

## GM Crop Regulations: Safety Net or Insurmountable Obstacle

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Regulations governing genetically engineered (GE) crops, even commodity crops, are overwhelming. For small-market GE crops, regulations have become almost impossible, especially for crops produced and tested in publicly-supported institutions, such as universities. At the AAAS symposium titled “*GM Crop Regulations: Safety Net or Insurmountable Obstacle?*” (<http://aaas.confex.com/aaas/2011/webprogram/Session2860.html>) held in Washington, DC, six speakers presented key impediments posed by US regulations, particularly when public institutions are trying to follow them, and offered possible improvements. The presenters focused their talks (summarized below) on two primary reasons that specialty GE foods are not currently commercially available: First, the current regulatory system is viewed as not sufficiently science-based and hence too costly to be justified for small-market crops; and second, the complexities of the regulatory system at the USDA, US EPA, and US FDA make the path to commercialization tedious, costly, time-consuming, and burdensome.

### Why We Need to Craft Science-based Regulations for GM Crops and Animals in the United States

— Nina Fedoroff, Pennsylvania State University

Dr. Fedoroff initially stressed attaining global food security—without destroying the environment—as a key challenge facing the world’s growing population in the twenty-first century. Scientists must adapt plants to a hotter, drier world using less water, producing less pollution, and, overall, having a lowered environmental footprint. GE crops may be capable of surmounting some of these challenges and reaching the market if researchers are given an opportunity to get past a maze of regulations.

Fedoroff and other speakers asked why the commercialization of GE crops has reached what is basically an impasse. Even the large-market crop alfalfa, recently given government go-ahead, may yet be stymied by litigation challenging government approval. In the 1970s and 1980s, there was general agreement that the potential hazards of GE crops must be systematically evaluated. A US National Academy of Sciences Council white paper published in 1987 said that there was no evidence that recombinant DNA technology was inherently hazardous and that the introduction of recombinant DNA engineered organisms into the environment should be based on the properties of the modified organism, not on the process through which it was generated. Thus, Fedoroff opined, what we *should* evaluate is the *product* and *not* the process by which GE crops are created. That basic thought – product not process – has been lost in an expensive, complex, and time-consuming maze of regulations.

Three agencies are given the task of evaluating risks: USDA Animal and Plant Health Inspection Service (APHIS), the US Food and Drug Administration (FDA) and the US Environmental Protection Agency (EPA). These agencies are required to regulate GE products using existing regulations. One especially problematic result of this approach is that EPA treats GE crops as if they were toxic chemicals.

### Two case studies illustrate the problems with current regulations

#### CASE ONE

#### A View from the Trenches: Challenges in Bringing GE crops to market: Enhanced Disease Resistance in Peanuts

— Elizabeth Grabau, Virginia Tech

Sclerotinia blight, a devastating fungal disease of peanuts, was first found in the US in Virginia in 1971. The pathogen produces oxalic acid, which predisposes infected plants to infection and disease. Fungicide control

is only partially effective and extremely expensive. The Virginia Tech group introduced a barley gene into peanuts that encodes for oxalate oxidase, the enzyme that degrades oxalic acid and thus confers resistance to the disease. Although oxalate oxidase is present naturally in a number of food products, regulations required extensive toxicity data and testing for allergenicity.

Dr. Grabau described rigorous testing of the GE peanuts for environmental health and safety risk assessments this past seven years, including six years of field tests, 2004 – 2010. Field tests required by APHIS are different than those required for a crop produced by a conventional breeding program. Results over the years were evaluated by APHIS, FDA, and EPA not once, but a series of times. Each time, additional requirements were imposed as part of the assessment process. Grabau described the regulations as complex, expensive, and time-consuming. In addition to the time and effort of faculty and staff, hundreds of thousands of dollars have been spent.

Although Grabau expressed a fear that the peanuts may never get to market, they may finally be near the end of their trials. Grabau and colleagues are hopeful of approval for marketing in 2011.

## **CASE TWO**

### **A View from the Trenches: Challenges in Bringing GE Crops to Market: Resistance to Plum Pox Virus in Plum Tree**

— Ralph Scorza, USDA Fruit Research Station, Kearneysville, WV

Dr. Scorza described a 21 year effort to develop and market a GE plum tree capable of overcoming the plum pox virus. These plum trees, developed in greenhouses in 1990, employ gene silencing to confer resistance to the virus. After 1990, the trees underwent eleven years of field testing in both the US and Europe, involving ecological studies such as gene flow into the environment and non-target effects.

After 15 years of study and interactions with APHIS, FDA, and EPA, Scorza's group (over a five-year period) submitted data packages to APHIS and then the other two agencies. The GE plum was approved by APHIS and FDA and was conditionally registered by EPA in 2010. Unconditional registration is expected in 2011.

It has taken Scorza 21 years to get to this point. However, he believes that they could get some future GE product through the system more quickly, now that they know the process.

However, their Fruit Research Station—like Virginia Tech described above—is a public institution. They have had relatively little grant support for this work and it is not the type of work that rewards scientists with publications in the highly rated peer-reviewed journals. Many public sector scientists therefore choose to publish exciting proofs of concept but do not take these results to products.

## **The Present Regulatory Systems, Their Complexity and Costs**

— Drew L. Kershen, University of Oklahoma

Mr. Kershen provided a lawyer's perspective to the symposium. He was the most emphatic among the speakers at the symposium that there is no evidence of unique risks posed by GE crops. Not only the US Academy of Science, but numerous other Academies of Science around the world have come to similar conclusions. Interestingly, European countries, so often negative to GE crops, express surprise at the *benefits* of GE crops. Nonetheless, at the end of 2010, the United States, instead of moderating, seems to be tightening the regulation of GE crops.

Kershen noted that direct negative impacts of the current regulatory burden include time and cost; abandonment of research; and transfer of research to other countries. Another direct impact is the litigation brought against cultivating GE crops, even after they have undergone regulatory hurdles and been approved. Because other countries often follow the lead of the US, another direct impact may be tightened regulations in other countries.

Kershen insists regulatory attitudes must change. Specifically, he advocates changing the “fundamental underlying statute” so that no extra regulations would control GE plants. He wants to “get the regulators out of business.”





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