

## **Regulate Synthetic Biology Now: 194 Countries** *SynBio industry's wild west days are numbered*

PYEONGCHANG, SOUTH KOREA– In a unanimous decision of 194 countries, the United Nation's Convention on Biological Diversity (CBD) today formally urged nation states to regulate synthetic biology (SynBio), a new extreme form of genetic engineering. The landmark decision follows ten days of hard-fought negotiations between developing countries and a small group of wealthy biotech-friendly economies. Until now, synthetic organisms have been developed and commercialized without international regulations; increasing numbers of synthetically-derived products are making their way to market. The CBD's decision is regarded as a "starting signal" for governments to begin establishing formal oversight for this exploding and controversial field.

"Synthetic Biology has been like the wild west: a risky technology frontier with little oversight or regulation," Jim Thomas of ETC Group explained from CBD negotiations in Korea. "At last the UN is laying down the law."

"This international decision is very clear," Thomas added. "Not only do countries now have to set up the means to regulate synthetic biology, but those regulations need to be based on precaution and not harming the environment. The good news is that precaution won the day."

This decision comes at a critical time. The SynBio industry is bringing some of its first products to market, including a vanilla flavour produced by synthetically modified yeast and specialized oils used in soaps and detergents derived from synthetically modified algae. In December, bay area SynBio firm Glowing Plants Inc. intends to release synthetically-engineered glow-in-the-dark plants to 6,000 recipients without government oversight. The United States is not a signatory to the CBD, making it one of only three countries that will not be formally bound by this decision (the other 2 are Andorra and the Holy See).

Compared to conventional genetic engineering, synthetic biology poses serious risks to the environment, biodiversity and health as well as to the cultures and livelihoods of Indigenous peoples and local communities. Scientists warn that modified algae and yeast could have unpredictable effects if they escape. New applications could also disrupt the behaviour of plants, insects and potentially whole ecosystems. For example, dsRNA crop sprays<sup>[1]</sup> disrupt the action of genes, which may kill targeted pest, but will also affect other organisms in unpredictable ways by silencing genes.

"The multibillion-dollar SynBio industry has been slipping untested ingredients into food, cosmetics and soaps; they are even preparing to release synthetically modified organisms into the environment," said Dana Perls of Friends of the Earth-U.S. "This decision is a clear signal that synthetic biology urgently needs to be assessed and regulated. "Governments need to step in to do that."

Many of the diplomats negotiating at the UN Convention had instructions to establish a complete moratorium on the release of synthetically modified organisms. However, they faced stiff opposition from a small group of wealthy countries with strong biotech industries, particularly Brazil, Canada, New Zealand, Australia and the UK.

After a week of negotiations, battle lines were drawn between the pro-SynBio states on one side and African, Asian, Caribbean and Latin American countries on the other side. Notable among the latter group were: Malaysia, Bolivia, Philippines, Saint Lucia Antigua, Ethiopia, Timor Leste and Egypt.

Global South representatives raised concerns that synthetic biology products intended to replace agricultural commodities could devastate their economies and degrade biodiversity. Many delegates were also concerned that synthetically modified organisms could create biosafety risks – e.g. the possibility of synthetic algae escaping into waterways, producing a solar-powered oil spill.

A network of international organizations including Friends of the Earth, ETC Group, Econexus and the Federation of German Scientists had been closely monitoring the negotiations and providing input for over 4 years. Civil society groups first raised the topic of synthetic biology at the CBD in 2010.

"It was good to see delegates of the South stand up for the interests of their farmers, peasants and biodiversity here in Pyeongchang," said Neth Dano, Asia Director of ETC Group. "This is not the moratorium many of us wanted, but it's a good step in the right direction."

"Synthetic biology involves many novel, experimental, little understood techniques and outcomes, and this greatly increases the risks involved to the environment, human health, food security and livelihoods," said Helena Paul of EcoNexus. "Our technical cleverness tends to blind us to our ignorance; the UK wishes to play a leading role in synthetic biology and does not seem to want precaution to stand in the way, so this COP decision is a helpful corrective to that dangerous policy."

### **What's in the CBD decision?**

The CBD's three-page decision outlines its recommendations for member countries' approaches to synthetic biology. The CBD urges all member countries to:

- Follow a precautionary approach to synthetic biology.

- Set up systems to regulate the environmental release of any synthetic biology organisms or products. These regulations must ensure that activities in one country cannot harm the environment of another. (Article 3 of the CBD)
- Ensure that no synthetic biology organisms are released for field trials without a process of formal prior risk assessment.
- Submit synthetic biology organisms, components and products to scientific assessments that consider risks to conservation and sustainable use of biodiversity as well as human health, food security and socio-economic considerations.
- Encourage research funds to assess the safety of synthetic biology as well the socio-economic impacts of the technology.
- Support developing countries to develop their capacity to assess synthetic biology.

The decision also:

- Establishes an ongoing process within the Convention on Biological Diversity, including an expert group which will establish a definition of synthetic biology and identify whether existing governance arrangements are adequate.
- Invites other UN bodies to consider the issue of synthetic biology as it relates to their mandates.

#### **Notes to Editors:**

The full text of the decision agreed by COP 12 of the CBD is available by request: [dru@etcgroup.org](mailto:dru@etcgroup.org)

Synthetic biology covers a range of new genetic engineering techniques that either build from scratch or “edit” the genetic code of living organisms. It’s a rapidly expanding industry that re-engineers microbes and other organisms to produce industrially useful compounds. For more information about, visit [www.synbiowatch.org](http://www.synbiowatch.org)

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**References** 1. dsRNA stands for double stranded RNA. These molecules are a part of the finely tuned gene regulation of an organism. They will switch off specific genes, but their mode of action and interaction is not well understood.