

Information Note¹

- Event:** *Applications for and Security Aspects of Synthetic Biology*
- Organizers:** International Council of Life Sciences (ICLS), BGI, and the International Association for Synthetic Biology (IASB). The meeting is being sponsored by the UK Foreign and Commonwealth Office, the US Federal Bureau of Investigations and the Alfred P. Sloan Foundation
- Date and venue:** 7-8 March, 2013, Hong Kong Special Administrative Region of the People's Republic of China
- Participants:** *States:* Canada; People's Republic of China; Japan; UK; US
- International organizations:* 1540 Committee Group of Experts; INTERPOL; Biological Weapons Convention-Implementation Support Unit (BWC-ISU); Organization for the Prohibition of Chemical Weapons (OPCW); United Nations Office of Disarmament Affairs (UNODA);
- Non-Governmental Organizations, Industry, Academia, and Other Entities:* Alfred P. Sloan Foundation; ANBio-Brazil; Chinese University of Hong Kong; Desktop Genetics; ICLS; IASB; GenScript; Hong Kong University of Science and Technology; Japan BioIndustry Association; Joint Genome Institute; Malaysian Biotechnology Information Centre; MIT; Pakistan Academy of Sciences; Shanghai Generay Biotech Co., Ltd; Taihe Biotechnology Co., Ltd; Tokyo Institute of Technology; University of Hong Kong; University of Technology-Malaysia

1. **Objectives of the workshop**

The meeting *Applications for and Security Aspects of Synthetic Biology* aimed to bring together global experts from policymaking, law enforcement, industry, academia, research and development, international organizations, and non-governmental organizations to discuss how best to develop and exploit synthetic biology safely and responsibly. The meeting followed on and built upon meetings in Heidelberg, Germany and Shanghai, People's Republic of China, of last year. The main focus of the meeting was the advancement and future development of synthetic biology, along with a code of conduct that promotes biosafety and biosecurity in commercial transactions in gene synthesis products.

2. **Background**

Synthetic biology refers broadly to the design and construction of biological devices and systems and it has been the subject of governments' and science community's initiatives or calls for responsible governance and address of the ethical, societal and legal implications including licensing, monitoring, and codes of conduct, in order to reduce the risk of occupational hazards, accidental release, and/or deliberate misuse. As a scientific field, synthetic biology spans many disciplines including biology, engineering, systems science, genomics, genetic engineering and bioinformatics. Synthetic biology developments

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promises rapid and spectacular advances in virtually every field of human endeavor, including agriculture, medicine, energy, materials sciences, energy, fuel and the environment. However, by reducing the time span from concept to application, synthetic biology also has the potential to facilitate the creation of novel biological weapons, complicate interdiction efforts, and increase the risk of accidental risk to life and the environment if appropriate safeguards are not in place.

To address the problem of outsourced gene synthesis, the International Gene Synthesis Consortium (IGSC) and the International Association for Synthetic Biology (IASB) have separately developed Codes of Conduct for their members to seek to ensure that they do not unwittingly fulfill gene synthesis orders for those who would misuse the science for weapons purposes. These Codes require members to:

- Check orders against databases of dangerous gene sequences and suspect clients;
- Maintain records of all orders; and
- Have established contacts with law enforcement agencies so they know whom to call when there is a suspicious order

Developing industry-specific Codes of Conduct was a major step towards addressing the risk that legitimate trade synthetic genes may be unwittingly subverted for nefarious purposes. At the time of their introduction, these Codes covered companies providing upwards of 80% of the world's supply of synthetic genes. However, gene foundries (companies that synthetically manufacture genes to order commercially) are appearing in the People's Republic of China and their share of the world trade in synthetic genes has grown considerably and continues to do so while other emerging centers are in the Far East, such as India and Malaysia. Efforts are underway to recruit companies in these emerging markets to adhere to the Codes in one form or the other. ICLS organized a meeting (in partnership with IASB, IGSC, the UK Foreign and Commonwealth Office and the US Federal Bureau of Investigations) in Heidelberg, Germany in March 2012 to initiate discussion on how to globalize adherence to the Codes. A further meeting was held in Shanghai, People's Republic of China in August 2012, organized by the James Martin Center for Non-Proliferation Studies (part of the Monterey Institute for International Studies). This event was conducted with US State Department funding and with the participation of, inter alia, IASB, IGSC and ICLS) to introduce Chinese corporations to the synthetic biology governance issues and the Codes.

3. **Highlights**

Plenary discussions and formal presentations addressed the recent developments in synthetic biology, codes of conduct and the supply chain, compliance and implementation of codes and relevant national and international obligations, as well as the topic of a potential global forum to address policy aspects of synthetic biology. Participants agreed that the *IASB Code of Conduct for Best Practices in Gene Synthesis* (online at: <http://iclscharter.org/files/2012/11/The-IASB-Code-of-Conduct-for-Best-Practices-in-Gene-Synthesis.pdf>) and the *IGSC Harmonized Screening Protocol: Gene Sequence & Customer Screening to Promote Biosecurity* (online at: <http://iclscharter.org/files/2012/11/IGSC-Harmonized-Screening-Protocol.pdf>) are comprehensive in nature and no new codes are necessary.

Representatives from Brazil, Canada, Japan, Malaysia, Pakistan, People's Republic of China, UK, and US highlighted the biosafety / biosecurity challenges posed by synthetic biology and the policy initiatives to address them at the national level. Of note, the FBI representative discussed the US Government's Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA (full text online at: <http://www.phe.gov/Preparedness/legal/guidance/syndna/Documents/syndna-guidance.pdf>) and the role of law enforcement in engaging with and assisting industry in voluntarily adopting its principles. The UK representative informed the participants about the recently released report called *A Synthetic Biology Roadmap for the UK* which was produced by an independent panel of experts for the government's

Department for Business Innovation and Skills and sets out a shared vision for realizing the potential of synthetic biology in the UK. The Roadmap is available online at: <http://www.rcuk.ac.uk/documents/publications/SyntheticBiologyRoadmap.pdf> and its companion document is called *The A3 Synthetic Biology Roadmap Landscape* (online at: <http://www.rcuk.ac.uk/documents/publications/SyntheticBiologyRoadmapLandscape.pdf>).

The BWC-ISU representative noted that all relevant scientific and technological advances in biotechnology (including synthetic biology) are covered by the BWC and this fact has been reaffirmed in the Review Conferences' Final Declarations. The 1540 expert brought to the attention of the participants the obligations on all States relating to resolution 1540 (2004) to adopt, inter alia, legislation to prevent the proliferation of biological weapons and their means of delivery, and establish appropriate domestic controls over related materials to prevent their illicit trafficking. She also emphasized the definition of "related materials" for the purpose of resolution 1540 (2004) as being linked to materials, equipment and technology covered by "relevant multilateral treaties and arrangements, or included on national control lists..." Thus, since the BWC applies to biological agents and toxins that are synthetically produced or modified, they also fall under the purview of resolution 1540 (2004). The 1540 expert also noted that the 1540 Committee's own tool for monitoring the implementation of the resolution, the 1540 matrix, has a specific field on "genetic engineering" and a blank field for other measures where the committee may record regulatory or policy measures on synthetic biology governance if reported by States or posted on the governmental websites, with a view toward sharing effective practices amongst governments. Currently, only the US 1540 matrix reflects measures taken in synthetic biology governance.

4. **Additional comments**

For further information, please contact the 1540 Committee's Group of Experts by e-mail at 1540experts@un.org.