June 2, 2016

Invited Comments to the National Research Council Committee on "Future Biotechnology Products and Opportunities to Enhance the Capabilities of the Biotechnology Regulatory System"

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Introduction

Many new biotechnologies, and new genetic engineering methods in particular, are on the horizon, or already beginning to produce products. These will bring with them additional regulatory challenges. However, I want to focus here on some of the current deficiencies of the U.S. regulatory system for engineered organisms to highlight several of the main challenges for the future, including for organisms developed through new engineering technologies. Important lessons can be learned from current experience with genetically engineered (GE) crops and their regulations.

Due to time limitations, I will limit my remarks to biological science-based risk assessment. In fact, social sciences and considerations need to be included in any adequate risk assessments of the future. One ongoing problem that I will not cover here is the contamination of non-engineered crops by engineered genes. The financial burden from this unwanted and unasked for contamination falls entirely on farmers that grow non-engineered crops. This is fundamentally unfair and must be addressed and reversed.

Major lessons can be learned from our experience with current genetically engineered crops. Crops resistant to herbicides are the most widely grown because they have been highly profitable to the companies that produce them. That motivation continues, and we see new engineered herbicide resistant crops coming from the biggest companies for that reason. Large companies that control much of the germplasm of several major crops will likely continue to focus on high-value traits that are useful across many regions, because this increases market size and reduces transaction costs. And because they may be widely used, they will have generally increased potential for impact compared to more restricted traits.

So, generally of great concern are engineered crops grown on large areas of land, and which thereby may have large ecosystem and public health effects. Many of these impacts on the

environment or people have to do with the way such crops are grown, i.e. the farming systems they are adapted to, rather than direct harm from the engineered trait itself, although those more direct and immediate risks should also be carefully considered.

This implies that these indirect risks should be a focus of regulations, but they are currently largely ignored or even explicitly excluded from evaluation.

In addition, the process by which regulations are developed is important for public confidence and effectiveness. The current processes are excessively technocratic, paternalistic, and exclude meaningful active and ongoing public participation at all levels.

So, I will focus on what we have learned about some current problems with our regulatory system that have emerged over the years. This is not an exhaustive list, but rather highlights several important issues. Remedies to these should be applicable to most of the products of plant genetic engineering and other biotechnologies that emerge in coming years.

We Must Ensure that all Potentially Harmful Applications of Biotechnology are Adequately Regulated According to the Process used to Make them

Previous NRC committees, including the recently completed one, have all concluded that some engineered organisms could be harmful to human health or the environment. And this possible harm includes newer engineering methods. It is not necessary for all, or most, or even many, engineered organisms to be harmful in order to justify mandatory, rigorous regulation. One particularly harmful trait should be considered to be unacceptable. The most straightforward way to ensure that the regulatory agencies assess the risks of engineered organisms is by using the processes used to create them as a trigger for regulation.

Starting from the accepted assumption that some engineered organisms will present risks, our risk assessment system needs to be mandatory to ensure that any potentially risky new traits should be assessed for safety. FDA's current voluntary system leaves the self-interested developer of a new crop to determine whether it should be regulated. But furthermore, the agency has little authority to determine how safety should be assessed. That is again left to the self-interested developer of the trait. If some kind of red flag is observed in the currently very limited tests typically performed, FDA can require a mandatory risk assessment. But the limited array of tests makes it much less likely that such a red flag would be detected in the first place. Mandatory tests also need to include

those for long term harm that may develop over long periods of time, which are not currently required or performed.

At USDA we now see many engineered crops, over 30 by current count, going entirely unregulated. These include several that contain traits virtually identical to those previously regulated, including those engineered for herbicide resistance, as well as native and exotic trees and biofuel crops that could spread in the environment. New herbicide resistant crops in particular, if commercialized, would likely increase undesirable and harmful herbicide use, with increased human and environmental exposure, and a furtherance of the pesticide and GE treadmill, as their predecessors have. And these crops may be made using genome editing techniques as well as by older transgenic methods.

The main reason they are not being regulated, according to USDA, is that they do not contain any plant pest genes. This is an abdication of the agency's responsibility, since the Plant Protection Act of 2000 (PPA) gives the USDA broad authority to regulate not only whether the engineered organism may be a plant pest, but also a potential noxious weed. The statutory language for defining noxious weeds in particular is very broad, and would cover almost any type of potential risk to the environment or public health. This is needed for covering possibly unanticipated risks from rapidly developing new technologies.

So, after 16 years, the agency is long overdue to develop regulations that include this broad noxious weed authority, and to regulate all newer types of engineered organisms. I need to emphasize this broad authority, because previous drafts of regulations under the PPA arbitrarily and greatly narrowed the noxious weed authority given to the agency by congress, and would have allowed potentially very harmful engineered organisms to be commercialized without oversight. This is unacceptable.

The USDA also should maintain regulatory authority after its safety assessment, even if the crop is approved as safe, rather than the current deregulation process. This would also be useful for new technologies, for which unanticipated risks may later arise. Similarly, as recommended by the NRC in 2002, USDA should use an adaptive management approach for ongoing evaluation of commercialized crops, something that is not currently done in a systematic manner. This kind of monitoring is also especially important for risks that may take considerable time to develop, such as pest resistance.

A Reasonably Precautionary Approach Needs to be Taken with Potentially Harmful Technologies, Especially those Involved with Food and the Open Environment

The ubiquity and intimate biological functions of food, not to mention the cultural importance, increase the need to ensure its dietary safety. The extensiveness of agriculture and its huge consumption of resources elevates the care with which it should be assessed for environmental and social impacts.

This means that the burden should be on the developer and regulators of engineered organisms to show that they are safe, using adequate tests. Where those tests leave doubts about safety, the organism should not be commercialized. Currently, the burden is often on the public to essentially prove harm before an engineered product is denied approval, or restricted in its use, or taken off the market.

In addition to developing a high standard for human dietary safety, we also need higher standards for farmers and farm workers, and for exposure to these crops or the chemicals associated with engineered organisms. For example, the current worker protection standards at EPA are based on acute risk rather than chronic risk and exposure, as they should be.

Part of the rationale for a non-precautionary risk assessment is the presumed benefits or need of the engineered product. However, those benefits may narrowly accrue to the company selling the product rather than society more broadly, while the broader society is subjected to potential risk.

I will address risk vs. benefit in more detail below.

Direct and Indirect Risks

Much of the focus of current risk assessment is on what I will call direct risk, while less direct or indirect risks at the system level are usually ignored, even though they may be more far reaching.

Direct risks could occur for newer forms of genetic engineering as well as older types. For example, a pesticidal RNAi or one developed though genomic editing, may harm non-target organisms if ingested, absorbed, or inhaled. These risks will need to continue to be assessed, and better assessment methods are needed. For example, sub-lethal harm can be as important as mortality, but is often neglected, as are harmful changes in behavior. Interference with honeybee ability to use its homing mechanisms to find flowers and its hive, for example, can be lethal to the colony. Trophic cascades are almost rarely considered. And even for *in vitro* assessments using non-target organisms, the standard

array of indicator species usually do not reflect either the particular ecosystem(s) where the engineered plant will be grown, or the more sensitive species of a clade. All of these well-known issues need to be reconsidered.

But many of the greatest risks and harms are indirect, often several steps removed from the engineered organism itself. The development of pests resistant to controls is an obvious, and generally predictable, example. The engineered crop itself does not directly harm the environment, but rather the pest causes harm by developing resistance to the control. We have already seen this, with dire consequences, with weeds developing resistance to glyphosate, and several insect pests developing resistance to several Bt genes, resulting in increased herbicide use, and increasing tillage that contributes to soil erosion.

Both USDA and EPA need to consistently regulate for potentially far-reaching indirect harm. USDA in particular has said that it has limited authority to regulate for these types of harm. But as noted above, a reasonable interpretation of the noxious weed authority of the PPA would provide such authority.

Another example of indirect harm, as well as the need to apply a precautionary approach, is the harm to monarch butterflies probably largely due to loss of milkweed in the core summer breeding areas of the Midwest as an indirect result of growing genetically engineered herbicide (glyphosate) resistant crops.

But more broadly, technological developments that have the potential to further entrench current globally harmful and unsustainable agricultural practices should not be allowed, or should be restricted in ways that do not further such systemic agricultural harm. In the United States industrial monoculture has been shown to be largely responsible for “dead zones”, reduced crop diversity and resiliency, loss of soil and soil fertility, increased pesticide use and loss of biodiversity, excessive fresh water use, and large contributions to climate change.

It is likely that the current, most widely grown engineered crops contribute to the entrenchment and expansion of monocultures, although indisputable causality is difficult to show. For example, corn rootworm, often the major insect pest of corn grown in the U.S., is largely controllable by crop rotation. In other words, it is essentially a pest created by monoculture. Soil applied insecticide use allowed corn monoculture to be grown. Engineered Bt for rootworm, though it reduced the volume of chemical insecticide use, allows corn monoculture to be grown more easily (i.e. with less labor), and probably therefore more widely. And, because of the narrow spectrum of pests that Bt controls—

generally a good thing when used in ecologically-based farming systems—the acres treated with chemical insecticides has risen from about 30 percent before Bt corn to about 80 or 90 percent now according to recent research.

It should be unacceptable to approve technologies that allow the furtherance of highly destructive current dominant agriculture.

Conclusion: Risk vs Benefit – How Much Risk is Acceptable?

One of the main justifications for allowing potentially harmful technologies to be approved by regulatory agencies is the perceived need for them, or their supposed benefits. FIFRA is, for example, ostensibly a risk/benefit statute. And beyond formal regulations, subtle (or not-so-subtle) pressure can be applied to regulators and politicians to approve products in part due to perceived need or benefits.

But the assessment of the benefits of genetic engineering and other technologies typically do not include consideration of viable agroecological alternatives that provide multiple ecosystem services and have been shown to be highly productive and profitable. Similarly, conventional breeding methods often can accomplish what more controversial genetic engineering has been predicted to accomplish, but has often failed to do. So in virtually all cases, alternatives exist to GE approaches, and in most cases those alternatives have advantages over GE.

Therefore, a fulsome benefits assessment that includes alternatives that are known to be highly sustainable would often obviate the claimed "need" arguments used directly or indirectly to justify potentially risky technologies. Transitioning to such systems requires providing material help to farmers in the form of incentives, information, loans, insurance, subsidies to cover costs of transition, and so forth, and sometimes additional research. But unless we commit to moving in such directions, in part by requiring new technologies, including newer genetic engineering methods, to advance agroecological principles, we will continue to reinforce a globally destructive form of agriculture. This is now considered scientifically unacceptable for fossil fuels due to their contribution to climate change, and it should be unacceptable for industrial agriculture that also causes tremendous harm on a global scale.