EPA’s Proposed Biotech Policy Turns a Deaf Ear to Science

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The U.S. Environmental Protection Agency (EPA) has proposed to further expand its regulatory coverage of transgenic crops in a way that cannot be justified on the basis of either scientific evidence or experience. The results of both scientific studies and practical experience gained over the past several decades support the conclusion that molecular modification techniques are no more dangerous than any other modification techniques now in use. A further increase in the regulatory burden would impose steep barriers to scientific innovation and product development across all sectors of our economy and would not only fail to enhance safety, but would be likely to prolong reliance on less safe and obsolete practices.

The two most widely adopted genetically modified (GM) crops are illustrative. Insect-resistant GM crops, primarily cotton and corn, require less pesticide than conventional crops. Pesticides are toxic not only to targeted insects, but can also affect non-target beneficial insects, and aquatic life. At high levels of exposure they are toxic to farm workers. Decreasing the use of pesticides is better for farm workers and has less impact on biodiversity. Moreover, contamination by carcinogenic mycotoxins has been shown to be as much as an order of magnitude lower in GM than in non-GM corn. The availability of herbicide-tolerant soybeans has promoted the rapid adoption of no-till farming, a method that markedly decreases soil erosion, builds soil quality, and decreases the carbon footprint of agriculture.

Twenty-five years ago, the White House Office of Science and Technology Policy published a policy statement (51 Federal Register; 23302 June 26, 1986) that created a “Coordinated Framework for the Regulation of Biotechnology” in the United States. At the time the Coordinated Framework was articulated, a degree of caution seemed reasonable. The Framework sought to achieve “a balance between regulation adequate to ensure health and environmental safety while maintaining sufficient regulatory flexibility to avoid impeding the growth of an infant industry.” At that time it was acknowledged that the framework should be “expected to evolve in accord with the experiences of the industry and the agencies, and, thus, modifications may need to be made.”

Since then, the results of extensive research, coupled with years of experience, has led to the conclusion that...
there is no scientific basis to single out plants produced by transgene insertion for special regulatory review, nor to distinguish these products from others on the basis of the process used to create them. The EU has spent more than €500 million doing GM biosafety research over the past 25 years. Its recent lengthy report can be summarized in one sentence: crop modification by molecular methods is no more dangerous than crop modification by any other method. Every serious scientific body that has analyzed the data, including the U. S. National Academy of Sciences and the British Royal Society, has come to the same conclusion.

As long ago as the late 1980s, a committee of the National Academy of Sciences that studied the question of introducing genetically modified plants into the environment concluded that regulation should focus on the properties of the genetically modified organism, not the process by which it was modified. There is now abundant evidence that the most appropriate regulatory approach would be to require review only of truly novel traits introduced into plants without regard to the methods used for their introduction. Yet the regulatory apparatus in the U.S. has increasingly moved in the opposite direction toward ever greater regulation and increased data requirements for transgenic plants, despite the abundant accumulation of data attesting to their safety.

The scientific community has a strong interest in keeping regulations science-based and commensurate with the risk of the products at issue. In March 2011, the EPA announced (in the Federal Register) a draft proposed rule to codify data requirements for plant incorporated protectants (PIPs). This draft was forwarded by the EPA to the U.S. Department of Agriculture (USDA), Department of Health and Human Services and Congress for review in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act. Based on initial reviews of that draft proposal and recent EPA actions associated with biotechnology-derived crops, it is clear that the EPA is departing from a science-based regulatory process, instead walking down a path toward a policy based on the controversial European “precautionary principle” that goes beyond codifying data requirements for substances regulated as PIPs for the past 15 years. While this principle is politically popular in some constituencies, it is not supported by experience gained over the past several decades with transgenic crops.

We are particularly troubled by proposals to expand the EPA’s current oversight into areas such as virus resistance and weediness. These areas have been adequately addressed by the USDA since 1986. Already, the EPA has expanded its oversight into virus resistance, which previously had been the purview of the USDA’s Animal and Plant Health Inspection Service (APHIS) and which the EPA prudently proposed in 1994 to exempt from its regulations. Under the draft proposed rules, the EPA would further expand its regulations and data demands to other areas historically covered by USDA-APHIS without the slightest justification based on either data or experience.

It is most troubling that the EPA is also proposing to increase its regulation to cover matters which are still not deemed to be threats even after years of study, such as gene transfer from plants to microorganisms. In other actions, the EPA has expressed its right to regulate plants engineered for altered growth (e.g., by suppression of ethylene production) the same way it regulates synthetic plant growth regulators. The agency does so based on a generous interpretation of the enabling legislation, despite the absence of any scientifically credible hazard.

Such an expansion in regulatory purview would reverse long established and highly successful policy under the Coordinated Framework. Such a shift would

1) create a duplicative regulatory system for very low risk products delivering substantial, demonstrated environmental benefits;
2) increase costs, reduce efficiency and prolong the review timelines, thereby discouraging innovation;
3) dramatically increase the hurdles already facing academic institutions and companies attempting to improve so-called minor use or specialty crops through modern biotechnology; and
4) adversely impact trade in safe and wholesome commodities produced by U.S. growers because of the stigma attached to anything characterized as a “pesticide” (a regulatory label for DNA that is unique to the U.S.) and with no concomitant increase in product safety. In addition, any expansion in regulatory oversight not resulting from documented risk could have global ramifications, as policymakers in other countries routinely consider U.S. policymakers as leaders in the regulation of crops derived from biotechnology.

It is astonishing that the EPA would attempt such an expansion of its regulatory activity in this sphere. We now have the results of more than 30 years of transgenic plant research and 15 years of experience growing and consuming biotechnology-derived crop plants on a large scale. None of the hypothetical risks articulated at the dawn of this era has been realized and caused new environmental problems. On the contrary, billions upon billions of meals derived from these crops have been eaten by humans and livestock around the world with no ill effects. Moreover, environmental impacts of production agriculture and the carbon footprint of agriculture have been significantly reduced using transgenic crops. At the same time, farmers have benefited economically, socially, and through improved health. These indisputable results make a compelling case for the reduction of existing regulatory burdens. There is absolutely no justification in either scientific data or experience for the regulatory expansion proposed by the EPA.

Over the last two decades, advances in sequencing and genomic analysis have revealed that biotechnology is more precise and less disruptive to the genome than traditional plant breeding. In fact, recent genomic, proteomic, and metabolomic comparisons of varieties bred (using conventional and transgenic methods)
demonstrate that transgenic plants with incorporated novel traits more closely resemble the parental variety than do new varieties of the same crop plant produced by more traditional breeding or mutagenesis techniques. These findings support the crop-level observations that transgene insertion is not inherently disruptive and that transgenic crops present no new or greater hazards than crops produced by breeding techniques now considered conventional. Indeed, they are not only less disruptive, but far more precise because they introduce or modify the sequence or expression of well-characterized genes in predictable ways, objectives which cannot be achieved by any previous method.

Recent EPA actions signal an intent to expand the agency’s regulatory oversight over products regulated by USDA for more than two decades and to products for which there has never been a justification for regulation. These actions are not only inconsistent with regulatory directives mandated by the current administration, but they also erode the integrity of the Coordinated Framework. Such expanded regulation would serve only to increase costs, hinder research, undermine the long-term viability of public university research programs, and limit product development from the private sector. The proposed actions would threaten our ability to produce high quality food at an affordable price and to feed a growing population. They would also weaken the competitive advantage of U.S. public research programs in the global research arena, all with no increase in safety for consumers, farmers, or the environment — indeed, the contrary would be the case in many instances.

The academic community is committed to ensuring that the environmental and food safety benefits of biotechnology-derived plants continue to accrue, and it is essential that all agencies respect the scientific basis for regulation and division of regulatory responsibilities established by the Coordinated Framework. It is critical that regulations focus on scientifically demonstrated hazards, rather than being driven by issues of perception or political expediency. Therefore, we urge that the pending EPA regulatory actions be reconsidered and the rule-making proposal be limited to requirements for substances that have traditionally been regulated by the EPA, such as PIPs, and then only to those requirements that are fully justified on the basis of sound science.

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