

# **Biology in (or creating?) a World Without Borders**

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**NC STATE**

# Governance challenges raised by synthetic biology, genome editing, biotechnologies...

1. Hard to define what it actually is
2. Governance systems are struggling to keep pace with the technological change – once/if consensus occurs, technology changes (i.e. CRISPR/gene drives)
3. Transboundary issues (International Governance)
4. Digital Sequence Information
5. Safety, Security & Environment
6. New and de-centralized actors

# International Deliberations

- U.N. Convention on Biological Diversity
- Cartagena Protocol on Biosafety to the Convention on Biological Diversity (Cartagena)
  - Nov. 2018 – (In part called for) broad international cooperation, knowledge sharing and capacity-building to support, inter alia, Parties in assessing the potential adverse effects on the conservation and sustainable use of biodiversity from living modified fish and other living modified organisms produced through new developments of modern biotechnology, including LMOs developed through genome editing and LMOs containing engineered gene drives
- Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (Nagoya Protocol)
- International Treaty for Plant Genetic Resources for Food and Agriculture (ITPGRFA)
- International Union for the Conservation of Nature

**Criteria to be considered a new and emerging issue:**

12. *Further decides* that the following criteria should be used for identifying new and emerging issues related to the conservation and sustainable use of biodiversity:

- (a) Relevance of the issue to the implementation of the objectives of the Convention and its existing programmes of work;
- (b) New evidence of unexpected and significant impacts on biodiversity;
- (c) Urgency of addressing the issue/imminence of the risk caused by the issue to the effective implementation of the Convention as well as the magnitude of actual and potential impact on biodiversity;
- (d) Actual geographic coverage and potential spread, including rate of spread, of the identified issue relating to the conservation and sustainable use of biodiversity;
- (e) Evidence of the absence or limited availability of tools to limit or mitigate the negative impacts of the identified issue on the conservation and sustainable use of biodiversity;
- (f) Magnitude of actual and potential impact of the identified issue on human well-being;
- (g) Magnitude of actual and potential impact of the identified issue on productive sectors and economic well-being as related to the conservation and sustainable use of biodiversity;

**Definition of a Living Modified Organisms**

(g) "Living modified organism" means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;

(h) "Living organism" means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids;

(i) "Modern biotechnology" means the application of:

- a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or
- b. Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection;

(j) "Regional economic integration organization" means an organization constituted by sovereign States of a given region, to which its member States have transferred competence in respect of matters governed by this Protocol and which has been duly authorized, in accordance with its internal procedures, to sign, ratify, accept, approve or accede to it;

(k) "Transboundary movement" means the movement of a living modified organism from one Party to another Party, save that for the purposes of Articles 17 and 24 transboundary movement extends to movement between Parties and non-Parties.

# CBD: Call for Information (Feb 15)

- The relationship between synthetic biology and the criteria set out in decision IX/29, paragraph 12, (see attachment to this email) in order to contribute to the completion of the assessment requested in decision XII/24, paragraph 2, building on the preliminary analysis prepared by the Executive Secretary in document SBSTTA/22/INF/17; **(new and emerging issue)**
- New technological developments in synthetic biology since the last meeting of the Ad Hoc Technical Expert Group in December 2017, including the consideration, among other things, of concrete applications of **genome editing (this is a new request)** if they relate to synthetic biology, in order to support a broad and regular horizon scanning process;
- The current state of knowledge by analyzing information, including but not limited to peer-reviewed published literature, on the potential positive and negative environmental impacts, taking into account human health, cultural and socioeconomic impacts, especially with regard to the value of biodiversity to indigenous peoples and local communities, of current and near-future applications of synthetic biology, **including those applications that involve organisms containing engineered gene drives**, taking into account the traits and species potentially subject to release and the dynamics of their dissemination; and
- Living organisms developed thus far through new developments in synthetic biology that may fall outside the definition of living modified organisms as per the Cartagena Protocol.

# Participate in Online Forum

- Scheduled to take place sometime in March 2019. All information that is obtained through these discussions feed into the final recommendations from the Ad-Hoc Technical Expert Group. They will meet in June and produce a report.
- This is an opportunity to directly engage with the global community around a set of topics related to synbio and gene drives.
- This process (in my opinion) desperately needs more voices from those researching all aspects of synbio and gene drives in order to provide an evidence (multiple forms) based discussion.
- In order to participate in, or observe, the online forum you need to be nominated and registered. This is a simple process but does require a signed letter from the head of your department/dean. **February 15th is the deadline to register for the open online forum.**

[https://bch.cbd.int/synbio/nomination\\_natl\\_experts/](https://bch.cbd.int/synbio/nomination_natl_experts/)

# Nagoya Protocol - Digital Sequence Information (Access & Benefits Sharing)

- **Question: is digital sequence information equivalent to physical material?**
- A scoping study commissioned by the CBD found that the use of information on genetic resources, including in synthetic biology, could create opportunities for new forms of non-monetary and monetary benefit sharing (Laird and Wynberg, 2018).
  - It also noted the risk that DSI would undermine existing approaches to benefit-sharing by avoiding the need for access to genetic resources themselves.
  - If the genetic information is deemed to fall within the scope of “genetic resources” in the CBD, the challenge will be defining whether and how the principle of sovereignty over genetic resources and the system of access and benefit sharing based on this principle can address these vastly different dynamics.
- Interesting note: the report to the Secretariat at the SBSTTA meeting in July 2018 was completely bracketed, showing how far countries are towards consensus
- **Nov. 2018 - Parties noted the divergence of views (definition) regarding digital sequence information and biological diversity, and established a process to clarify the concept of digital sequence information on genetic resources and consider benefit-sharing arrangements relating to its use**

# Nagoya Protocol Participation. Call for studies

- To commission a science based peer-reviewed fact-finding study on the concept and scope of digital sequence information on genetic resources and how digital sequence information on genetic resources is currently used building on the fact-finding and scoping study;
- To commission a peer-reviewed study on ongoing developments in the field of traceability of digital information, including how traceability is addressed by databases, and how these could inform discussions on digital sequence information on genetic resources;
- To commission a peer reviewed study on public and, to the extent possible, private databases of digital sequence information on genetic resources, including the terms and conditions on which access is granted or controlled, the biological scope and the size of the databases, numbers of accessions and their origin, governing policies, and the providers and users of the digital sequence information on genetic resources and encourages the owners of private databases to provide the necessary information;
- To commission a peer-reviewed study on how domestic measures address benefit-sharing arising from commercial and non-commercial use of digital sequence information on genetic resources and address the use of digital sequence information on genetic resources for research and development

<https://www.cbd.int/abs/dsi-gr.shtml>



# International Treaty on Plant Genetic Resources for Food and Agriculture

- recognizing the enormous contribution of farmers to the diversity of crops that feed the world;
- establishing a global system to provide farmers, plant breeders and scientists with access to plant genetic materials;
- ensuring that recipients share benefits they derive from the use of these genetic materials with the countries where they have been originated.
- the Multilateral System, puts 64 of our most important crops – crops that together account for 80 percent of the food we derive from plants – into an easily accessible global pool of genetic resources that is freely available to potential users in the Treaty's ratifying nations for some uses.

# Access & Benefits Sharing Agreement

- The Treaty facilitates access to the **genetic materials** of the 64 crops in the Multilateral System for research, breeding and training for food and agriculture.
- Those who access the **materials** must be from the Treaty's ratifying nations (194) and they must agree to use the **materials** totally for research, breeding and training for food and agriculture.
- The Treaty prevents the recipients of **genetic resources** from claiming intellectual property rights over those resources in the form in which they received them, and ensures that access to **genetic resources** already protected by international property rights is consistent with international and national laws.
- Those who access **genetic materials** through the Multilateral System agree to share any benefits from their use through four benefit-sharing mechanisms established by the Treaty.

<http://www.fao.org/plant-treaty/overview/en/>

**Potential implications of new synthetic biology and genomic research trajectories on the International Treaty for Plant Genetic Resources for Food and Agriculture (ITPGRFA or 'Treaty')**

October 2017

**Potential implications of new synthetic biology and genomic research trajectories on the International Treaty for Plant Genetic Resources for Food and Agriculture**

A study commissioned by the Secretariat of the International Treaty on PGRFA, FAO

Conducted by:

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Margo Bagley, J.D., Emory University School of Law  
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The designations employed and the presentation of material in this publication do not imply the expression of any opinion whatsoever on the part of the Food and Agriculture Organization of the United Nations (FAO) concerning the legal or development status of any country, territory, city or area or of its authorities or concerning the delimitation of its frontiers or boundaries. The mention of specific companies or products of manufacturers, whether or not these have been patented, does not imply that these have been endorsed or recommended by FAO in preference to others of a similar nature that are not mentioned.

This study reflects the technical opinions of its authors, which are not necessarily those of the FAO, or the Secretariat of the International Treaty on Plant Genetic Resources for Food and Agriculture in particular.

45 FAO, 2017

Prepared for the  
International Treaty on Plant Genetic Resources for Food and Agriculture

October 2017

# Our assessment's findings.....

- The evolving technological, legal and institutional context surrounding the exchange and use of digital sequence information (DSI) for synthetic biology and genomic research may affect access and benefit-sharing (ABS) frameworks under the ITPGRFA
- The availability of sequence data through decentralized data libraries and organizations may challenge the multilateral system set up by the ITPGRFA
- Other factors including partial sequence combinations, and the fact that the same sequence may occur in multiple organisms, further challenge the ABS principles.
- New forms of benefit sharing should be explored

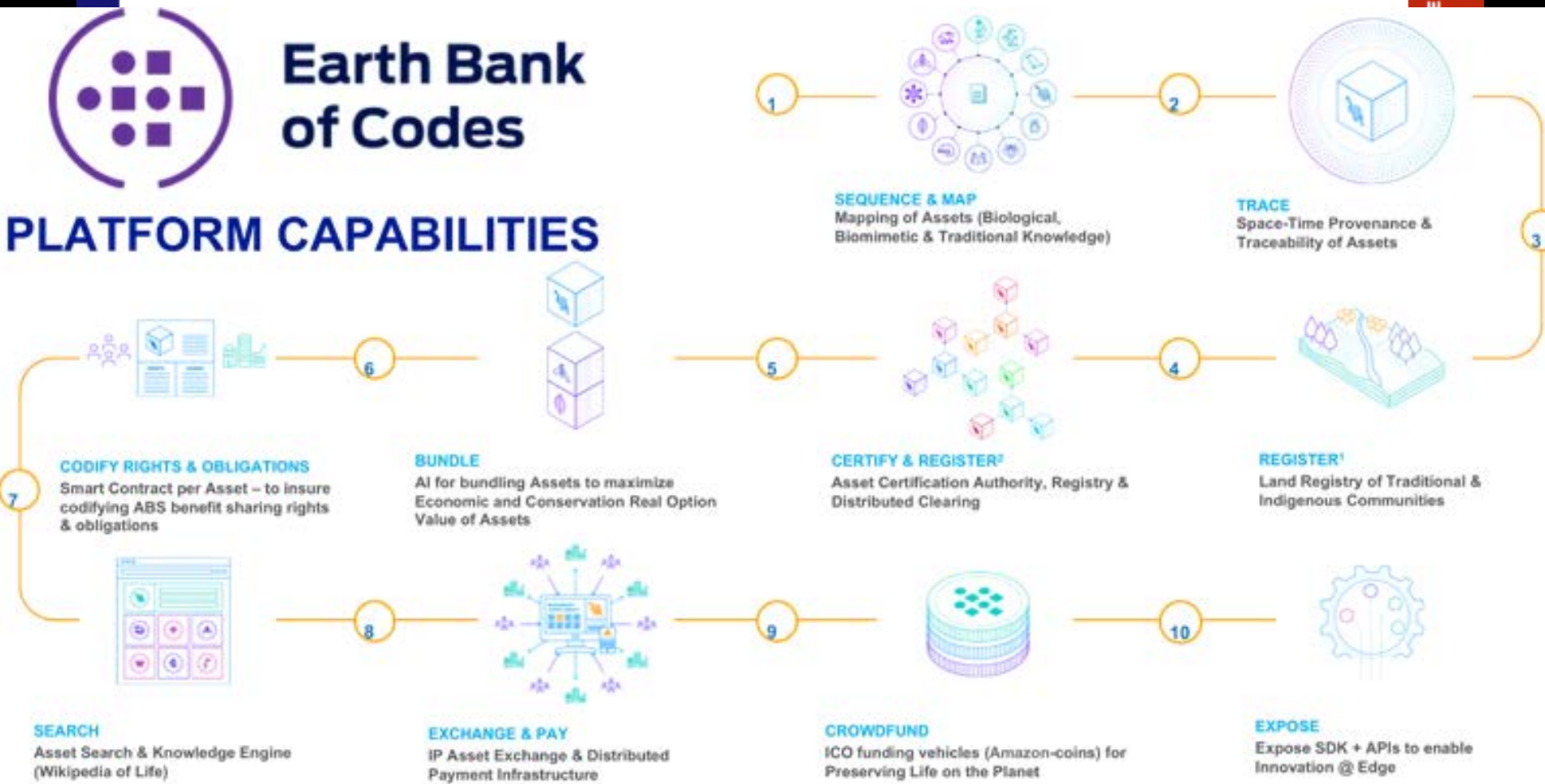


PERSPECTIVE



# Earth Bank of Codes

## PLATFORM CAPABILITIES



SOURCE : EARTH BANK OF CODES

<http://www.pnas.org/content/early/2018/04/18/1720115115/tab-article-info>

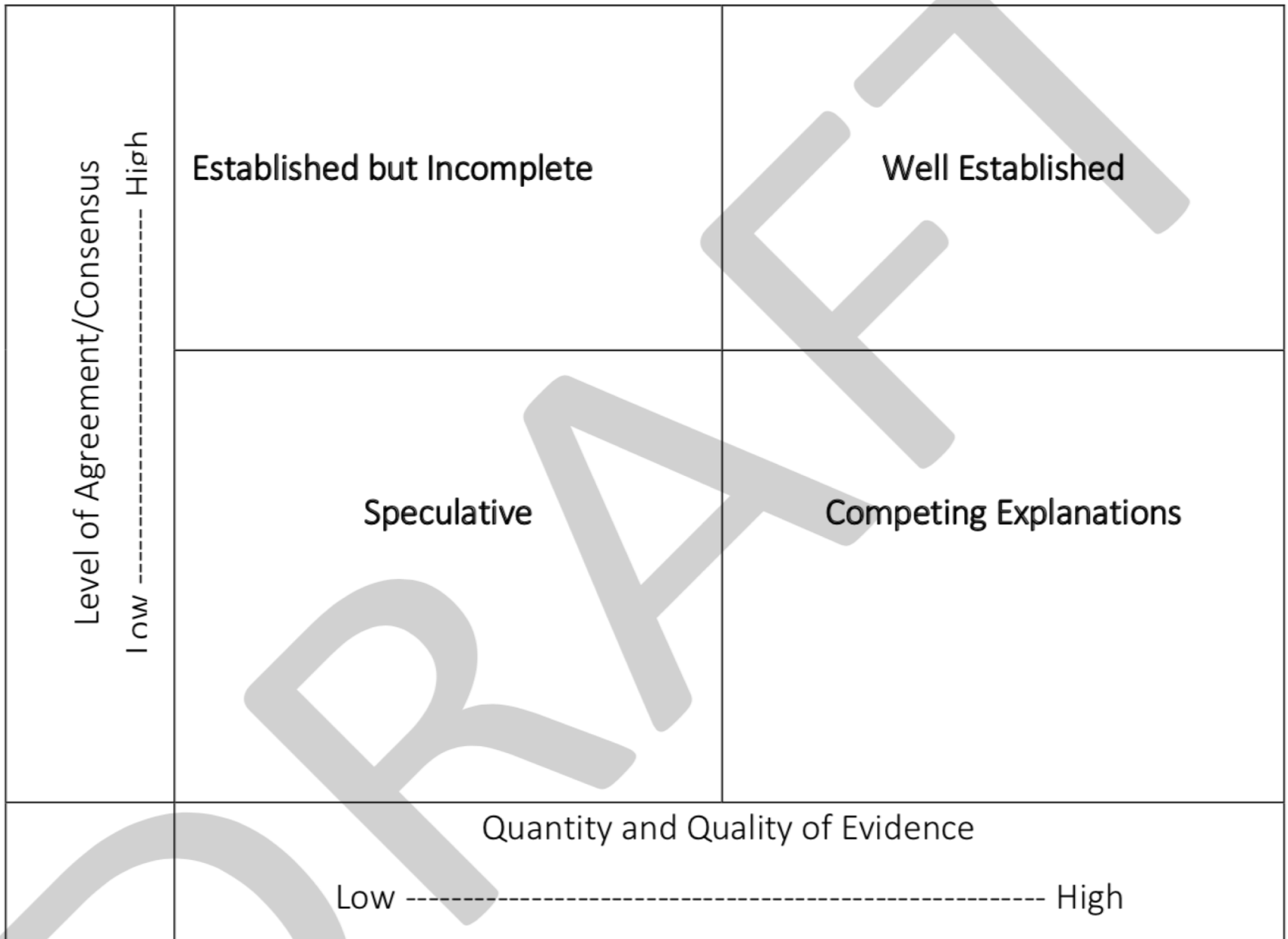
# International Union for Conservation of Nature (IUCN)

- IUCN is a membership Union uniquely composed of both government and civil society organizations.
- It provides public, private and non-governmental organizations with the knowledge and tools that enable human progress, economic development and nature conservation to take place together.
- Created in 1948, IUCN has evolved into the world's largest and most diverse environmental network.
- 1,300 Member organizations and the input of some 13,000 experts.
- IUCN is the global authority on the status of the natural world and the measures needed to safeguard it. (Red List of Threatened Species) <https://www.iucnredlist.org/>
- Experts are organized into six commissions dedicated to species survival, environmental law, protected areas, social and economic policy, ecosystem management, and education and communication.

# Resolution WCC-2016-Res-086 - “Development of IUCN policy on biodiversity conservation and synthetic biology”

- examine the organisms, components and products resulting from synthetic biology techniques and the impacts of their production and use, which may be beneficial or detrimental to the conservation and sustainable use of biological diversity and associated social, economic, cultural and ethical considerations;
- recommend how IUCN, including its Commissions and Members, could approach the topic of synthetic biology and engage in ongoing discussions and deliberations with the synthetic biology community;
- assess the implications of Gene Drives and related techniques and their potential impacts on the conservation and sustainable use of biological diversity as well as equitable sharing of benefits arising from genetic resources;
- develop IUCN guidance on this topic, while refraining from supporting or endorsing research, including field trials, into the use of gene drives for conservation or other purposes until this assessment has been undertaken.

<https://www.iucn.org/theme/science-and-economics/our-work/other-work/synthetic-biology-and-biodiversity-conservation/development-iucn-policy-synthetic-biology>



**Figure 3.1:** Qualitative uncertainty terms. Synthesis of Moss and Schneider (2000) and IPBES (2016).



# Draft Assessment Findings

1. Synthetic biology and engineered gene drive have important implications for the conservation and sustainable use of biological diversity {1.1, 4.3} that are both direct {5} and indirect {6} (well established).
2. New tools are needed for effective conservation and sustainable use of biological diversity {1.1} (well established).
3. The practice of synthetic biology is increasing rapidly, with major developments being promised and some delivered across multiple sectors {1.6} (well established).
4. Engineered gene drive systems may be a transformative tool for direct conservation applications {5.2.1, 5.3.1} (speculative) as well as in other sectors like public health {6.3} (speculative), where they could have an indirect impact on conservation {5.2.1, 5.3.1, 6.3}.
5. Synthetic biology and engineered gene drive may be beneficial to conservation and sustainable use of biodiversity {4-6} (speculative).
6. Synthetic biology and engineered gene drive may be detrimental to conservation and sustainable use of biodiversity {4-6} (speculative).
7. Values, worldviews, and lived experiences influence the development, assessment, and governance of synthetic biology and engineered gene drives {2-3} (well established).
8. Indigenous and local communities are key actors in research, governance and decisions around synthetic biology and engineered gene drive for conservation (well established).
9. Multiple existing governance structures are relevant to synthetic biology (well established), but synthetic biology and engineered gene drives raise questions and challenges for these frameworks (competing explanations).
10. This “Assessment of Synthetic Biology and Biodiversity Conservation” is neither a risk assessment of individual synthetic biology and gene drive applications, nor of these technologies as a whole {3.4, 4.3} (well established).

<https://www.iucn.org/theme/science-and-economics/our-work/other-work/synthetic-biology-and-biodiversity-conservation/development-iucn-policy-synthetic-biology>

# Breaking Down Barriers to Biology

Communities with increased access to biology

# May 2008 – 1<sup>st</sup> U.S. DIYbio meet-up




# Pre-community labs



# Inside BUGSS

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# 2018 - Community Labs and Incubator Spaces



# Developing and promoting accessible safety resources

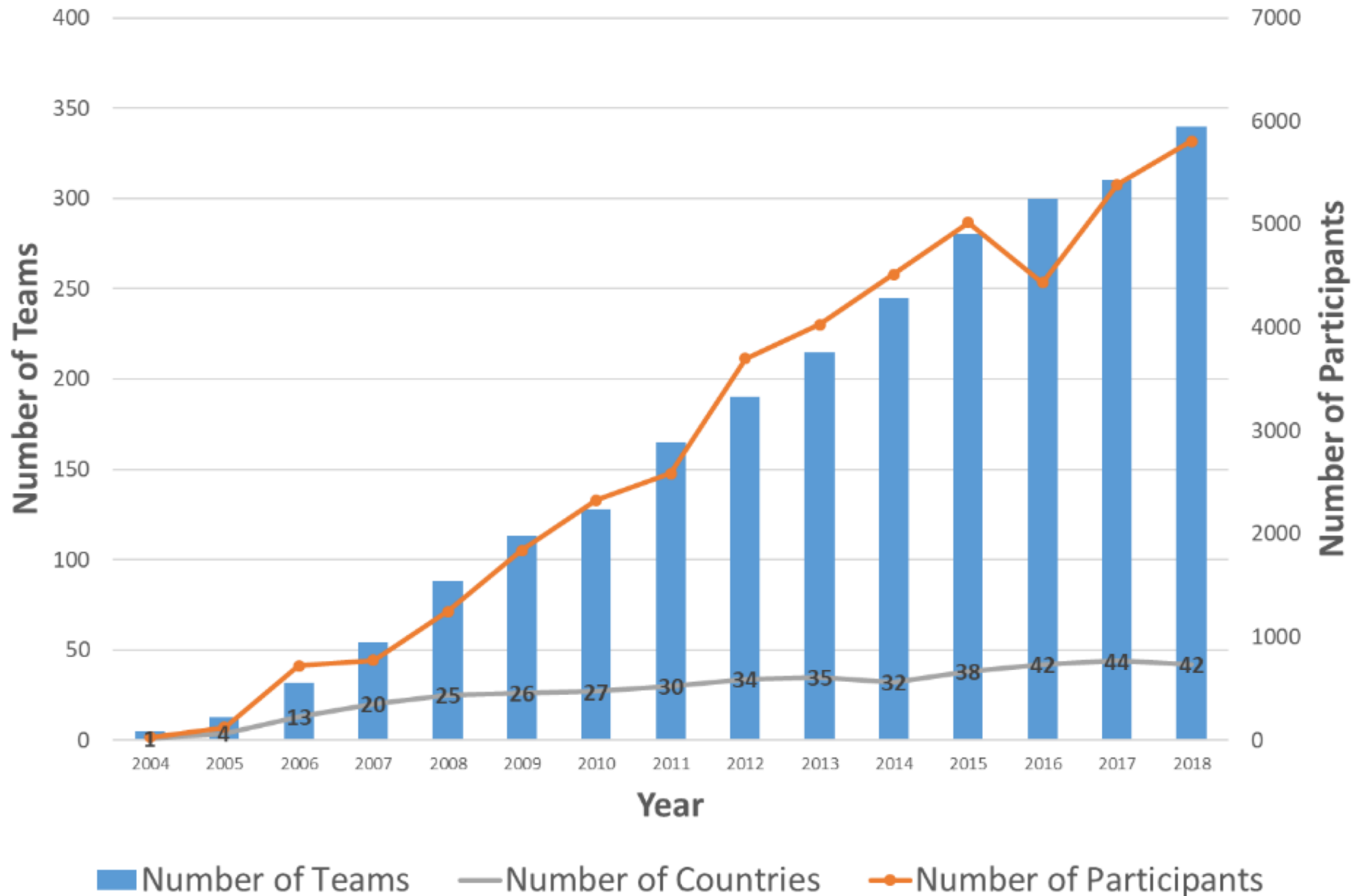
- Currently visiting labs across the U.S. & abroad to review the state of DIYbio as it relates to capabilities, trends, and needs around biosafety and security.
- Embedded biosafety fellow at Genspace for a year.
  - Fellow will work side-by-side with members, learning about their needs and developing pilot programs around biosafety and security protocols.
- Developing biosafety boot-camp course for DIYbio community to be offered late spring 2019

The kids are alright...

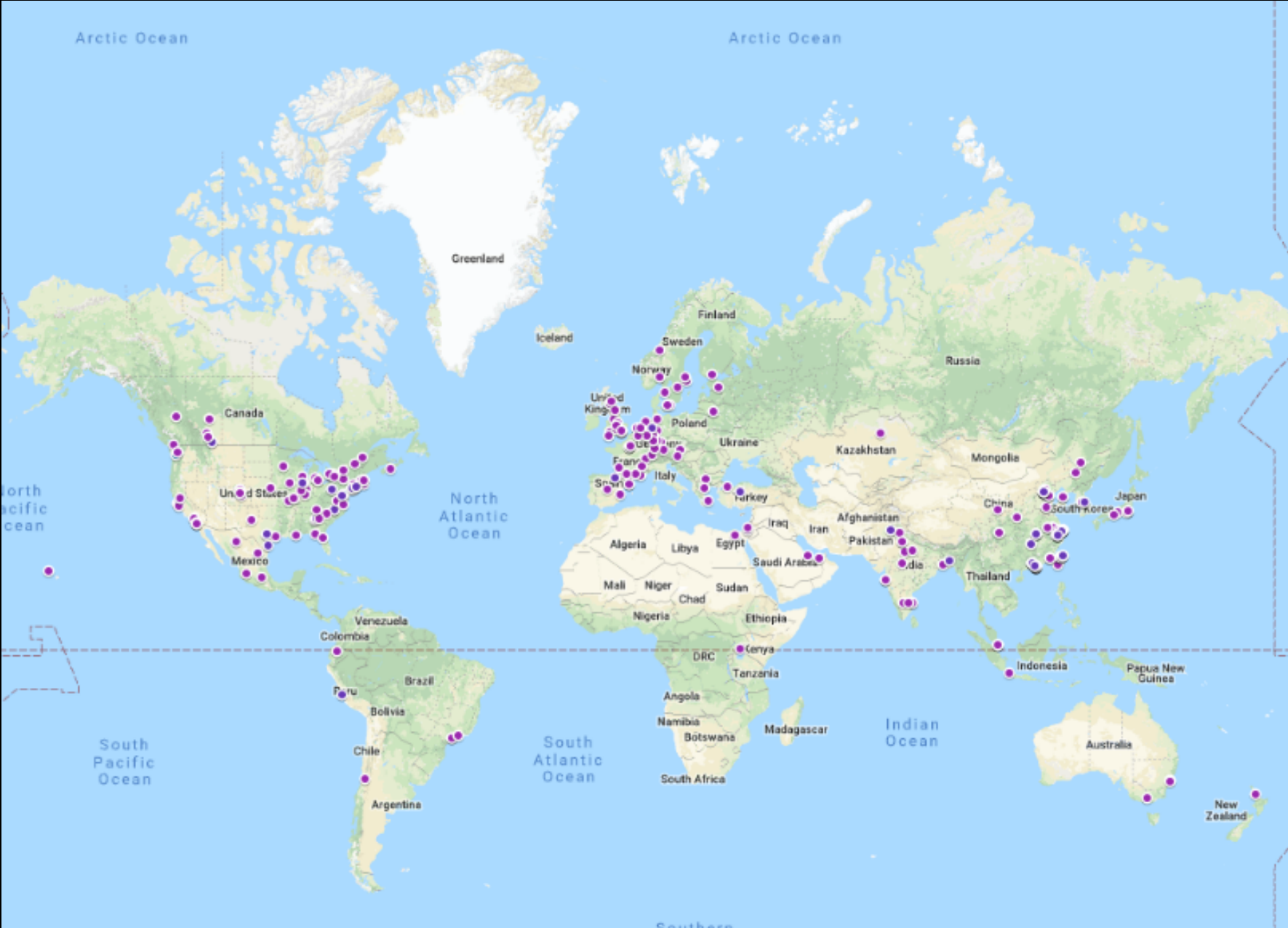




# Global Participation in iGEM 2004-2018



# 2018 iGEM Teams - Generational Shift



## Safety & Security at iGEM

iGEM is unique in its comprehensive and thorough approach to synthetic biology. Leading the field in fostering an environment of mindful and responsible work.

Safety & Security are not only key [facets of iGEM](#), but important factors which every team must carefully consider in the scope of their work. Through grappling with the difficult biosecurity and biosafety questions that are raised by synthetic biology in general, or by their project in particular, iGEM is cultivating a workforce that is mindful of their work and potential uses of their product, regardless of intent.



A message from [Piers Millett](#), iGEM Director of Safety and Security.

**iGEM is a competition - rewarding and fun.**

It is important that safety efforts keep everyone safe but do not unduly restrict what can be achieved.

As a result, iGEM has implemented a graduated safety system:

- Some activities are absolutely prohibited, such as an environmental release or the use of dangerous pathogens. In some cases, such as those involving gene drives, special waivers may be available.
- Other activities are subjected to high levels of scrutiny, such as the use of animals, or parts from exotic organisms, or certain types of anti-microbial resistance.
- Many projects only involve standard lab organisms and parts known to be safe (the [White List](#)) have a proportionate level of oversight.

<http://igem.org/Safety>

# iGEM Human Practices

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2018

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## HUMAN PRACTICES

Through Human Practices, iGEM teams consider whether their projects are responsible and good for the world. They engage creatively with issues relating (but not limited) to ethics, sustainability, safety, and security. These issues are complex and don't have simple answers. Teams therefore often conduct public engagement: inviting stakeholder input to shape the direction of their work.

"Human Practices is the study of how your work affects the world, and how the world affects your work."  
— Peter Carr, Director of Judging



### Introduction

Learn about Human Practices and why it is an important part of iGEM.

[READ MORE](#)



### How to Succeed

All teams are expected to engage in Human Practices. Check out our tips for teams and the medal and prize criteria.

[READ MORE](#)



### Resources

Getting started? These resources can help you think about how to integrate human practices in your project design

[RESOURCES](#)

[http://2018.igem.org/Human\\_Practices](http://2018.igem.org/Human_Practices)



# Introducing **AgBioFEWS**

**A**gricultural **B**io**te**chnology  
In Our Evolving  
**F**ood, **E**nergy and **W**ater **S**ystems,

**Graduate Research Training grant accepting PhD  
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AgBioFEWS is a NSF funded graduate research training program offering PhD candidates across multidisciplinary fields of study the opportunity to examine the science, policy, and public engagement aspects and impacts of Agricultural Biotechnology on Food, Energy, and Water.

Program Fellows receive a PhD in a natural/social science, or humanities graduate program (see options), and a graduate minor in Genetic Engineering and Society, and will:

- Embark on their studies embedded with NC farms, with later opportunities for international internships
- Collaborate on an interdisciplinary cohort project
- Take advanced interdisciplinary graduate courses and incorporate AgBioFEWS into thesis
- Receive \$34,000 stipends

<https://research.ncsu.edu/ges/academics/agbiofews/apply/>

**Feb 1 deadline for this year**

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<https://research.ncsu.edu/ges/arts-work-in-biotech/>

# Thank you...

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Funded in parts by:



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