

# The USDA's Anti-Science Activism

Politics are hijacking the regulatory process.

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U.S. Department of Agriculture Secretary Tom Vilsack must have been on vacation the day President Obama pledged in 2009 that “Science and the scientific process must inform and guide decisions” made by his administration and that “political officials should not suppress or alter scientific or technological findings and conclusions.” Why else would Vilsack, last December, have disregarded his own department’s scientific review and conclusion that a new, genetically engineered crop variety should be approved because it is safe for humans and the environment?

A comprehensive environmental review by USDA scientists had concluded that a genetically engineered alfalfa variety was substantially equivalent to other conventional varieties and posed no genuine risks. Vilsack chose to ignore those findings and pandered to the organic food lobby by announcing that the Agriculture Department might forbid farmers to plant the alfalfa variety on huge swaths of American cropland.

Organic farmers — who produce less than one percent of the nation’s agricultural output — have long complained that the cultivation of biotech crops jeopardizes their own production

because plants of the same species can cross-pollinate with one another. Organic farmers may not use the products of biotechnology, but unintended cross-pollination by a neighbor’s genetically engineered plants could in certain circumstances “contaminate” organic crops. A federal court even rescinded the USDA’s initial approval in 2005 of a biotech alfalfa variety on the grounds that the department failed to complete an Environmental Impact Statement addressing the issue of “coexistence” between genetically engineered and conventional varieties.

But even after the USDA’s subsequent environmental review concluded that coexistence was not a problem, Vilsack nevertheless sowed confusion and concern among American plant breeders and farmers by proposing geographic restrictions as well as minimum separation distances from other crops for the commercial cultivation of the genetically engineered alfalfa variety. This would have signaled an abandonment of any semblance of a scientific underpinning of regulation, and it would have been disastrous news for the vast majority of American farmers who have eagerly embraced genetic engineering technology that has delivered substantial economic and environmental benefits over the past two decades.

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## Affecting the Human Environment

To fully understand the context of Vilsack’s actions, some background is essential.

Under the National Environmental Policy Act of 1969 (NEPA), federal government agencies are required to consider the effects



that any “major actions” they take may have on the “human environment.” The obligation is triggered by all manner of decisions, such as proposing a new regulation, building a new federally funded highway, or approving a new agricultural technology.

If an agency concludes that its action will have no significant impacts, it issues a relatively brief Environmental Assessment that explains the basis for that decision. But if significant effects are likely, the agency must prepare a comprehensive and voluminous Environmental Impact Statement (EIS) that details every conceivable effect, runs to hundreds of pages, and requires thousands of bureaucrat-hours.

Since NEPA was enacted, however, prodding by environmentalists and decisions by compliant judges have expanded its coverage to such an extent that courts now interpret the term “human environment” to include not just tangible ecological harms that affect people and human communities, but also impacts that are economic, social, cultural, historic, or aesthetic. One decision by a federal district court in Minnesota illustrates just how liberally the statute is interpreted:

Relevant as well is whether the project will affect the local crime rate, present fire dangers, or otherwise unduly tap police and fire forces in the community, ... the project’s impact on social services, such as the availability of schools, hospitals, businesses, commuter facilities, and parking, ... harmonization with proximate land uses, and a blending with the aesthetics of the area, ... [and a] consideration of the project’s impact on the community’s development policy ... [such as] urban blight and decay [and] [n]eighborhood stability and growth....

In other words, not just genuine ecological risks but virtually any impact that can be imagined may constitute a cognizable harm under NEPA if a sympathetic judge agrees. Thus, if agencies fail to address some tangential, inconsequential issue, they can be tripped up by a litigant who alleges that the environmental review was incomplete or that the conclusions were inadequately documented. Both kinds of allegations have lately plagued USDA approvals of genetically engineered crops, with hugely disruptive effects.

Federal court decisions in 2006 and 2007 resulted in the revocation of field trial permits to test several different genetically engineered varieties, establishing the precedent that nearly any cultivation of a new genetically engineered plant would require an EIS. Two additional lawsuits filed to stop the approval and commercial sale of genetically engineered alfalfa and sugar beet varieties have been a nightmare for plant breeders, the seed industry, and especially farmers. Ironically, in none of those cases was there any actual environmental harm; quite the opposite, in fact.

Before approving the new alfalfa and sugar beet varieties, which were crafted to be resistant to the herbicide Roundup, USDA scientists evaluated data from hundreds of government-monitored field trials over a period of nearly a decade, along with numerous other studies of the real-world effects of other Roundup-resistant crops (marketed as “Roundup Ready”). The trait is harmless to humans and other animals, and several other

Roundup Ready crop varieties, including corn, canola, soybeans, and cotton, are grown annually on more than 60 million acres in the United States alone.

Not surprisingly, the USDA concluded that commercial use would have no significant environmental impacts. Departmental scientists prepared an Environmental Assessment for both varieties explaining their rationale, and the USDA approved them. That was not enough, however, for two federal judges in San Francisco who ruled that the Environmental Assessments were legally insufficient and revoked both approvals. Both decisions have proven to be a tremendous headache for farmers and seed breeders.

Roughly 5,500 farmers across the country had planted more than a quarter million acres of Roundup Ready alfalfa when, in 2007, Judge Charles Breyer revoked its approval over concerns about Roundup-resistant weeds and potential effects on organic farmers — concerns that USDA scientists and regulators had already considered and rejected. Fortunately, Roundup Ready alfalfa had not yet been widely adopted, and Judge Breyer’s decision permitted farmers to continue to grow and then harvest the alfalfa crop they had already planted. The court’s injunction only prohibited the sale of new seed until the USDA could complete the EIS and then re-approve the variety.

For America’s sugar beet growers, whose crop accounts for about half of the refined sugar consumed in the United States, the outcome was far worse. In August 2010, Judge Jeffrey White revoked the USDA’s approval of Roundup Ready sugar beets on similar grounds. Although Judge White permitted Roundup Ready beets then in the ground to be grown to maturity and harvested, his decision has sown monumental confusion because an estimated 95 percent of the sugar beets currently grown in the United States are of the Roundup Ready variety. With such intense demand for the genetically engineered variety, sugar beet breeders have cut back substantially on their production of conventional seeds, meaning that beet growers cannot easily switch back to conventional varieties because supplies of seed are inadequate. The commodity price of sugar shot up by 55 percent between August and November 2010, largely as a result of the court’s decision.

### Vilsack Steps In

The USDA finished its draft EIS for alfalfa in 2009 and, by December 2010, it had jumped through the hoops necessary to re-approve the crop. But in spite of the conclusion of the environmental review that the genetically engineered alfalfa was substantially equivalent to other varieties and posed no problems for regulators, farmers, or consumers, Secretary Vilsack proposed reapproving the product only on the condition that it not be planted within five miles of non-genetically engineered seed crops, solely to help make production a little easier for organic farmers. That restriction would have made an estimated 20 percent of the nation’s alfalfa production, and nearly half of western states such as California and Oregon that

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are significant alfalfa producers, off-limits to the Roundup Ready variety.

Vilsack insisted at the time that the planting restrictions were necessary to help biotech and organic crops coexist more peacefully. But such unprecedented restrictions ignore the realities of seed production and give short shrift to the needs of conventional farmers. It seems that the secretary of agriculture needs a cram course in plant biology and genetics, as well as in the USDA's own regulations.

Pollen is disseminated by the wind. Organic farmers and activists have long argued that plants on an organic farm cross-pollinated by a neighbor's genetically engineered crops would no longer be considered organic and therefore would be denied the higher price such foods command in the marketplace. Therefore, organic producers have demanded mandatory minimum planting distances and even a government-administered fund that would compensate organic farmers who were financially harmed by cross-pollination.

These claims and demands are specious. For one thing, they ignore the way that "organic" is defined by the production stan-

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dards of Vilsack's own department. The USDA's rules for organic production, which do bar the *intentional* use of genetically engineered crops, are based on process, not outcomes. In other words, as long as organic growers adhere to permissible practices and do not intentionally plant genetically engineered seeds, unintentional cross-pollination by genetically engineered plants (or for that matter, the drift of a prohibited pesticide onto their crops) does not cause those crops to lose their organic status.

Individual organic growers might promise retailers and consumers that their products will be completely free from all non-organic "contaminants," but that is a commitment they should know is difficult to keep. Tolerances for the presence of various unwanted substances are routinely incorporated into the standards for organic and other foods. Because farming takes place out-of-doors and in dirt, and products must be stored, the presence of actual contaminants like insect parts, rodent hairs and feces, and toxic molds is a fact of life, so federal safety regulations establish maximum limits for these things. The same rationale was at play when the USDA and representatives from the organic food industry jointly developed the standards for organic production.

Unwanted pollen flow is an issue that farmers and seed breeders have had to address for decades. Long before the advent

of the modern techniques of biotechnology, common law and agronomic customs recognized that seed breeders and organic farmers were producing specialized products and should therefore bear the responsibility to protect the genetic composition of their crops. Farmers and breeders must protect sweet corn from cross-pollination by the unpalatable field corn varieties fed to livestock, for example. And in a starker example, they must prevent canola from being cross-pollinated by rapeseed, which contains potent natural toxins. But there are a number of easily adoptable and flexible agronomic techniques, such as isolation distances and buffer zones, that growers can and do use successfully to preserve the identity of their crops.

For alfalfa, the Association of Official Seed Certifying Agencies, which sets standards for the purity of nearly all seed crops, requires buffer zones of just 165 feet in order to maintain the genetic integrity of certified seed and 900 feet for so-called foundation seed, where genetic standards are most exacting. That is sufficient to prevent nearly all cross-pollination but, of course, no amount of isolation would be perfect.

To provide an even greater margin of protection, farmers wishing to plant Roundup Ready alfalfa had even volunteered to implement their own planting restrictions that would put the onus on commodity growers to extend buffer zones up to a mile from non-genetically engineered seed breeders. Predictably, the organic industry rejected that offer, preferring restrictions that would essentially ban biotech crops from huge swathes of American cropland. Ronnie Cummins, director of the Organic Consumers Association, said "there can be no such thing as coexistence" with genetic engineering.

Such intransigence belies the organic industry and Secretary Vilsack's claim to want peaceful coexistence. After all, coexistence implies willingness for two parties to exist alongside one another. Forbidding the cultivation of biotech plants in such a large area could therefore only be seen as sacrificing the needs of conventional agriculture to the supposed interests of organic growers. More important, it would sacrifice a highly useful technology on the altar of green intolerance while actually causing harm. Genetically engineered crops have proven to be superior to organic in numerous ways that benefit humans and the natural ecosystem. Because yields are higher and they require lower inputs, biotech varieties conserve water and farmland and are more sustainable. They lessen the need for chemical pesticides and make possible more environment-friendly agronomic practices such as no-till farming, which causes less soil erosion and runoff and releases less carbon into the atmosphere. And genetically engineered grains are less susceptible to infestation by fungi and have lower levels of dangerous fungal toxins than organic grains. Farmers have found biotech crops to be so reliable and cost-effective that

plant genetic engineering has been the most rapidly adopted agriculture technology in history, expanding worldwide from just 4.2 million acres in 1996 to over 330 million acres in 2010.

After a tremendous backlash from the vast majority of American farmers who want access to biotech crops — as well as both Democratic and Republican farm-state politicians — the USDA finally relented and approved Roundup Ready alfalfa without the planting restrictions at the end of January 2011. But this is hardly a case of “no harm, no foul.” As Illinois farmer John Reifsteck wrote, “The problem is that Vilsack let politics hijack the regulatory process. He very nearly capitulated to a small group of outspoken activists who think that the retrograde methods of organic farming should take precedence over just about every other form of agriculture, including highly productive methods that are essential if we’re serious about keeping people fed and food prices in check.”

### More Obstacles

The USDA announced one week later that the genetically engineered sugar beets would be “partially deregulated” even though the EIS had not yet been completed. In an attempt to comply with the court order barring complete re-approval, the USDA issued four pages of mandatory, quite draconian limitations and conditions that will at least make it possible for some growers to plant the variety in 2011. Nevertheless, as a result of all this dithering, the uncertainty in the entire regulatory process will discourage breeders from developing and farmers from cultivating not only genetically engineered sugar beets, but other genetically engineered crops as well.

Environmental activists have already filed new lawsuits challenging the alfalfa re-approval and the sugar beet partial deregulation. They have also challenged the experimental field testing of a genetically engineered variety of eucalyptus, modified to increase tolerance to cold temperatures. Any of the dozens of fully approved biotech crop varieties now grown in the United States, or others currently being field tested, could be the activists’ next target. Moreover, every other new variety now being developed and future varieties yet to be created will be subject to a lengthy, expensive, redundant, and wholly unnecessary EIS.

The basis for these preposterous machinations can be laid at the door of generations of empire-building USDA bureaucrats. Genetically engineered crop varieties have been a huge boon to farmers, consumers, and the natural environment because they produce higher yields with lower inputs and reduced environmental effects. Last year the European Commission published the second report from a 25-year-long study that found that biotech crops are as safe, and sometimes safer, for consumers and

the environment as conventionally bred plant varieties. It also concluded that biotech varieties can help farmers globally to meet the needs of a rapidly rising world population while also addressing the related challenges of climate change in a sustainable way.

Countless other evaluations by scientific bodies worldwide over more than two decades have concluded that there is no scientific justification for regulating genetically engineered crops any differently from conventional ones. Nevertheless, U.S. regulatory agencies, including the USDA, Environmental Protection Agency, and Food and Drug Administration, have implemented costly and wholly unnecessary regulatory policies that subject only biotech crops to years of government-monitored pre-commercial testing and approval requirements.

It is ironic that only genetically engineered varieties, which are more precisely crafted than “conventional” ones and whose development and environmental impacts are carefully scrutinized by the USDA and EPA, are subject to the extra burden of compulsory EISs. Indeed, the asymmetrical burden exists only because the USDA rejected the advice of the scientific community some 25 years ago and chose instead to require a mandatory, discriminatory pre-approval process for genetically engineered plants, thereby spawning the “major actions” that trigger the EIS obligation.

Now, because of Secretary Vilsack’s trial-balloon planting restriction policy and his continuing insistence that some type

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of coexistence plan be developed, even products that do reach the marketplace could eventually be subject to the vagaries of politically driven limitations that serve only the interests of the organic food industry and biotech’s opponents. At best, his dithering creates uncertainty among agribusiness companies, which is anathema to expensive long-term research and development.

Some may be tempted to attribute Vilsack’s missteps to inadvertent bumbling by his advisers within the Agriculture Department. But a likelier explanation is the malevolent influence of USDA Deputy Secretary Kathleen Merrigan, who boasts a long and unsavory history of pro-organic, anti-biotechnology advocacy and actions. While a staffer on the Senate Agriculture Committee during the 1980s, Merrigan was instrumental in obstructing the approval of bioengineered veterinary drugs and in excluding genetically engineered crops from the “organic” rubric. Her record of anti-biotechnology activism constitutes an obvious conflict of interest that should have required her recusal from biotech-related deliberations and meetings at the USDA

(or better still, prevented her appointment to the department).

As in all newly elected administrations, President Obama and his minions made commitments to regulate in accordance with the dictates of science and to act in the public interest. They have failed spectacularly, instead consistently adopting unscientific, anti-technology, anti-business, economy-slowness, job-killing policies. This latest example is one of the most egregious. If Obama's concerns about the importance of scientific integrity in the regulatory process were genuine, both Vilsack and Merrigan would be history.

### Mitigating NEPA

If the president and Congress want to avoid such debacles in the future, they will need to reform or systematically work around NEPA's traps and pitfalls and deny activists the ability to interfere with the legitimate, appropriate actions of government agencies.

The purpose of NEPA is to ensure that agencies consider whether their actions may harm the environment. This is a reasonable goal, one that is very different from the anti-biotech NEPA litigation to obstruct the cultivation of new varieties that are forced to endure years of environmental testing and analysis just to clear approval hurdles. The statute has been hijacked by environmental activists in order to slow or prevent government agencies from taking actions the litigants do not like. Since the law requires agencies to consider almost any conceivable impact, no matter how meticulous the agency is in preparing an Environmental Assessment or EIS, the statute offers fertile ground for bad-faith, obstructionist litigation.

Remarkably, because the NEPA obligation is purely procedural, courts are not permitted to consider the fact that genetically engineered crop varieties have offsetting benefits to farmers, consumers, and the natural environment. The mere fact that the USDA did not properly document its evaluation of theoretical negative effects is sufficient grounds for revoking the approvals.

NEPA is therefore a recipe for stagnation, a particular problem for "gatekeeper" regulatory agencies that must grant approvals before a product can be tested or commercialized. Something must be done to change the system. But what? Short of substantive reform of the underlying statute by Congress — the preferable and definitive solution — agencies themselves can take some minor steps to mitigate the act's worst effects.

Under the NEPA statute, every agency may establish a set of "Categorical Exclusions" that exempt whole classes or types of activities from the EIS obligation. These may include routine or repetitive actions that, based on past experience, do not have significant impacts on natural, cultural, recreational, historic, or other resources; and also those that do not otherwise, either individually or cumulatively, have any significant environmental impacts. Because they fall into those categories, most small-scale field trials of genetically engineered plants have been categorically excluded by the USDA.

However, the exclusion stipulates that all large-scale field tests,

as well as any field release of biotech organisms involving unusual species or novel modifications, still generally require an Environmental Assessment or EIS. But the list of excluded or included activities could be modified via notice-and-comment rulemaking in which the agency sets forth the complete analysis and rationale for excluding the activity. The USDA could propose categorical exclusions for some of the classes of genetically engineered crops with which it now has more than two decades' of pre-commercial and commercial experience, including herbicide-tolerant varieties of common crop species. But such carve-outs would leave intact NEPA's fundamentally flawed, process-based approach to biotechnology.

The most reasonable and definitive approach, therefore, would be to eliminate the agency actions that trigger the NEPA obligation initially — namely, case-by-case reviews of virtually all field trials and of the commercialization of genetically engineered plants. That would offer the triple advantages of relieving the USDA's NEPA woes, making regulators' approach to genetic engineering more scientifically defensible and risk-based, and making it possible to dismantle a huge and superfluous regulatory bureaucracy. As the scientific community has been saying for over two decades, the decision to subject genetically engineered and conventional organisms to *sui generis* regulatory standards cannot be justified scientifically. The increasing prevalence of obstructionist litigation now shows that the irrationality of regulatory policy has wide ripple effects: it discourages farmers from using the safest and most efficient technologies, imposes direct and indirect costs on farmers and taxpayers, and is damaging to the nation's economy.

Recent NEPA lawsuits have prevented the marketing of products that offer palpable, demonstrated benefits to farmers, consumers, and the environment. Nuisance litigation intended to slow the advance of socially responsible technologies is abusive, irresponsible, and anti-social. And so are those who file such suits. It is long past time for NEPA's abusive paperwork requirements to be lifted from such an important and beneficial technology. **R**

### READINGS

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