

A SUMMARY OF THE PRINCIPLES FOR THE OVERSIGHT OF SYNTHETIC BIOLOGY

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Abstract

In March 2012, a broad coalition of more than 100 organizations from around the world released *The Principles for the Oversight of Synthetic Biology*, the first global civil society declaration to outline principles that must be adopted to protect public health and the environment from the risks posed by synthetic biology, and to address the field's economic, social and ethical challenges. Until these governance principles are in place, the coalition calls for a moratorium on the release and commercial use of synthetic organisms and products.



I. Employ the Precautionary Principle

The Precautionary Principle must be applied to synthetic biology because the risks of the technology are inherently unpredictable with potentially far-reaching and irreversible impacts. The Precautionary Principle, integrated into many international conventions and national laws, is aptly described in the Wingspread Consensus Statement on the Precautionary Principle:

“When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically. In this context the proponent of an activity, rather than the public, should bear the burden of proof. The process of applying the Precautionary Principle must be open, informed and democratic and must include potentially affected parties. It must also involve an examination of the full range of alternatives, including no action.”

II. Require mandatory synthetic biology-specific regulations

Implementing enforceable and prosecutable synthetic biology-specific regulations must be a prior condition for future developments in synthetic biology.

Such regulations should complement and **strengthen**, not replace worker protections, environmental regulations, drug laws and restrictions on pathogens, among others. These regulations should also be considered as a framework for new biotechnology laws as the current regulations around biotechnologies are inadequate and outdated.

Voluntary, self-regulation by practitioners is not a substitute for synthetic biology-specific regulations enacted by governments and international treaties. Self-regulation does not allow for oversight or public participation, diminishes transparency and does not provide recourse in the event of worker/public health accidents, environmental disruption or economic harms.

III. Protect public health and worker safety

Adequate and effective synthetic biology oversight requires an immediate emphasis on preventing known and potential human exposures to synthetic organisms not proven safe.

Existing workplace safety procedures and laws must be augmented to take into account the unique risks and challenges to human health posed by organisms created through synthetic biology. Many of the organisms engineered through synthetic biology (e.g., algae) are easily aerosolized and can easily be inhaled and escape confinement.

The public must be informed if such work is being conducted in their community.

IV. Protect the environment

Synthetic biology requires the strictest levels of physical, biological and geographic containment as well as independent environmental risk assessment for each proposed activity or product.

Governments must require pre-market environmental impact and lifecycle risk assessments for each distinct synthetic organism, each synthetic construct and the products derived from synthetic organisms and constructs. The failure to fund environmental impact research for risk-relevant [SynBio] research necessitates a moratorium on the release and commercial use of synthetic organisms, cells or genomes into the environment.

V. Guarantee the right-to-know and democratic participation

Full and comprehensive public and worker participation should be provided throughout the decision-making processes involving synthetic biology.

Human health and environmental effects must be communicated throughout the complete stream of commerce so that users of products of synthetic biology know the hazards of the organisms/products.

All products created through synthetic biology should be labeled at all phases — in the lab, while in transport and, if commercialized, on the physical products. Marketing materials and advertisements for these products must state that they are products of synthetic biology.

The public must have the legally enforceable right to halt dangerous applications, not just comment after decisions have been made.

VI. Require corporate accountability and manufacturer liability for all products

Those using synthetic biology must be financially and legally accountable for any harm to public, worker health or the environment.

Manufacturers must provide information sufficient to permit a reasonable evaluation of the safety of the synthetic organism for human health and the environment. If there are no data, the product(s) should not be on the market. Developers must demonstrate that they can accept the financial and legal liability that could come from manufacture, use and disposal of their products.

VII. Protect economic and environmental justice

It is necessary to ensure that the development of synthetic biology does not deepen economic and social injustices.

Biomass to feed synthetic microbes will be extracted from or cultivated mostly in the global South, disrupting fragile ecosystems and exacerbating environmental damage from industrial crop production. Patents on synthetic biology processes, synthetic organisms or products derived from synthetic biology could further the privatization and control of natural occurring products and processes.

<http://www.synbiowatch.org/wp-content/uploads/2013/05/Principles-for-the-oversight-of-synthetic-biology-web-2.pdf>

