejection) may also add cost to the system without public health benefit.

Overall Findings and Recommendations on How to Perform Future Periodic Evaluation of the Federal Purchase Ground Beef Program

Finding C2: In developing its current purchase specifications for ground beef, AMS did not follow a procedure based on the scientific principles described by 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,

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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 CDC 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.

Finding C3: Microbiological data collected by processors and AMS to verify compliance with testing requirements in purchasing contracts could be valuable for use in process control, improvement, and future program modifications.

Recommendation C3: AMS should develop a system for regular and continuous use of data collected in its purchasing program for evaluation of program outcomes and process controls applied by suppliers and for developing recommendations for future actions. The committee suggests that if AMS has specific questions about the details of appropriate data analysis methods it discuss the matter further with relevant experts; with FSIS, USDA Office of Risk Assessment and Cost-Benefit Analysis statisticians or risk modelers; or with AMS personnel who are competent to analyze data by using time-series process control analysis.

Finding C4: An important issue that needs attention is the disposition of product lots when testing indicates that they do not meet AMS specifications. The committee determined that the final disposition of such product should be based on scientific principles that protect public health without wasting economic resources.

Recommendation C4: AMS's goal should be to protect public health by removing potentially unsafe product from the food supply through safe disposition, when advisable, such as directing it to safe further processing, rather than removing it completely from the Federal Purchase Ground Beef Program. In addition to providing guidance as to how such product is diverted, AMS could provide a mechanism for verifying its appropriate diversion. AMS is encouraged to develop science-based approaches for proper use of raw materials that do not meet its specifications.

Finding C5: AMS has identified current hazards of concern in raw ground beef for children in the NSLP (*E. coli* O157:H7 and *Salmonella*).

Recommendation C5: Although *E. coli* O157:H7 is the most important concern in raw beef products, other Shiga toxin–producing enterohemorrhagic *E. coli* serotypes (such as O26, O45, O103, O111, O121, and O145) are also capable of causing human infection. Other enteric pathogens that may occur in ground beef and are considered by experts and public health authorities to be of potential major concern to sensitive populations (such as schoolchildren) are antibiotic-resistant (especially multiple-drug–resistant) strains of *Salmonella*. The committee believes that it would be useful for AMS to follow developments associated with those pathogens and other emerging pathogens and to create strategies for the protection of vulnerable consumers. It is recommended that AMS apply formal and transparent procedures to perform periodic evaluations of pathogens of concern, including those of emerging concern. Efforts to accomplish that task should be through AMS partnerships with sister agencies, such as ARS and FSIS, but also with CDC and national advisory committees and other organizations.

Finding C6: AMS has sought advice and input from ARS, FSIS, industry, and the National Research Council (the current committee) in establishing and reviewing its specifications**.**

Recommendation C6: The committee recommends that outreach for advice continue and be expanded by considering the use of existing advisory bodies on microbiological criteria, such as NACMCF, for periodic evaluation of purchasing specifications for meat and other commodities.

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APPENDIX A

COMMITTEE MEMBERS' BIOGRAPHIC SKETCHES

GARY R. ACUFF (*Chair*) is a professor of food microbiology and director of the Center for Food Safety at Texas A&M University. He is also a member of the Department of Animal Science, the Faculty of Food Science, and the Graduate Faculty. Dr. Acuff's expertise is in the microbiological quality and safety of foods, including a focus on heat resistance of *E. coli* O157:H7 as influenced by ground beef storage and holding temperatures and methods of decontamination of red meat carcasses. His professional memberships include the American Society for Microbiology, the Society for Applied Microbiology and the International Association for Food Protection (IAFP). He served as president of IAFP in 2008 and currently serves on several advising and planning committees for the professional organizations noted above, including the National Research Council and Institute of Medicine Standing Committee on the Use of Public Health Data in FSIS Food Safety Programs. He was a member of the Editorial Committee for the 4thedition of the *Compendium of Methods for the Microbiological Examination of Foods*, published in 2001, and served as a member of the U.S. Department of Agriculture National Advisory Committee on Microbiological Criteria for Foods from 1992 to 1997. He received his B.S. in biology from Abilene Christian University and his M.S. and Ph.D. in food science and technology from Texas A&M University.

WILLIAM K. HALLMAN is a professor in the Department of Human Ecology and director of the Food Policy Institute of Rutgers University. He is also a member of the graduate faculties of psychology, nutritional sciences, and planning and public policy of Rutgers, the State University of New Jersey. Dr. Hallman's current research examines public perception of controversial issues concerning food, health, and the environment. Recent research projects have looked at consumer perception and behavior concerning agricultural biotechnology, animal cloning, avian influenza, accidental and intentional food contamination incidents, and food recalls. He was recently awarded a $2 million grant from the U.S. Department of Agriculture to study public awareness of, perception of, and reactions to intentional and unintentional food contamination. His current research projects include studies of public perception of and responses to food safety risks, the use of nanotechnology in food, and public understanding of health claims made for food products. Dr. Hallman serves on the Executive Committee of Rutgers Against Hunger (RAH) and helped to found the New Brunswick Community Farmers Market. His honors include the 2009 Robert Wood Johnson Foundation Investigator Award in Health Policy Research and the 2004 Team Award for Research Excellence (Team Leader—Food Biotechnology Program) at Rutgers. He earned his Ph.D. in experimental and social psychology from the University of South Carolina.

KERRI B. HARRIS is the president and CEO of the International HACCP Alliance, associate director of the Center for Food Safety, and associate professor in the Department of Animal Science of Texas A&M University. She assisted in the standardization of Hazard Analysis and Critical Control Points (HACCP) training programs and helped to develop the Train-the-Trainer course and the accreditation program for HACCP training providers. She has published multiple refereed journal articles and other publications, is a coauthor of two book chapters, and has presented at multiple national meetings. She is responsible for team teaching a HACCP course for graduate and undergraduate students and for coordinating various HACCP and food safety industry training programs. Dr. Harris has received several awards and recognitions for her contributions and has served on multiple boards and councils. A three-time graduate of Texas A&M University, Dr. Harris received her Ph.D. in nutrition in 1994.

CRAIG W. HEDBERG is a professor of environmental health sciences in the University of Minnesota School of Public Health. He previously served as supervisor of the Foodborne, Vector borne, and Zoonotic Disease Unit of the Minnesota Department of Health. His research focuses on foodborne-disease surveillance, surveillance of environmental factors associated with foodborne disease, the role of food workers in the occurrence of foodborne diseases, the use of epidemiological methods in outbreak investigations and disease control, and environmental contamination with enteric pathogens. Dr. Hedberg has served on National Research Council and Institute of Medicine committees, including two to review the U.S. Department of Agriculture Food Safety and Inspection Service methods and food safety programs, and currently serves on the Standing Committee on the Use of Public Health Data in FSIS Food Safety Programs. He received his Ph.D. in epidemiology from the University of Minnesota.

GUY H. LONERAGAN is a veterinary epidemiologist and a professor of food safety and public health at Texas Tech University. Dr. Loneragan joined the Texas Tech University Department of Animal and Food Sciences in 2010. His research uses epidemiological and systems approaches to study food safety; in particular, he works to fill data gaps concerning pre-harvest ecology and mitigation of *E. coli* O157:H7 and *Salmonella* and on antimicrobial drug resistance. He is an active member of the National Cattlemen's Beef Association (NCBA), the American Association of Bovine Practitioners, the Academy of Veterinary Consultants, the International Symposium of Veterinary Epidemiology and Economics, the Conference of Research Workers in Animal Diseases (CRWAD), and the International Association of Food Protection. Dr. Loneragan serves as a member of the Board of Directors of the Academy of Veterinary Consultants. He is a member of the College of Reviewers for the Alberta Prion Research Institute and a former member of the board of scientific reviewers for the *American Journal of Veterinary Research* and is involved with numerous working groups for NCBA. He also served as an alternate member for the 2007 secretary of agriculture Advisory Committee on Foreign Animal and Poultry Diseases, on the Steering Committee of the Food Safety Research and Response Network, and as Epidemiology Section leader for CRWAD. He received his veterinary degree from the University of Sydney, Australia, and his Ph.D. in epidemiology from Colorado State University.

JULIANA RUZANTE is the risk-analysis program manager for the Joint Institute for Food Safety and Applied Nutrition with the Food and Drug Administration and the University of Maryland. She previously worked for the University of Guelph and the Public Health Agency of Canada, mainly in developing and operationalizing a multifactorial framework to rank foodborne risks with multi-criteria decision analysis. At the Western Institute for Food Safety and Security, she developed training materials on animal health and food safety. She also worked as a quality assurance specialist for one of the largest pork and poultry processing companies in Brazil. Dr. Ruzante currently serves on the National Research Council and Institute of Medicine Standing Committee on the Use of Public Health Data in FSIS Food Safety Programs and served on previous National Research Council and Institute of Medicine committees studying Food Safety and Inspection Service inspection methods. She has served as an expert on the risks associated with *Cronobacter sakazakii* in follow-up formula in a meeting organized by the Food and Agriculture Organization and the World Health Organization. Dr. Ruzante received her D.V.M. from the University of São Paulo and her M.S. in preventive veterinary medicine and Ph.D. in comparative pathology from the University of California, Davis.

DONALD W. SCHAFFNER is an extension specialist in food science and a professor in the Department of Food Science at Rutgers, the State University of New Jersey. His research interests include quantitative microbial risk assessment and predictive food microbiology. He is the author or co-author of more than 100 peer-reviewed publications, book chapters, and abstracts, and he has received almost $4 million in grants and contracts (mostly grants). Dr. Schaffner has educated thousands of food-industry professionals through numerous short courses and workshops in the United States and more than a dozen other

countries. He has served on committees with the World Health Organization (WHO) and the Food and Agriculture Organization (FAO) of the United Nations and on National Research Council and Institute of Medicine committees, including the Standing Committee on the Use of Public Health Data in FSIS Food Safety Programs, and has chaired two expert workshops on microbial risk for WHO/FAO. Dr. Schaffner is serving a 5-year term as editor of *Applied and Environmental Microbiology*. In April 2007, he was appointed to serve a second term on the National Advisory Committee on Microbiological Criteria for Foods. He holds a Ph.D. in food science and technology from the University of Georgia.

JOHN N. SOFOS is a University Distinguished Professor, the director of the Center for Meat Quality and Safety, and the leader of the Food Safety Cluster of the Infectious Diseases Super Cluster in the Department of Animal Sciences of Colorado State University. He also serves as a scientific editor of the *Journal of Food Protection*. His current research interests are related to sources, ecology, and extent of bacterial pathogen contamination of foods; procedures to reduce contamination with and to inactivate or inhibit bacterial pathogens; stress adaptation of pathogenic bacteria; resistance of microorganisms to preservation procedures; and methods of sampling and detection of bacteria in foods. He has served on numerous national and international committees, task forces, and food safety advisory boards, including the U.S. National Advisory Committee on Microbiological Criteria for Foods; as chair of a Task Force on Natural Antimicrobials for the Council for Agricultural Science and Technology; and as a reviewer of the World Health Organization *Salmonella* in Poultry Risk Assessment. He served as chair of the Institute of Medicine Committee on the Review of the U.S. Department of Agriculture *Escherichia coli* O157:H7 Farm to Table Process Risk Assessment and the National Research Council and Institute of Medicine Committee on the Review of the Methodology Proposed by the Food Safety and Inspection Service to Follow-Up Surveillance of In-Commerce Businesses. He is a member of the National Research Council and Institute of Medicine Standing Committee on the Use of Public Health Data in FSIS Food Safety Programs. He has received the Distinguished Research Awards from the American Meat Science Association and the American Society of Animal Science. In 2001, he received a Certificate of Appreciation from the Cooperative State Research, Education, and Extension Service of the U.S. Department of Agriculture (USDA) and the USDA Secretary's Honor Award for Superior Service. Dr. Sofos received his Ph.D. in food microbiology from the University of Minnesota.

JOHN G. SURAK is principal of Surak and Associates, a full-service food safety and quality consulting service. He is professor emeritus of food science in the Department of Applied Economics and Statistics and former coordinator of international programs for the College of Agriculture, Forestry, and Life Sciences of Clemson University. His work focused on continuous performance improvement and other statistical process controls for post–farm-gate processing of food products. Dr. Surak's efforts included the development of international food safety management system standards. He is a former consultant to the U.S. Department of Agriculture (USDA) Agricultural Marketing Service on purchasing specifications for meat and poultry for the National School Lunch Program. Dr. Surak currently works with the food processing industry in developing food safety and quality management systems, designing and implementing process control systems, and implementing Six Sigma and business analytics systems. He is a recipient of the Reinventing Government Award from former Vice President Al Gore, the USDA Honor Award from former USDA Secretary Dan Glickman, and the South Carolina Milliken Medal of Quality Award. Dr. Surak holds certifications from the American Society of Quality in Quality Engineering, Quality Management, Quality Auditing, and HACCP Auditing and certification from the International HACCP Alliance in HACCP Train-the-Trainer. Dr. Surak earned his Ph.D. in food science and veterinary science from the University of Wisconsin–Madison.

KATHERINE M.J. SWANSON is the vice president of food safety at Ecolab, Inc. in St. Paul, MN. She has over 25 years of food safety management and quality experience, including a focus on cleaning and

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sanitation, *Listeria monocytogenes*, and microbial inactivation. In her current position, she provides internal and external leadership by identifying emerging food safety trends and new control strategies. Previously, as director of microbiology and food safety for the Pillsbury Company, Dr. Swanson developed and implemented Hazard Analysis and Critical Control Points and food allergen training and programs for research and development and operations, managed development of electronic specification systems, oversaw food quality system audits, and developed corporate product quality management systems. Dr. Swanson serves on two National Research Council and Institute of Medicine committees, including the Standing Committee on the Use of Public Health Data in FSIS Food Safety Programs. In 2009, she was elected to the International Association for Food Protection Executive Board. Dr. Swanson is a member of the International Commission on Microbiological Specifications for Foods and is the chair of its Editorial Committee. She was on the *Journal of Food Protection* Editorial Board from 1988 to 1999 and the *Food Protection Trends* Editorial Board from 2005 to 2007. She has received numerous awards, including the 2003 National Food Processors Association (now Grocery Manufacturers Association) Food Safety Award and the 2008 National Center for Food Safety and Technology Food Safety Award. Dr. Swanson received a Ph.D. in food science from the University of Minnesota.

MARTIN WIEDMANN is an associate professor in the Department of Food Science of Cornell University. His research interests include the pathogenesis, evolution, epidemiology, and diagnosis of bacterial foodborne diseases. His current work concentrates on the molecular characterization of *Listeria monocytogenes,* factors important for transmission along the food chain, and pathogenesis of animal and human foodborne disease. He joined the Cornell faculty in 1999 and is a member of the graduate fields of food science, microbiology, and comparative biomedical sciences. He serves as co-coordinator of the Cornell Food and Water Safety Program, and he participates in the Infection and Pathobiology Program and in the Cornell Genomics Initiative. In addition, he serves as director of the Cornell Institute of Food Science Summer Scholar Program and director of the Cornell Laboratory of Molecular Typing. He served on the Editorial Board of the *American Journal of Veterinary Research* from 1999 to 2001 and currently serves on the Editorial Board of the *Journal of Food Protection* and on the Editorial Board of *Applied and Environmental Microbiology*. He is a member of the National Research Council and Institute of Medicine Standing Committee on the Use of Public Health Data in FSIS Food Safety Programs. Dr. Wiedmann received a veterinary degree (D.V.M. equivalent) and Dr. med. vet. (Ph.D. equivalent) in veterinary medicine from the University of Munich, Germany, and a Ph.D. in food science from Cornell University.

APPENDIX B

Acronyms and Abbreviations

AMI	American Meat Institute
AMS	Agricultural Marketing Service
ARS	Agricultural Research Service
CAC	Codex Alimentarius Commission
CDC	Centers for Disease Control and Prevention
FSIS	Food Safety and Inspection Service
HACCP	Hazard Analysis and Critical Control Point
ICMSF	International Commission on Microbiological Specifications of Foods
MLG	Microbiology Laboratory Guidebook
NACMCF	National Advisory Committee on Microbiological Criteria for Foods
NSLP	National School Lunch Program
TDS-136	Technical Data Supplement 136
TRS-GB	Technical Requirements Schedule for Ground Beef
USDA	U.S. Department of Agriculture
USL	upper specification limit
XF trim	refers to beef fat with visible lean