**Synthetic Biology or GMOS 2.0: Principles for Getting It Right, This Time**

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Two years ago, a group of us developed a document called: "Principles for the Oversight of Synthetic Biology". The eight principles recognized that much of technology assessment/risk assessment misses having an integrated approach that looks at public health, worker safety, environmental protection, communities' right to know, democratic participation, corporate responsibility, manufacturer liability, and economic justice at the same time as approval of a new application of a technology.

PRECAUTIONARY PRINCIPLE

The Principles start with the Precautionary Principle. US Politicians like to deride the European Union for its use of the Precautionary Principle, but I would note that we are seeing extreme examples of the Precautionary Principle play out in US politics with Governors who have previously proclaimed that they are not scientists when it comes to Climate Change, suddenly becoming epidemiologists when it comes to Ebola. Our application of the Precautionary Principle is more nuanced.

We suggested that when applying the Precautionary Principle to Synthetic Biology we should first have a moratorium on the release and commercial use of synthetic organisms, cells or genomes until government bodies with full public participation have:

*Developed a research agenda that address the full breadth of the public's interest

*Assessed Synthetic Biology approaches against alternative approaches

*Conducted full and inclusive assessments of the technology including human health, environmental and socio-economic impacts of synthetic biology.

*Developed national and international oversight and security mechanisms that can keep pace with the risks of synthetic biology technologies.

REQUIRE MANDATORY SYNTHETIC BIOLOGY SPECIFIC REGULATIONS

We were criticized as calling for a moratorium as a way to kill synthetic biology. (In fact, two major environmental organizations would not sign on because we were not calling for a ban.) One of the things that could kill synthetic biology would be a continued failure to revamp the regulations for genetic engineering in the US and other countries to account for synthetic biology. The US government relies on the so-called "coordinated framework" developed in 1986 as a way to quickly shoe horn genetic engineering into existing regulations. It does not work well for genetic engineering and except perhaps in the area of synthetic biology derived drugs fails entirely for most synthetic biology products moving to market.

FDA

The US FDA has been using a process called "Generally Regarded As Safe" to approve genetically engineered plant based foods. This process should not be used for Synthetic Biology. Companies cannot be expected to do their own reviews and keep them secret from the

public. The FDA reviews genetically engineered versions of insects that care human disease as "New Animal Drugs". FDA is currently reviewing Oxitec's GE mosquitos. Synthetic Biology products that might be used for dietary supplements will generally escape any review by the FDA. Synthetic biology derived food flavorings will also sidestep most review. Vanillins derived from synthetic biology like that being developed by Evola might get the most review, but not because they are synthetic biology, but because vanilla has more comprehensive definitions in food law. The FDA needs to revamp its regulations related to GRAS, food additives, flavorings, genetically engineered animals, animal feed additives, cosmetics and dietary supplements to adequate review synthetic biology products.

EPA

The US EPA reviews genetically engineered microbes through the Toxic Substances Control Act. It does not approve the microbes, just looks at them before they enter commerce via a Microbial Activity Review Notice. Most of the US companies that submit these tell the EPA that everything in them is confidential business information. (I will show two of the recent MCANs from Solazyme, a synthetic biology company that are completely redacted.) If a company changes through the process of synthetic biology one of a dozen microbes commonly used in synthetic biology, they don't have to submit anything at all. If an organism is to be deliberately released from containment into the environment, EPA regulations require that submission of a TSCA Environmental Release Application and EPA approval before the organism is released into the environment. The number of applications for TERA and MCANs are increasing rapidly. The funding of EPA reviews of these TERA and MCAN documents is not going up. The staff in the division are nearing retirement age. The rewrite of TSCA now being considered by the US Congress needs to include updates to EPA's authority to regulate biotechnologies. The pesticide law likewise needs revisions for microbes engineered to function as biocidal agents.

USDA

The US Department of Agriculture has regulated genetically engineered organisms used in agriculture through its authority to regulate plant pathogens. This authority is already allowing genetic engineering that does not use pathogens like agrobacterium to perform the gene transfer. The USDA has no authority to regulate products of synthetic biology. The Inspector General of the USDA directed the APHIS branch to develop regulations for the oversight of genetically engineered animals and insects, but APHIS still has not developed those regulations. Field trials for one genetically engineered insect, a pink boll worm, were approved for Arizona, but suspended due to outcry from organic cotton growers worried that their crops would become contaminated by the insects and they would not be able to sell their crops as "organic". APHIS is considering allowing the release of genetically engineered diamondback moths in upstate New York despite still not developing regulations for their oversight.

THE COURTS

If the US fails to develop adequate regulations for the oversight of synthetic biology derived plants, animals and microorganisms. It is likely that de-facto regulations will come primarily through tort law and national environmental policy act law suits. Already, US rice growers have lost Asian markets when experimental "pharma" rice contaminated shipments to Asia. US wheat growers lost sales to Asia and Europe last year when Monsanto's experimental GE wheat was found in Oregon and Montana. If microorganisms that have been engineered by synthetic biology contaminate the beer of a local brewery in Berkeley, Boston, or Rockville, all center of synthetic biology experiments, expect lawsuits. Big firms will be able to survive these lawsuits, the little ones won't. For the sake of the little guys, the US had better get the regulation right.