

Summary of Comments from the International Advisory Group on Biosafety and Biosecurity  
(IAG) on the World Health Organization (WHO)  
Biosecurity Guidance Document

Prepared by the International Council for the Life Sciences

About the IAG

The IAG - which was created in November 2006 – is a standing group of international and Russian experts interested in enhancing biosafety and biosecurity. Its main objectives are to:

- Increase awareness of the importance of biosafety and biosecurity within the scientific community, government, industry (public-private cooperation) and society more broadly;
- Review, assess, and offer the expertise of national and international programs in biosecurity and biosafety according to international standards;
- Provide recommendations for use by federal agencies and other international entities as needed, on programs and activities to improve biosafety and biosecurity and enhance national and international security;
- Assist, as needed, to help implement new programs and activities.

Non Commercial Partnership "Center of Modern Medical Technology" (NP TEMPO) and the International Council for the Life Sciences (ICLS) jointly coordinate the IAG. The Group's terms of reference can be found at annex A. Significant financial and intellectual support was provided by the Global Partnership Program of Foreign Affairs and International Trade Canada for the activities in 2006 that led to the creation of the IAG, its first meeting in 2007 and the cost of translating the World Health Organization (WHO) Biosecurity Guidance Document into Russian.

WHO Biosecurity Guidance Document: A Discussion

This document was discussed at the first IAG meeting of 2007 on 31 March in Heidelberg, Germany. The discussion was moderated by Terence Taylor, President and Director of the ICLS and IAG Co-Chairman, and Vitaly Zverev, Director of the I.I. Mechnikov Institute of Vaccines and Sera and Acting IAG Co-Chairman.

One of the document's contributors, Dr. Ali Mohammadi, was present at the meeting as an IAG member, which was invaluable to the discussion. Dr. Mohammadi provided an overview of the guidance document and stated that this document is intended to act as a trigger for countries to set up their own relevant procedures and regulations. He told the group the document should be viewed as a starting point for more detailed rules and operating procedures. The group welcomed an opportunity to review and discuss the document and submit comments to the WHO.

*General Reaction*

IAG members, especially those from Russia, gave much praise to the WHO and its effort to address this complex issue. In general, IAG members were receptive to receiving guidance to enhance their laboratory security and safety. Several members were unclear about some aspects

of the document, including new terms that may not translate well from English, and believed that several sections seemed repetitive. IAG members expressed a desire for clarity on the purpose of the document, i.e. what should be done with it and by whom?

The IAG suggested expanding the first sentence in the section on page 13 (titled “scope of this document”) to read –

*This document introduces a new concept and approach to minimize or prevent the occurrence and consequences of human error within the laboratory environment **as well as to mitigate the consequences of natural and man-made impacts, capable of leading to an emergency situation (bolded text represents the additional language):***

### *Language*

It should be noted that the UN translates only final documents into the official UN languages. It is important, however, for non-English speakers to be able to comment on draft documents. At the request of the IAG, Foreign Affairs Canada supplied a Russian version of the WHO biosecurity document, which was much appreciated by all IAG members.

Several Russians, however, who are fluent in both English and Russian, suggested alternative ways in which the English document could have been translated into Russian; to a certain extent, this was to be expected, but efforts were made by the moderators to keep discussion about translation to a minimum. Regardless of the differing ideas on translation, the Russian IAG members highlighted a few terms they found problematic and provided suggestions for improving them.

The guidance document defines bioethics as, “the study of the ethical and moral implications of biological discoveries, biomedical advances, and their applications as in the fields of genetic engineering and drug research. In this document, bioethics is one of the three components that contribute to a successful biorisk management culture.”

The merit for including this concept into the guidance document (and the WHO three pronged biorisk management approach) was the subject of considerable debate. A number of the Russian IAG members thought it irrelevant to the purpose of the document. Thus, the rationale for the inclusion of “bioethics” in this document needs to be carefully explained if it is to be readily accepted globally.

It was suggested that the term biological laboratory, which does mention the term national, should also incorporate the term state-owned. WHO defines the term on page iii as, “a facility within which microorganisms, their components or their derivatives are collected handled and/or stored. Biological laboratories include clinical laboratories, diagnostic facilities, regional and/national reference centres, public health laboratories, research centres (academic, pharmaceutical, environmental, etc.) and production facilities (manufacturers of vaccines, pharmaceuticals, large scale GMOs, etc) for human, veterinary and agricultural purposes.”

To some IAG members, the term “biorisk management” implies the possibility to develop strategies aimed at both increasing and reducing the manifestations of biological risks.

Suggested alternative phrases, some of which are already used in the document, such as “measures to reduce or minimize biological risks,” are clearer. The preference was for biological risks to be spelled out instead of combining the two words into biorisk.

On page iv, the definition of control is “the combination of engineered and procedural measures that ensure valuable biological material (VBM) are used only *as intended* (emphasis added).” The document discussed in Heidelberg translated the last phrase *as conceived*; this was found to be insufficient. One suggestion was to use instead “in accordance with security (regime) rules and safety requirements for VBM.” Another alternative would be to use the Russian phrase, в соответствии с назначением, which translates “as intended.”

The WHO defines dual-use on page iv as, “initially used to refer to the aspects of certain materials, information and technologies that are useful in both military and civilian spheres. The expression is increasingly being used to refer not only to military and civilian purposes, but also to harmful misuse and peaceful activities.” The first definition of dual-use had more traction with the group. Many IAG members found the phrase harmful misuse and peaceful activities (roughly translated into dangerous undue use and non-use in peaceful activities) as a cumbersome phrase with which many were unfamiliar; one suggestion was to remove the second sentence. One alternative, which is used by the ICLS, is to omit the term dual-use and use the term misuse or possible misuse. Another suggestion was to find a way to include the terrorist component into the first definition, and it would then be sufficient.

The Laboratory Biosafety Manual third edition, which introduces the concept of biosecurity, limits the discussion to pathogens and toxins, not Valuable Biological Materials (VBM). This new term, featured in the Biosecurity Guidance document, is defined on page v as “biological materials that require (according to their owners, users, custodians, caretakers or regulators) administrative oversight, control, accountability, and specific protective and monitoring measures in laboratories to protect their economic and historical (archival) value, and/or the population from their potential to cause harm. VBM may include pathogens and toxins, as well as non-pathogenic organisms, vaccine strains, foods, genetically modified organisms (GMOs), cell components, genetic elements, and extraterrestrial samples.”

The new term was well received by some but not by others. One suggestion was to split the VBM concept into two: materials that could be described as Hazardous Biological Materials (HBM) and those materials that are non-hazardous but valuable could be defined as Valuable Biological Materials (VBM). Most of the group perceived the guidance document to be mainly about materials that could be described as HBM and not VBM.

Another idea is to find a different term than VBM, possibly one already in circulation, to refer to the biological materials present at a biological laboratory. The section describing the distinctions within VBM is helpful, but an IAG member suggested including, as part of the definition, a reference to diseases endemic or eradicated from different geographical areas. Another suggested the guidance document could go farther and provide a matrix for types of facilities, types of VBM they may have and suggestions on how to evaluate if current safety and security systems are sufficient, and if not, suggestions on how to improve them.

An additional language challenge, however, is that the English language uses two terms - biosafety and biosecurity – with separate definitions to cover a concept that is covered with one term by some other languages, such as Russian and German. For example, the Russian Ministry of Health 2003 Biosafety Regulations defines this one word as the “...protection of personnel, external human population and environment from exposure to pathogenic biological agents provided by a system of management, medico-biological measures, facility design, construction and operational practices.” While this definition is not explicit in the ways in which the exposure could happen – such as unauthorized access, loss, theft or accidental exposure – it does not preclude these possibilities.

Instead of, or in addition to a list of definitions, supplemental information explaining the concepts these words are used to convey would be helpful to non-English speakers.

#### *Describing the Context of the Need for Biosecurity – Citing Specific Examples*

The examples drawn upon in this document, such as the de novo synthesis of viruses, the 2001 anthrax attacks in the U.S., the IL-4 mousepox experiment and the reconstruction in 2005 of the 1918 influenza virus from recovered victims, are cited to illustrate challenges presented by advances in the life sciences. Most of these references, however, are Western-specific, and for some individuals from emerging economies, this may be their first knowledge of these incidents. The objective – proving why there is a need for global biosecurity – should be met without relying entirely on the most common references familiar to only those already active in this topic.

The first reference to the anthrax letters<sup>1</sup> (reference number 5) in the guidance document is in the introduction.

*Pathogens and toxins have been used, even in the recent past, to threaten and harm people, to disrupt society, economies and the political status quo (5).*

To some IAG members, this sentence was seen as a personal insult to their scientific research as opposed to a reference to the incident in the U.S. Regrettably, individuals do not always look at references. The starting point for most scientists is that organizations working with pathogens in the past and in the present are doing so to benefit, not hurt, society. Having this type of sentence so soon in the document may deter otherwise interested parties from reading the document. It implies scientists are part of the problem rather than part of the solution. Also, for some, due to the amount of people who die every day from naturally occurring infectious disease, the reference to the anthrax attacks in the U.S. is not a compelling example as to why biosecurity should be an issue of global priority.

#### *Document’s Relationship with National Legislation*

Pages two and three of the document include references to actions taken at the national level to enhance biological security, though specific examples are not offered.

---

<sup>1</sup> Reference number 5 from the WHO Laboratory Biosecurity Guidance Document, (5) 2001 Anthrax attacks ([http://en.wikipedia.org/wiki/Cases\\_of\\_anthrax](http://en.wikipedia.org/wiki/Cases_of_anthrax))

*...several regulatory approaches to limit unauthorized access to biological agents and toxins available in biological laboratories are now being carefully considered and implemented worldwide.*

*In recent years, several countries have developed and implemented laboratory biosecurity legislation to regulate possession, use and access to biological materials to permit their appropriate use.*

One IAG member suggested the creation of a searchable database for such legislation.

IAG members also discussed reconciling existing legislation with the suggestions of the guidance document. For example, page 19 of the document suggests establishing effective control procedures for VBM. Individuals from countries with existing legislation would like the document to provide guidance on how to assess the viability of their current measures and, if found to be insufficient, how to improve these measures.

#### *Physical and Personnel Security*

IAG members expressed that they would have appreciated additional information on these topics in the guidance document.

#### *Structure*

An IAG member suggested a new structure for the document, which is illustrated below.

### **Aim**

To raise awareness of the need for global biosecurity

### **Objectives**

1. Provide the reasons for improving biosecurity (to include historic use and current threats).
2. Provide a clear separation between the terms biosafety and biosecurity so that the understanding, if not the actual term, can be translated into all languages. Also include similarities/conflicts.
3. Describe a good structure for biosecurity management and how it would interact with biosafety.
4. Provide a formula for nations to assess their existing framework.
5. Provide detailed guidance on the reasons and methodology for Personnel Security (i.e. Do you know who you have employed and who has access to pathogens and toxins?). This is the most cost effective and important part of the whole process.
6. Provide guidance regarding physical security measures and how to prioritize them.
7. Introduce the reader to the concept of material control and accountability.
8. Outline guidance for transportation security.

### *Gap Analysis*

According to page six, the WHO Biosecurity guidance document states that it is a goal-setting document, and should be interpreted as suggestive rather than prescriptive.

*Member States are encouraged to introduce these concepts within their local contexts and to develop national frameworks for the security of biological materials they consider valuable, in recognition of the ever-increasing importance of global regulatory harmonization (10)<sup>2</sup>. In the absence of national regulatory guidance, laboratory managers are encouraged to consider adopting a biorisk management approach adapted to their particular situation and developing guiding principles to be implemented in response to the specific needs of their facilities.*

The guidance document stresses that, given the current global situation, additional regulation and biological risk management are required. However, without a clear assessment of current capabilities, it is difficult to determine the shortcomings of current systems and how to measure if biological risks are being minimized, save counting the number and types of incidents such as accidental release or laboratory acquired infections. Some countries are still working to enhance their laboratory biosafety measures; the guidance document could provide suggestions for integrating biological risk management while enhancing laboratory biosafety, and possibly for increasing laboratory capacity. An integrated approach would make sense for laboratories with limited resources as opposed to efforts to enhance biosafety and biosecurity separately. It would also be helpful if the WHO could provide guidance to countries on how to assess the efficacy of their existing policies, guidelines, best practices and regulations relating to the concept of biorisk management. This would provide a metric that could be used to monitor improvements and document best practices.

### *Conclusion*

All IAG members valued the opportunity to discuss the WHO Laboratory Biosecurity Guidance document. It is extremely important for the group's activities to continue to have a representative from the WHO involved as a member. The ability to have the document in Russian, in addition to English, opened up the discussion to several scientists who have biosafety and biosecurity responsibilities, but have had limited exposure to this document due to language barriers. The IAG would like to continue to stay connected with WHO as the Laboratory Biosecurity Guidance document evolves over time.

---

<sup>2</sup> Ibid, (10) Sundelius B, Grönvall J. Strategic dilemmas of biosecurity in the European Union. *Biosecurity and bioterrorism: biodefense strategy, practice, and science*, 2004, 2(1):17-23.