We're NOT ready for the Next Wave of Genetic Engineering

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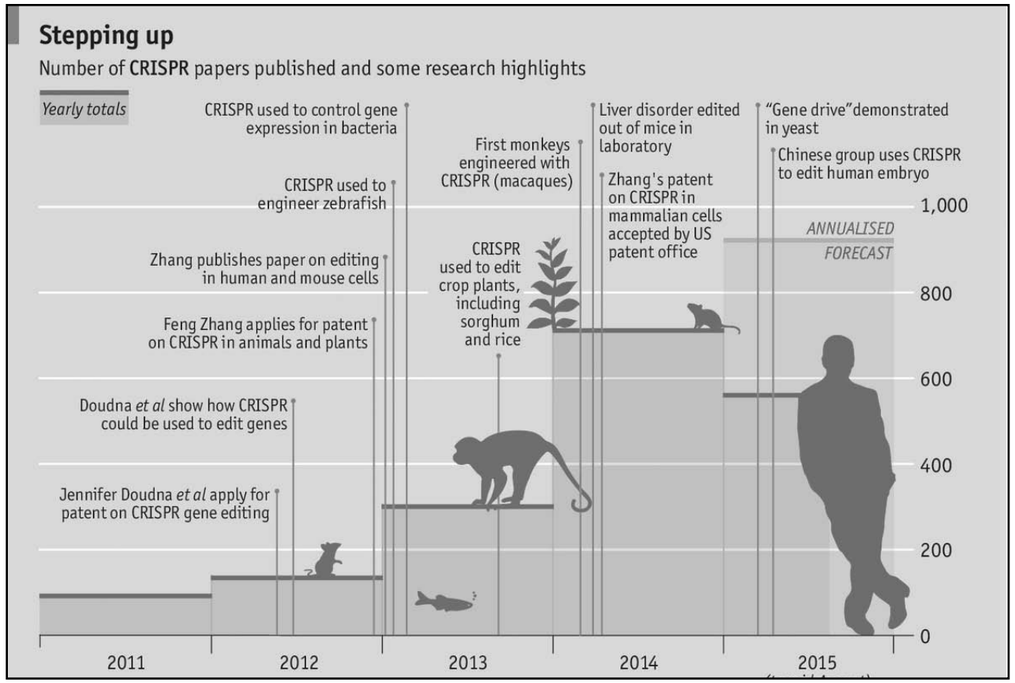

Mini pet pigs. Non-browning apples. Engineered mosquitoes. These are just a few products in the pipeline of biotechnology companies. As the cliché goes: when you have a hammer, everything looks like a nail. Genetic engineering is being pushed as the solution to all of our problems, real or imagined. Disturbingly, these products of the future are largely regulated by laws passed before genetic engineering even existed. Our outdated, ineffective regulatory regime cannot protect us from risks associated with genetic engineering, because it isn't designed to even identify all of the possible risks.

The Coordinated Framework

In the United States, GMOs are regulated according to the Coordinated Framework for the Regulation of Biotechnology, which outlines the roles of federal agencies in overseeing the production and sale of GMOs. Generally speaking:

- United States Department of Agriculture (USDA) ensures that GMO crops are safe to grow
- Environmental Protection Agency (EPA) ensures that they will not harm the environment
- Food and Drug Administration (FDA) ensures GMOs are safe to eat.

However, the agencies essentially use the same regulatory processes that they use for conventional (non-GMO) products, which miss many of the novel risks of genetic engineering.

For example, the FDA classifies certain foods as "GRAS" (Generally Recognized as Safe) if they are common ingredients that have been shown to be safe (like salt or baking soda), which exempts them from any further FDA review. The FDA has treated many GMO foods as GRAS, meaning they enter the market and are consumed without undergoing rigorous safety assessments.

This is troubling considering that we don't know the potential long-term impacts of consuming GMOs, or whether introducing new traits could trigger allergic reactions. Similarly, both USDA and the EPA use outdated regulatory processes for assessing new GMO products that don't address their unique risks, including the human and environmental health consequences of increased use of the weedkillers like Roundup that GMO crops are designed to be grown with.

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The List of Flaws in the Coordinated Framework Goes On.

Agencies rely on industry data to make decisions, don't really review environmental impact, and don't monitor the products once they reach market. Yet the biotechnology industry claims that they are being overregulated. Last summer, the White House directed federal agencies to revamp the Coordinated Framework, including clarifying the responsibilities of each agency. That process is ongoing, but in the meantime, the biotechnology industry is moving to come up with new products at an unprecedented pace.

Most GMO products that we are familiar with have either had foreign genes inserted into them (for example, inserting the trait that provides corn with resistance to Roundup) or target genes turned off (such as silencing the gene that causes apples to brown). But this type of genetic engineering has a limitation—it doesn't allow the easy spread of an edited trait to all members of a species in a particular ecosystem. When GMO organisms are released into the ecosystem, their offspring would have a 50/50 chance of inheriting the edited genes

CRISPR/Cas 9: The Next Generation of Biotechnology

If the Coordinated Framework is failing in its regulation of current biotechnology products, it is completely incapable of addressing the newest technological advances. Most GMO products that we are familiar with have either had foreign genes inserted into them (for example, inserting the trait that provides corn with resistance to Roundup) or target genes turned off (such as silencing the gene that causes apples to brown). But this type of genetic engineering has a limitation—it doesn't allow the easy spread of an edited trait to all members of a species in a particular ecosystem. When GMO organisms are released into the ecosystem, their offspring would have a 50/50 chance of inheriting the edited genes.

A process called "gene drive" bypasses this problem by making it much more likely that offspring will inherit a desired gene. Scientists recently discovered a tool that can facilitate gene drive while also make gene editing more precise. The CRISPR/Cas9 system inserts a mutation into an organism that is copied so that both chromosomes are altered, ensuring that the gene is always passed on to offspring. In a trial involving mosquitoes, 99 percent of offspring inherited the inserted gene. (The technology is still evolving and is limited to species with certain traits, such as those that sexually reproduce and have short generations.)

By now you can probably think of a few ways where this technology could go wrong.
For instance, perhaps you programmed a species of mosquitos to only produce male offspring, thereby collapsing the species and removing a carrier of diseases like malaria. But this could have ecological repercussions, including impacts on species that rely on the mosquitos for food, as well as the rise in other disease-carrying pests filling in the void created by removing mosquitos. Unfortunately, while the technology for facilitating gene drive has advanced, knowledge of the ecological ramifications is lagging way behind.

Furthermore, CRISPR/Cas 9 gene drive is a nightmare from a regulatory perspective.
How do you begin to assess the ecological implications of altering an entire species? How do you contain gene drive changes to particular ecosystem or country? The National Academies of Science (NAS), which has largely been a proponent of GMOs, advocates caution, concluding "there is insufficient evidence available at this time to support the release of gene-drive modified organisms into the environment." Their recent report highlights how the Coordinated Framework is currently unable to regulate such technology.

Biotech companies often grumble that the current regulatory system stifles innovation. The opposite is true: our regulatory system has favored industry and accelerated their products to market at the risk of our health and our environment. Not only do we need to improve our risk evaluation, but we must also weigh these risks against non-biotech solutions. There are safer, more affordable ways to combat disease-spreading mosquitos and to raise adequate supplies of food. We need a regulatory system that recognizes that, instead of creating rules that favor risky new technologies being sold by agribusiness giants.