

Regulation of Genetically Engineered Crops
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July 16, 2004

I. Overview of the Regulatory Framework

A. USDA – APHIS (Animal & Plant Health Inspection Service)

*Primary regulator of GE crops. APHIS regulates both the initial testing phase (approves the protocol for growing test plots of potential GE crops), and grants approval for the general release of GE crops (once a GE crop is approved for general release any restrictions on growing that crop are essentially between the grower and the seed company).

*APHIS regulates GE food crops separately from GE pharmaceutical and industrial crops. Generally speaking, GE pharm/industrial crops have stricter protocols during the initial testing stages.

B. FDA

*Regulates the health aspects of GE crops. FDA has limited their focus to assessing the allergic potential of consuming certain GE crops.

C. EPA

*EPA's primary involvement is in the regulation of GE crops that have had a pesticide inserted into their genome. In their own words, they are not regulating the plant but the pesticide producing protein within the plant. APHIS is still the primary regulator of the GE crop itself.

Example: Bt corn; EPA only regulates the Bt not the GE plant itself.

D. State & Local

*A couple of states have some additional requirements on GE crops (e.g. Minnesota requires an additional permit for the initial field test of certain crops), but California is not one of them.

*Counties have no jurisdiction over GE crops, except of course in the case of Mendocino County.

II. USDA – APHIS Regulations

Under the jurisdiction of the Federal Plant Pest Act, USDA APHIS (Animal and Plant Health Inspection Service) regulates the preliminary stages of a potential transgenic crop – movement, monitoring, and field-testing is all under APHIS jurisdiction. APHIS also has the responsibility to “deregulate” GE plants, which is what happens prior to a particular GE crop variety going on the market. Once a GE crop is deregulated by APHIS, there is no longer a legal regulatory framework in place; the only restrictions on GE crops that have been approved for general release are between the grower and the seed company. APHIS regulates GE products grown for “pharmaceutical or industrial intent” separately from GE food crops. APHIS generally has much stricter requirements for the initial test plots of pharmaceutical and industrial crops, than it does for GE food crops with relatively well known transgenic properties, such as herbicide resistance or Bt-derived insect pest resistance.

III. FDA

The Food & Drug Administration (FDA) is the group that regulates the health aspects of GE crops. In a nutshell, they have said that there is no proof that GE crops are nutritionally different from their traditional counterparts and so they have done very little with regard to GE regulation. The main issue that they have dealt with is the potential for allergenic reactions in transgenic foods. For example, if part of a peanut gene was spliced into some other crop, it could potentially cause allergic responses in people that were allergic to peanuts, even though they were actually eating soybeans or corn or some other transgenic crop.

IV. Certified Organic guidelines

GE crops are not allowed in certified organic produce. *See Neal MacDougall's Document for more specific information on the California Certified Organic Farmers (CCOF) requirements and considerations concerning the GE crops issue.*

V. California Department of Food & Agriculture; Ventria Bioscience GE Pharmaceutical Rice

As mentioned above, neither California law nor the California Department of Food & Agriculture (CDFA) has any separate requirements for growing GE crops above and beyond APHIS' regulations. However, a few states do have some minor requirements for GE crops apart from APHIS' jurisdiction, so it does appear that states have the ability to place further restrictions on GE crops.

The only regulatory/legal reason we heard about Ventria Bioscience's potential for growing GE pharmaceutical rice in California is due to the "California Rice Certification Act of 2000". The Act requires that *any* novel rice variety be approved by the California Rice Commission prior to production, without regard to being conventional or GE. The Act is also the reason that the California Department of Food & Agriculture (CDFA) was involved, because CDFA is named as the overseer of this rice law. So in the case of growing GE rice in California, Ventria Bioscience had a two-step approval process – obtain approval from APHIS and also obtain approval from the California Rice Commission in order to grow a variety of rice new to California. As it turns out, Ventria did not have their permit approval in place from APHIS for conducting field tests this 2004 growing season, so CDFA had a relatively easy decision to reject Ventria's request. Once Ventria has their APHIS permits in order, it seems likely that CDFA will allow the test plots under certain conditions. If Ventria were growing GE pharmaceutical corn, for example, instead of rice, the approval process would have likely been done entirely through APHIS, and we may have never been informed of the potential for the crop being grown in San Luis Obispo County.

VI. County Regulations

Simply put, there are none. All regulatory authority is currently held by USDA-APHIS.

In the next section, we will discuss the likelihood that GE crops are currently being grown in San Luis Obispo County. One thing is certain, though, GE crops represent, at most, a tiny fraction of our County's current agricultural production. However, in nearby Fresno County, GE crops, specifically Roundup Ready Cotton, are widely grown. We recently spoke with the Fresno County Department of

Agriculture and they confirmed that growers are under no obligation to inform the Ag Department that they are growing GE cotton. In other words, local ag officials in Fresno County are aware that GE cotton is being grown, but it is not tracked, monitored, or dealt with any differently than conventional cotton varieties.

In addition to the GE crops approved for general release, there are numerous GE crops that have been approved for field tests in California; these tests are designed to study both the efficacy and safety of the proposed GE crop. Even for GE crops undergoing field tests, which are subject to much greater scrutiny than GE crops approved for general release, there is currently no legal standing that would compel growers to notify the County Department of Agriculture that they are growing GE crops. Theoretically, APHIS could make notification of local officials part of the compliance process, but we have found no indication that this have ever been required.

VII. GE Crops Grown in San Luis Obispo County – Current Status

There are four GE crops that have been approved for general release that are currently widely grown in the United States: soybean, canola, corn, and cotton. Of those four, only cotton and corn are grown commercially in California. It is well documented that GE cotton is being grown throughout the state on large-scale acreage; it is likely that GE corn is being grown in some parts of the state, but any numbers on the total amounts or percentage of acreage is difficult to determine. Nationally, GE cotton constitutes roughly 75% of the cotton grown and GE corn comprises 40% of total corn acreage.ⁱ

Of these GE crops approved for general release, corn is the only one occasionally grown in SLO County on a commercial basis. Corn is a very minor crop in SLO County and when grown is typically destined for Farmers Markets and similar outlets, whose growers seem unlikely candidates for purchasing GE corn seed. Although there is no obvious indication that GE corn is being grown commercially in SLO County, since there is no notification required for GE crops in general release, it is certainly possible. An effort to contact seed companies in order to determine if GE corn is currently planted in the County proved inconclusive. In addition to corn, several GE crops have been discussed as potentially being grown in SLO County at the present time, namely alfalfa and carnations. Although GE alfalfa has not been approved for general release, several companies have current permits for field-testing within California. To the best of our knowledge, none of these test plots are being grown in SLO County, but again, it is possible. Several GE carnations have been developed, one modified to have a longer shelf life and another for an unusual color; neither has been approved by APHIS for use in the United States, either for general release or test plots, and it is therefore unlikely to be found growing in the County.ⁱⁱ

It is important to note, that although none of the major crops grown in SLO currently have GE varieties, all of our County's Top 10 crops have GE varieties in the development phase. It is highly possible, and even likely, that there will be GE varieties available for every major crop grown in SLO County within the next ten or twenty years. **SEE ATTACHED TABLE**

Cal Poly has grown both GE cotton and GE corn for research purposes; these were primarily grown in controlled greenhouse experiments on a very small scale. In one research project, advanced agricultural students studied the different mechanisms of herbicide resistance, comparing a ryegrass that has evolved resistance to glyphosate (Roundup) with GE crops that have been intentionally modified for glyphosate resistance. Cal Poly has conducted another research project that included a

small outdoor planting of GE crops interspersed with conventional crops; students studied the lab techniques used to isolate and determine transgenic DNA sequences. Cal Poly plans on conducting further research on GE crops in the future, utilizing both greenhouse conditions and field plots.

References

I. General References

The following sources were utilized in compiling the regulatory information described above. For more detailed information on the process of GE crop regulation, visit the following websites.

1. Biotechnology Regulatory Services. Animal & Plant Health Inspection Service. United States Department of Agriculture. <http://www.aphis.usda.gov/brs/>
2. Transgenic Crops: An Introduction and Resource Guide. Colorado State University. <http://www.colostate.edu/programs/lifesciences/TransgenicCrops/>
3. Genetically Engineered Organisms: Public Issues Education Project. Cornell Cooperative Extension. <http://www.geo-pie.cornell.edu/gmo.html>
4. Food & Environment: Biotechnology. Union of Concerned Scientists. http://www.ucsusa.org/food_and_environment/biotechnology/index.cfm

II. Specific References

ⁱ Challenges and Opportunities for Horticultural Biotechnology. California Agriculture. April – June 2004 (58:2), pp 68-71.

ⁱⁱ Global Status of Approved Genetically Modified Plants. Biotech Crop Database. AGBIOS website. <http://www.agbios.com/dbase.php?action=Synopsis>

San Luis Obispo County's Top 10 Crops – GE Potential

No.	Crop	Existing *	General Release from APHIS Pending***	Research Stage
1	Winegrapes	None	No	Yes (PD resistance)
2	Broccoli	None	No	Yes
3	Strawberries	None	No	Yes
4	Cattle	N/A	N/A	N/A
5	Head Lettuce	None	No	Yes
6	Vegetable Transplants	N/A	N/A	N/A
7	Indoor Decoratives	None in US**	No	Yes
8	Cut Flowers	None in US**	No	Yes
9	Avocados	None	No	Yes
10	Cauliflower	None	No	Yes
	Corn	Yes	N/A	Yes (for additional GE varieties)

*Existing means any GE crop that has been cleared for general release, e.g. the Roundup Ready cotton commonly grown in the Central Valley.

**According to the AgBios website the GE carnation with longer shelf life was only approved for use in Australia and the European Union. There is also a GE sunflower that has been developed but that is only approved for growing in Canada.

***According the USDA Aphis database, the only crops commonly grown in SLO County that have GE varieties pending general release are: alfalfa (it appears that Monsanto has at least temporarily withdrawn its request for a general release), creeping bentgrass/turf, squash, and wheat. None of these are in the Top 20 dollar value crops, except for bedding plants, sod, and groundcover which lumped together are the 15th valued crop in the County. Of crops commercially grown in San Luis Obispo County only corn currently has a GE variety approved for general release.