



April 30, 2015

Dr. Braulio F. de Souza Dias
Executive Secretary
Secretariat of the Convention on Biological Diversity
413 St. Jacques Street West, Suite 800
Montreal, Quebec
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Dear Secretariat,

I am writing in response to the Secretariat's request for Submissions of information on Synthetic Biology, on behalf of Friends of the Earth US, the North American representative to Friends of the Earth International.

In direct response to the Secretariat's questions, please see our concerns and request for included information below, and thank you for this opportunity to participate in this critical conversation.

(i) How to address the relationship between synthetic biology and biological diversity;

Environmental release of synthetic organisms, threats to the integrity of species:

While it is already difficult to assess the safety of single transgenic organisms, synthetic biology raises the level of complexity enormously. There has been virtually no scientific effort to thoroughly assess the environmental or health safety of synthetic organisms, which can have tens or hundreds of entirely novel genetic sequences. Its techniques can create thousands of novel organisms at once. Most of the organisms being engineered through synthetic biology (algae, yeast, *E. coli*, viruses) naturally and regularly swap genes, and so genetic contamination from escaped organisms should be expected.

Organisms genetically engineered via synthetic biology techniques are already being released into the environment intentionally, in research and production processes for materials (algal biofuels) and consumer products (bioluminescent plants). Synthetic biology organisms designed for intentional environmental release and use include organisms designed to be used in agriculture for nitrogen fixation and organisms to assist in mining operations.

Synthetic organisms could escape unintentionally from laboratories, biorefineries, and production vats through faulty containment systems or human error. No containment or

suicide mechanisms are 100 percent effective, and while some types of pollution can be cleaned up, once in the environment, synthetic organisms, which naturally self-replicate, may be impossible to recall.ⁱ The escape of organisms engineered via synthetic biology into the environment – either intentionally or otherwise – could have serious and unforeseeable consequences, including genetic contamination of wild species, disruption of natural ecosystems and release of chemical and biological pollutants.^{ii,iii} Currently there are no systems in place for monitoring or evaluating the impacts of synthetic biology on ecosystems or biodiversity.

Increased demand for feedstocks to feed synthetic biology organisms could impact critical ecosystems and biodiversity:

Synthetic biology may facilitate the creation of a new “bioeconomy” in which plant matter is processed into commercial products through synthetic organisms such as algae, yeast and bacteria. This increased demand for biomass could have serious impacts on biodiversity and the livelihood and food security of smallholder farmers, forest-dwellers, livestock-keepers and fishing communities who depend on biodiversity, especially in the developing world. The feedstocks for these organisms (sugar, other biomass) are produced via large-scale, chemical-intensive industrial monocultures. Expanding sugarcane or other plantations to meet feedstock demand from a growing synthetic biology industry could exacerbate the current destruction of critical savannah and rainforest ecosystems in Latin America (including some of Brazil’s most eco-sensitive areas of land), Africa and South East Asia.^{iv}

First generation biofuels have already led to massive changes in land use, impacting the food and water supply. So-called “next generation” biofuels could exacerbate this problem by transforming previously “low-value” forest and agricultural “wastes” such as straw, leaves and branches into valuable feedstocks and by growing biomass on “marginal” lands for chemical and energy companies. In fact, these resources are important components of nutrient rich soil and help its capacity to sustain biodiversity and sequester CO². Increased demand for biomass to produce biofuels through synthetic organisms will add even more pressure on soils, water resources and ecosystem integrity. Additionally, “marginal” lands are often the source of livelihood for small-scale farmers, pastoralists, women, and indigenous peoples. This demand will also compete with food security, livelihood needs, biodiversity and conservation goals since there is simply not enough land or plant matter for all the uses that are being contemplated. With an estimated 86% of global biomass stored in the tropics or subtropics, developing countries are already being tapped as the major source of biomass to supply industrial-scale feedstock for fermentation tanks and biorefineries.^v

Synthetic biology “nature equivalent” products could displace sustainable small farmers and producers:

Synthetic biology companies are now partnering with the world’s largest flavor and fragrance, cosmetics, food ingredients and pharmaceutical companies to use synthetically engineered microbes to produce compounds produced naturally by plants. Products already in development include flavorings such as vanilla, liquorice and saffron, sweeteners such as stevia,

lauric acid (currently sourced from coconut and other plant oils) for laundry detergents and strategic materials such as tire rubber.

Commodities currently produced by small farmers may be displaced in favor of synthetic biology products, many of which are being misleadingly marketed as “natural,” and the land they preserve may in turn be converted into industrial-scale plantations for soy, beef or sugar. This could also result in accelerated destruction of intact and biodiverse ecosystems and tropical forests across the global south.

Commercial applications of synthetic biology’s designer organisms have the potential to destabilize traditional commodity markets, disrupt trade, displace workers and eliminate jobs. Moreover, commercial synthetic biology products may have significant socio-economic impacts on women who are particularly dependent upon biodiversity for their livelihoods. For example, in Tanzania, women are the crucial cocoa producers in the Morogoro Region. If synthetic biology cacao is introduced to the market, there could be a significant impact on the natural cacao market across the global south, and severe socio-economic adverse effects on women’s livelihoods in general.

(ii) The similarities and differences between living modified organisms (as defined in the Cartagena Protocol) and organisms, components and products of synthetic biology techniques;

The Cartagena Protocol on Biosafety does not fully or adequately cover synthetic organisms, their products, or synthetic biology processes and technologies. Friends of the Earth U.S. would like to see a wider definition of Living Modified Organisms (LMO) following the Codex definition, which would describe an LMO as any organism that has been modified by modern biotechnology.

We would also like to see the definition of a Synthetically Modified Organism (SMO) include any organism modified using in vitro nucleic acid techniques, whether or not there is a novel combination of genetic material. In vitro nucleic acid techniques considered to be synthetic biology include (but are not exclusive to):

- Synthetic chromosomes
- Synthetic gene technologies
- Genome engineering
- Gene editing
- Gene targeting (GT)
- Sequence-specific nucleases (SSNs)
- Zinc-finger nucleases (ZFNs)
- Clustered Regularly Interspaced Short Palindromic Repeats and associated protein genes (CRISPR-Cas system)
- Transcription Activator-Like Effector Nucleases (TALENs)
- RNA-dependent DNA methylation (RdDM)

Gene silencing via RNAi pathway RNAi-based pesticides

Synthetic biology refers broadly to genetic engineering techniques which have a greater speed of production and breadth of possibilities for applications than previous genetic engineering techniques. These techniques include the use of computer-assisted, biological engineering to design and construct new synthetic biological parts, devices and systems, and to redesign existing biological organisms. The techniques move beyond the more historical incremental changes to an organism's genetic pathways and DNA from genetic engineering. The speed of changes that could impact organisms and ecosystems could be unprecedented. In this manner, synthetic biology differs from "conventional" genetic engineering in its technique, scale, and its use of novel and synthetic genetic sequences – raising new risks to biodiversity.

(iii) Adequacy of existing national, regional and/or international instruments to regulate the organisms, components or products derived from synthetic biology techniques;

Despite synthetic biology's rapid growth, its potential environmental and social impacts have not been adequately assessed, and there are virtually no national or international regulations to help ensure synthetic biology and its products do not harm biodiversity and livelihoods.

Until the proper regulations and safety mechanisms have been put in place, such as those suggested in *The Principles for the Oversight of Synthetic Biology*, Friends of the Earth U.S. believes there must be a moratorium on the environmental release and commercial use of synthetic organisms. While synthetic biology may be a useful tool in helping to better understand biological systems, it carries too many risks and unanswered questions to be allowed outside the lab at this time.

Friends of the Earth U.S. supports the establishment of an international regulatory regime and set of mechanisms to provide oversight of synthetic biology and its associated organisms, components and products under the Convention of Biological Diversity. We would like to see the firm application, at the national and international level, of the Precautionary Principle to the environmental and commercial release of organisms, components and products resulting from synthetic biology, with attention to environmental and socio-economic impacts. We would like to see assessment of risks and consequences of the application of synthetic biology on the environment, health and biodiversity. Until an international risk assessment is conducted for the whole field and a set of international regulations are put in place, Friends of the Earth advocates for an international moratorium on commercial and environmental release of organisms, components and products resulting from synthetic biology.

(iv) An operational definition of synthetic biology, comprising inclusion and exclusion criteria;

Synthetic biology, although still undefined, can be described as 'extreme genetic engineering,' and refers broadly to the use of computer-assisted, biological engineering to design and

construct new synthetic biological parts, devices and systems, and to redesign existing biological organisms. Synthetic biology differs from “conventional” genetic engineering in its technique, scale, and its use of novel and synthetic genetic sequences – raising new risks to biodiversity.

Friends of the Earth U.S. would like to see the definition of synthetic biology include in vitro nucleic acid techniques, whether or not there is a novel combination of genetic material. This definition should not be exclusive to the examples of techniques as listed above, but should recognize that the types of synthetic biology techniques are continuing to rapidly emerge.

(vi) Best practices on risk assessment and monitoring regimes currently used by Parties to the Convention and other Governments, including transboundary movement, to inform those who do not have national risk assessment or monitoring regimes, or are in the process of reviewing their current risk assessment or monitoring regimes;

A broad coalition of 111 environmental, religious, consumer, scientific, worker safety and human rights groups calls for the proper governance of synthetic biology. [The Principles for the Oversight of Synthetic Biology](#), are rooted in seven principles which safeguard public health and the environment from the novel risks of synthetic biology and to ensure open, meaningful and full public participation in decisions regarding its uses. Friends of the Earth urges Parties to the Convention and other Governments to refer to these Principles as guidelines for proper regulations and safety mechanisms.

Sincerely,

Dana Perls
Friends of the Earth U.S.

ⁱ Snow, A. “Risk of Environmental Releases of Synthetic GEOs.” Presentation for the Presidential Commission for the Study of Bioethical Issues. July 8, 2010. <http://www.howplantswork.com/wp-content/uploads/2011/02/risks-of-environmental-releases-of-synthetic-geos.pdf>

ⁱⁱ Creating a Research Agenda for the Ecological Implications of Synthetic Biology. Woodrow Wilson Center. (2014) http://web.mit.edu/cis/Publications/SYNBIO_res_agenda.pdf

ⁱⁱⁱ New Directions: The Ethics of Synthetic Biology and Emerging Technologies. Presidential Commission for the Study of Bioethical Issues. December 2010, Washington, D.C.

^{iv} Mendonca, Maria Luisa. "Brazil: sugar cane plantations devastate vital Cerrado region." *Pacific Ecologist* 17 (2009): 25+. *Academic OneFile*. Web. 18 Aug. 2014.

^v ETC Group. 2010. The New Biomasters: Synthetic Biology and The Next Assault on Biodiversity and Livelihoods. www.etcgroup.org