155th STIG Policy Platform (PoP) Seminar, Graduate School of Public Policy, The University of Tokyo
Bioeconomy Study Group Special Program “How to embed safety, security and ELSI/RRI and create an ecosystem for engineering biology - learning from iGEM experience"
Date: Wednesday, September 11, morning (9:30-12:00)
Venue: Online by Zoom

Biosecurity Perspectives in Synthetic Biology and Engineering Biology

合成生物学・エンジニアリングバイオロジーにおけるバイオセキュリティの視点

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What is biosecurity?

バイオセキュリティとは？

What is the difference between biosafety and biosecurity?

バイオセーフティとバイオセキュリティの違いは？

Biosafety: To protect people and the environment from the risks of pathogens

バイオセーフティ： 人や環境を病原体のリスクから守ること

Biosecurity: To protect pathogens from bad people or inappropriate behavior

バイオセキュリティ： 病原体を悪い人や不適切な行為から守ること

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Examples of different types of hazards applicable to different biosecurity sectors

Biosecurity Sector	Hazard Definition
Food safety（食品安全）	A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect
Zoonoses（人獣共通感染症）	A biological agent that can be transmitted naturally between wild or domestic animals and humans
Animal health（動物）	Any pathogenic agent that could produce adverse consequences on animal health
Plant health (or pest) （植物）	Any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products
“Biosafety” in relation to plants and animals （動植物のバイオセーフティ）	A living modified organism (LMO) that possesses a novel combination of genetic material obtained through the use of modern biotechnology that is likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health (Cartagena Protocol on Biosafety).
“Biosafety” in relation to food （食のバイオセーフティ）	A recombinant DNA organism directly affecting or remaining in a food that could have an adverse effect on human health
Invasive alien species （外来侵入種）	An invasive alien species outside its natural past or present distribution whose introduction and/or spread threatens biodiversity

Renault V, Humblet MF, Saegerman C. Biosecurity Concept: Origins, Evolution and Perspectives. Animals (Basel). 2021 Dec 28;12(1):63. doi: 10.3390/ani12010063.

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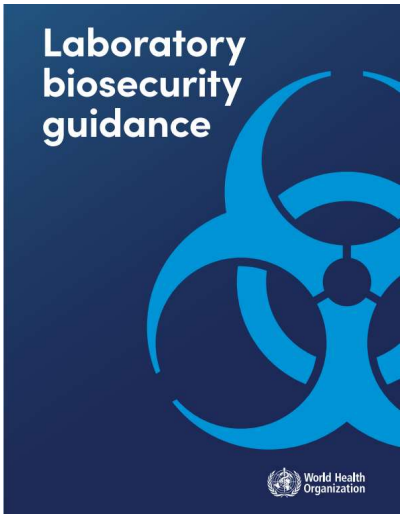
According to the WHO, laboratory biosecurity consists of …

WHOの定義によれば、実験室におけるバイオセキュリティとは…



https://www.who.int/publications/i/item/9789240095113

- Consequence-driven **biosecurity risk assessment**
  結果主導のバイオセキュリティリスク評価
- **Emerging technologies** and **potential threats** (Cybersecurity, information security, molecular techniques, artificial intelligence)
  新興技術と潜在的な脅威（サイバーセキュリティ、情報セキュリティ、分子技術、人工知能）
- International and national **legislation/regulation**
  国際的および国内の法律／規制
- Strengthening the role and responsibility of **institutional biosafety committees**
  施設バイオセーフティ委員会の役割と責任の強化
- **Ultimate situations** – war, civil unrest, devastating natural disasters
  究極の状況 - 戦争、市民の不安、壊滅的な自然災害

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Three cases that iGEM students should know about

iGEM学生が知るべき過去のバイオ事例

1. Bioterrorism by Rajneesh (1984)
   Salmonella contamination of restaurant salad bars (Bacteria were purchased from ATCC)
   ラジニーシ教団によるレストランサラダバーへのサルモネラ混入（菌株をATCCから購入）
2. Anthrax mail terror attack (2001)
   The September 11 attacks and anthrax mail attacks led to the enactment of the USA PATRIOT Act
   9月11日同時多発テロ、炭疽菌郵送テロが米国愛国者法の制定につながった（FBIの捜査権限の強化）
   The suspect of the anthrax mail terror attack was a researcher at the USAMRIID (Insider crime)
   炭疽菌郵送テロの犯人が米国陸軍感染症医学研究所の研究員であった（インサイダー犯行）
3. Recombinant mousepox virus experiment
   Recombinant mousepox virus acquired unexpected pathogenicity (technology to render vaccines ineffective) 組換えマウスポックスウイルスが思わぬ病原性を獲得（ワクチンの無効化技術）

Important viewpoints from biosecurity

バイオセキュリティからの重要な視点

1. Proper provision and management of pathogens
2. Eligibility as a researcher
3. Research designs (Dual use research of concern)

1. 病原体の適正な供与・管理
2. 研究者としての適格性
3. 研究内容の精査（デュアルユースリスク）

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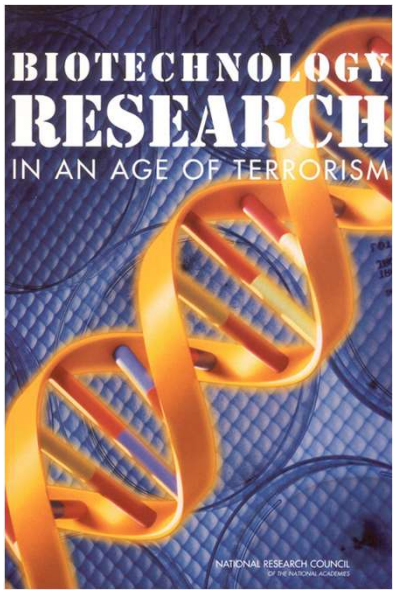
Fink report（2004）: A turning point for considering the dual-use dilemma

デュアルユース問題を考える転機となったFinkレポート （2004年）



The Criteria for Review: **Seven classes of experiments** that require review and discussion before they are undertaken or, if carried out, before they are published in full detail

1. Would demonstrate how to render a vaccine ineffective.（ワクチンの無効化）
2. Would confer resistance to therapeutically useful antibiotics or antiviral agents.（有用抗菌剤等への耐性獲得）
3. Would enhance the virulence of a pathogen or render a nonpathogen virulent.（微生物の毒性増強）
4. Would increase transmissibility of a pathogen.（病原体の伝染性増強）
5. Would alter the host range of a pathogen.（病原体の宿主変更）
6. Would enable the evasion of diagnostic/detection modalities.（病原体の検知抵抗性）
7. Would enable the weaponization of a biological agent or toxin.（病原体や毒素の兵器化）

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Synthetic biology as an emerging threat

病原体に対する懸念の評価

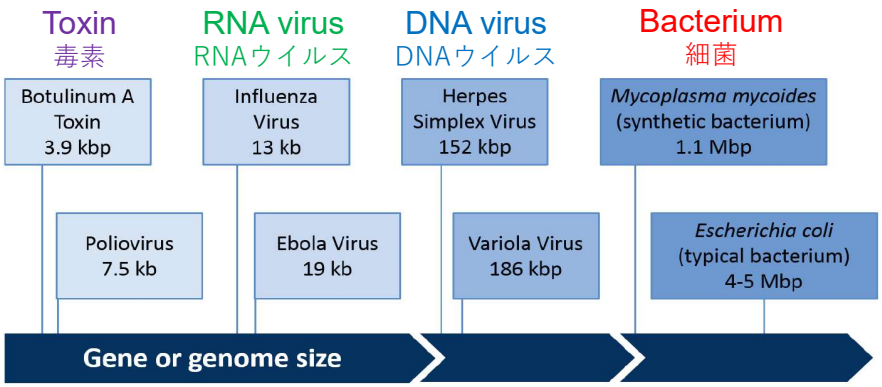

FIGURE 4-2 Relative scales of genetic information encoding familiar bacteria, viruses, and toxins. A single large toxin gene (smallest size represented in the figure, kilobase pairs) is shown in the leftmost box (lightest blue). Progressively larger genome sizes are shown in progressively darker hues moving to the right: single-stranded RNA virus genomes (kilobases), double-stranded DNA virus genomes (kilobase pairs), and bacteria (megabase pairs). The difficulty of DNA assembly and booting is partly a function of genome size and structure.
SOURCE: Adapted from John Glass, J. Craig Venter Institute.

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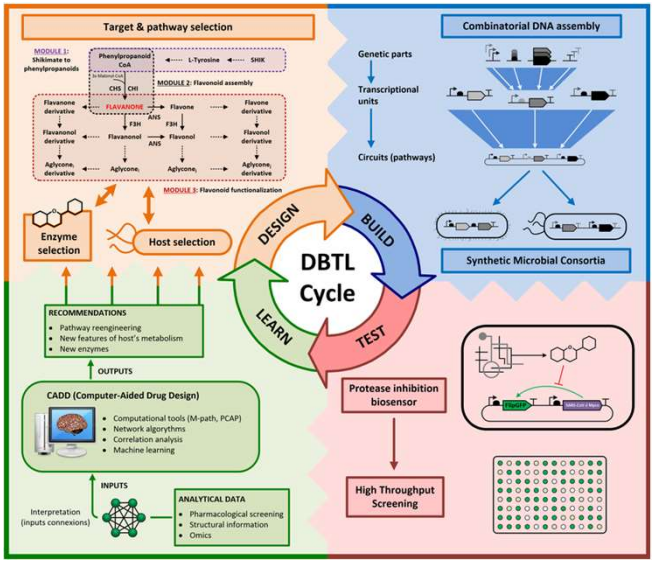
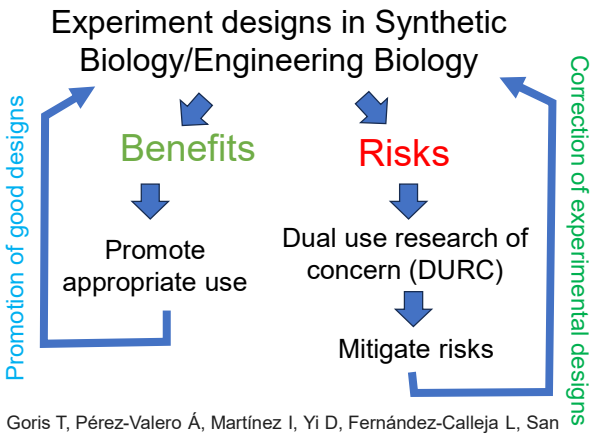
DBTL cycle should be considered not only from the scientific viewpoints but also from the biosecurity/ethical guides

DBTLサイクルは科学的観点だけでなく、バイオセキュリティ／倫理的ガイドからも考慮されるべきである





Goris T, Pérez-Valero Á, Martínez I, Yi D, Fernández-Calleja L, San León D, Bornscheuer UT, Magadán-Corpas P, Lombó F, Nogales J. Repositioning microbial biotechnology against COVID-19: the case of microbial production of flavonoids. Microb Biotechnol. 2021 Jan;14(1):94-110.
doi: 10.1111/1751-7915.13675. Epub 2020 Oct 13.