

**2008 Meeting  
Geneva, 1-5 December 2008**

**Meeting of Experts  
Geneva, 18-22 August 2008**  
Item 5 of the provisional agenda  
**Consideration of national, regional and  
international measures to improve biosafety  
and biosecurity, including laboratory safety  
and security of pathogens and toxins**

**ENHANCING BIOSECURITY IN THE LIFE SCIENCES:  
RECOMMENDATIONS OF THE U.S. NATIONAL SCIENCE  
ADVISORY BOARD FOR BIOSECURITY**

Submitted by the United States of America

**Background**

1. Life sciences research is critical to our understanding of life at all levels – ecosystems, organisms, biological systems, organs, cells, and molecules. Advances in the life sciences have led to new pharmaceuticals, diagnostic procedures, preventive strategies, treatments, and cures for myriad acute and chronic diseases and conditions. In addition, life sciences research has contributed to improvements in animal and plant health and the food supply.
2. However, the information gained from life sciences research also could be used for destructive purposes that threaten the health and safety of life on our planet, presenting a “dual use” dilemma. This threat has been recognized and articulated by individuals, organizations, and governments around the world. In recent years, there have been increasing calls globally to address the possibility that new information from life sciences research could be subverted for malevolent purposes and to consider new biosecurity measures to minimize this risk.

**The U.S. Government Response**

3. Recognizing the importance of addressing this issue, the U.S. Government established the National Science Advisory Board for Biosecurity (NSABB) (<http://www.biosecurityboard.gov>) to recommend strategies for overseeing and responsibly handling life sciences research that could yield information and technologies with the potential

for benevolent and malevolent application – or “dual use research.” The NSABB has up to 25 voting members with expertise in a diverse array of professional fields, including microbiology, molecular biology, infectious diseases, epidemiology, biosafety, biosecurity, plant health, food production, bioethics, national security, intelligence, and law. The Board also has “ex officio” members from all of the Federal agencies with an interest in the conduct and support of life sciences research.

4. The NSABB was charged with proposing an oversight framework for the identification, review, conduct, and communication of life sciences research with dual use potential that considers and protects national security concerns and the progress of the life sciences. Since the Board is a Federal advisory committee, its recommendations are not U.S. policy. Rather, they are the thoughtful consensus views of a group of non-governmental experts that provide a framework for the Federal government to develop a comprehensive system for the responsible identification, review, conduct, and communication of dual use research.

### **The NSABB’s Recommendations for Oversight of Dual Use Research**

5. In June 2007, the NSABB issued a report titled, “Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information”<sup>1</sup>. A premise of the report is that policies should promote a free and open exchange of information in the life sciences to the maximum extent possible, while fostering awareness of the dual use potential of research, strengthening a culture of understanding and responsibility within the scientific community and the public, and instituting oversight procedures to minimize the risk of misuse of research information.

#### Elements of the Oversight Framework

6. In its report, the NSABB identifies principles that should underpin the oversight of dual use life sciences research, lists key features of such oversight (e.g., federal guidelines, awareness and education, evaluation and review of research for dual use potential, assessment and management of risk, compliance, and periodic evaluation at the institutional and federal levels of the impact and effectiveness of oversight procedures), and proposes roles and responsibilities for researchers, institutions, the institutional review entity, and the NSABB and other federal government entities. The report describes the major steps in local oversight of dual use life sciences research, including evaluation of life sciences research for its dual use potential, as well as identification, review, and communication of research with the greatest dual use potential – known as “dual use research of concern.”

#### Criterion and guidance for identifying dual use research of concern

7. A fundamental task of the NSABB was to develop criteria for identifying dual use research of concern. The proposed criterion is “research that, based on current understanding, can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied by others to pose a threat to public health and safety, agricultural crops and

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<sup>1</sup> Available online at: [http://www.biosecurityboard.gov/Framework%20for%20transmittal%200807\\_Sept07.pdf](http://www.biosecurityboard.gov/Framework%20for%20transmittal%200807_Sept07.pdf).

other plants, animals, the environment, or materiel.” As guidance for those assessing research for its dual use potential, the NSABB identified seven broad categories of information that might be generated by life sciences research that has a high potential for being dual use of concern.

8. NSABB members agreed that principal investigators, using the criterion described above, should conduct the initial evaluation of their research for its potential as dual use research of concern. Those projects initially identified as dual use research of concern—which are estimated to be few—would undergo additional institutional review that involves interactive discussion among reviewers to assess the potential ways information, technologies, or biological agents from the research could be misused to pose a threat; the likelihood that the information might be misused; the potential impacts of misuse; and the strategies for mitigating the risks that information from the research could be misused. To guide this review process, the NSABB developed “Points to Consider in Risk Assessment and Management of Research Information That Is Potentially Dual Use of Concern”(Appendix 4 of the “Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information”report<sup>1</sup>).

#### Responsible communication

9. The NSABB also recommends strategies and has developed tools to help ensure that research information with dual use potential is communicated responsibly and in a manner that addresses both biosecurity concerns and the need for open sharing of research results and technologies. These tools include a set of principles for the responsible communication of research with dual use potential; points to consider for identifying and assessing the risks and benefits of communicating research information with dual use potential, including options for the communication of such research information; and considerations for the development of a communication plan for research with dual use potential.

#### Codes of conduct

10. In fulfillment of one of its specific charges, the NSABB also provides recommendations on the development of a code of conduct for scientists and all laboratory personnel that could be adopted by professional organizations and institutions engaged in the performance of life sciences research. These are articulated in “Considerations in Developing a Code of Conduct for Dual Use Research in the Life Sciences”(Appendix 3 of the “Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information” report<sup>1</sup>) which provides a conceptual foundation for understanding the dual use issue, describes the nature and utility of codes of conduct, articulates the fundamental principles of responsible conduct with regard to dual use research, and provides guidance on addressing the dual use issue in specific phases of the research process.

#### Outreach and education

11. Since its inception, the NSABB has been concerned that awareness and appreciation of the significance of the dual use issue is low among life scientists. Thus, the NSABB’s report underscores the importance of education and training in biosecurity issues for all life scientists and describes previous, ongoing, and future approaches to meeting the aims of promoting awareness and understanding. Among other strategies, the NSABB has called for the

development of educational tools. Toward that end, the NSABB has established a Working Group on Outreach and Education that will propose awareness-building and educational strategies for the U.S. Government and private sector to implement.

#### International engagement

12. Since life sciences research is a global endeavor, the NSABB established a Working Group on International Engagement to foster international dialogue about dual use research oversight. The Working Group has held two roundtables to date and is planning a third in November 2008. These meetings have included participants from a diverse array of nations and have inspired them to continue the dialogue upon return to their home country.

#### **Next Steps**

13. The U.S. Government is in the process of seeking broad input from the public on the issues presented in the NSABB's proposed Oversight Framework. The process includes a Public Consultation meeting held July 15, 2008 to offer a public forum for discussion and comment on the NSABB's report. When the consultation process is concluded, the U.S. Government will then determine how to take the NSABB's recommendations and public commentary into account for the purpose of future policy making in this arena.

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