Meeting Report: Security Aspects of Synthetic Biology

5-7 March, 2012, Heidelberg, Germany

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Introduction

Advances in synthetic biology, genomics, genome design tools and information technology raise the risk that commercial producers of synthetic genomes might be used unwittingly to assist in the production of designer biological weapons.

To address this issue, two associations, the International Association for Synthetic Biology (IASB) and the International Gene Synthesis Consortium (IGSC), created independent codes of conduct based on customer screening, gene sequence screening, record keeping and points of contact with law enforcement. Subsequently, the US Department of Health and Human Services (DHHS) in October 2010[1] issued customer and sequence screening guidelines for the sale of synthetic genes.

The International Council for the Life Sciences (ICLS) convened a meeting of industry representatives, government officials, academics, nongovernmental organizations (NGOs), international agencies, clients of the gene synthesis industry and citizen scientists in Heidelberg, Germany in March 2012. The meeting addressed practical issues of implementing and developing the codes, the feasibility of creating a 'seal of approval' for those implementing the codes, and how to promote wider adoption of the codes. It also addressed how to expand the scope of the codes to others involved in synthetic biology, such as academics, citizen scientists and corporations with in-house synthetic biology capabilities. A document recording the outcomes of the meeting was agreed by participants, together with a plan of action, to continue the efforts towards global adoption of the codes (Appendix A).

To raise awareness of, and advance the tenets of the codes, an international conference is planned in conjunction with BGI's International Genomics Conference in Hong Kong in November-December 2012.

[1] The DHHS "Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA" is at http://www.phe.gov/Preparedness/legal/guidance/syndna/Documents/syndna-guidance.pdf

Next Steps

The immediate next steps are for IASB and IGSC members to follow up on technical issues per the Agreed Outcomes document. These efforts are already underway. In addition, the following activities are envisaged:

1. ICLS and BGI to coordinate in adding a two-hour session on synthetic biology into the agenda of the International Conference on Genomics in Europe, being organized by BGI in Copenhagen, Denmark 24-26 May 2012. ICLS will provide the agenda and suggested speakers;

2. A small working group will create a generic version (i.e. no references to national authorities or national regulations) of the US Department of Health and Human Service's "Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA" with a view to promoting this internationally and through the BWC Meetings of Experts;

3. ICLS will contact INTERPOL to assess their ability to take on some international responsibility with regard to both customer screening and follow up action if suspect orders are identified;

4. ICLS will coordinate with the Implementation Support Unit of the Biological and Toxin Weapons Convention (BWC-ISU) on the possible participation of representatives from IASB and IGSC and other experts in the BWC meeting of experts scheduled for July 2012 in Geneva.

ICLS and BGI will coordinate with those at the Heidelberg meeting to organize a one-day session during BGI's International Conference on Genomics in Hong Kong (29-30 November 2012) and a one-day workshop on 1 December 2012 to publicize and promote the industry's codes of conduct and follow on the work of the Heidelberg meeting.

Conclusion

This was an important meeting, being the first time the global gene synthesis industry had gathered together since the drafting of the various codes and guidelines. It thus offered the first opportunity to exchange ideas on what was working and where improvements could be made.

The meeting also marked the first step in building a global forum for discussing all policy, safety and security aspects of synthetic biology in order to facilitate its rapid, safe and responsible development and to ensure that all players globally are operating to the same high standards. This will, as seen in the record of the outcomes, require broader involvement in subsequent activities, both geographically and in terms of institutions and sectors, to build upon the excellent work already done by other groups.

Acknowledgments

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Meeting participants in Heidelberg, Germany

Appendix A
Synthetic Biology: Addressing Global Security Outcomes of the Meeting

A meeting was held in Heidelberg, Germany 5-7 March 2012 to address global security issues arising from developments in synthetic biology. The meeting was attended by participants from companies that synthesize genes, their clients, governmental and intergovernmental agencies, non-governmental organizations, academia and citizen scientists from seven countries and two international organizations. The following has been approved by the participants as representative of the sense of the meeting. It is understood that the government officials in attendance, in agreeing that this is a fair representation of the meeting, have not committed their governments to any of the positions or decisions taken.

Client Screening

It was agreed that client screening was of primary importance and that members of the International Association for Synthetic Biology (IASB) and the International Gene Synthesis Consortium (IGSC) would find value in some standardization of how they broached the issue of screening with their clients. To this end, it was agreed to establish a small working group to draft texts on client and sequence screening for prominent display on constituent companies' web sites, for inclusion in their terms and conditions, and as necessary for use in flyers. 31 March 2012 was set as the deadline for the group to circulate draft language to the broader membership.

Members of IASB, IGSC and the Biological and Toxin Weapons Convention Implementation Support Unit (BWC-ISU) also called for more governmental support in client education on the need for both client and sequence screening.

Members of IASB, IGSC, academia and citizen science groups also suggested that a licensing/registration system for purchasers of synthetic genes, perhaps with different levels such as private and institutional licenses, might be desirable, but would be a matter for governments to establish. In the absence of a licensing system, members of the citizen science groups asked the gene synthesis companies for greater clarification of what would be required on their part to enable gene synthesis companies to accept orders for synthetic genes from citizen scientists.

Sequence Screening

It was also acknowledged that, while both IASB and IGSC had adopted sequence screening procedures which met or exceeded the requirements of the US federal guidance, the issue of sequence screening would soon become more complexand might require screening for novel metabolic pathways and constructs which might code for toxic or pathogenic products. Furthermore, the meeting noted that there are issues arising from how to interpret lists such as those of the Australia Group and the Select Agent List, which are enumerated at the organism level, when sequence screening is conducted at the gene level. It was agreed to set up a working group to address issues related to sequence screening. The meeting's participants noted that national governments may take concrete technical and other steps at the national and international levels to promote effective sequence and customer screening. Governments and commercial gene synthesis providers should collaborate to identify and implement those concrete steps over time.

It was also agreed to discuss further the idea of holding a meeting with Synthetic Genomics Inc. to discuss the utility of its Archetype tool and other tools and methods for sequence screening.

In relation to both client and sequence screening, it was agreed that members of IASB and IGSC have developed robust rules but, as already envisaged in their codes, they will need to monitor continually developments in the field so that these codes may be adaptive to technological and market changes.

Points of Contact

The meeting acknowledged the value of establishing points of contact between gene synthesis companies and others working in synthetic biology on the one hand, and law enforcement officials on the other when orders of concern are received along the lines of the US Federal Bureau of Investigation's (FBI) Synthetic Biology Tripwire Initiative.

The Implementation Support Unit of the BWC noted the meeting's request to make available the contact details of the BWC Points of Contact of which there are currently 79.

The meeting also recommended engaging INTERPOL as the potential international point of contact where national authorities lacked the technical competence to provide national law enforcement points of contact. The International Council for the Life Sciences (ICLS) agreed to follow up with Interpol counterparts by 30 April 2012. It was noted that INTERPOL had been unable to be at this meeting but had requested to be informed of its outcomes and included in future activities.

Seal of Approval

The meeting saw that there could be value in establishing a 'seal of approval' for gene synthesis companies to establish that they were following good business practice as laid out in the IASB and IGSC codes of conduct and the US DHHS Guidance. However, there was not complete agreement on the objectives, value, mechanism or funding for such as system. Areas of potential value were identified as including:

- providing reassurance that the science was proceeding responsibly thereby helping to maintain public trust in the sector;
- reducing the burden on clients, particularly for smaller clients such as individual principal investigators, in conducting due diligence when purchasing synthetic genes; and
- helping in the globalization of the codes of conduct in approaches to corporations in Asia, the Middle East and Latin America.

It was agreed that companies could now, on an individual basis, engage private third party auditors to certify that they were in compliance with the US federal screening guidance and advertise this on their marketing collateral. It was further agreed that this issue should be revisited at the November meeting in Hong Kong to assess the value of this approach drawing on the experience of those who had chosen to be certified.

Expanding Engagement

This discussion addressed how to involve more stakeholders in efforts to ensure that synthetic biology was pursued safely and responsibly, including more players in the synthetic gene sector,

and others in academia and elsewhere active in basic research or applied R&D. It was acknowledged that different commercial entities, such as current oligo synthesizers, fabrication centers or other intermediaries, may need to be brought into the codes concerning the manufacturing, handling and trade in synthetic genes. It was also agreed that further consideration was required on how to address the issue of clients whose orders are rejected either in compliance with applicable laws and regulations or due to the commercial considerations arising from the cost of compliance.

It was agreed to engage experts on the transport of biological materials and customs controls to participate in subsequent meetings.

A broad range of engagement activities were discussed, aimed at leveraging existing networks engaged in awareness raising about and promoting biosafety and biosecurity issues and encouraging transparency. Examples of networks to engage would be the International Federation of Biosafety Associations, the Biosafety and Biosecurity International Conference Process and the EU/UNICRI CBRN Centres of Excellence.

ICLS undertook to develop and seek inputs into a calendar of events for synthetic biology activities internationally for circulation to participants in the meeting and others who could not attend. ICLS also agreed to coordinate activities with other participants on a case-by-case basis to:

1. engage with NGOs which express concerns with synthetic biology ;

2. engage the Six Academies, the Inter Academy Panel, BIO, AAAS and Imperial College; and

3. ensure representation of the meeting participants in major conferences such as Synthetic Biology 6.0 (9-11 July 2013), Imperial College's Environmental Impacts of Synthetic Biology conference (June 2013) and others.

The FBI representatives at the meeting undertook to bring up biosecurity issues in a planned conference with corporate global security officers and offered to engage its international WMD offices.

Global Outreach

The meeting welcomed the ICLS and BGI announcement of their plan to hold an international conference on synthetic biology and security issues in Hong Kong on 1 December 2012. This conference was to coincide with BGI's International Genomics Conference 28-30 November 2012, the last day of which would be dedicated to synthetic biology issues.

Participants were informed of the opportunities offered by the July 2012 BTWC Meeting of Experts in Geneva. The BWC-ISU undertook to convey to States Parties the outcome of this meeting. The BWC-ISU further offered to facilitate the participation of IASB and IGSC representatives in the meeting and to introduce them to representatives of States Parties to the Biological and Toxin Weapons Convention.

Another group of participants agreed to coordinate on how best to promote the concepts of screening guidance to the States Parties of the Biological and Toxin Weapons Convention.

Glossary

Synthetic biology	There are varying definitions of synthetic biology. A useful operational definition is: a. the design, engineering and construction of new biological parts, devices and systems; and, b. the redesign of existing biological systems for useful purposes.
Genomics	The study of the genomes of organisms. The field includes efforts to determine the entire DNA sequence of organisms and fine-scale genetic mapping. The field also includes studies of intragenomic phenomena such as heterosis, epistasis, pleiotropy and other interactions between loci and alleles within the genome. In contrast, the investigation of the roles and functions of single genes is a primary focus of molecular biology or genetics. Research of single genes does not fall into the definition of genomics unless the aim of this genetic, pathway, and functional information analysis is to elucidate its effect on, place in, and response to the entire genome's networks.
Gene foundry	A corporation organization that synthesizes genes and genomes to order.
Fabrication center (Fab)	Named after the fabrication, or Fab, service laboratories established in the early semiconductor industry to make it easier for academic and small industrial labs to design and manufacture small quantities of custom chips. Biological fabrication centers aim to provide industrial and academic partners tools to facilitate and speed up the design, construction, and characterization of engineered genetic systems from standard biological parts in order to 'allow many academic researchers to rapidly prototype, test, and translate their foundational discoveries and ideas into practice'.
Synthetic biology constructs	New biological metabolic pathways designed and constructed using the techniques of synthetic biology.
Citizen scientist	Amateur or non-professional scientist who conducts scientific research. Citizen science has been defined as "the systematic collection and analysis of data; development of technology; testing of natural phenomena; and the dissemination of these activities by researchers on a primarily avocational basis".[2]

[2] See www.openscience.org.

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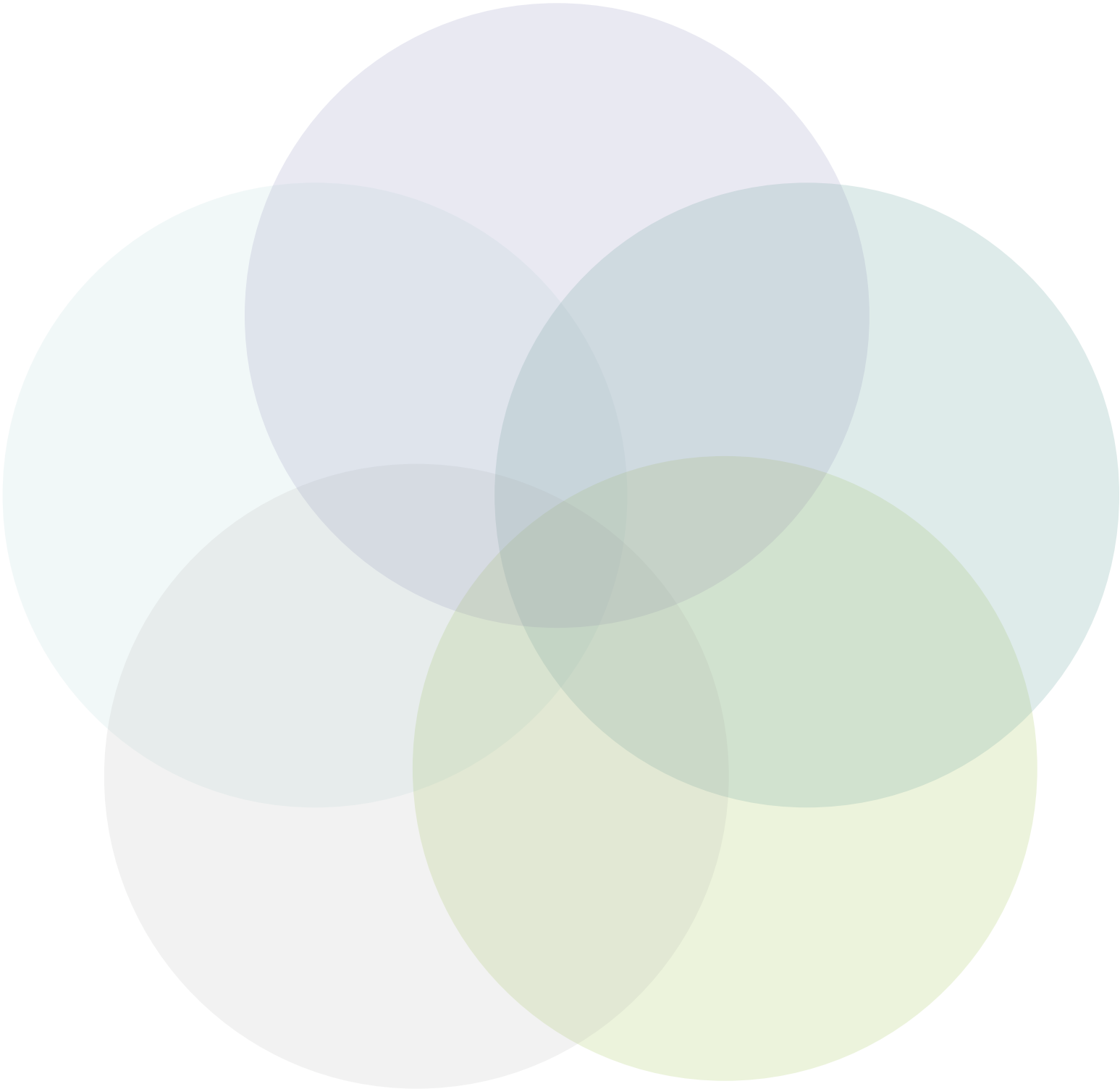

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