In the previous issue of Applied Biosafety (Volume 11, Number 2, 2006), I explained the role of ABSA and its partners in the development of an internationally recognized biorisk management standard for laboratories. This process will take place through a series of European Committee for Standardization (CEN) workshops, resulting in a formal document known as a CEN Workshop Agreement (CWA). I would like to take this opportunity to update you on our progress.

A decision from the European Commission regarding CEN Workshop funding is imminent. All indications are very positive, but the devil is in the details. We won't know the specifics until we see the contract. In anticipation of a successful funding initiative, we have taken our first steps toward the process.

We recently completed a workshop hosted by Dr. Stefan Wagener and the Public Health Agency of Canada in Winnipeg, Manitoba. It was attended by three representatives from Canada and one each from China, Scotland (Det Norske Veritas [DNV]), Britain (EBSA), Australia, Geneva (WHO), Sweden (EBSA), Singapore (A-PBA), and the U.S. (ABSA). We drafted a skeleton outline and a few descriptive examples of the possible text of a working document that might be used as a tool for the first CEN Workshop. When funding is approved and we have the go-ahead, we will enlist your help in providing a critical review of these and potentially other documents. As we will have only one year from the date of funding to hold three or four workshops and finalize the CWA, we hope to hit the ground running. Remember to send me a short e-mail (biosafety@mcn.org) stating or reconfirming your interest in being part of this review team.

I've been asked what the benefits of this voluntary standard will be. Originally, I thought that most American institutions would have little use for it. Then I remembered that one of the most common questions I'm asked by many colleagues is, "I know we practice biosafety, but it's not well documented; do I need a formal biosafety program and, if so, what should it actually look like?" If we have a CWA, we could simply provide them this standard and say, "Here are the management requirements for such a program."

In the longer view of benefits, some countries are in the process of developing biosafety as a national requirement, but have no solid guidance for creating the basic program. Other countries and institutions would like to develop biorisk management programs but are, for whatever reasons, reluctant to use the current American, Canadian, or "Western" documents as guidance. It is our hope that this CWA will, with its basis in the WHO Laboratory Biosafety Manual and its international derivation, serve as an universally-accepted guidance document.

Another clear benefit is that the CWA will be based on a management system, rather than a set of technical performance-based criteria. It will allow the creation of a biosafety program in which technical elements are approached as the program developer is able, rather than as he must in order to meet specific technical performance criteria. Countries or institutions, where money is so scarce as to preclude adoption of our often-expensive Western controls, are more likely to develop a program that allows them to meet basic biosafety requirements as they are able. The important part is that they must understand and define the risks; and with the help of a Guidance Document, they will have suggestions and examples of approaches. The final specific technical approach is, however, left up to the program developer.

It is important to remember that the focus right now is on writing the standard itself; the certification process is NOT part of this effort and will be addressed by another group at another time. No consideration is being given here about whether institutions self-certify or hire a certifier; if certification is through national or private certification agencies; if certifiers are trained in the process; who is to do that training? ABSA may ultimately become a certifying agency, or an organization that trains certifiers, or both. So may EBSA, DNV, or private commissioning agents. When the certification process is defined, all those wishing to qualify for a role will need to jump through the same hoops. Neither DNV, nor ABSA, nor EBSA, have an inside track on becoming a player in the ultimate process. At this time, we are simply facilitating the development of the standard that you, the biosafety professionals of the world, will write.

On another note, one of the Task Forces I appointed earlier this year has already submitted its final report to Council, two months ahead of schedule. The Philanthropic Activities Task Force, under the excellent leadership of Craig Welence, has presented Council with a prioritized list of philanthropic activities ABSA could provide to foster the awareness, evolution, and practice of biosafety in the U.S. and abroad. This Task Force also
developed a step-by-step set of proposal evaluation criteria that will ensure each philanthropic proposal, regardless of size or complexity, is afforded the same careful consideration. Council has unanimously agreed to appoint a new committee to oversee the implementation of the excellent recommendations of Craig’s team. As we become an increasingly recognized force in the field of biosafety, I believe we will see ever increasing numbers of proposals for ways we can contribute, at our own expense, to the evolution of our profession. I believe we have an obligation to undertake these efforts as we’re able, and this Task Force has given us the means to get started. I extend my sincere thanks to Craig and his excellent team for this fine work. The Council and I look forward to receiving the reports and recommendations of our other four Task Forces.

I have two things to ask of you, as members of ABSA. If you have not yet completed the member survey, please do so at your earliest convenience. Just go to the Members Only section of the web site and click on “Take the Members Survey.” While we have over 1,000 members, we’ve received less than 200 responses to the survey. We’re getting very interesting information, some of which you’ll hear about in Boston and may be useful to you when you seek professional development or advancement from your employers. Please add your information to the growing set of data.

Finally, pay close attention to our journal, Applied Biosafety. Its quality and utility have been growing steadily, thanks to our two superb co-editors and their editorial panels. It is now available online, as is the article submission process. We are currently assembling an electronic library and undertaking some translation efforts. Look for more great things to happen with Applied Biosafety.

In this past year of changes and challenges, I have had the privilege of working with many outstanding individuals, both on and off Council. Without the assistance and guidance of Betsy Gilman Duane, our Past-President, and Bob Hawley, our President-Elect, my job would have been much more difficult, and I thank them both for their dedication and support. I also tip my hat to our Councilors—a hard-working, committed group of professionals who help keep Council sharply focused on the health and welfare of ABSA. Many thanks to them all, and a special note of thanks to our departing Secretary, Rosamond Rutledge-Burns, and our two departing Council members, Patty Olinger and Chris Thompson, for their hard work. And last, but hardly least, a big “thank you” to Ed John Stygar, our Executive Director, and his tireless staff; without their support, dedication, and just plain hard work, our management transition would not have happened so seamlessly, nor would we be in such good hands today.

I feel very honored not only to have been your President this past year, but also to have had such wonderful people to work with. The next year will have its own unique set of challenges. Rest assured your Council and staff will keep ABSA strong, healthy, and successful.

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**EPA Pesticide Program Update: Data Requirements for Biochemical and Microbial Pesticides**

**Date of publication:** March 8, 2006

**Citation:** Federal Register, Volume 71, Number 45, Page 12071-12117

www.epa.gov/fedrgstr/EPA-PEST/2006/March/Day-08/p2185.htm

Purpose: EPA is proposing to update and revise its data requirements for the registration of microbial and biochemical pesticide products to reflect current scientific knowledge. These proposed revisions are intended to provide EPA with data and other information necessary to support the registration of a biochemical and microbial pesticide product, and will improve the Agency’s ability to make regulatory decisions about the human health and environmental effects of these pesticide products. EPA is also proposing to update the definitions of a biochemical pesticide and a microbial pesticide to more accurately describe these categories of pesticides, and to make a conforming change to the definition of microbial pesticide. EPA is announcing its policy to provide assistance to applicants when needed in determining what data are appropriate to support registration of a biochemical or microbial pesticide and encouraging applicants to request pre-submission meetings to discuss these data issues. EPA is announcing its intent to provide assistance to applicants in some narrow circumstances in preparation of an applicant’s data waiver.

**Chemical(s):** Various

**Comments:** Comments, identified by docket identification (ID) number EPA-HQ-OPP-2004-0415, must be received on or before June 6, 2006.

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