Regulatory Transparency Project

Unlocking Innovation & Opportunity

We Need Smarter Regulation of Food and Agricultural Biotechnology

Energy & Environment

John J. Cohrssen

Henry I. Miller

This paper was the work of multiple authors. No assumption should be made that any or all of the views expressed are held by any individual author. In addition, the views expressed are those of the authors in their personal capacities and not in their official/professional capacities.

To cite this paper: John J. Cohrssen, et al., "We Need Smarter Regulation of Food and Agricultural Biotechnology", released by the Regulatory Transparency Project of the Federalist Society, September 27, 2018 (https://regproject.org/wp-content/uploads/RTP-Energy-Environment-Working-Group-Paper-Food-and-Agricultural-Biotechnology.pdf).

27 September 2018

Table of Contents

I. Introduction

In the early 1970s a group of scientists — none involved in agriculture or food — raised concerns about the hypothetical hazards that might arise from the use of the newly discovered molecular genetic modification techniques (recombinant DNA technology) that could alter the inheritable characteristics of an organism via directed changes in its DNA.

That led to an initial voluntary moratorium on the use of the new recombinant DNA (r-DNA) techniques, and subsequently the creation by the National Institutes of Health of guidelines for the application of these techniques for *any* purpose. These "process-based" guidelines, which were applicable exclusively to the use of these new techniques, were in addition to the existing "product-focused" regulatory requirements of FDA, USDA and EPA. For example, without regulatory approval the "intentional release" of "recombinant organisms" into the environment or fermentation (in contained fermenters) at volumes greater than ten liters of was prohibited.

No similar blanket restrictions existed for plants or other organisms similarly modified by traditional techniques, such as chemical or irradiation mutagenesis.

Thus, premature and ultimately ill-founded concerns about the risks of r-DNA organisms in agriculture and environmental applications precipitated the regulation of r-DNA organisms triggered simply by the "process," or technique, for genetic modification, rather than the "product," i.e., the characteristics of the modified organism.

The regulatory burden on the use of recombinant DNA technology was, and remains, disproportionate to its risk, and the opportunity costs of regulatory delays and expenses are formidable. According to Wendelyn Jones at DuPont Crop Protection, "A survey completed in 2011 found the cost of discovery, development and authorization of a new plant biotechnology trait introduced between 2008 and 2012 was $136 million. On average, about 26 percent of those costs ($35.1 million) were incurred as part of the regulatory testing and registration process." Thus, given that at least 120 genetically engineered seeds with new traits have been approved by USDA, the public and private sectors have spent billions of dollars on complying with superfluous, redundant regulatory requirements that have priced public sector and small companies' agricultural research and development (R&D) out of the marketplace.

These inflated development costs are the primary reason that more than 99% of genetically engineered crops that are cultivated today are large-scale commodity crops — corn, cotton, canola, soy, alfalfa and sugar beets. Virus-resistant Hawaiian papaya, bruise- and fungus-resistant potatoes and non-browning apples are among the few examples of genetically engineered "specialty crops," such as fruits, nuts, or vegetables. Early concerns from the food industry about possible food contamination led to onerous USDA restrictions on the once-promising sector of "biopharming," which uses genetic engineering techniques to induce crops such as corn, tomatoes, and tobacco to produce high concentrations of high-value pharmaceuticals. Likewise, the once high hopes for genetically engineered "biorational" microbial pesticides and microorganisms to clean up toxic wastes are dead and gone. Not surprisingly, few companies or other entities are willing to invest in

the development of badly needed genetically improved varieties of the subsistence crops grown in the developing world.

While multinational corporate crop developers can bear these high regulatory costs for high-value, large-volume commodity grains, excessive regulation disproportionately affects small enterprises and, especially, public research endeavors, such as those at land-grant universities, which lack the necessary resources to comply with burdensome and costly regulatory requirements. Therefore, land grant universities have been put at a substantial competitive disadvantage and are seldom able either to expose their students to state-of-the-art breeding programs or to create important new varieties. The global regulatory compliance costs associated with a new insect-resistant or herbicide-resistant recombinant DNA-modified variety of corn, for example, which are, as noted above, around $35 million, do not include the resources spent on products that are never approved; the costs borne by growers, shippers and processors associated with segregation, traceability and special labeling; or the opportunity costs of compliance with unnecessary regulation.

II. The Benefits of Genetic Engineering and New Biotechnology Techniques (NBTs) in Agriculture

The history of agriculture is one of constant, incremental improvements to plants, animals and microorganisms to improve quality, yield and efficiency, as well as technologies for food production, environmental protection, and sustainability.

Although similar to other techniques for genetic improvement that have modernized agriculture, modern molecular genetic engineering, including NBTs, offers more precise and efficient ways to:

- Increase crop productivity by means of:
    - Disease and pest resistance
    - Drought resistance
    - Flood resistance
    - Adaptation to temperature variation
- Decrease cost of food animal production
    - Faster, more efficient growth
    - Easier to manage, e.g., hornless cattle
- Greater farm-to-market efficiency
    - Longer shelf-life, fresher produce
- Improved nutrition and taste

    - Improved nutrient quality
    - Added vitamins
- Environmental protection
    - More efficient water utilization
    - Reduced inputs such as fertilizers, herbicides and insecticides
    - Less runoff and soil erosion
    - Improved animals, with less toxic waste products
    - Bioremediation
- Improved food processing
    - Processing enzymes such as GE chymosin to replace rennet
- Manufacture of specialized products
    - Pharmaceuticals
    - Chemicals

In spite of decades of over-regulation, the contributions of molecular genetic engineering to agriculture have been prodigious. According to economists Graham Brookes and Peter Barfoot:

> Economic benefits at the farm level amounting to $15.4 billion in 2015 and $167.8 billion for the 20 year period 1996-2015 (in nominal terms). These gains have been divided 49% to farmers in developed countries and 51% to farmers in developing countries. About 72% of the gains have derived from yield and production gains with the remaining 28% coming from cost savings.

Genetic engineering has also led to significantly reduced negative impacts on the environment:

> GM traits have contributed to a significant reduction in the environmental impact associated with insecticide and herbicide use on the areas devoted to GM crops (Table 6). Since 1996, the use of pesticides on the GM crop area was reduced by 618.7 million kg of active ingredient (8.1% reduction), and the environmental impact associated with herbicide and insecticide use on these crops, as measured by the [Environmental Impact Quotient], fell by18.6%.

The authors have also quantitated the environmental benefits of reduced fuel use from less frequent herbicide or insecticide applications and a reduction in the energy use in soil cultivation:

> The fuel savings associated with making fewer spray runs (relative to conventional crops) and the switch to conservation, reduced and no-till farming systems, have resulted in permanent savings in carbon dioxide emissions. In 2015, this amounted to about 2,819

> million kg (arising from reduced fuel use of 1,056 million liters. Over the period 1996 to 2015 the cumulative permanent reduction in fuel use is estimated at 26,223 million kg of carbon dioxide (arising from reduced fuel use of 9,821 million liters).

Finally, they cite the benefits of "'no-till" and "reduced-till" farming systems:

> These production systems have increased significantly with the adoption of GM [herbicide-tolerant] crops because the GM [herbicide-tolerant] technology has improved farmers' ability to control competing weeds, reducing the need to rely on soil cultivation and seed-bed preparation as means to getting good levels of weed control. As a result, tractor fuel use for tillage is reduced, soil quality is enhanced and levels of soil erosion cut. In turn more carbon remains in the soil and this leads to lower [greenhouse gas] emissions.

III. The Risks of Genetic Engineering and New Biotechnology Techniques (NBTs) in Agriculture

The Recombinant DNA (r-DNA)-mediated genetic engineering (GE) involves cutting and splicing DNA with enzymes called restriction nucleases and often involves inserting a new tiny segment of DNA to change or improve an organism's characteristics. R-DNA and newer, even more precise techniques provide greater power, precision and efficiency than traditional methods for plant and animal breeding, food production, environmental applications, and so on.

The fundamental concern underlying the basis for regulation of GE in the 1970s was whether it conferred unique risks because of the combination of particular DNAs or the introduction into organisms of foreign genomic material. Numerous national and international scientific organizations have repeatedly addressed this question, and hundreds of risk-assessment experiments have been conducted, many under the aegis of the highly risk-averse European Commission. The results have led to a wide consensus that no unique or incremental risks are likely to arise from the use of the newer GE techniques.

Among scientists, there is a broad and longstanding consensus that GE crops and foods are no less safe than corresponding conventionally bred crops and foods. In the nearly half a century since its inception, not a single case of harm to human health or to an ecosystem attributed to a GE modification has been documented.

The National Academies of Science, Engineering and Medicine's Consensus Study Report, "Genetically Engineered Crops: Past Experience and Future Prospects (2016)," concluded that "no differences have been found that implicate a higher risk to human health safety from these GE foods than from their non-GE counterparts." Similarly, "Overall, the committee found no conclusive evidence of cause-and-effect relationships between GE crops and environmental problems. However, the complex nature of assessing long-term environmental changes often made it difficult to reach definitive conclusions."

This latest National Academies report is only the most recent in a decades-long history of scientific reports, the most definitive of which were published in 1987 and 1989. The conclusions of the former included:

- There is no evidence that unique hazards exist either in the use of [r-DNA] techniques or in the transfer of genes between unrelated organisms.
- The risks associated with the introduction of [r-DNA] engineered organisms are the same in kind as those associated with the introduction into the environment of unmodified organisms and organisms modified by other genetic techniques.

In the most comprehensive and unequivocal analysis, the 1989 U.S. National Research Council report, "Field Testing of Genetically Modified Organisms," on the risks of genetically engineered plants and microorganisms, concluded that "the same physical and biological laws govern the response of organisms modified by modern molecular and cellular methods and those produced by classical methods."

But this analysis went further, emphasizing that the more modern molecular techniques are more precise, circumscribed, and predictable than other methods:

> Recombinant DNA methodology makes it possible to introduce pieces of DNA, consisting of either single or multiple genes, that can be defined in function and even in nucleotide sequence. With classical techniques of gene transfer, a variable number of genes can be transferred, the number depending on the mechanism of transfer; but predicting the precise number or the traits that have been transferred is difficult, and we cannot always predict the phenotypic expression that will result. With organisms modified by molecular methods; we are in a better, if not perfect, position to predict the phenotypic expression.

In 2000, the U.S. National Research Council released another report weighing in on the scientific basis of federal regulation of genetically engineered plants. It concurred with earlier assessments by other groups that "the properties of a genetically modified organism should be the focus of risk assessments, not the process by which it was produced."

IV. New Breeding Techniques (NBTs)

In contrast to recombinant DNA technology, which most often involves adding a DNA segment, rapidly emerging new breeding techniques (NBTs) employ recently developed technologies that simply modify or edit existing DNA. These new "genome editing" techniques include zinc finger nucleases, TALENs, CRISPR-Cas9 and CRISPR-Cas13. The use of NBTs gives researchers the ability to readily modify specific genes without having to introduce DNA from another species. NBTs can far more precisely deliver the same changes as those from traditional, unregulated technologies such as induced mutagenesis.

Under the Obama administration, FDA proposed lumping NBT-modified animals into the same over-regulated regime as recombinant DNA-modified ones; FDA has not advanced this proposal

under the Trump administration, although FDA Commissioner Scott Gottlieb has said that he favors it. USDA has said that it will not regulate NBT-modified plants under the Plant Protection Act as it lacks legal authority unless the modified organisms contain genetic material from a regulated plant pest. EPA has expressed interest in expanding its scope of regulation.

V. Current Regulation of GE/NBTs in Agriculture

Thirty years ago, the White House published an overarching regulatory regime for agriculture research and products, the 1986 U.S. Coordinated Framework for the Regulation of Biotechnology (CF), which relied on existing laws to regulate GE products.

In a Faustian bargain to placate hostile politicians, please eager regulators, calm anxious industry, and protect worried consumer activists, the White House announced a risk-based regulatory framework that focused on the particular risk a biotechnology product might present, rather than on the genetic modification technique used to develop it. However, agency interpretations and implementation mainly ignored this risk-based guidance, and instead imposed a regulatory approach that required premarketing and even pre-field-testing review of new GE organisms. The rigorous and often dilatory case-by-case reviews constituted a level of scrutiny far in excess of what would be required for the same product achieved through less precise methods of conventional non-molecular modification.

The regulations (or guidances) actually implemented under the Coordinated Framework incorrectly claimed to be product-focused and risk-based, but are, in fact, process-based because they are in most cases triggered by the use of virtually any r-DNA modification, regardless of the existence of a demonstrable hazard. The USDA, EPA, and FDA are the principal agencies regulating GE crops, pesticides, herbicides, drugs, foods and animals. They address the products' hypothetical hazards to agriculture, the environment, and/or human and animal health. Thus, for example, depending on the crop and trait, one, two, or all three of these agencies may independently evaluate and regulate an agricultural product. In many cases, all of the reviews are arguably superfluous, creating uncertainty and significant expense for product developers.

In addition to the product-specific reviews, the National Environmental Policy Act (NEPA) requires that an environmental assessment or environmental impact statement be prepared for any "major federal action" that may have a significant impact on the "human environment." Accordingly, a GE product review requires yet another separate review to comply with NEPA, except for evaluations performed by the EPA, whose reviews are considered to be equivalent to those required under NEPA.

U.S. Department of Agriculture

The Department of Agriculture (USDA), through its Animal and Plant Health Inspection Service (APHIS), is responsible for the regulation of genetically engineered plants. The Plant Protection Act (formerly the Plant Pest Act) has long regulated the importation and interstate movement of listed organisms (plants, bacteria, fungi, viruses, etc.) that are plant pests. A plant that an investigator

might wish to introduce into the field is either on the prohibited list of plant pests, and therefore requires a permit, or it is not regulated.

For the regulation of r-DNA modified plants, APHIS extended the original concept of a plant pest (something known to be harmful) and invented a new category — "regulated article" — specifically defined as a potential plant pest to capture virtually every r-DNA-modified plant for case-by-case review, regardless of its potential risk.

In order to perform a field trial with a regulated article, a researcher must apply to APHIS and submit extensive paperwork before, during, and after the field trial. After conducting field trials for a number of years at many sites, the researcher must then submit a vast amount of data to APHIS and request "deregulation," which is equivalent to approval for unconditional release and sale. These requirements make genetically engineered plants extraordinarily expensive to develop and test. The cost of discovery, development, and regulatory authorization of a new trait introduced between 2008 and 2012 averaged $136 million (about a quarter of which were regulatory compliance costs), according to Wendelyn Jones of DuPont Pioneer, a major corporation involved in crop genetics.

APHIS's regulatory approach to r-DNA-modified plants is difficult to justify. Plants have long been selected by nature, as well as bred or otherwise manipulated by humans, for enhanced resistance or tolerance to external threats to their survival and productivity, such as insects, disease organisms, weeds, herbicides, and environmental stresses. Plants have also been modified for qualities attractive to consumers, such as seedless watermelons and grapes and the tangelo, a tangerine-grapefruit hybrid.

For new varieties of plants, risk is a function of certain characteristics of the parental plant (such as weediness, toxicity, or ability to "outcross" with other plants) and of the introduced or modified gene or genes. In other words, it is not the source or the method used to introduce a gene but its function that determines how it contributes to risk. Plant breeders conduct assessment of the risks and determine the approach to managing the new varieties. New varieties of plants (whichever techniques are used to craft them) that normally harbor relatively high levels of various toxins are analyzed carefully to ensure that levels of those substances remain in the safe range. Celery, squash, and potatoes are among the crops in need of such attention.

Under USDA's APHIS, however, it is primarily plants made with the newest, most precise techniques that are subjected to more extensive and burdensome regulation, independent of the level of risk. Thus, the concept of "regulated article" turns on its head the common-sense notion that the degree of safety regulation — i.e., government intrusion — should be commensurate with the risk of a product, process or activity.

The regulated article construct, which is based on the possibility that the presence of part of a regulated plant pathogen could confer plant pest risk on the GE plant, is bureaucratically contrived and scientifically baseless. It leads to incongruous results. For instance, plant transformation involving synthetic or non-pathogen-derived DNA introduced by a different technique such as biolistics is not subject to regulatory consideration by APHIS. In contrast, an identical product

created using a process involving the plant pathogen *Agrobacterium* or the S35 promoter from Cauliflower Mosaic Virus becomes a "regulated article," while as a practical matter none of these should be subject automatically to case-by-case review.

APHIS has advised that NBTs do not trigger oversight by APHIS because the agency lacks the statutory authority under the Plant Protection Act to regulate if the resultant organism does not contain DNA from a plant pest.

Food and Drug Administration

Since 1992 the Food and Drug Administration (FDA) has had a science- and risk-based approach toward "novel foods" made with any technology. FDA's Center for Food Safety and Nutrition does not impose discriminatory regulation based on the use of one technique or another, but conducts a more extensive review if, for example, the food contains a substance completely new to the food supply, has increased levels of a toxin, or would expose consumers to an unexpected allergen. In addition, FDA has resisted calls for mandatory labeling of genetically engineered foods as not materially relevant information under the federal Food, Drug and Cosmetic Act, and as not consistent with the statutory requirement that food labeling must be accurate and not misleading.

In implementing its policy, FDA created a Plant Biotechnology Consultation Program to work cooperatively with developers of GE plants to help them ensure foods made from their new GE plant varieties are safe and lawful. In this program, FDA evaluates the safety of food from the new GE crop before it enters the market. While established as a voluntary program, GE plant developers routinely participate with FDA to consider food safety and nutritional issues, such as whether the GE plant contains a new toxin or allergen or is as nutritious as its traditionally bred counterpart.

FDA has asserted regulatory jurisdiction over GE animals, taking advantage of a perceived regulatory vacuum. In 2008 the FDA's Center for Veterinary Medicine issued guidance that said that the altered DNA within every genetically engineered animal would be evaluated as a veterinary drug and subjected to the same onerous premarket approval procedures and regulations as drugs (such as pain relievers and anti-flea medicines used to treat animals). The rationale offered was that a genetically engineered construct "that is in a [GE] animal and is intended to affect the animal's structure or function meets the definition of an animal drug."

The failure of this approach is obvious from FDA's taking more than 20 years to complete a review of a faster-growing a GE salmon made by a company that first approached FDA in 1993. Today neither that salmon, nor any other GE food animal is marketed in the U.S. Although the FDA finally approved the GE salmon in 2015, Congress has prohibited its sale until such time that guidelines for its labeling are finalized. In contrast, the GE salmon has been approved in Canada and is popular among consumers there.

FDA similarly struggled for a protracted time to approve a limited field trial of a GE mosquito which was designed to reduce the population of these disease-carrying insects. Eventually FDA had to defer to EPA's broad authority over pesticides and transferred jurisdiction to that more suitable agency.

The once-promising sector of GE food animals in the U.S. has virtually disappeared. They were first developed 30 years ago in land-grant university laboratories, but those animal-science innovators have grown old without gaining a single approval for their work. Many academic researchers who have introduced promising traits into animals have moved their research to other nations, particularly Brazil. Many younger animal scientists have simply abandoned the field. As for the faster-growing salmon, regulators kept it in regulatory limbo while imposing costs of more than $75 million on its developers. Genetically engineered animals could be regulated elsewhere and under different paradigms at far less time and cost.

There is reason to worry that the use of "new breeding techniques," or NBTs, may not fare any better at FDA than the salmon. For example, a University of Minnesota animal scientist has used the TALENs technique to edit a gene in the Holstein dairy cattle breed to duplicate the DNA sequence of the hornless (*polled*) gene found in the Angus beef cattle breed. This gene editing results in Holstein cattle which exhibit the hornless trait, a modification that provides greater animal welfare for dairy cattle (i.e., by making mechanical dehorning unnecessary) and greater safety for dairy farmers (i.e., avoidance of being gored). But FDA has refused to consider the Holsteins under the same approach it uses for GE foods. Rather, FDA has asserted that the Holstein cattle contain a "new animal drug" and that, therefore, the animals cannot be released or marketed until a new animal drug approval is granted.

Environmental Protection Agency

The EPA regulates field tests and the commercial use of pesticides under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). In 2001, the agency issued final rules for the regulation of GE plants and created a new concept, "plant-incorporated protectants" (PIPs), defined as "pesticidal substances produced and used by living plants," but EPA regulation captures such pest-resistant plants only if the "protectant" has been introduced or enhanced by the most precise and predictable GE techniques.

Extensive testing is required for registration of these new "pesticides," including gathering copious data on the parental plant, the genetic construction, and the behavior of the test plant and its interaction with various species, among other factors. (These requirements could not be met for any plant with enhanced pest-resistance modified with older, cruder techniques, which are exempt from the FIFRA rules.) While FIFRA provides a 10-acre research exemption for pesticides, it does not apply to PIPs.

The EPA conducts repeated, redundant case-by-case reviews: before the initial trial, when trials are scaled up or tested on additional sites, and again if even minor changes have been made in the plant's genetic construct. The agency repeats that review again at commercial scale. The agency's classification of living plants as pesticides, even though the regulatory term is "plant-incorporated protectants," has been vigorously and widely condemned by the scientific community for decades.

The assessment of genetically engineered crops within the EPA is intended to regulate the pesticidal property rather than the crop itself. For instance, a GE Bt-containing crop is evaluated principally

through assessment of the PIP (the expressed Bt protein), provided the transformed crop otherwise shows similarity (in weediness and outcrossing potential) to its non-transformed counterpart. But the newly-introduced pesticidal trait and the plant itself are indivisible.

EPA's classification of fragments of DNA, nucleotides, and genes as pesticides has created its own set of incongruities. In contrast to crops created by conventional breeding, in which the genetic basis for the new traits is often complex and uncharacterized (because the techniques employed are less refined), GE crops (in which the genetic changes are more circumscribed) with new or enhanced pesticidal properties must be reregistered as pesticides at periodic intervals, and the seed or nursery stock must bear a pesticide label. Fines have been imposed on companies importing seeds from winter nurseries when they have not had the proper pesticide import permits.

Not surprisingly, only three crops engineered for disease resistance — papaya, plum and potato — have managed to receive EPA approval, in spite of the ease with which resistance genes can be transferred or edited. In contrast, the multitude of disease-resistant crops developed using traditional breeding methods faced no premarket regulatory review.

As to NBTs, under FIFRA there is an exemption for "pesticidal substances produced through conventional breeding of sexually compatible plants," so a lot depends on whether or not CRISPR-cas9 is considered conventional breeding by the EPA. The agency has not yet made a decision.

The Toxic Substances Control Act (TSCA) regulates chemicals other than pesticides. GE microorganisms are “new chemicals” subject to pre-market approval for testing and commercial release. Captured for review is any “new” organism that contains combinations of DNA from sources that are not closely related phylogenetically. As molecular genetic engineering techniques can easily create new gene combinations with DNA from disparate sources, EPA concludes that these combinations therefore “have the greatest potential to pose risks to people or the environment,” according to the agency press release that accompanied the rule.

From a risk perspective, EPA’s statement is a *non sequitur*. The particular genetic technique employed to construct new strains is irrelevant to risk, as is the origin of a snippet of DNA that may be moved from one organism to another. What matters is its function. Scientific principles and common sense dictate the questions that are central to risk analysis for any new organism. How hazardous is the original organism from which DNA was taken? Is it a harmless, ubiquitous organism found in garden soil, or one that causes illness in humans or animals? Does the newly transferred genetic material code for a potent toxin? Does the genetic change merely make the organism able to degrade oil more efficiently, or does it have other effects, such as making it more resistant to being killed by antibiotics or sunlight?

NBTs have created concern at EPA, where there are internal pressures to declare that all forms of molecular modification create “new chemicals,” which would still further expand the agency’s regulatory reach under TSCA. If EPA were to adopt this broader “new chemicals” approach, there is legitimate concern that products from these new techniques would face the same fate as r-DNA-

modified microorganisms, only one of which has been approved by EPA since it declared them to be new chemicals in 1997.

VI. Better Regulation: The Way Forward

As discussed above, there is no evidence that simply inserting DNA into a genome via r-DNA technology leads to unique or incremental risks, nor is there any published evidence that heterologous (foreign) DNA insertions pose any unique risks. Compared with conventional breeding, the insertion of well-characterized fragments of DNA or modifications using recombinant DNA technology or NBTs does not increase the probability of unintended, adverse effects. In fact, as quoted above from a 1989 National Research Council report, "With organisms modified by molecular methods, we are in a better, if not perfect, position to predict the phenotypic expression." In practice, that means a lower likelihood of unintended negative consequences of genetic modification.

The simplest, approach to avoiding the inappropriate expansion of the scope of regulatory policy would be to exclude NBTs from the Coordinated Framework, so that organisms modified with them would be treated no differently than the products of conventional breeding. But that would still leave r-DNA modification over-regulated and would neglect the opportunity to address the longstanding, irrational, insupportable fears about hypothetical hazards, which led to the flawed regulatory regimes that have prevailed for 40 years.

That brings us to the second approach — correcting the implementation of the Coordinated Framework by requiring regulatory and guidance changes at USDA, EPA and FDA, so that those agencies would adhere to the risk-based regulatory approach originally proposed. Almost a half-century of experience with GE organisms and two decades of extensive experience with commercial GE crops have shown that use of r-DNA technology alone does not generate greater risk concerns than organisms modified with other techniques. It is past time for regulatory reform to remove the excessive burdens on research and development, which would both encourage innovation and begin to alleviate public misapprehensions fed by government over-regulation.