

**ASEAN Regional Forum
Workshop on Biorisk Management
Manila, Philippines
September 28-30, 2010**

Co-Chairs' Summary Report

1. Pursuant to the 17th ASEAN Regional Forum Ministerial meeting in Hanoi, Vietnam, July 2010, the ASEAN Regional Forum Workshop on Biorisk Management was held on 28-30 September 2010 in Manila, Philippines. The Workshop was co-chaired by Ambassador Generoso Calonge of the Philippines, Mr. James Nachipo of Australia, and Ms. Sharon White of the United States.
2. The Workshop was attended by representatives and experts from Australia, Canada, India, Indonesia, Japan, the Republic of Korea, Lao PDR, Malaysia, Mongolia, Pakistan, Papua New Guinea, the Philippines, Russia, Singapore, Sri Lanka, Thailand, Timor Leste, and the United States. Invited guests represented the following organizations: the World Health Organization, the Asia-Pacific Biosafety Association, and the Mahidol-Oxford Tropical Medicine Research Unit. Participants held the view that the intergovernmental organizations provided valuable international and regional context to the discussions.

International Efforts on Biorisk Management

3. The Philippines, the United States, and Australia chaired the opening session of the workshop. In opening remarks, the co-chairs noted the importance of interagency cooperation and a cross-disciplinary approach to implementing biorisk management strategies, as well as highlighted the important role that the ARF plays in bringing together regional experts to share experiences on biosafety and biosecurity.
4. Dr. Greg Smith, from the Australian Animal Health Laboratory, introduced the topic of biorisk management, which incorporates a balanced approach to biosafety

and biosecurity to minimize risks associated with both naturally-occurring and deliberate misuse of dangerous human and animal pathogens. Dr. Smith provided a history of biological incidents, stressing the threats posed by lone perpetrators, and noted that interest in misusing bioagents is on the rise. He stressed the importance of personnel security, as people interested in misusing agents often have had scientific and medical expertise, and noted that while historically lab accidents have caused more casualties, the unrealized potential of biological weapons calls for a robust biorisk management system.

5. Ms. Maureen Ellis, senior biosecurity advisor for the Global Partnership Program in the Canadian Department of Foreign Affairs and International Trade and co-chair of the International Federation of Biosecurity Association, described the health and security interface of biological risks and introduced the primary elements of biorisk management including biosecurity and biosafety, noting that terminology in this field is not uniform across regions. Ms. Ellis noted that the current state of biosafety was inadequate worldwide and that many collections of dangerous pathogens are not sufficiently secure, pointing to the critical need to do more in these areas and to provide assistance to countries with inadequate resources and expertise. Ms. Ellis outlined the three components of biorisk management: 1. Assessment, which includes hazard identification and evaluation of the likelihood of consequences; 2. Risk Mitigation, including addressing issues related to engineering, practices and procedures, equipment, and administrative control; and 3. Performance, addressing how people and things function over time. She stressed that biothreat management requires proper practices and encouraged participants to focus on people, learn from each other by sharing best practices, bring different disciplines together, capitalize on the strengths of all stakeholders, and recognize that all of us have a role to play.

6. Ms. Naoko Noro and Mr. Shinsuke Tomotsugu of the Research Institute of Science and Technology for Society (RISTEK) of the Japan Science and Technology Agency, provided an overview of the Japanese response to the 2009 H1N1 pandemic and the 2010 outbreak of Foot and Mouth Disease (FMD) in Miyazaki prefecture. Ms. Noro noted that while Japan has an overall strong medical system, it encountered problems due to a lack of an effective risk assessment system, a lack of human resources trained in areas such as public communication and crisis management, an ineffective risk communication strategy

that did not project a unified voice. Ms. Noro pointed out the special success of the Sendai Method, which was initiated by a deputy mayor with infectious disease expertise and deviated from the national action plan by utilizing all the local clinics to accept H1N1 patients so as not to overwhelm other medical institutions and lab facilities. Mr. Tomotsugu outlined the Japanese response to the 2010 FMD outbreak, highlighting the important role of local governments and the economic considerations that influenced their decisions. He highlighted the best practices of Ebino City, which unlike other city governments, took a proactive collaborative response to communicate between the district leaders and municipal officers and to identify burial disposition sites for slaughtered livestock. He highlighted the importance of early notification and testing to assist in hedging risk, the need to prepare and preposition equipment and material, the value of early identification of burial sites, the need for a quick response, and the need to share information among all stakeholders at all levels of government.

7. Dr. William So, from the U.S. Federal Bureau of Investigation (FBI), presented on the law enforcement perspective on biosecurity. He outlined the law enforcement role of the FBI in the U.S. system and highlighted efforts by the FBI's Biological Countermeasures Unit to enhance bioterrorism awareness through outreach to academia, industry, and scientific communities. Dr. So stressed the importance of communication with state and local experts, as well as interagency communication at the national level. He described the international and national biosecurity threat environment and stressed the importance of instilling a culture of responsibility in industry and academic institutions. He discussed specific challenges, including the expansion of dual use research of concern and rapid advances in synthetic biology, but urged that new legislation and regulations to meet these challenges should be informed and not so restrictive as to stifle scientific progress.

8. Dr. Cecelia Williams, from the U.S. Sandia National Laboratories, introduced the history of the development of the European Committee for Standardization (CEN) Standard for Laboratory Biorisk Management, noting that these are management standards designed to complement technical standards such as GSP and JSP as well as related standards on quality control (ISO 9000) and the environment (ISO 14000). CEN Workshop Agreement (15793) is the first and only international standard for all laboratories that work with pathogens and toxins.

The CEN Standard is a performance based document that provides a framework of best practices and procedures based on the Plan, Do, Check, and Act model and is comprehensive to cover a broad range of laboratories. It is designed to be an international framework that can still incorporate local solutions to local problems. She noted that the CEN Standard currently has not yet moved towards becoming a formal certification or accreditation system and lacks a mechanism for international harmonization and a certifying body, but that efforts are currently underway to develop a system before competing standards are developed, that takes into account the need for flexibility to address local concerns. She concluded by outlining a vision for future advances in biorisk management, including heightened awareness, clarified terminology, development of targeted training strategies, commitment from stakeholders for implementation, and increased capacity to address needs and provide accountability.

9. Dr. Remigio Olveda, Director of the Philippine Research Institute for Tropical Medicine (RITM), presented on the history and functions of RITM and introduced case studies on RITM responses to infectious disease outbreaks in the Philippines, highlighting coordination with international organizations such as the WHO. Dr. Olveda described the RITM strategy and methodology to biosecurity risk assessment, detailing how RITM has developed a mitigation plan to lower risks associated with weaknesses in physical security, program management, personnel security, material controls and accountability, transportation security, and information security. Specific recommendations included enhancing physical security with new equipment and technologies, improving access control procedures, and wherever possible using simple measures to improve security.

10. Dr. Maria Nerissa Dominguez, from the Philippines Country Office of the World Health Organization, presented on the WHO's International Health Regulations 2005 (IHR 2005), outlining the history of IHRs and noting that the goal of IHR 2005 is to ensure maximum public health security while minimizing the impact on international transport and trade. Dr. Dominguez discussed how the new IHR expands to cover all public health emergencies of international concern, provides for an adapted response, and stresses containment at the source rather than just at international points of entry of borders. The IHR calls for strong national health infrastructure connected to the global alert and response system. She stressed that implementation of the IHR will lead to faster response to detect

and contain public health threats, contribute to international health security, and demonstrate countries' willingness to be respected partners. She noted effective implementation will require designating an IHR focal point, mobilizing resources and developing national actions plans, strengthening alert and response capacities, strengthening capacities at points of entry, providing for threat readiness, sustaining international cooperation among countries and with the WHO, and providing continued monitoring of IHR implementation.

11. Dr. William So, from the U.S. FBI, presented on the Amerithax investigation, noted the wide scope of the investigation including cooperation among many governments and institutions and the development of new forensic techniques. International cooperation remains valuable as other countries possessed specific investigative skills useful to the investigation. The investigation highlighted the risks of insider threats and the importance of identifying possible motivations for misuse of biological agents. Dr. So noted that the Amerithax case is a case model for the importance of continuous screening of personnel who work with select agents.

12. F/Supt. Jose Embang, of the Philippine Department of Interior, presented on confidence-building measures (CBMs) in compliance with the Biological Weapons Convention (BWC). He outlined the process by which the Philippines organized itself to prepare the formal documents on CBMS for submission to the BWC ISU, stressing the importance of multi-sectoral engagement and leveraging existing networks of interagency stakeholders. He outlined the various elements of the CBMs and the relevant Philippine agencies contributing to the reports. He noted that the Philippines, under the new government, will continue to organize the official submission of CBMs on the BWC, will organize a local workshop on CBMs and assist other countries to submit CBMs. The Philippine delegation noted that the development of the CBMs was useful for gaining self-confidence in the domestic structure of biological research.

13. During discussions on the presentations, participants noted the need to initiate biorisk management strategies at the source of infectious disease incidents in hospitals and fields, rather than view biorisk management as just a laboratory based system. Also, participants stressed that laboratories should be defined beyond research institutions to include facilities in hospitals and educational

institutions as well as private institutions. Participants discussed an all hazards approach, recognizing that existing infrastructures, such as those for poison control, can be leveraged to provide important capacities for other hazards.

National Efforts on Biorisk Management

14. Pakistan, Japan, Indonesia, Philippines, Malaysia, and Thailand presented on their respective countries' national efforts to mitigate biorisk, and current strategies, initiatives, and challenges. All presentations acknowledged the potential that a bioagent may be accidentally released into the environment or obtained with the intention to use it as a biological weapon exists and that a collaborative international effort is needed in order to effectively / successfully prevent the accidental release of a bioagent and counter terrorist biological weapons threats. These presentations noted the importance of international obligations under the BWC and UNSCR 1540. They noted the need to integrate biosafety and biosecurity practice and discussed the important role that BSL 3 and 4 laboratories play in national health strategies. They also noted that different countries have different priorities with respect to biothreat mitigation.

15. The presentations discussed how to implement a biosecurity culture and how best to instill a culture of responsibility. Presenters identified key tools, including national action plans that incorporate a biorisk management system, administrative measures and legislation, laboratory accreditation procedures, effective export controls, codes of conduct on biosecurity incorporated in academic programs, and biosafety and biosecurity networks among laboratory facilities. They stressed that political will at the highest government levels is necessary for progress and that there should be clear breakdown of responsibilities and roles for all stakeholders. They noted the importance of reaching across different government agencies and government sectors, and outreach to all stakeholders including the private sector, academia, and biological safety and security associations. In particular, they stressed the need for raising awareness in education institutions, called for enhanced research review processes for dual-use research, and noted that good security and safety practices should be incorporated in biological education programs. Finally, several countries, including Indonesia and the Philippines, discussed newly developed national biosecurity and biosafety associations and the

role they can play in promoting best practices and certification of quality control and quality assurance.

16. These presentations raised a number of concerns and challenges, including lack of trained manpower, the prohibitive expense of safety and security equipment, lack of dedicated funding to support biosafety and biosecurity, demographic changes with aging populations, population diversity, the large movements of people within the region, and the need for further training for law enforcement personnel. The presenters called for international cooperation and assistance. They also noted the need for solid consensus between donors and host institutions on requirements and solutions, and recommended searching for synergy with other existing programs and mechanisms, donor coordination, and developing creative mechanisms for robust funding, possibly incorporating private sector funding. The presenters encouraged further work on enhancing regional networks for biosafety and biosecurity.

Implementing a Biorisk Management Strategy

17. Dr. Peter Daniels, from the Australian Animal Health Laboratory (AAHL), presented on capacity building for laboratory biosecurity, noting that successful capacity building is dependent upon having a clear and shared understanding of what is to be achieved and a clear understanding of who is responsible for what. Dr. Daniels outlined AAHL's Regional Program, based on a people centered approach to capacity building and incorporating an iterative, incremental approach to training rather than one-off trainings events. He listed factors for successful capacity building, including buy-in by top management, clear policies and plans, effective communication with all involved government stakeholders, access to necessary expertise, and a process for external audit and review of progress. He noted the importance of gap analysis for helping internal stakeholders gain self knowledge and a better understanding of their own institutions.

18. Dr. Shanna Nesby-O'Dell, from the U.S. Centers for Disease Control, presented on qualitative and quantitative approaches to risk assessment. Dr. Nesby-O'Dell noted that all approaches require knowledge of biological agents and laboratory operations, a team approach incorporating management and all involved in operations, a site-specific evaluation before work starts at the

laboratory, and the establishment of appropriate safety precautions across a range of elements. She outlined the CDC's 5-Step Biosafety Risk Assessment, consisting of identifying agent hazards, identifying hazards related to work activities, determining a preliminary biosafety level, conducting a worker assessment, and finalizing the biosafety level and reviewing with key stakeholders. She noted that quantitative approaches, in contrast to qualitative approaches, are standardized allowing for comparisons across institutions, but can be inflexible and rigid. She recommended combining both types of approaches and encouraged using qualitative to analyze work at the bench. She announced that the WHO will be holding a 10 day train-the-trainer course in biorisk management for the SEARO region in November. She described CDC outreach work in Africa and noted several challenges, including the need for time and continued attention, need for mentorship, turnover of human resources, and the loss of momentum as management priorities change. During discussion, Dr. Nesby-O'Dell noted particular challenges posed by animals in the laboratory environment and that current models do not always effectively address these concerns, though she stated that the United States is working to develop similar tailored risk assessment modules for animal health and for other healthcare environments such as hospitals.

19. Dr. Jean Bosco Ndiokubwayo, from the World Health Organization, presented on the state of biosafety, biosecurity, and biorisk assessment in the African region. He noted that biosafety and biosecurity are relatively new topics to the region and so governments lack capacity for effective biorisk management. He noted particular challenges related to biological agents, including a lack of guidance for handling and storage, the lack of national regulations, lack of training programs, and inadequate equipment. In particular he stressed the lack of awareness of biosafety and biosecurity at the highest political levels, the lack of local technical expertise, and the lack of money for maintenance of laboratories. He noted that progress had been made on raising general awareness, securing political commitment from countries to strengthen laboratory capacity, and enhanced support from international partners and that the WHO will continue to support countries, train biosecurity officers, enhance international partnerships, and help countries procure equipment and reagents.

20. Dr. Cecelia Williams, from the U.S. Sandia National Laboratories, presented on assessing security risks of biological facilities, noting that the process is very

similar to assessing risk for biosafety. She noted that the purpose of risk assessment is to help meet international, national, and local regulations and commitments including those under the BWC and UNSCR 1540; to assist in deciding which scenarios should be protected against; and helping design appropriate strategies to deny, contain, or deter such threats. The process includes characterizing assets and threats, taking note of motive, means, and opportunity; developing and evaluating possible threat scenarios that include both insider and outsider threats and both physical and operational characteristics of the facility; and characterizing the risk and developing a risk statement. She noted the value of using multiple criteria decision making quantitative approaches, which can incorporate weighted criteria and provide comparisons across institutions, though she noted the current lack of data for quantifying some elements. She introduced the Lab Biosecurity Risk Assessment Report (Biosecurity RAM) currently under development by Sandia and offered to provide information on as to the availability of this computer tool to participants once finalized. In conclusion, she noted that the benefits of biosecurity risk assessment include educating responsible personnel, learning about work activities in the laboratory, and the ability to establish appropriate mitigation efforts.

21. Dr. Lauren Wilson, of the Chemical, Biological, Radiological, and Nuclear Data Center of the Australian Federal Police presented on suspicious behavior in the laboratory. Dr. Wilson stressed the importance of recognizing, reporting, and investigating suspicious behavior and the need to raise awareness among laboratory personnel about possible indicators that might suggest someone is interested in misusing a biological agent. She noted that such judgments are subjective and that there is not any one single indicator of behavior. For outsiders, she suggested paying attention to unusual interest in laboratory facilities and attempts to breach physical controls or to acquire access passes or codes. She noted many possible indicators for insider threats, including changes in ideology, appearance, and work habits and she introduced contributing factors that could affect personnel, including personal crises, financial issues, and mental health concerns. Dr. Wilson stressed that prevention was better than needing to respond to an incident, and recommended the development of clear reporting guidelines for suspicious behavior and robust outreach to laboratory personnel about the risks and

how to report concerns. Workshop participants noted the value of national reporting hotlines as important platforms for reporting suspicious activity.

22. Dr. Stuart Blacksell, of the Mahidol-Oxford Tropical Medicine Research Unit (MORU), presented on the U.S. National Select Agent Registry/Centers for Disease Control (NSAR/CDC) registration process, noting that not only is certification a prerequisite for access to U.S. National Institute of Health funding, but that it provides a good model for developing functional ability to work with select agents. Dr. Blacksell discussed the web-based process for initiating registration and outlined elements included in the registration process including measures on restricting access and how to perform security checks on personnel, training and the importance of dual-use awareness, incident response plans for many kinds of scenarios, and developing select agent inventories with clear audit trails. He noted that for some areas, the U.S. system provides prescriptive guidelines, but that it may not always be clear how to adapt the guidelines to other countries. Dr. Blacksell also discussed the growth of BSL 3 and 4 laboratories in Southeast Asia and outlined areas for potential cooperation with foreign donors, including on accreditation, training, and management. He called for the creation of a regional standard for BSL 3 accreditation and urged foreign donors to assist in the development of local expertise in laboratory servicing, BSC accreditation, and BSL and HEPA testing.

23. Dr. Teck Mean Chua, head of the Asia-Pacific Biosafety Association, presented on best practices of biorisk management, noting the role of regional biosafety organizations. Dr. Chua recommended that best practices should have the support of senior management, be sustainable, promote accountability, be improved through regular assessment, be performance based and easy to implement, and incorporate a holistic approach with balanced integration across the management, science and engineering components of biorisk management. He addressed several key recommendations from the CWA 15793, outlining the role of national policy; biorisk management policy and the need to keep senior management engaged; and the establishment of necessary infrastructure, noting that technical issues are all too often left to contractors who lack full understanding of laboratory requirements. Dr. Chua discussed the biorisk assessment process as the backbone of biorisk management, and noted the importance of fully understanding the rationale behind policies rather than simply following

procedures. He also raised the importance of committees formed of trained personnel for providing the necessary subjective judgments on whether risks are acceptable. He concluded by calling for the ASEAN Regional Forum to hold exercises on biosafety and biosecurity with threat scenarios in order to discuss how to act regionally and to apply and test related skills. During discussion, Dr. Chua noted that the various biosafety associations offer important information on equipment related to biosafety and biosecurity on their websites. Participants discussed the differences in laboratory situations among countries.

Working Group Discussions

24. The workshop participants divided into three working groups to discuss specific aspects of biothreat management in more detail. The First Working Group addressed the development of national lab accreditation mechanisms, focusing on the importance of national regulations, the need to build expertise and develop human resources, and approaches to accreditation and oversight. The participants noted the importance of tiered solutions to better address the varying capabilities and capacities among regional countries while continuing to meet international standards. Participants discussed the differences among accreditation standards and debated how best to effectively harmonize their application and accreditation.

25. Working Group One participants concluded that one possible approach to effective development and implementation of national regulations could utilize national biosafety organizations as instruments to develop regulations and present and advocate their adoption to national governments. The regulations should delegate responsibility and authority, address funding, include indicators and metrics, be applicable across sectors and all types of laboratories, build upon existing accreditation efforts, suggest a framework for implementation, and address oversight and accountability of high containment labs. Next, pilot laboratories could act as model champions to demonstrate effective implementation of the regulations. Participants concluded a training strategy needs to be tiered for different stakeholders, should be local, should use existing in-country platforms and professionals, should use materials and products in local languages, should address funding and sustainability, should incorporate follow-up activities, should utilize various adult training techniques, and should consider standardized core competencies. Participants concluded that oversight plans should identify the role

of national authorities and should address the types of laboratories, the type of information collected, and how to protect that information. Finally, participants noted that biosafety accreditation needs to address who performs the assessment, the purpose of the assessment, whether and how biosafety accreditation should be combined with other standards, the training needs of auditors, costs of accreditation and training, and how to build upon existing programs and models.

26. The Second Working Group discussed the expanded role of national and regional biosafety associations in biorisk management, focusing on the role of biosafety associations in biorisk management, biosafety associations' support for the CEN Biorisk Management Standard, and sustainability of biosafety associations. For each sub-topic, participants identified key roles, mechanisms, or strategies, and corresponding biosafety association activities.

27. Under the role of biosafety associations in biorisk management, Working Group Two participants addressed the role that biosafety associations play in advancing biorisk management. The roles and activities recommended by the working group included (1) promoting the implementation of biorisk management standards and best practices, (2) provisioning technical support to the development of national/regional/international standards and guidelines, (3) networking and sharing information and experiences, (4) awareness raising among all sectors, (5) raising the profile of associations with governments, and (6) technical support for maintenance and certification of equipment (e.g. biosafety cabinets). Participants concluded that each role and associated activity may be different at the international, regional, national level and each country may have different priorities of importance for each role. Under the topic of biosafety associations support for the CEN Biorisk Management Standard, participants addressed what mechanisms are needed to support the implementation of the CEN standard. The mechanisms and activities recommended by the working group included, (1) gaining a better understanding of the CEN standard, (2) sharing lessons learned from those laboratories implementing the CEN standard, (3) identifying the benefits of implementing CEN standard, (4) getting more involved in the CEN standard development process, and (5) developing a system for biosafety associations to evaluate and report how they are implementing the CEN standard. Participants concluded that there is a general lack of understanding of CEN standards and a need for education on CEN standards at all levels. Finally, under

the topic sustainability of biosafety associations, participants discussed how biosafety associations can remain empowered and sustainable over the long term. The strategies and activities recommended by the working group included (1) developing clear work and business plans, (2) engaging in fundraising activities, (3) accrediting biosafety associations workshops and courses, (4) ensuring association remains a neutral platform, (5) maintaining support networks from regional and international associations down to national level associations, and (6) expanding networking and raising the profile of associations. Participants concluded that sustained funding is a major obstacle for the sustainability of biosafety associations in the long-term.

28. Working Group Three discussed raising awareness about biorisk management, gap analysis and strategies for improvement. The group discussed multiple long and short-term methods to improve national biorisk management including curriculum development and certification, which would raise its profile and increase professionalism. A key component to drive this national effort is a whole-of-government approach and awareness-raising among policy makers. This whole-of-government approach is applicable to countries regardless of their national progress on biorisk management. International forums and organizations such as the BWC, WHO, OIE and others should also be leveraged in these efforts to remind governments of the importance of biorisk management. Additionally, mechanisms that already exist which are engaged in national gap analysis should be similarly leveraged. Hopefully these efforts will also catalyze a positive shift in safety culture.

29. Participants in Working Group Three concluded that a “whole of government” approach is the most critical necessity in driving to improve national biorisk management. This would include new national policies, national gap analysis, and organizational codes of conduct. The group also agreed bolstering the capacity of scientists and users was important and key implementing mechanisms are train-the-trainer programs and twinning. Engineers with expertise in biocontainment facilities are also a key cohort to build indigenous capacity. Regional partnerships and collaboration within and without other forums, such as ASEAN+6 are also excellent opportunities to bolster national biorisk management efforts.

Conclusions and Steps Forward

30. The three working groups presented their conclusions to the full plenary session and discussed the development of an ARF best-practices document on Biorisk Management. The chairs announced that this document would continue to be developed with an aim of having the document proposed for consideration at the ARF Inter-Sessional Meeting on Counter-Terrorism and Transnational Crime and the ARF Senior Officials' Meeting and finally for recommendation to ARF Ministers for endorsement at the 18th ASEAN Regional Forum Ministerial Meeting in Indonesia in 2011. The Philippine Chair noted the Philippines looks forward to next years' ARF Biorisk Management Workshop, which will focus on detection and surveillance as important components of the issue.