

**METHODS COMMITTEE REPORTS**

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## Committee on Microbiology and Extraneous Materials

**JAMES R. AGIN, CHAIR**

Ohio Department of Agriculture, 8995 E. Main St,  
Reynoldsburg, OH 43068

**WAYNE A. ZIEMER, CHAIR**

U.S. Department of Agriculture, FSIS/OPHS, 950 College  
Station Rd, Athens, GA 30605

**MELISSA CHERI NEWMAN, SECRETARY**

University of Kentucky, Department of Animal and Food  
Sciences, 204 W.P. Garrigus, Lexington, KY 40546-0215

**DENNIS E. GUILFOYLE**

U.S. Food and Drug Administration, ORA, Northeast  
Regional Laboratory, 158-15 Liberty Ave, Jamaica, NY 11433

**KEVIN VOUGHT**

Minnesota Department of Agriculture, 950 W. Plato Blvd,  
St. Paul, MN 55107

**LORALYN LEDENBACH**

Kraft Foods Inc., 801 Waukegan Rd, Glenview, IL 60025

**MICHAEL H. BRODSKY**

Brodsky Consultants, 73 Donnamora Crescent, Thornhill,  
ON L3T-4K6, Canada

**WALTER HILL**

6511 19th Ave, NE, Seattle, WA 98115

**DAN RICE**

New York State Department of Agriculture and Markets, Food  
Laboratory Division, 10B Airline Dr, Albany, NY 12235

**JOSEPH L. FERREIRA**

Centers for Disease Control and Prevention,  
NCID/DBMD/FDDB, 1600 Clifton Rd, NE, Mail Stop  
G-29, Atlanta, GA 30333

**BRENDA G. WERNER**

Cornell University, 125 Stocking Hall, Ithaca, NY 14853

**BARBARA M. MARTIN**

U.S. Department of Agriculture, APHIS, VS, 1800 Dayton  
Rd, Ames, IA 50010

**ROXANNE SHIVELY**

U.S. Food and Drug Administration, Microbiology OIVD  
CDRD, 2098 Gaither Rd, Rockville, MD 20850

**TODD MARROW**

University of Guelph, 95 Stone Rd W, Guelph, ON  
N1H-8J7, Canada

**ROBERT W. PHILLIPS, SAFETY ADVISOR**

U.S. Department of Agriculture, FSIS-OPHS, 950 College  
Station Rd, Athens, GA 30605

**PAUL WEHLING, STATISTICAL ADVISOR**

Medallion Laboratories, 9000 Plymouth Ave N,  
Minneapolis, MN 55427

**ROBERT A. LABUDDE, STATISTICAL ADVISOR**

Least Cost Formulations Ltd, 824 Timberlake Dr, Virginia  
Beach, VA 23464

### Committee Actions

The Study Directors, General Referees and Committee H members have had an active year. Committee H members have been involved as expert reviewers for several AOAC projects, including Department of Homeland Security initiatives for evaluation of hand-held assays for *Bacillus anthracis*, evaluation of prescreening technologies for suspicious powders, including sample collection standards, sample collection validation methodologies and environmental performance evaluation, and involvement in the Best Practices for the Validation of Microbiological Methodology project with the U.S. Food and Drug Administration.

Currently, the Committee has 5 topic areas: Food Microbiology-Dairy, Food Microbiology-Nondairy, *Bacillus anthracis* topics, Efficacy Testing of Disinfectants, and Genetically Modified Organisms. The General Referee position in the Food Microbiology-Dairy topic area is currently vacant, and there are no active studies in this topic. The Genetically Modified Organisms topic area is currently inactive.

#### *Topics Discussed at Committee Meeting*

Russell Flowers discussed the history and activities of the Best Practices in Microbiological Methods Task Force. Originally this concept was from an FDA contract with AOAC to recommend the best practices for evaluating microbiological methods in the food, pharmaceutical and medical fields. A draft report was submitted to AOAC on September 2, 2005.

Flowers summarized the contract objectives. Committee H will be asked to review the final recommendations and determine how they could be integrated into the AOAC OMA process.

Michael Brodsky discussed the matrix extension aspects of the Best Practices Task Force. As part of the Best Practices

Task Force recommendations, Committee H will be asked to review and determine how the recommendations could be integrated into the AOAC OMA process.

An issue was raised regarding the acceptability of an environmental sampling protocol that was reviewed previously by Committee H. It was decided that the Chairs would reevaluate the document and forward to the OMB for approval. In addition, a possible working relationship with the Committee on Environmental Quality would be investigated.

#### Other Action

There was request to add a topic area of Microbiology Pharmaceuticals. Maria Ines Cereijo and Cristina Fernandez were recommended as Topic Advisors.

### Methods for First Action

**2005.05** *Evaluation of the Assurance GDS™ for Shigatoxin Genes Method in Selected Foods: Multilaboratory Collaborative Study*

**2005.04** *Evaluation of the Assurance GDS™ for E. coli O157:H7 Method in Selected Foods: Multilaboratory Collaborative Study*

**2005.03** *Enumeration of Total Coliforms and E. coli in Foods by the SimPlate® Coliform and E. coli Color Indicator Method and Conventional Culture Methods: Collaborative Study*

**2004.11** *Identification of Bacillus anthracis from Culture Using Gas Chromatographic Analysis of Fatty Acid Methyl Esters*

### General Referee Reports

#### Food Microbiology, Nondairy

Wallace H. Andrews and Thomas S. Hammack. *See J. AOAC Int.* (2006) **89**, 304–318.

#### Food Microbiology, Dairy

Vacant. Topic area General Referee position is currently vacant. Committee Chairs will contact potential General Referee candidates.

#### Efficacy Testing of Disinfectants

Stephen F. Tomasino, U.S. Environmental Protection Agency and Candace McManus, U.S. Food and Drug Administration.

#### Genetically Modified Organisms

Markus Lipp, Monsanto Co. Currently, no activity in this topic area.

#### Bacillus anthracis

General Referee Report 2004–2005. Co-General Referees Tony Hitchins, and James E. Brown for *Bacillus anthracis* studies.

*Background.*—An ongoing series of validation studies on *Bacillus anthracis* detection methods, organized by AOAC INTERNATIONAL, is being conducted for the U.S. Department of Homeland Security (DHS). This report gives the current status of all methods studies completed and those

under development. Due to the security-sensitive nature of these studies, the collaborative studies in their entirety shall remain confidential, with only the method details dissemination being permissible. More information may be available by contacting standards@dhs.gov.

*Completed studies.*—*AOAC Official Method 2004.04 Identification of Presumptive Isolates of Bacillus anthracis, Confirmatory Method: First Action 2004.* This methodology is the reference standard for use in *Bacillus* method comparison studies. The study was published this year as *Validation of Methods for Confirmatory Identification of Presumptive Isolates of Bacillus anthracis* [Popovic, T., Hoffmaster, A., Ezzell, J.W., Abshire, T.G., & Brown, J.E. (2005) *J. AOAC Int.* **88**, 175–177].

**2004.11** *Identification of Bacillus anthracis from Culture Using Gas Chromatographic Analysis of Fatty Acid Methyl Esters: First Action 2004.* This instrumental method, produced by MIDI Incorporated (Newark, DE), is for identifying isolates of *Bacillus* as *B. anthracis* or as related species. The study was published this year as *Identification of Bacillus anthracis from Culture Using Gas Chromatographic Analysis of Fatty Acid Methyl Esters* [Sasser, M., Kunitsky, C., Jackoway, G., Ezzell, J.W., Teska, J., Harper, B., & Parker, S. (2005) *J. AOAC Int.* **88**, 178–181].

**2004.08** *RAMP® Anthrax Test Cartridge: First Action 2004.* This is a rapid instrumental method for presumptive laboratory detection of *Bacillus anthracis* spores in environmental samples. The study was published this year as *RAMP® Anthrax Test Cartridge* [Stephenson, J. (2005) *J. AOAC Int.* **88**, 202–203].

*Planned studies.*—The RAMP® Anthrax Test Cartridge method has First Action approval only for use by trained technicians under laboratory conditions. In practice, the method would be used under field conditions by first responders to suspicious events. Ideally this means it has to be rugged enough to withstand potential environmental insults during storage and use of the instrument and cartridge. AOAC INTERNATIONAL, on behalf of DHS, has convened a panel of experts (Chaired by Mark Coleman, OMB) to design an experimental protocol to evaluate the effect of environmental factors on this method. This study will also include a method evaluation of material sampling at an event scene. This is not simple because an event scene is potentially a crime scene. Thus evidential material sampling priorities of different government agencies come into play. The degree of competence of first responders in sampling and use of the RAMP® method is another crucial factor in field application of the method. However, the evaluation of the human variability factor and training to reduce it will be a separate study. Finally, it is anticipated that other anthrax methods will be submitted for AOAC validation studies in 2005–2006.

### Recommendations

Continue development of the planned studies and continue progress toward Final Action status for the approved methods.