

Developing Regional and National Biosafety and Biosecurity Strategies for the Middle East and North Africa (MENA)



The International Council for the Life Sciences

Prepared by: ICLS with the assistance of a core group of experts from the Middle East and North Africa (MENA)

Preface

More than 100 participants from around the world convened in Abu Dhabi, UAE from 12-14 November 2007 for **Biosafety and Biosecurity International Conference 2007 (BBIC 2007): A Seminar for the Life Sciences and Policy Communities in the MENA Region**.

Conference participants explored biosafety, biosecurity, environmental health and infectious disease issues specific to the MENA region¹ and interacted with experts from other parts of the world.

The conference's recommendations can be grouped under five main themes:

- Building human resources;
- Building national and regional legal, institutional and physical infrastructure;
- Developing national and regional capacity for prevention and preparedness;
- Improving opportunities for scientists and industry to participate in policy-making;
- Monitoring and reporting on implementation of recommendations.

In order to carry out these recommendations, a core group of participants worked together to agree an action plan to carry out the conference outcomes, including the development of a framework for a regional biosafety and biosecurity strategy, and to begin planning BBIC 2009, hosted in Casablanca, Morocco from April 2-4, 2009.

The conference featured the following themes for the MENA region:

- Developing and Implementing Strategies for Biosafety and Biosecurity at the National and Regional level
- Confronting Biological Risks
- Strengthening Infectious Disease Surveillance
- Regional Training Centers for Biosafety, Biosecurity and Infectious Disease
- Institutional, Physical and Legal Infrastructures to Manage Biological Risks

The framework served as the basis for discussion at the Biosafety and Biosecurity International Conference 2009. As a result of those discussions, some amendments to the framework were suggested and the conference adopted the amended framework by acclamation.

¹ For the purposes of this process, MENA is defined as the following countries: Mauritania, Morocco, Algeria, Tunisia, Libya, Egypt, Sudan, the Palestinian Authority, Jordan, Lebanon, Syria, Iraq, Iran, Pakistan, Saudi Arabia, Yemen, Oman, the United Arab Emirates, Qatar, Bahrain and Kuwait.

Who we are

The International Council for the Life Sciences is a non-profit organization dedicated to enhancing global biological security and safety and reducing the risks of the misuse of the life sciences through the promotion of international standards and the sharing of best practices. The ICLS identifies the most urgent biological risks and promotes global standards for ICLS members to adopt and promote. www.iclscharter.org

The Environment Agency of Abu Dhabi (EAD) is a governmental agency that was established in 1996 with the overall function of protecting and conserving the environment as well as promoting sustainable development in the Emirate of Abu Dhabi, the capital of the United Arab Emirates. www.ead.ae/en/ EAD partnered with the ICLS for both BBIC 2007 and BBIC 09. Biosafety and Biosecurity International Conference 2007 website can be found at www.biosafetyandbiosecurity-2007.org

Royal Scientific Society (RSS) – Jordan is the largest applied research institution, consultation and technical service provider in Jordan. RSS was established in 1970 as an independent, not-for-profit non-governmental Organization (NGO), containing 7 technical centers that house 38 laboratories that are nationally and internationally accredited, and employing more than 600 members and staff; they also partnered with the ICLS for BBIC 09. www.rss.gov.jo

The Moroccan Ministry of Education, Higher Education, Training and Scientific Research is in charge of implementing the national policy for Education and scientific research. Inside this frame and aware of the extreme importance of Biosafety and Biosecurity to overcome dual use of scientific research findings, the Ministry has decided to put in place regulations and codes of conducts for scientists including life sciences. The Ministry is an ICLS partner and hosted BBIC09 in Casablanca, Morocco from April 2-4, 2009. www.enssup.gov.ma

Contact us:

Terence Taylor
President
International Council for the Life Sciences
1747 Pennsylvania Avenue, NW 7th Floor
Washington, DC 20006
USA
Tel: +1(202) 659 8058
Fax: +1 (202) 659 8074
Taylor@iclscharter.org

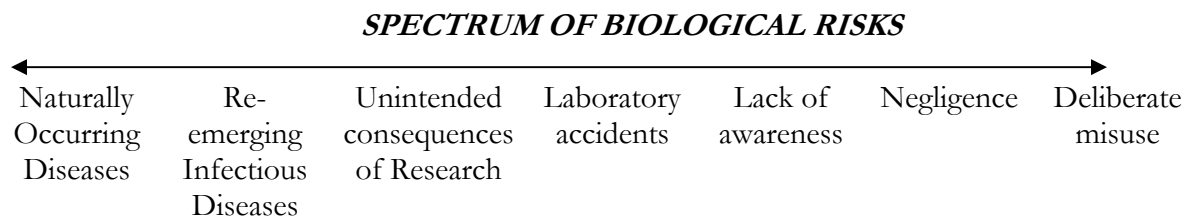
For more information please email:

Tim Trevan at trevan@iclscharter.org

Introduction

Extraordinary advances in biotechnology have brought enormous benefits to medicine, public health, the food industry, agriculture, and industrial processes. However, technological advances also bring with them risks to public safety and security through the possibility of their misuse. Furthermore, in addition to man-made biological risks, humans continue to face natural biological risks such as the threat of pandemics of new and re-emerging infectious diseases.

These risks are best represented as a spectrum, ranging from emerging and re-emerging infectious disease through accident and misadventure to deliberate misuse.



In order for the full humanitarian and economic benefits of biotechnology advances to be realized, it is essential that these risks are properly identified, understood, and effectively managed.

For this purpose, the Biosafety and Biosecurity International Conference 2007 was held in Abu Dhabi, UAE November 12-14, 2007. The conference specifically addressed how the risk spectrum applied to the Middle East and North Africa (MENA) region, and assessed what actions would be required by the countries of the region to be fully prepared to manage and mitigate risks across the spectrum.

The conference made many recommendations for how the issues of biosafety and bio-security for the MENA region could be advanced. This paper seeks to provide a framework for how the recommendations of the conference can be implemented.

General Conference Overview

The conference concluded that biosafety and biosecurity are becoming increasingly important strategic issues for all countries in the world. However, they are becoming especially so for countries of the MENA region for the following reasons:

1. With land, fresh water and ocean resources coming under increasing stress as the human population continues to grow, biotechnology will become ever more important to humankind;
2. With greater human population density, pandemics of new or reemerging diseases become ever greater threats;
3. With greater human dependency on biotechnology, the danger posed at each point on the biological risk spectrum increases;
4. Thus humankind needs a holistic approach to bio-safety and bio-security to manage and mitigate risks across the entire breadth of the biological risk spectrum;
5. This is especially so in the MENA region where water and food security are so vulnerable;
6. Furthermore, the constant massive traffic of people, animals, food and goods between countries of the region and between MENA and other parts of the globe further raises the bio-threats to the area.²

The conference noted that many of the biological threats facing the world require concerted global or regional action. National action, while absolutely necessary, cannot always be sufficient to contain or manage biological risks. The need for effective concerted supranational efforts means that cooperating countries need to have a common understanding of the global and regional risks which in turn requires a common risk assessment methodology and common prevention activities. While biological risks do vary from region to region and country to country, without a common methodology for assessing risks and formulating appropriate policies and practices to manage and mitigate these risks, any international effort will be neither concerted nor effective.

² MENA has constant mass flow of people between countries of the region (e.g. labour from Egypt and Sudan travelling to other countries of the region for work, pilgrims travelling to Holy Places) and between the region and other parts of the globe (e.g. labor from South Asia and Southeast Asia seeking work in MENA countries, illegal immigration from Sub-Saharan Africa, citizens of the MENA area travelling the globe for business and pleasure, the airports of the region as major hubs for travel between Europe and Africa/Asia). Likewise, food and goods are shipped from all around the world into the MENA region. These flows of people, animal and foods each bring with them the possibility of disease being spread.

The conference noted that a holistic approach to the entire spectrum of biological threats requires that:

- a. governments nationally and regionally are structured and prepared for preventing, identifying and dealing with biological crises;
- b. countries of the region have the physical, institutional and legal infrastructure in place to benefit from biotechnology while protecting against biological risks;
- c. countries of the region have the trained and equipped human resources required to manage and mitigate biological risks; and
- d. Scientists and policymakers regularly interact.

A core group of individuals who attended BBIC 2007 met in Abu Dhabi from May 11-13, 2008 to discuss a framework for national biosafety and biosecurity strategies and a regional strategy for the MENA.

Framework for National Strategies and a Regional Strategy

A strategy should underpin two strategic objectives:

- Biological Risk Control
- Bio Preparedness (including Detection and Response)

Based on a comprehensive risk analysis (including risk assessment, risk management and risk communication), the strategy should also include the following strategic elements:

- Human and Laboratory Capacity building
- Legislation, regulation (international and national)
- Scientific responsibility, ethics-based codes
- Coordination
- Awareness
- Partnership and collaboration
- Border Control
- Surveillance
- Emergency response
- Diagnostics
- Monitoring
- Reporting and reviews.

The proposed biosafety and biosecurity strategy requires the establishment of a steering committee at both the regional and national levels to take responsibility for strategic leadership for the development, implementation and oversight of an effective biosafety and biosecurity system in countries and the region as a whole.

Principal Elements of Strategy

Human Capacity

Human skills in all areas – scientific, technical, policy, risk assessment – are necessary for countering broad spectrum biological risks in the human population, plant, animal and environmental sectors.

This ability should be built by:

- A survey of existing human resource capacity and related educational and training programs;
- Identifying and prioritize vulnerabilities (lack of training, curricula, etc.);
- Making a plan for closing the gaps; and
- Oversight, monitoring and accreditation.

Laboratory and Infrastructure Capability

A need for cross-region ability to meet identified needs in countering broad spectrum biological risks in the human population, plant, animal and environmental sectors. This ability should be built by:

- A survey of existing laboratory and other related infrastructure and biosafety standards for handling various classes of micro-organisms across all sectors;
- Identifying and prioritize vulnerabilities (lack of training, equipment, protocols, facilities etc.);
- Making a plan for closing the gaps; and
- Oversight, monitoring and accreditation.

Legislation, Regulation and Standards (International, Regional and National)

It is necessary to ensure that regional and national strategies appropriately take account of national and international obligations and best practices. In order to achieve this:

- Existing legislation, regulations, guidelines and standards should be reviewed and gaps identified;
- Identification of key organizations and empowered individuals to form a national authority to act as policy makers and coordinators for all biosafety and biosecurity issues;
- Enhance the participation of academia and industry in policy making;
- Increase the adherence to biosafety and biosecurity standards for handling various classes of micro-organisms and establish regional standards as necessary;
- Establish legislation and protocols for cross-border cooperation; and
- Establish legislation and protocols for emergency situations.

Scientific Responsibility and Ethics-Based Codes

There needs to be a system to ensure individual and collective responsibilities are understood and effectively exercised to promote the safe and secure use of the life sciences. This could be done through ethically based codes, charters or other governance mechanisms. This may include the creation of National Committees for Science Ethics, Bioethics or Biosecurity.

Coordination (Regional and National)

To successfully develop and implement the national and MENA regional biosecurity and biosafety strategy it is vital to engage in interdepartmental, cross-sector and cross border collaboration (as needed). It is suggested that each country's identified national competent authority be the focal point for the coordination of the regional strategy. A small secretariat may be needed to provide assistance.

Awareness

There is a need to raise awareness of the importance of dealing with biological risks and the necessary steps to counter them. Steps that need to be taken include:

- Developing an outreach and communications strategy for raising awareness for:
 - Policy officials
 - Life science and related non-life science professionals from government, academia and the private sector
 - Front line workers
 - Students at all levels in the education system
 - General Public; and
 - Media
- Legislative and regulatory promotion
 - Web-based database for sharing best practices and other information
- The creation of relevant associations, such as a MENA biosafety and biosecurity association and associations at the national level. Linkages should be established with biosafety and biosecurity associations operating in other regions of the world to help further a global network.

Partnership and Collaboration

To successfully develop and implement a biosecurity and biosafety strategy it is vital to engage in interdepartmental, cross-sector, cross border and regional partnerships, both private and public, in order to maximize available resources and to share capabilities, expertise and information.

Border Control

In order to reduce the risks to public health, safety, security and the environment it is essential that measures, facilities and trained personnel are in place at border crossings, ports and airfields that take account of the regulations that relate to international trade and traffic. This includes:

- Training and equipment;
- Licenses, permits and permissions; and
- Protocols.

Surveillance

It is essential to put in place measures to enable early detection, identification of biological risks (including confirmation of area freedom/zero status) and effective responses in all sectors in accordance with regional and international agreements and legal obligations.

Emergency Response

There must be effective and tested measures and plans in place to deal with major emergencies.

Including:

- Training of first responders and key workers;
- Equipment, including pre-positioned stockpiles, and facilities;
- Surge capacity;
- Biological alert/alarm system and emergency network for coordination;
- Test exercises (both in table-top and field form); and
- Sharing of experience across borders and with international inter-governmental organizations (e.g. WHO, OIE, FAO) as necessary.

Diagnostics

There must adequate measures developed for timely, front line diagnostics and referral system (an inter-connected network that is comprehensive enough for the needs of the region). This includes:

- Common protocols;
- Biosafety standards for handling various classes of micro-organisms;
- Test equipment;
- Trained staff; and
- Safe and secure transport of samples.

Monitoring and Review

It is necessary to set up an effective national system for monitoring the development and implementation of the national biosafety and biosecurity strategy, including compliance with legislation and regulations. This system should also analyze the effectiveness of all aspects of biosafety and biosecurity management and enable its continuing suitability in a changing environment.

Reporting

A system should be established to ensure national governments' international and regional reporting responsibilities are properly conducted and their domestic reporting requirements are complied with. Reporting will take various forms.

Recommendations from BBIC 2007 in Abu Dhabi, UAE and BBIC 2009 in Casablanca, Morocco

BBIC 2007's recommendations to strengthen biological safety and security fell under five main themes:

- Building human resources;
- Building national and regional legal, institutional and physical infrastructure;
- Developing national and regional capacity for prevention and preparedness;
- Improving opportunities for scientists and industry to participate in policy-making; and
- Monitoring and reporting on implementation of recommendations.

In addition, it was recommended to establish a Standing Committee to assess the feasibility of one or more Regional Training Centers (RTC).

It is thus proposed by the Core Group to establish four thematic ad hoc Working Groups to address the first four themes, a Steering Committee on implementation, and a temporary Standing Committee to address the feasibility of Regional Training Centre(s).

BBIC 2009, with a few additions and amendments, endorsed the recommendations of BBIC 2007 and the Core Group as contained in the Framework document circulated to participants in BBIC 2009. The conference also suggested that the ICLS should provide secretariat support pending the development of a standing regional secretariat.

1. The Steering Committee on Implementation

Purpose: The purpose of this committee would be to:

- Provide a mechanism for reporting gaps analyses to governments;
- Contribute to the development of biosafety and biosecurity strategies at national and regional levels;
- Assist in the planning and organization of Biennial Conferences;
- Report on implementation to the Biennial Conference;
- Select materials to be posted on a dedicated website to support implementation of the Action Plan. Such materials might include conference, working group and Committee presentations and papers, action plans, resource and contact lists;
- Maintain smooth, regular communications among conference participants between annual conferences; and
- Establish a funding mechanism.

Membership: To be effective, membership of the Steering Committee should include each of the Chairs of the four thematic committees and of the RTC Standing Committee along with members of the Secretariat and representatives of appropriate international and regional organizations. In addition, regional representatives from government (scientists and policy-makers), industry and academia, and international industry associations would all be able to benefit the work of this committee.

2. Ad Hoc Working Group I: Human Capital Development

Purpose: The purpose of this Working Group would be to review existing materials from other regions and nations and to develop tailored regional and national materials as follows:

- Curricula for teaching bio-safety, bio-security and bio-ethics to biotechnology professionals, frontline workers, policy officials and students at all levels, and to improve awareness of these issues in general;
- Curriculum for training the trainers;
- Best Practices for industry and other relevant laboratories;
- A Code of Bioethics for all scientists and professionals in the biotechnology sector; and
- Methodologies to assess existing human bio-safety/security capabilities and to identify training needs.

In addition, this Working Group would encourage the dissemination of ideas and scientific knowledge between scientists and policy-makers nationally, regionally and internationally by:

- Encouraging scientists', policy-makers' and other stakeholders' participation in national, regional and international conferences on biosafety and biosecurity and infectious disease;
- Facilitating and arranging exchanges of scientists, policy-makers and other stakeholders and between scientific institutions at the international, regional and national levels;
- Developing national and regional non-governmental networks of interested parties, e.g. through industry, scientific and professional associations, including establishing a Middle East and North Africa Biosafety Association; and
- Creating a website and biosafety and biosecurity digital library for the MENA Region for networking, information exchange and dissemination of information amongst the MENA biosafety and biosecurity community.

Membership: This Working Group should include regional representatives from the health, agricultural, environmental and fisheries sectors, academia and industry, along with a few select international experts with relevant experience.

3. Ad Hoc Working Group II: Institutional, Physical and Legal Infrastructure

Purpose: The purpose of this Working Group would be to review existing infrastructure in the region, to identify needs for further development, and to develop action plans to address these needs. Specific areas to address could include:

- Development of common systems and methods;
- Identification, where already established, of the National Authority within each government to act as the principal national policy-making and focal point on all issues pertaining to biosecurity and biosafety, and, where these do not exist, encouragements of national governments to form them;

- Creation of a database of existing legislation and resources, establishment of in-country points of contact, and identification of national points of contacts within the region;
- Assessing national and regional infrastructure needs at the institutional, legal and physical levels and development of action plans to address these needs;
- Creation of a national committee of experts, designation of centres of expertise in each area of biosafety and biosecurity, and creation of national contact lists for these experts and centres;
- Identification of existing diagnostic and analytical capabilities, and of needs in this area;
- Evaluation of existing capabilities vis-à-vis IT tools for biosafety and biosecurity;
- Evaluation of capabilities to turn actionable data into timely and appropriate action at national and regional levels, and of needs in this area;
- Identification and review of existing standards, accreditation and monitoring systems;
- Evaluation of existing regulations, practices and capabilities, and of needs for transport of pathogens and other related biological material; and
- Evaluation of national and regional implementation of the relevant provisions of existing international and regional obligations, such as the International Health Regulations, the Biological and Toxin Weapons Convention, UN Security Council Resolution 1540, and IMO and ICAO regulations.

Membership: This Working Group should include regional representatives from the law and order (Ministry of Interior/Defense), health, agricultural, environmental and fisheries sectors, academia and industry, along with a few select international experts with relevant experience.

4. Ad Hoc Working Group III: National and Regional Prevention and Preparedness

Purpose: The purpose of this Working Group would be to:

- Develop and share tools and methodologies for national and regional bio-risk assessment;
- Identify the biosafety and biosecurity and disease outbreak scenarios of most concern nationally and regionally and to develop preparedness plans for dealing with each scenario;
- Test the developed preparedness plans using appropriate methods, such as field and table top exercises, and amend them as necessary;
- Share the tested preparedness plans with other countries of the region;
- Identify existing public health surveillance capabilities and future needs, including disease surveillance for humans, animal and plant disease. Surveillance should be simple, flexible, accurate, representative, complete, affordable and timely. For national surveillance:
 - Create relevant check lists;
 - Undertake situation analyses and needs assessments;
 - Identify weak points;
 - Develop a plan of action to improve surveillance through:
 - Involvement of all health providers and other stakeholders;

- Improvement of laboratory diagnostics and the establishment of national referral laboratories;
 - Activating public health laws in each country concerning reporting and notification;
 - Developing guidelines and protocols accredited by WHO;
 - Training relevant staff; and
 - Raising awareness within the medical and public communities;
- Identify existing diagnostic capacity and outbreak reporting procedures and future needs; and
- Identify border control issues of relevance to national and regional biosafety and biosecurity strategies and future needs to develop these, including in relation to:
 - Cooperation;
 - Exchanges of experience and medical samples for confirmation leading eventually to an established quality assurance system so that all laboratory results will be accepted by others;
 - Develop a regional plan;
 - Implementing the International Health Regulations (IHR); and
 - Screening at the borders of humans, animals and food, with due regard to human rights and dignity.

Membership: This Working Group should include regional representatives from the law and order (Ministry of Interior/Defense), health, agricultural, environmental and fisheries sectors, academia and industry, along with a few select international experts with relevant experience.

5. Ad Hoc Working Group IV: Policy-Making

Purpose: The purpose of this Working Group would be to:

- Identify international/regional gaps on biosafety and biosecurity issues, and propose mechanisms to create needed policies, standards and regulations at the international/regional levels;
- Identify and propose ways to encourage stakeholders' awareness of all key issues in the biosafety and biosecurity area, through greater interaction between policy-makers on the one hand and scientists, academics and industry on the other;
- Identify and propose ways to broaden scientists', academia's and industry's participation in and input into policy-making on issues relating to biosafety and biosecurity and infectious disease surveillance; and
- Identify needs and propose ideas for national and regional communications plans in the event of major biological crises.

Membership: This Working Group should include regional representatives from the law and order (Ministry of Interior/Defense), health, agricultural, environmental and fisheries sectors, academia and industry, along with a few select international experts with relevant experience.

6. Standing Committee to Assess the Feasibility of Regional Training Centre(s)

Purpose: The purpose of this committee would be to:

- Analyze the region's needs for training in the biosafety and biosecurity area;
- Assess the feasibility of establishing one or more Regional Training Centers;
- Assess the requisite resources to establish Regional Training Centre(s) to meet the MENA area needs;
- Identify suppliers of and funding sources for the requisite resources;
- Make recommendations to the next Annual Conference; and
- As far as possible, use existing training curricula and facilities.

Membership: This committee should include representatives from each of the countries/institutions interested in hosting a Regional Training Centre, health, agricultural, environmental and fisheries sectors, academia and industry, along with a few select international experts with relevant experience.

Timing

The revised framework will be distributed to the scientific and policy communities in the MENA region in accordance with plans approved by the Steering Committee.

The revised framework document will serve as a roadmap for the creation of national and regional biosafety and biosecurity strategies in the MENA region.

Resources

The following organizations, non-profits, government entities have agreed to work together to help develop and implement biosafety and biosecurity strategies at the national and regional level.

Environment Agency of Abu Dhabi (EAD)

International Council for the Life Sciences (ICLS)

Ministry of Education, Higher Education, Training and Scientific Research for the Kingdom of Morocco

Royal Scientific Society of Jordan (RSS)

Steering Committee

Chair: Dr Abdulhafid Debbagh

- Dr. Sabah Al Momin
- Dr. Rana Amini
- Dr. Ahmed K. Bashir
- Dr. Ruth Berkelman
- Dr. Suleiman al Busaidy
- Dr. Eltayeb Ali
- Dr. Bassam Hayek
- Dr. Bassam al Hijawi
- Dr. Rima Khabbaz
- Dr. Maan al Hakim
- Dr. Ali Akbar Mohammadi
- Dr. Anwar Nasim
- Dr. Assad Ramlawi
- Dr. Mohammad Sharif
- Ms. Heather Sheeley
- Mr. Terence Taylor
- Dr. Khalid Temsamani
- Mr. Tim Trevan
- Dr. Gazi Yehia



The International Council for the Life Sciences