

# What in the world does synthetic biology governance look like?

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# 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. Assessing ecological risk of novel organisms
4. Transboundary issues (International Governance)
5. Digital Sequence Information
6. New and de-centralized actors

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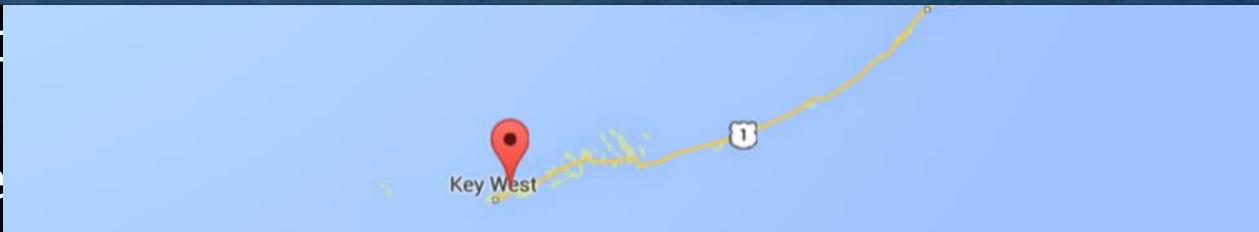
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# Oxitec (Intrexon) Mosquito in Florida Keys: non-viable offspring



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# International Deliberations

- U.N. Convention on Biological Diversity
- Cartagena Protocol on Biosafety to the Convention on Biological Diversity (Cartagena)
- 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)
- U.N. Bioweapons Convention
- International Treaty for Plant Genetic Resources for Food and Agriculture (ITPGRFA)
- International Union for the Conservation of Nature

# Convention on Biological Diversity

- **Questions: Should synthetic biology be considered a new and emerging issue**
  - This designation enables CBD to establish specific rules/recommendations for synbio as opposed to LMOs
- Synbio has been discussed under the CBD since 2010
- Multiple online forums and an ad-hoc technical expert group (AHTEG) have been established
- Charge now includes gene drives
- Will be discussed at the COP/MOP this November where a new AHTEG will most likely be formed

# International Union for the Conservation of Nature (IUCN)

- **2018: Part 1: Scientific and Policy Assessment.** IUCN will conduct a broad assessment of the current state of science and policy around synthetic biology and gene drives
  - Identify potential applications and products that might impact conservation and the sustainable use of biological diversity, both negatively and positively.
  - Going out for public comment end of August 2018
- **Part 2: Policy Development.** Finalize an IUCN policy to guide the Director General, Commissions, and Members on biodiversity conservation in relation to synthetic biology.
- **Part 3: IUCN World Conservation Congress (2020)**



# Assessing ecological risk of novel organisms (2014)

1. Comparators
2. Phenotypic characterization
3. Fitness, genetic stability, and lateral gene transfer
4. Control of organismal traits
5. Monitoring and surveillance
6. Modeling
7. Standardization of methods and data



# Radically different time frames

- Novelty and Speed
  - Synthetic biology techniques push beyond incremental changes to organisms and the leap from old to “new” could transcend common evolutionary pathways.
- Generation of useful ecological data could lag far behind the technology
  - Ecological data follows ecological time-frames
  - While methodologies and tools for synthetic biology are rapidly changing

# Digital Sequence Information - Nagoya

- **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 recent SBSTTA meeting in July was completely bracketed, showing how far countries are towards consensus

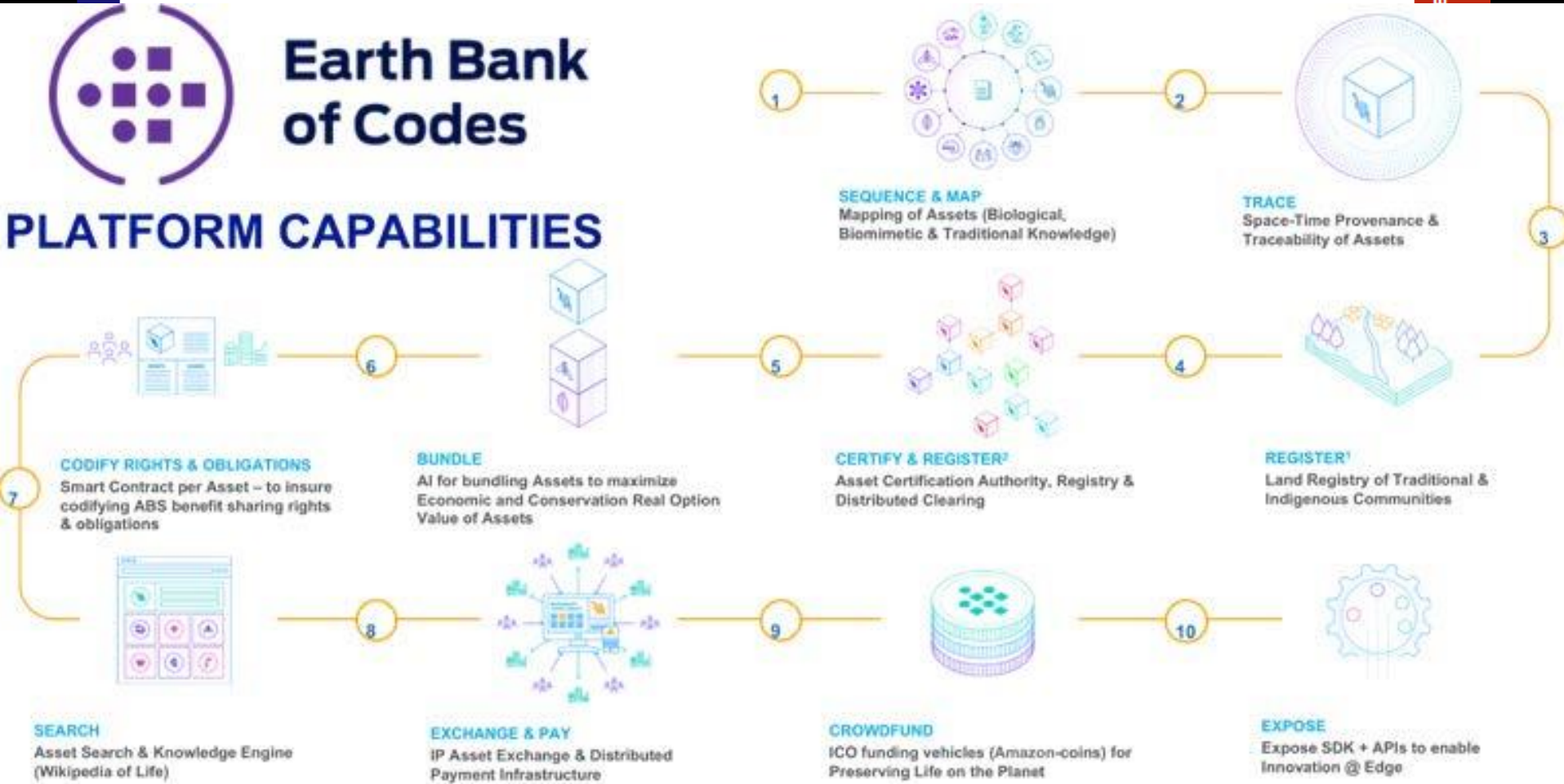


PERSPECTIVE



# Earth Bank of Codes

## PLATFORM CAPABILITIES



SOURCE : EARTH BANK OF CODES

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



Food and Agriculture  
Organization of the  
United Nations



The International Treaty  
ON PLANT GENETIC RESOURCES  
FOR FOOD AND AGRICULTURE

Scoping Report

**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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Prepared for the

International Treaty on Plant Genetic Resources for Food and Agriculture

October 2017

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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.

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Available: [www.fao.org/fileadmin/user\\_upload/faoweb/plant-treaty/GB7/gb7\\_90.pdf](http://www.fao.org/fileadmin/user_upload/faoweb/plant-treaty/GB7/gb7_90.pdf)

# International Treaty for Plant Genetic Resources for Food and Agriculture

- 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.



# Registries of “standard” biological parts

(courtesy of Linda Kahl)



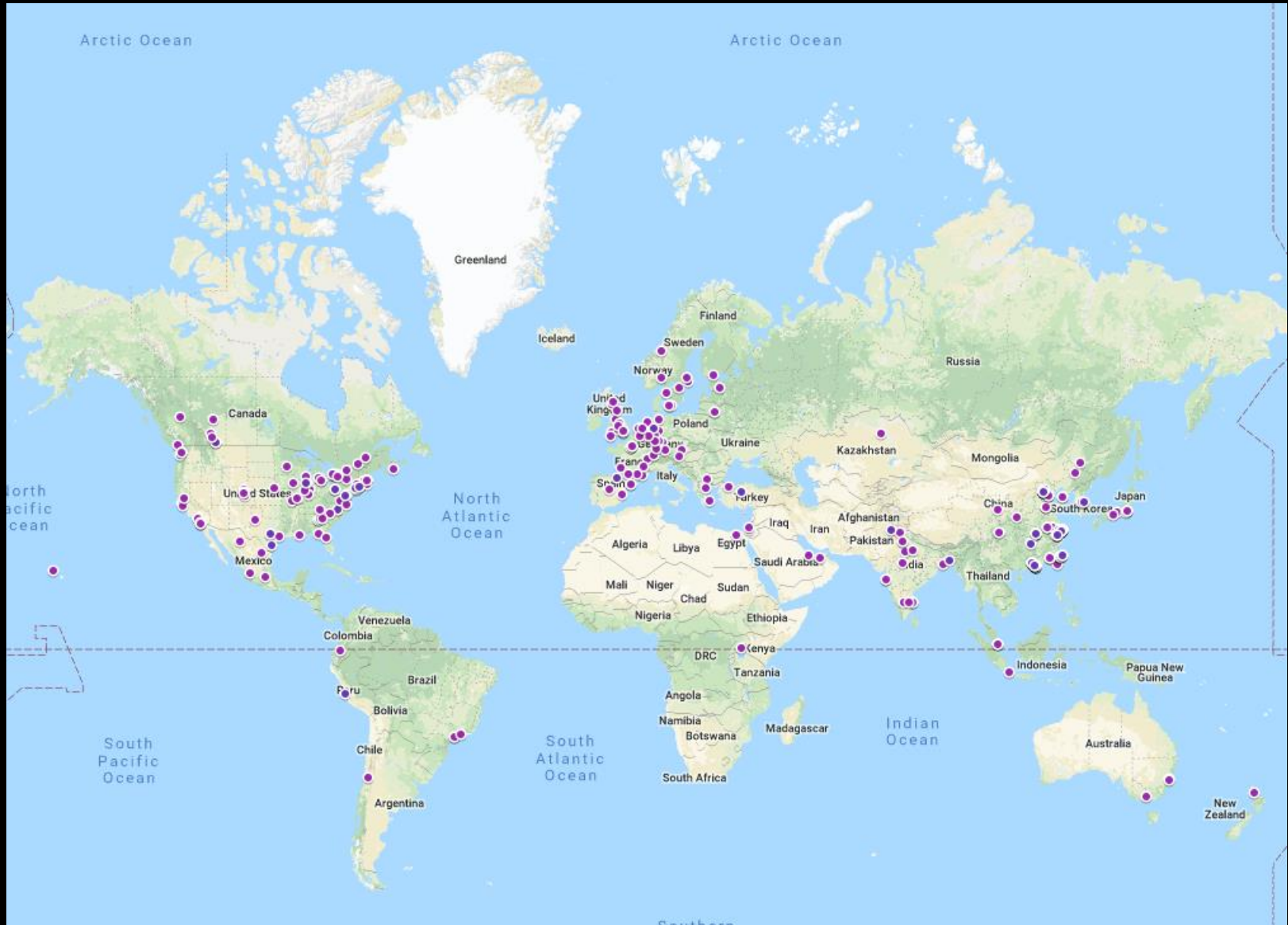
Standard European Vector Architecture



# Recent EU/US ruling on genome edited plants

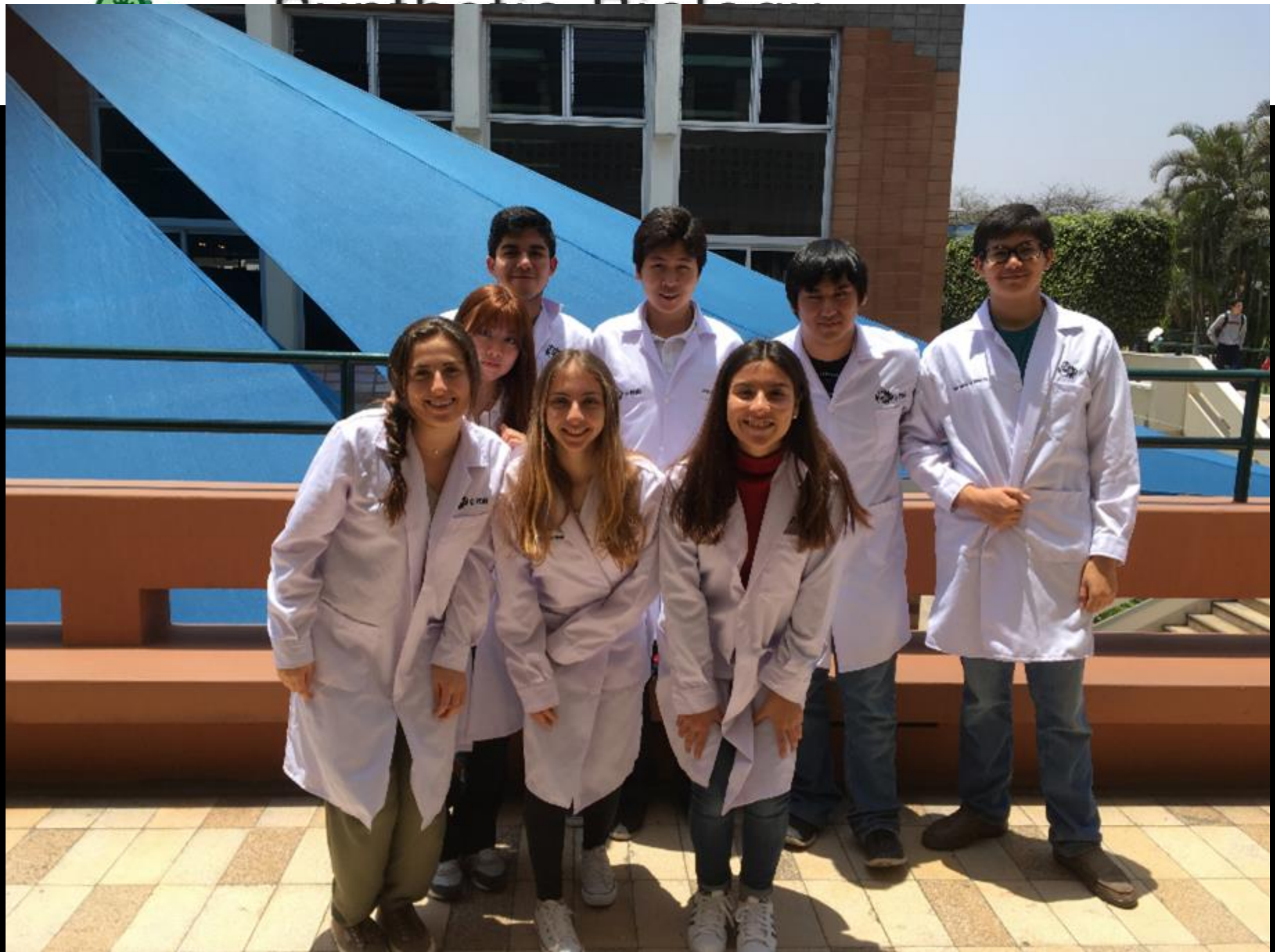
- “USDA does not regulate or have any plans to regulate plants that could otherwise have been developed through traditional breeding techniques as long as they are not plant pests or developed using plant pests”
- EU decision says is that plants produced using genome editing are different than traditional breeding and would need to go through its 2001 directive’s risk assessment prior to their release (GMO law)

# Generational Shift



2018 iGEM Teams





# New and de-centralized actors



**May 2008 – 1<sup>st</sup> DIYbio meet-up in U.S.  
December 2010 – 1<sup>st</sup> community lab in U.S. opens in  
Brooklyn, NY**



# Map of community labs and biotech incubators





# Inside BUGSS

YouTube Search

Baltimore, MD 0:02 / 7:43

**The Rise of Do-It-Yourself Biology: A Look at the Baltimore Underground Science Space (BUGSS)**

1,237 views 15 likes 0 dislikes SHARE

**STIP IdeaLab**  
Published on Nov 12, 2015

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The Rise of Do It Yourself Biology: A Look at the Baltimore Underground Science Space (2015)

This short documentary explores the Baltimore Underground Science Space (BUGSS), a community

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# Learn from DIY biologists

The citizen-science community has a responsible, proactive attitude that is well suited to gene-editing, argues **Todd Kuiken**.

One of the top science stories of 2012 involved a furore about the wisdom

expertise needed to create a deadly insect or virus are far beyond the capabilities of

the world — received CRISPR-Cas9 plasmids in their starting kits. These kits contain more than 1,000 standard biological parts known as BioBricks, the DNA-based building blocks that participants need to engineer a biological system for entering into the competition. Other components of the CRISPR-Cas9 system are also available from the iGEM registry (<http://parts.igem.org/CRISPR>).

Yet few DIY biologists seem to be using the technology. Both Tom Burkett, founder of the Baltimore Under Ground Science Space in Maryland, and Ellen Jorgensen, executive director of Genspace — a community lab in Brooklyn, New York — say that their users are interested in CRISPR-Cas9, and Genspace will be offering a workshop on it in March. But none of the projects currently being pursued in these spaces require it. Users of the La Paillasse community lab in Paris are similarly focused on projects that do not need CRISPR-Cas9.

The materials might be available, but the knowledge and understanding needed to make edits that have the desired effects



Users of the Baltimore Under Ground Science Space are not yet using CRISPR-Cas9.

is reserved

10 MARCH 2016 | VOL 531 | NATURE | 167

<http://www.nature.com/news/governance-learn-from-diy-biologists-1.19507>

# Encuentro por el Desarrollo Abierto de Tecnologías: Do-It-Yourself Biology (DIY-BIO) y Biología Sintética

24 y 25 de Agosto 2018  
Universidad Peruana Cayetano Heredia

Organizado por:



UNIVERSIDAD PERUANA  
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Día 01 - 24 de Agosto

Campus Sur: Av. Armendáriz 445- 495,  
Miraflores

2:30 - 3:00 pm

**Introducción a la Biología Sintética y el caso de Perú**  
Daniel Guerra, PhD - Universidad Peruana Cayetano Heredia

3:00 - 3:20 pm

**Do-It-Yourself Biology (DIY-BIO): El puente entre la sociedad y la academia**  
Todd Kuiken, PhD - North Carolina State University | Genspace

3:20 - 3:40 pm

**Hardware Científico Abierto y DIY-BIO para la Ciencia Comunitaria: Proyecto UTBlome**  
Juan Pedro Maestre, PhD - University of Texas | Global Open Science Hardware

3:40 - 4:00 pm

**Do-It-Yourself Biology (DIY-BIO): El caso de Perú**  
Pierre Padilla, MS - Universidad Peruana Cayetano Heredia | Global Open Science Hardware

4:20 - 4:50 pm

**Fundación iGEM y la Importancia de una estrategia en Biología Sintética para América Latina**  
Ricardo Chavez, MS - iGEM Foundation | Instituto Tecnológico y de Estudios Superiores de Monterrey  
Guilherme Kundlatsch - iGEM Foundation | Universidade Federal de São Carlos

4:50 - 5:00 pm

**iGEM: El caso de Perú**  
Keren Espinoza, MS - Universidad Peruana Cayetano Heredia  
Nina Markham, PhD - Colegio Franklin Delano Roosevelt  
Daniel Guerra, PhD - Universidad Peruana Cayetano Heredia

5:00 - 5:30 pm

**Regulaciones y Bioseguridad: Permitiendo el aprendizaje práctico de la Biología Sintética**  
Todd Kuiken, PhD - North Carolina State University | Genspace

5:30 - 6:00 pm

**Regulaciones y Bioseguridad: El caso de Perú**  
David Castro, MS - Ministerio del Ambiente de Perú

# Tipping points?

- How do we help ensure safe and responsible research and build new innovation models?
  - We could drive these emerging communities underground or out of existence
  - New governance approaches (and not top down) are needed to support responsible innovation for emerging genomic technologies in distributed networks
- Need to create a culture of responsibility
  - Publication culture – both journals and press
  - Funding culture
  - Investigator culture
  - Our collective citizen culture

# Questions...



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