Almost three years ago, our association, together with EBSA and colleagues from Det Norske Veritas (DNV), a Norwegian company specializing in risk management, recognized the potential value of an internationally-acceptable standard for laboratory biosafety and biosecurity based on a management system approach. ABSA, EBSA, and DNV proceeded to investigate the feasibility of this idea and we found that the European Commission was very interested in seeing such a standard developed. The EC was so interested, in fact, they indicated their willingness to contribute significantly to the cost of such an effort. DNV, ABSA, EBSA, and, ultimately, the Asia-Pacific Biosafety Association (A-PBA) developed a strong business plan based on many discussions and meetings. With the strong support of the ABSA Council, we have participated as a Team member for the past two years. Drs. Paul Huntley (DNV) and Stefan Wagener (ABSA) have presented updates on the progress of the effort at the past two annual ABSA Conferences and on other platforms, and our Past-President Betsy Gilman Duane wrote about this effort in her President’s Page columns in Applied Biosafety last year. However, since the effort is now approaching reality, I want to, once again, tell all ABSA members about this important global project.

The vision of the project is to safeguard life, property, and the environment from biological risks through the development and adoption of internationally-recognized standards in the area of the management of biological materials, organisms and their products, primarily within the laboratory environment. The project encompasses several goals:

- Improve performance through the adoption of recognized good practice;
- Facilitate international exchange and collaboration;
- Increase awareness and adoption of management system approaches within the sector;
- Provide organizations with a means for internal audit and third-party certification; and
- Provide stakeholders with a standard to be used as a benchmark in setting requirements for facilities.

The aim of the project will be to develop an internationally-recognized standard and accompanying guidance document based on the WHO Laboratory Biosafety Manual. The main focus will be on biological agents and materials in a laboratory setting. The use of a management system approach (i.e., OHSAS 18001 or ISO 17025) will allow for a holistic approach encompassing people, facilities, and working procedures. It is our intent that the standard itself not be prescriptive in nature, but rather based on the philosophy that the operator must understand and manage the risks. Supporting the standard, the guidance document will be written to help organizations determine how adequate measures can be identified and implemented to satisfy the requirements of the standard.

The combination of regulatory and guidance documents is commonly employed by European health and safety directorates; an American equivalent is, for example, the Bloodborne Pathogens Standard and the OSHA Compliance Directive used to guide field inspectors in enforcing the Standard. It's important to note that the proposed standard is, by design, voluntary and not intended to replace any national or sub-national regulatory requirements that may apply to the laboratory or facility.

We have chosen to develop this standard using the CEN Workshop model. CEN (Comité Européen de Normalisation, or the European Committee for Standardization, at www.cenorm.be) is an internationally-recognized standards development body, much like ISO. The CEN model brings stakeholders together at workshop sessions in which the stakeholders actually write the standard; stakeholders include institutions and companies with a vested interest in biosafety, and biosafety professionals from around the world. Consequently, it is not ABSA, EBSA, A-PBA, or DNV that write this standard. It is all of us as part of the international biosafety community with the aforementioned organizations primarily facilitating the process.

We envision developing working documents so that the first workshop is productive and not merely a training session for workshop participants. We believe that three or four workshops will ultimately yield a standard and guidance document accepted by participants and issued by CEN as what’s called a CEN Workshop Agreement. The EC is familiar with the CEN model and recognizes DNV as a European company with strong experience in managing standards development under the CEN process.

It’s very important that ABSA members recognize that they and their international biosafety partners bear the primary responsibility for writing this standard and developing the methods ultimately to be used to certify laboratories against the standard, and even to identify and set training requirements for the certifiers them-
selves. As mentioned before, the role of the DNV/ABSA/EBSA/APBA Team is to facilitate this process, with DNV overseeing the process as an experienced and acceptable manager of EC and other funds. The Team is being led by Stefan Wagener; I am a member of and an ABSA representative to this Team.

The current status of the project is as follows:
• A gap analysis of the WHO Laboratory Biosafety Manual has been completed, identifying those parts of the manual that can be used for a management system-based standard and those parts better suited for the guidance document;
• A budget, timeline and proposal has been submitted to the European Commission (EC); and
• A formal request for funding has been submitted to the EC on behalf of the four partners.

We are currently awaiting a decision by the EC; the Commission has indicated a willingness to provide as much as 75% of the approximately €500,000 budget; the remainder will come from workshop participants and non-European stakeholder sources. The ABSA Council has unanimously approved up to $10,000 in support of this effort and has confirmed its continuing commitment to the project. We expect the EC’s decision in late summer and will have one year from the date of funding to complete the process.

Starting this summer, we will need to provide several very capable biosafety professionals to help write the working documents which will serve as the strawmen, or starting points, for the CEN Workshop process. Team members need to be ABSA members and must have a significant experience in biosafety and biosecurity and/or a solid working knowledge in quality management systems. Many of you have already told me of your interest in participating in this effort. Now is the time for you to express or confirm that interest by sending me a brief e-mail (biosafety@mcn.org) that includes your contact information.

By providing guidance and realistic design and performance criteria in a management systems context, this international standard promises to help propel biosafety into the 21st century and to extend its influence to those areas of the world where assistance is most needed.

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**CDC Meeting Summary**
Submitted by Elizabeth Gilman Duane, Wyeth, Cambridge, MA

On March 7-8, 2006, several members of ABSA were invited participants at a Select Agent Biosecurity meeting convened by the Centers for Disease Control and Prevention (CDC) and facilitated by the Association of Public Health Laboratories. The goal of the meeting was to seek input from participants on how to provide more information on Select Agent Security Plan compliance for registered facilities and those applying for registration. The meeting, which was held in Atlanta, began with presentations covering Risk Assessment, Chain of Custody, Select Agent Security in Public Health and Academia, and Incident Response. The remainder of the meeting was dedicated to four focus groups that were tasked with evaluating certain aspects of the Security Section of the Select Agent regulations as well as draft guidance documents. Given that the Select Agent regulation is primarily a performance standard many registrants have had questions related to compliance. The 4 focus groups included: Risk Assessment, Risk Mitigation, Administration and Recordkeeping, and Guidance Documents. At the conclusion of the meeting each focus group reported on their findings and discussions. A publication of the meeting findings is slated to be completed 60 days from the conclusion of the meeting. The American Biological Safety Association appreciated the opportunity to participate.

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**EPA Pesticide Program Updates from EPA’s Office of Pesticide Programs—3/28/06**

**New Telephone Line Established for Information about Antimicrobial Pesticides**

The National Pesticide Information Center (NPIC) is now taking inquiries, via their telephone help-line and web-based services, regarding antimicrobial pesticides and pesticide products. Therefore, EPA’s Antimicrobial Division hotline has been terminated, and EPA web pages with references to the Agency hotline are being updated to reflect this change.

NPIC is a toll-free telephone service that provides objective, science-based information about a wide variety of pesticide-related subjects. The service is available daily, 6:30 a.m. - 4:30 p.m. (PT), and the toll-free phone number is 1-800-858-7378.