

## GENERAL REFEREE REPORTS

## Committee on Biological Threat Agents

### *Bacillus anthracis* and Other Select Agents

#### TONY HITCHINS

U.S. Food and Drug Administration, HHS, HFS-711, 5100 Paint Branch Pkwy, College Park, MD 20740-3835, Tel: 301-436-1649, Fax: 301-436-2644, E-mail: Anthony.Hitchins@fda.hhs.gov

#### Background

As reported last year, a series of validation studies on *Bacillus anthracis* detection methods (1–5), organized by AOAC INTERNATIONAL, was conducted for the U.S. Department of Homeland Security (DHS). This year, in broadening of the scope of such studies to encompass other select agents, DHS through AOAC set up a Stakeholders Panel on Agents for Detection Assays (SPADA). The mission of SPADA was to establish inclusivity, inclusivity, and environmental factors panels for potential select agent methods with current focus on polymerase chain reaction (PCR) methods and on samples of air particulates obtained by filtration. In addition of course, SPADA will design the experimental protocols and acceptance criteria of the relevant method studies. In order to facilitate its mission, SPADA set up several Working Groups (WGs) for the various select agents and one for environmental factors. The WGs were composed of internationally recognized experts on the detection of various agents and environmental substances. Each WG had a few representatives from AOAC including Committee L. The role of the experts was to establish scientific criteria for choosing the strains for select agent panels from candidate lists of *available* strains, and for choosing the environmental factors.

*Bacillus anthracis* WG.—The group has agreed to recommend to SPADA an intrinsic panel of 15 strains and extrinsic panel of 15 near-neighbor strains (*Bacillus cereus* and *Bacillus thuringiensis*). The group has now started the process of recommending study parameter values for method acceptance.

*Francisella tularensis* WG.—The group has tentatively agreed to recommend to SPADA an intrinsic panel of at least 15 strains and extrinsic panel of at least 15 near-neighbor strains.

*Yersinia pestis* WG.—The group has agreed on intrinsic and extrinsic panel sizes of 25 strains each.

*Environmental Factors* WG.—The WG is finalizing its potentially very large candidate list before beginning the culling process to a more manageable sized panel. The candidate panel is large because the factors to be considered include (1) organic or inorganic compounds that comprise

white powders and soil varieties and (2) lower and higher eukaryotic organisms including pollen, insect and mammalian components that may potentially cross react in a candidate method. In addition, some further strains of the microbes considered by the select agent WGs will also be included.

#### Recommendations

It is recommended that SPADA and the WGs continue working towards submission of the combined study protocol package for consideration by Committee L.

#### References

- (1) *Official Methods of Analysis* (2005) 18th Ed., AOAC INTERNATIONAL, Gaithersburg, MD, Method **2004.08**
- (2) *Official Methods of Analysis* (2005) 18th Ed., AOAC INTERNATIONAL, Gaithersburg, MD, Method **2004.04**
- (3) *Official Methods of Analysis* (2005) 18th Ed., AOAC INTERNATIONAL, Gaithersburg, MD, Method **2004.11**
- (4) ASTM, Work Item No. 8273, Version 10.2, *Standard Practice for Bulk Sample Collection and Swab Sample Collection of Visible Powders Suspected of Being Biological Agents from Nonporous Surfaces: Collaborative Study*
- (5) Locascio, L.E., Harper, B., & Robinson, M. (2007) *J. AOAC Int.* **90**, 299–333

## Biological Weapons

#### MARK A. POLI

U.S. Army Medical Research Institute of Infectious Diseases, Integrated Toxicology Division, Ft Detrick, MD 21702-5011, Tel: 301-619-480, Fax: 301-619-2348, E-mail: mark.poli@det.amedd.army.mil

#### Background

In 2003, the Department of Homeland Security (DHS) partnered with AOAC to develop and validate voluntary consensus standards for hand-held assays (HHAs) against biological threat agents. Since then, AOAC has facilitated the development of a standard protocol for the collection of “white powders” from hard surfaces as well as a comparison of several HHAs for *Bacillus anthracis* spores. In 2006, AOAC formed a Working Group on Standards for Hand-Held Assays (WGS). This working group was tasked by DHS with overseeing further development and validation of *B. anthracis* HHAs, field-testing the protocol for collecting white powders, and moving forward with developing assay specifications and study designs for HHAs for ricin.

The WGSB assigned specific task groups to address different aspects of ricin HHAs. A Task Group on Product Specification and Study Design was chaired by Tetsuhisa Goto and Mark Poli and consisted of 14 individuals representing government, assay developers, law enforcement, and first responders. This Task Group worked closely with AOAC staff to address the following specific tasks: Identify HHA users; develop and implement a user survey to determine performance expectations of HHAs; document user product performance expectations; draft acceptance criteria for HHAs; submit recommendations for acceptance criteria and supporting documentation to WGSB; draft study designs for internal, independent, and collaborative studies.

At a WGSB meeting on December 8, 2006, the Task Group submitted the results of the user survey as well as draft acceptance criteria for ricin HHAs addressing the following parameters: inclusivity testing, exclusivity testing, sensitivity, specificity, threshold concentration, reference method, lot-to-lot variability, interferences, and ruggedness. After some discussion and modification by the WGSB, these criteria were accepted.

Study designs for in-house, independent laboratory, and collaborative studies were also drafted and sent to the newly formed Methods Committee on Biological Threat Agents (Committee L) for review.

Other Task Groups were assembled for ricin HHAs as well, including the Task Group on Experts, the Task Group on

Laboratory Selection, and the Task Group on Labeling and Package Inserts. However, work among these task groups was discontinued when DHS suspended the project.

A study design for a precollaborative study for a botulinum toxin test kit entitled "Evaluation of the Botulinum Toxin ELISA for the Detection of Toxins A, B, E, and F in Select Foods" is under development at AOAC on behalf of Richard Whiting and Sasha Sharma of U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, and Joanne Andreadis and Susan Maslanka from the Botulism Public Health Research and Preparedness Laboratory, Centers for Disease Control and Prevention. This study design is currently awaiting further input from the Study Directors and will be submitted to Committee L (newly formed Committee on Methods for Biological Threat Agents) in the near future.

### Recommendations

(1) *Ricin HHA acceptance criteria*.—Recommend acceptance by WGSB.

(2) *Ricin study design(s)*.—Recommend acceptance. DHS has suspended the project to support studies and requests publication of study designs in *J. AOAC Int.* as guidelines for interested companies. Recommend moving forward with this.

(3) *Botulinum toxin ELISA study design*.—Recommend further review after input from Study Directors.