DNA Synthesis Screening and the Biological Weapons Convention

2024 Meeting of States Parties

16 December 2024

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Agenda

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- **Why talk about DNA synthesis screening?**
  T. Alexanian
- **BWC Agreements related to DNA synthesis screening**
  P. Millett
- **Filling the information gap with a global map of DNA synthesis providers and policies**
  M. Ameneiros
- **Common Mechanism: a free, open-source tool to support synthesis screening**
  T. Alexanian

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Opening Remarks

Piers Millett

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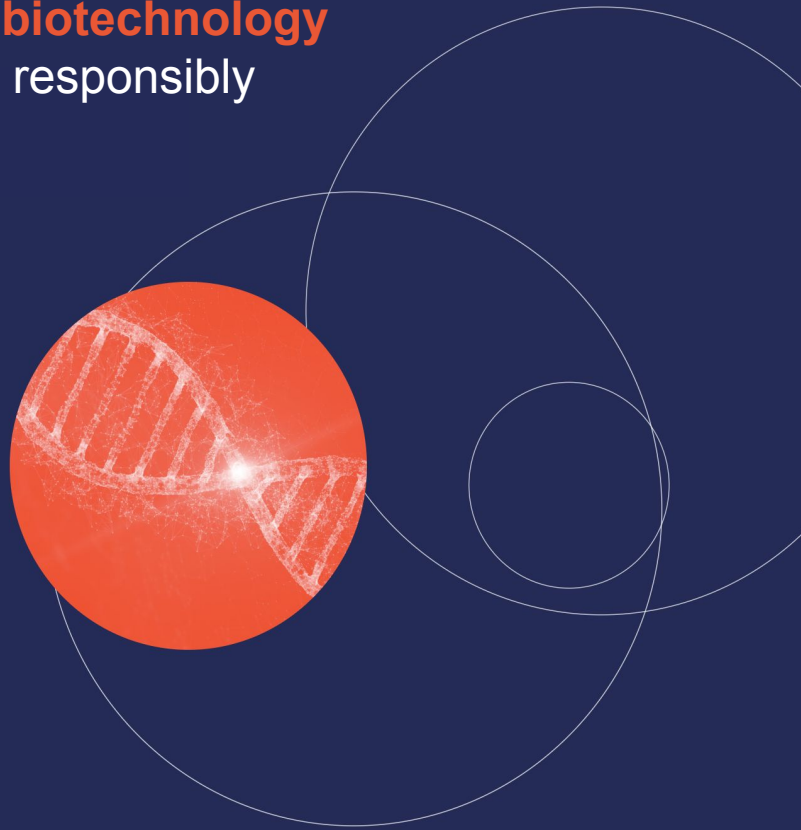
Safeguarding modern bioscience and biotechnology
so it can advance and flourish safely and responsibly

IBBIS works with global partners
to strengthen biosecurity norms and develop innovative tools to uphold them

Our work helps reduce the risk
of catastrophic events that could result from deliberate abuse or accidental misuse of bioscience and biotechnology



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Why talk about DNA synthesis screening?

Tessa Alexanian

Why talk about DNA synthesis screening?

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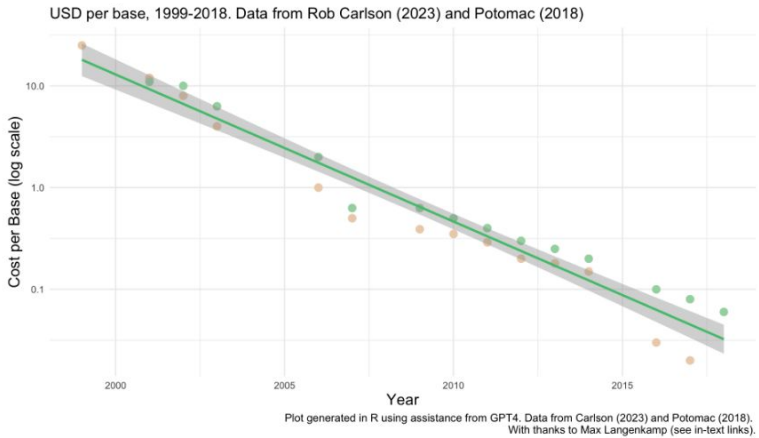
It’s easier than ever to read, write and edit DNA & RNA

Decreasing cost and increasing length



Custom Mail-Order

Benchtop Printers

Images: Founder’s Pledge, Aric Crabb/Bay Area News Group, DNAScript

Why talk about DNA synthesis screening?

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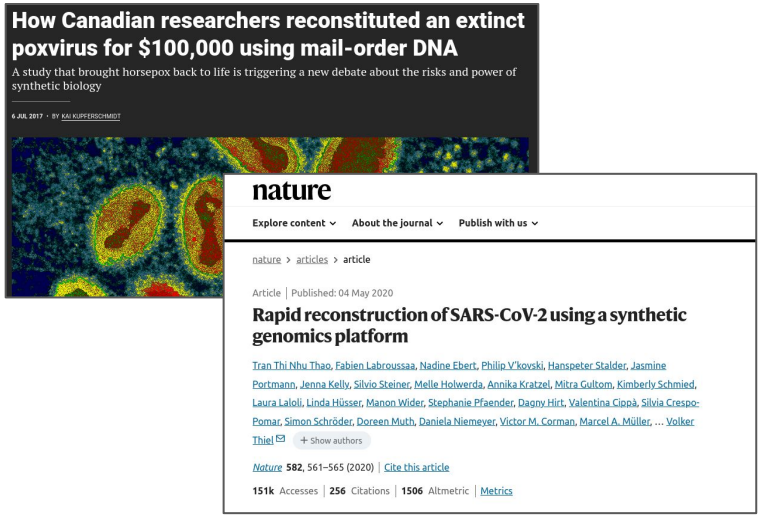
Synthetic DNA could be accidentally or deliberately misused

Acquisition: from a digital sequence to functional pathogen



How Canadian researchers reconstituted an extinct poxvirus for $100,000 using mail-order DNA

A study that brought horsepox back to life is triggering a new debate about the risks and power of synthetic biology

6 JUL 2017 · BY KAI KUPFERSCHMIDT

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Article | Published: 04 May 2020

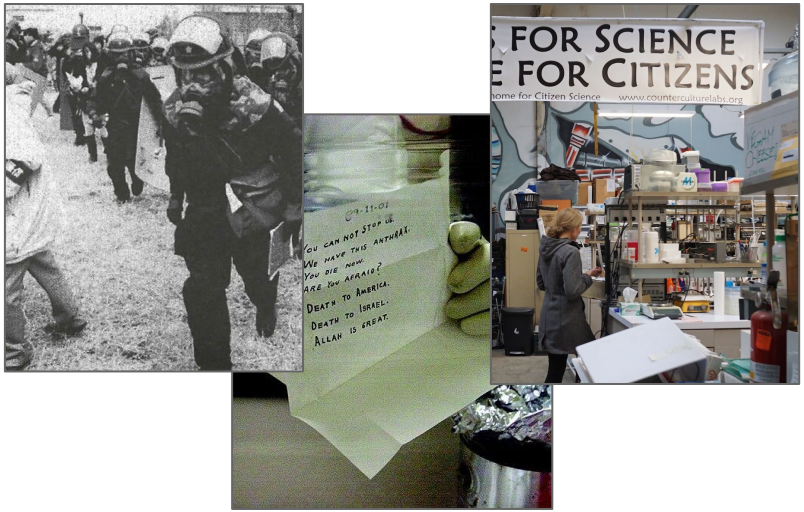
Rapid reconstruction of SARS-CoV-2 using a synthetic genomics platform

Tran Thi Nhu Thao, Fabien Labroussaa, Nadine Ebert, Philip V'kovski, Hanspeter Stalder, Jasmine Portmann, Jenna Kelly, Silvio Steiner, Melle Holwerda, Annika Kratzel, Mitra Gultom, Kimberly Schmied, Laura Laloli, Linda Hüsser, Manon Wider, Stephanie Pfaender, Dagny Hirt, Valentina Cippà, Silvia Crespo-Pomar, Simon Schröder, Doreen Muth, Daniela Niemeyer, Victor M. Corman, Marcel A. Müller, ... Volker Thiel + Show authors

Nature **582**, 561–565 (2020) | Cite this article

151k Accesses | **256** Citations | **1506** Altmetric | Metrics

Engineering: more people able to engineer pathogens and toxins



Images: Counter Culture Labs

Why talk about DNA synthesis screening?

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Synthesis screening standards have been developed for over 15 years

2006: pathogen acquisition concerns raised by journalist ordering smallpox DNA

This article is more than **17 years old**

Lax laws, virus DNA and potential for terror

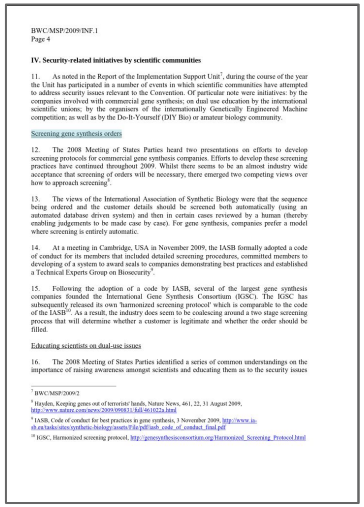
- **Loopholes mean anyone can order gene sequences**
- **Scientists back voluntary regulation as first step**

The smallpox virus last wreaked havoc on the human population in 1977 before a World Health Organisation programme eradicated it from the planet. It now exists only in government laboratories in the US and Russia.

But ordering part of this long-dead pathogen's DNA proved easier than anyone dared imagine. All it took was an invented company name, a mobile phone number, a free email address and a house in north London to receive the order by post.

What the investigation makes clear is that anyone, without any attempt to prove they are part of a legitimate research organisation, can order DNA sequences from any potential pathogen without fear of extensive questioning. In our case, VH Bio Ltd did not realise it was supplying part of the smallpox genome, but many scientists argue that it is the responsibility

2009: BWC MSP discusses screening gene synthesis orders, IGSC launches



BWC/MSP/2009/INF.1
Page 4

IV. Security-related initiatives by scientific communities

11. As noted in the Report of the Implementation Support Unit[7], during the course of the year the Unit has participated in a number of events in which scientific communities have attempted to address security issues relevant to the Convention. Of particular note were initiatives: by the companies involved with commercial gene synthesis; on dual use education by the international scientific unions; by the organisers of the internationally Genetically Engineered Machine competition; as well as by the Do-It-Yourself (DIY Bio) or amateur biology community.

Screening gene synthesis orders

12. The 2008 Meeting of States Parties heard two presentations on efforts to develop screening protocols for commercial gene synthesis companies. Efforts to develop these screening practices have continued throughout 2009. Whilst there seems to be an almost industry wide acceptance that screening of orders will be necessary, there emerged two competing views over how to approach screening[8].

13. The views of the International Association of Synthetic Biology were that the sequence being ordered and the customer details should be screened both automatically (using an automated database driven system) and then in certain cases reviewed by a human (thereby enabling judgements to be made case by case). For gene synthesis, companies prefer a model where screening is entirely automatic.

14. At a meeting in Cambridge, USA in November 2009, the IASB formally adopted a code of conduct for its members that included detailed screening procedures, committed members to developing of a system to award seals to companies demonstrating best practices and established a Technical Experts Group on Biosecurity[9].

15. Following the adoption of a code by IASB, several of the largest gene synthesis companies founded the International Gene Synthesis Consortium (IGSC). The IGSC has subsequently released its own 'harmonized screening protocol' which is comparable to the code of the IASB[10]. As a result, the industry does seem to be coalescing around a two stage screening process that will determine whether a customer is legitimate and whether the order should be filled.

Educating scientists on dual-use issues

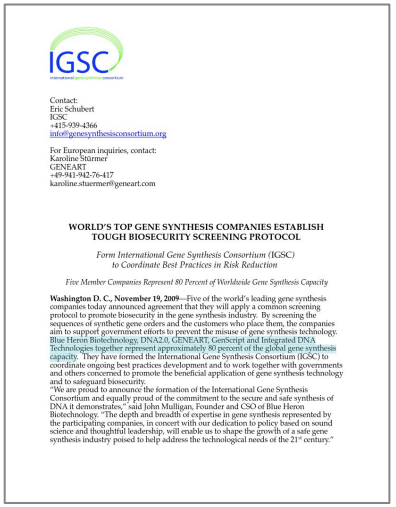
16. The 2008 Meeting of States Parties identified a series of common understandings on the importance of raising awareness amongst scientists and educating them as to the security issues

[7] BWC/MSP/2009/2

[8] Hayden, Keeping genes out of terrorists' hands, Nature News, 461, 22, 31 August 2009, http://www.nature.com/news/2009/090831/full/461022a.html

[9] IASB, Code of conduct for best practices in gene synthesis, 3 November 2009, http://www.ia-sb.eu/tasks/sites/synthetic-biology/assets/File/pdf/iasb_code_of_conduct_final.pdf

[10] IGSC, Harmonized screening protocol, http://genesynthesisconsortium.org/Harmonized_Screening_Protocol.html



IGSC

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WORLD'S TOP GENE SYNTHESIS COMPANIES ESTABLISH TOUGH BIOSECURITY SCREENING PROTOCOL

Form International Gene Synthesis Consortium (IGSC) to Coordinate Best Practices in Risk Reduction

Five Member Companies Represent 80 Percent of Worldwide Gene Synthesis Capacity

Washington D. C., November 19, 2009—Five of the world's leading gene synthesis companies today announced agreement that they will apply a common screening protocol to promote biosecurity in the gene synthesis industry. By screening the sequences of synthetic gene orders and the customers who place them, the companies aim to support government efforts to prevent the misuse of gene synthesis technology. Blue Heron Biotechnology, DNA2.0, GENEART, GenScript and Integrated DNA Technologies together represent approximately 80 percent of the global gene synthesis capacity. They have formed the International Gene Synthesis Consortium (IGSC) to coordinate ongoing best practices development and to work together with governments and others concerned to promote the beneficial application of gene synthesis technology and to safeguard biosecurity.
"We are proud to announce the formation of the International Gene Synthesis Consortium and equally proud of the commitment to the secure and safe synthesis of DNA it demonstrates," said John Mulligan, Founder and CSO of Blue Heron Biotechnology. "The depth and breadth of expertise in gene synthesis represented by the participating companies, in concert with our dedication to policy based on sound science and thoughtful leadership, will enable us to shape the growth of a safe gene synthesis industry poised to help address the technological needs of the 21st century."

Images: Guardian,

Why talk about DNA synthesis screening?

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How do we balance access and security?

1. Recognize potentially risky sequences
toxins, pathogen genomes, virulence factors

2. Decide whether to trust user or customer
with risky sequences by screening legitimacy

Images: Waterloo iGEM 2015, Counter Culture Labs

Why talk about DNA synthesis screening?

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How do we balance access and security?

Sequence Screening

Customer Screening

Images: Waterloo iGEM 2015, Counter Culture Labs

Why talk about DNA synthesis screening?

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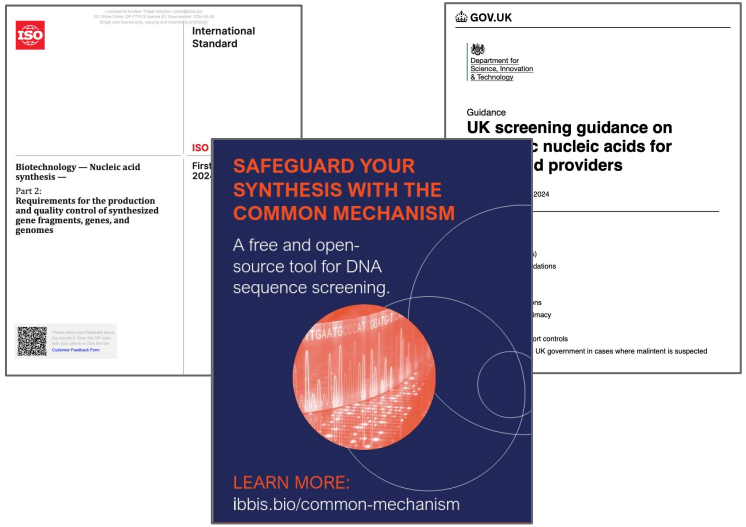
Why are we talking about screening right now?

Changing risk landscape: AI tools, long synthesis, biofoundries, benchtop printers

New standards, tools and regulations changing incentives around screening



Images: Kilobaser, Counter Culture Labs

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BWC Agreements related to DNA synthesis screening

Piers Millett

Working Paper: the BWC in the age of synthetic DNA

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The Biological Weapons Convention in the Age of Synthetic Nucleic Acids

Tessa Alexanian, Ayelet Berman, Isaac Heron, Piers Millett*

Abstract

This chapter examines whether and how the Biological Weapons Convention, UN Security Council Resolution 1540, and the Chemical Weapons Convention govern synthetic nucleic acids. Building on the rules of treaty interpretation, we demonstrate that synthetic nucleic acids fall within the scope of these international non-proliferation laws. We further argue that member states are obliged to adopt control measures, including with respect to synthetic nucleic acid. To this end, member states should adopt and implement synthesis screening procedures. This procedure requires synthetic nuclei acid providers to screen the sequences being ordered and the customers who are making the order. Synthesis screening as a method for preventing the proliferation of bioweapons is widely endorsed by the biosecurity community, including BWC member states. Moreover, it is compliant with BWC criteria as it enables to effectively control transfer of and access to prohibited nucleic acid, without hampering peaceful uses. Finally, we make three recommendations regarding the implementation of synthesis screening under the BWC. First, reaching an agreement that nucleic acid screening is consistent with BWC obligations. Second, integrating the topic into future BWC work through establishing a multistakeholder initiative for developing screening best practices. Third, harmonising international and domestic control measures governing synthetic nucleic acids.

Keywords Biological Weapons Convention, synthetic biology, biosecurity, nucleic acid synthesis, gene synthesis, export controls, treaty interpretation, dual-use research, biosafety, international law, nonproliferation

1 Introduction

Biological weapons are governed by three main international non-proliferation instruments: the 1975 Biological Weapons Convention (BWC), the 1997 Chemical Weapons Convention (CWC)[1], and 2004 Security Council Resolution 1540 (SCR 1540),[2] (hereinafter referred to jointly as the "international non-proliferation instruments" or the "international instruments"). Scientific and technological developments have opened the door to the potential development of new types of, or new ways to produce, biological or chemical weapons that were not envisaged when these instruments were adopted. Nucleic acid synthesis, often referred to as gene synthesis (the terms are used interchangeably), is one such technology. It allows for the

1

DNA synthesis screening helps to implement international obligations under the BWC, UNSCR 1540 and CWC

Article I: “origin or method of production”

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Biological weapons made using synthetic DNA are covered:

BWC Article I covers “biological agents or toxins **whatever their origin or method of production**, of types and in quantities that have no justification for prophylactic, protective, or other peaceful purposes”

Preamble defines intent of BWC is to “exclude completely the possibility of bacteriological (biological) agents and toxins being used as weapons”.

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Biological weapons made using synthetic DNA are covered:

7th BWC RevCon Final Dec: “Article I applies to all scientific and technological developments in the life sciences and in other fields of science relevant to the Convention.”

ISU Summary of RevCon agreements: “biological agents or toxins, naturally or **artificially created or altered, as well as their components, whatever their origin or method of production**”, including “synthetically produced analogues” of toxins.

Article III: “not to transfer to any recipient”

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States already committed not to transfer synthetic DNA destined to be used in weapons:

Article III: “...*not to transfer to any recipient whatsoever, directly or indirectly, and not in any way to assist, encourage, or induce any State, group of States or international organizations to manufacture or otherwise acquire any of the agents, toxins, weapons, equipment or means of delivery specified in Article I”*

Article III: Statements at Review Conferences

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States already committed not to transfer synthetic DNA destined to be used in weapons:

ISU Summary of RevCon agreements: “appropriate measures” for implementing Article III, include **“effective national export controls”** (called for by the Sixth, Seventh and Eighth Review Conferences) and **“measures to control access to and handling”** to **“ensure that biological agents and toxins relevant to the Convention are protected and safeguarded”** (Sixth Review Conference)

Article IV: “any necessary measures”

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States should take measures to prohibit and prevent synthetic DNA being used to make weapons:

BWC Article IV: “*take **any necessary measures to prohibit and prevent** the development, production, stockpiling, acquisition, or retention of agents, toxins, weapons, equipment and means of delivery specified in Article I…within the territory of such State, under its jurisdiction or under its control anywhere.”*

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States should take measures to prohibit and prevent synthetic DNA being used to make weapons:

ISU Summary of RevCon agreements: national measures adopted should “exclude use of biological and toxin weapons in terrorist or criminal activity” (Fourth Review Conference) and, more generally, to prevent anyone from carrying out activities prohibited by the BWC (Seventh and Eighth Review Conferences).”

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States should take measures to prohibit and prevent synthetic DNA being used to make weapons:

2011 Background Doc on S&T developments:

- “Advances in synthesis technology could challenge restrictions to access of certain agents provided by biosecurity provisions.”
- “Such measures are relevant to implementation of Article IV of the Convention, in reducing the risk of the exploitation of synthetic biology in violation of Articles I and III.”

Article X: “avoid hampering … peaceful purposes”

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Effective control measures should be designed to make a reasonable distinction between prohibited and peaceful uses:

Article X: *the Convention shall be implemented in a “manner designed to avoid hampering the economic and technological development of State Parties… or international cooperation in the field of peaceful biological activities….including the international exchange of biological agents and toxins….for… use or production of biological agents and toxins for peaceful purposes…”*

DNA Synthesis is not new to the BWC

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States Parties have already considered DNA synthesis screening:

- **2009 Meeting of Experts background document** described industry-led screening efforts.

BWC/MSP/2009/INF.1

- **7th RevCon S&T Review** by states included details of industry-led screening efforts

BWC/CONF.VII/INF.3/Add.1

DNA Synthesis is not new to the BWC

IBBIS

States Parties have already considered DNA synthesis screening:

2015 Iranian Working Paper:

- “developments in enabling technologies including high throughput systems for sequencing, synthesizing and analyzing DNA … should provide opportunities for enhanced cooperation and making vaccines, medicines and diagnostics production simpler, faster, cheaper and more efficient in developing countries”

- “new developments in the field of science and technology … shall, in no way, be the pretext to impose any trade limitations (sanctions) or hamper the economic or technological development of the States Parties”.

BWC/MSP/2015/MX/WP.15

DNA Synthesis is not new to the BWC

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States Parties have already considered DNA synthesis screening:

2018 NAM working paper: “There is a need to regulate these activities, to ensure that they do not lead to any concerns related to ethics, safety and security as well as any uses contrary to the Convention… Such regulation must, however, be undertaken in a manner that does not hamper scientific and technological developments that are in keeping with the spirit and letter of the Convention, which are of benefit, more especially to developing countries.”

BWC/MSP/2018/MX.2/WP.12

DNA Synthesis is not new to the BWC

IBBIS

States Parties have already considered DNA synthesis screening:

2018 Australian working paper: synthetic biology might be managed "by careful regulation of materials, including the distribution of synthetic DNA and methods for generating novel organisms"

BWC/MSP/2018/MX.2/WP.3

DNA Synthesis is not new to the BWC

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States Parties have already considered DNA synthesis screening:

2018 US working paper: “The capability to chemically synthesize or genetically engineer viruses … should serve as a strategic warning to BWC States Parties that biosecurity controls and preparedness – that rely primarily on controlling access to dangerous, existing pathogens – may be insufficient… Given that **gene synthesis is performed by an array of international companies, and benefits legitimate research in many BWC State Parties, achieving greater safety and security around it will require discussions at international fora.”**

BWC/MSP/2018/MX.2/WP.5

DNA Synthesis is not new to the BWC

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States Parties reached a common understanding on the importance of DNA synthesis screening:

2012 Meeting of States Parties Report: “States Parties identified opportunities for maximising benefits from these enabling technologies while minimizing risks of their application for prohibited purposes, including, for example, supporting … **the beneficial applications of gene synthesis technologies while ensuring their use is fully consistent with the peaceful object and purpose of the Convention.”**

BWC/MSP/2012/5

Conclusions: BWC and synthesis screening

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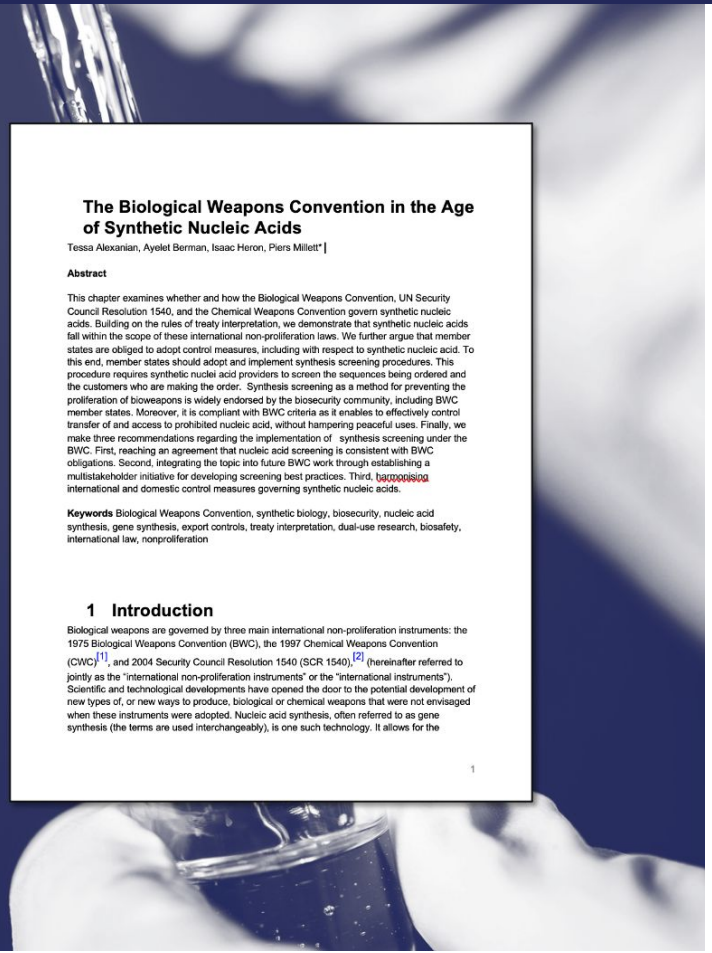
- BWC States Parties **highlighted DNA synthesis screening** as an important control measure
- Screening **allows for distinction between peaceful and prohibited** applications
- Screening is **consistent with BWC obligations**, including need for control measures that do not hinder peaceful use
- To meet their commitments under the BWC, **governments should adopt or implement screening guidelines** for both export and domestic control



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Filling the information gap with a global map of DNA synthesis providers and policies

Mayra Ameneiros

The information Gap: Real examples

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Can a non-state actor order potentially dangerous DNA?

2006: **Journalist** orders smallpox DNA under an invented company name

2020: **Journalist** reports that "*a few DNA synthesis companies will send me what I asked for, with no screening*"

Guardian article

This article is more than **17 years old**

Lax laws, virus DNA and potential for terror

- **Loopholes mean anyone can order gene sequences**
- **Scientists back voluntary regulation as first step**

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But ordering part of this long-dead pathogen's DNA proved easier than anyone dared imagine. All it took was an invented company name, a mobile phone number, a free email address and a house in north London to receive the order by post.

What the investigation makes clear is that anyone, without any attempt to prove they are part of a legitimate research organisation, can order DNA sequences from any potential pathogen without fear of extensive questioning. In our case, VH Bio Ltd did not realise it was supplying part of the smallpox genome, but many scientists argue that it is the responsibility of companies selling custom-made pieces of DNA to check their orders for potentially dangerous sequences.

Vox article

But what if I asked them to print for me the genetic code of the influenza that caused the **1918 flu that killed millions of people**? What if I sent them the instructions for a new disease that I have reason to believe is dangerous? What if I was doing legitimate research, but my lab didn't adhere to modern safety standards?

The answer is that a few DNA synthesis companies will send me what I asked for, with no screening to check whether they're sending out a pathogen that ought to be carefully controlled. (Synthetic DNA is not a live virus, of course; I'd have to be a talented biologist with specialized knowledge, lots of resources, and access to expensive tools to use it maliciously.)

Some companies — including most industry-leading ones — do follow US guidelines that require a background check and also check the DNA sequence against a list of known hazardous ones and would stop me from making this dangerous order — but a **recent report** found no evidence of any laws requiring laboratories to follow those guidelines in any country in the world. Doing so adds some time and expense to the ordering process, so there is some incentive to cut corners.

The Information Gap - Global DNA Synthesis Screening Map

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Can a non-state actor order potentially dangerous DNA?

- Which companies sell synthetic DNA and DNA printers?
- Do those companies screen their orders?

How can we move towards a world where all orders are screened?

- Are companies already required to screen by national or international policy?
- How can IBBIS most effectively increase the number of orders that undergo screening?
- Should everyone accessing synthetic DNA be screened?

Current information available

Where can we access this information?

- **Associations**: Global Biofoundries Alliance, International Gene Synthesis Consortium
- **Market research** reports
- **Internal** from direct communications

Global Biofoundries Alliance Map

What does this information look like?

- Disorganized
- Inaccurate and incomplete
- Not fit-for-purpose

Global DNA Synthesis Screening Map

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Landscape:

- Production and transfer of synthetic DNA are **poorly understood**.
- There is uncertainty around the **global supply**, with assumptions that dominant suppliers are based in the US and China.

Synthetic DNA could pose risks (e.g., creating new pathogens), so understanding its production, screening, and transfer is essential for biosecurity.

Global DNA Synthesis Screening Map

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Goal:

- To gather a comprehensive, global picture of synthetic DNA providers (made, sold, resold), screening practices, and governing policies.

How we achieve this?

- Compile existing knowledge on DNA synthesis companies and their screening practices. Review this information.
- Conduct new research (open source research and interviews).
- Conduct research globally: Africa, Latin America, and MENA.
- Multiple languages (e.g., Arabic, Chinese, French, Spanish).
- Co-production of the Map. Collaboration is essential.
  Open to receive feedback and existing knowledge on this topic.
- Map laws and regulations governing synthetic DNA in different countries.

Global DNA Synthesis Screening Map

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Project Timeline:

- The project has already **started** and we expect results by the **end of 2025.**
- Continuous research throughout the year.
- Ongoing data collection and analysis will inform the project's progress.

Outcomes:

- Online mapping tool and report.
- Providers, status of screening, policies, awareness.
- Information & findings will be disseminated to relevant stakeholders: Briefings.

Next steps:

- Evaluate how to enhance the map.

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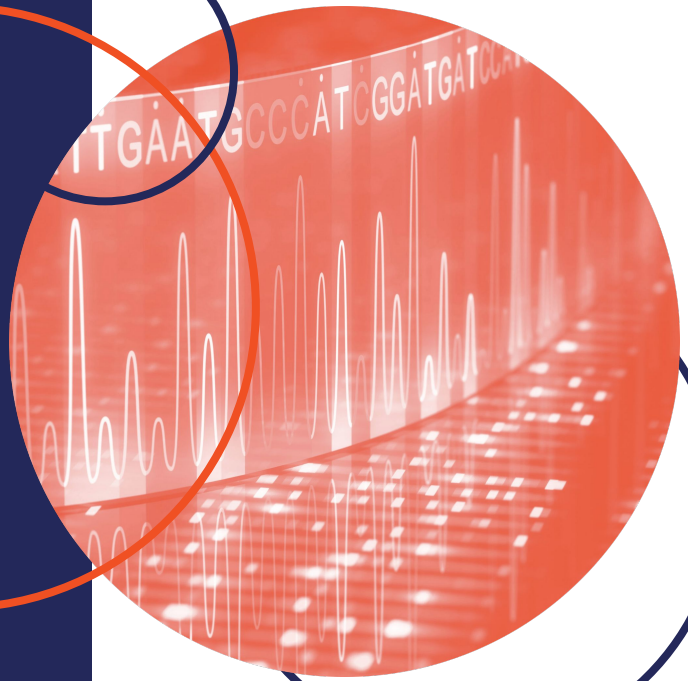

Common Mechanism: a free, open-source tool to support synthesis screening

Tessa Alexanian

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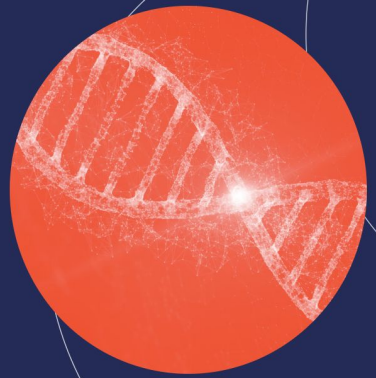
Safeguarding modern bioscience and biotechnology
so it can advance and flourish safely and responsibly

for DNA synthesis:

Increasing the share of synthesis orders
for which sequences and customers are screened

Supporting international standards
that are inclusive and rigorous



Developing resources for sequence and customer screening

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How do we balance access and security?

1. Recognize potentially risky sequences
toxins, pathogen genomes, virulence factors

2. Decide whether to trust user or customer
with risky sequences by screening legitimacy

Images: Waterloo iGEM 2015, Counter Culture Labs

Developing resources for sequence and customer screening

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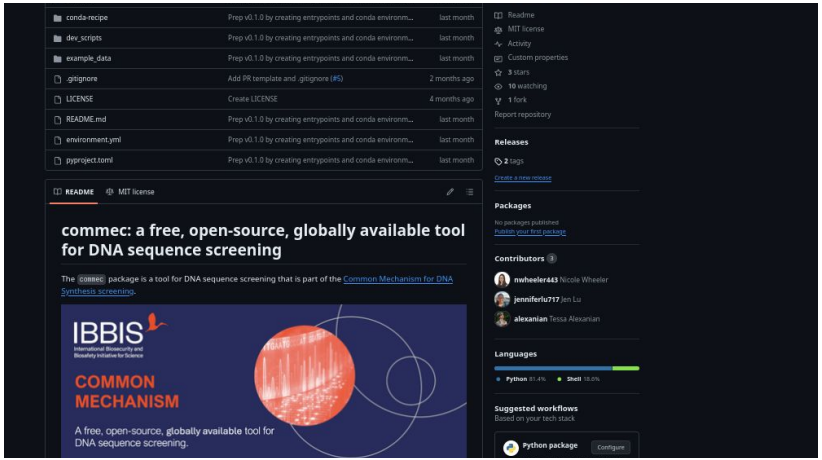
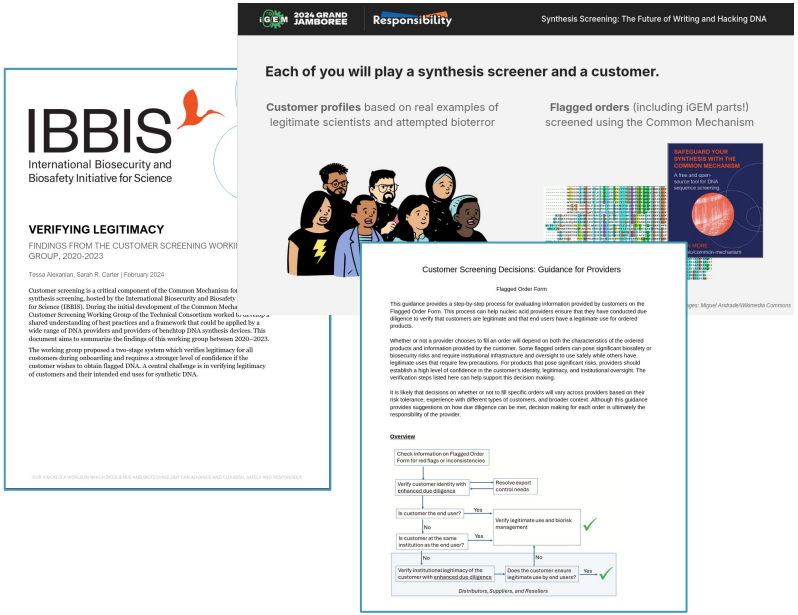
Current Common Mechanism resources

commec: a free, open-source globally available tool for sequence screening



Customer Screening: whitepaper, customer screening game, decision flowcharts



Addressing challenges faced by DNA providers

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Screening is an increasingly difficult economic burden	commec software and databases are free and open-source
Tools and resources are not globally accessible	Hosted in Swiss organization, developed by international consortium
Synthesis orders often contain sensitive IP	Software runs locally, no need to share data with IBBIS
Customer screening relies on subjective judgments of “legitimacy”	Structured templates and flowcharts for requesting information and verifying legitimacy

Sequence screening: can we catch risky sequences?

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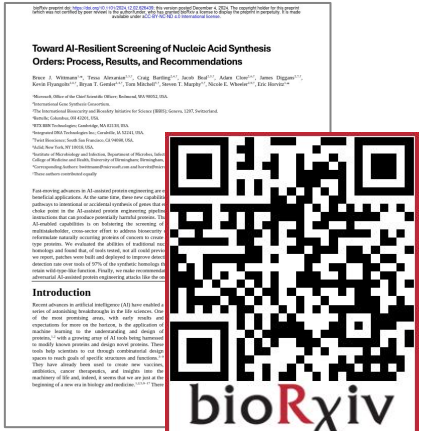
ORIGINAL ARTICLE

Progress and Prospects for a Nucleic Acid Screening Test Set

Validating the Common Mechanism software

- International test sets collaboration tested >1,000,000 sequences
- Common Mechanism flags with accuracy on par with industry screening tools, <2% false positives



Toward AI-Resilient Screening of Nucleic Acid Synthesis Orders: Process, Results, and Recommendations

Introduction

bioRχiv

Demonstrating AI resilience

- Pathogen sequences redesigned with **AI could fool screening** tools looking for natural proteins
- Vulnerability disclosure from Microsoft, **tools able to catch 97% of AI evasion attempts**

Customer screening: how can we move towards standards?

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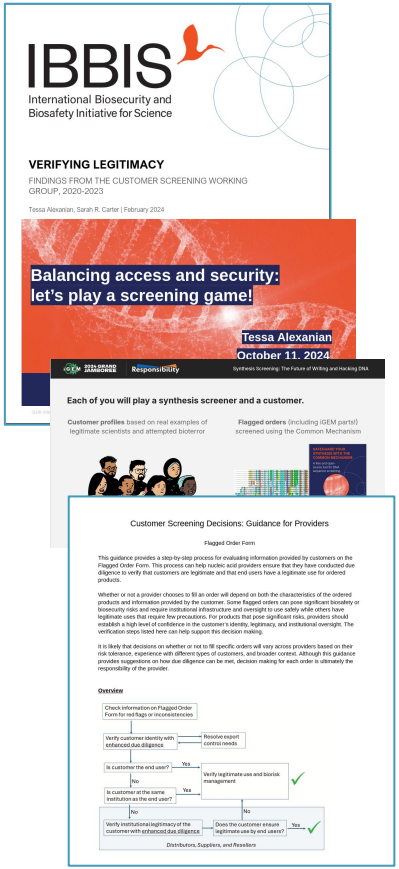


How to be both rigorous and flexible?

- **Standards for verifying**: Customer identity? Individual legitimacy? Institutional legitimacy?
- **Edge cases**: customers without institutions, distributors and resellers, export controls

Moving into a pilot-stage with screening forms

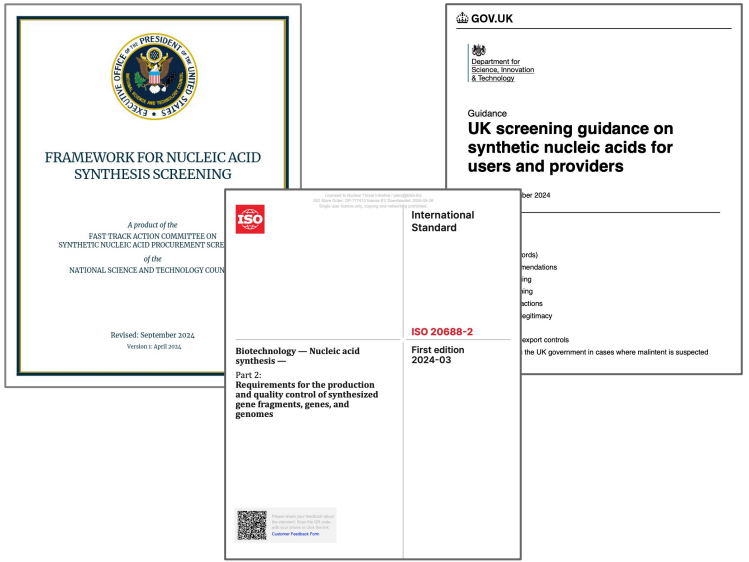
- Forms and decision guidance will be released January 2025
- Screening workshops run around the world, incorporated into training materials

Moving towards international standards

Synthesis screening needs international collaboration

- US and UK guidance have international implications
- Building AI resilience requires global collaboration on vulnerability disclosure and information hazards
- IBBIS seeking to incorporate control lists from more countries

New standards, tools and regulations
changing incentives around screening



Developing resources for sequence and customer screening

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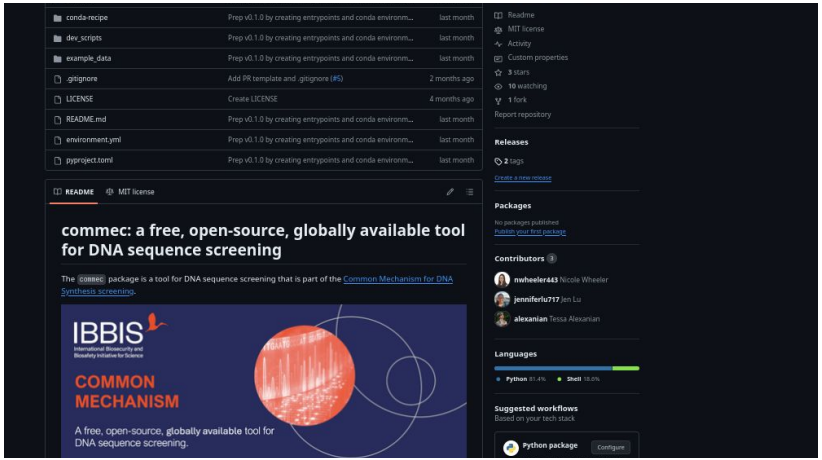
You can use IBBIS software and customer screening resources now

commec: a free, open-source globally available tool for sequence screening



Reach out to screening@ibbis.bio for help getting set up!

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DNA synthesis screening and the Biological Weapons Convention

Q&A and Discussion


Thank You!