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Safety Regulations for New GMO Crops

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Market Report	Yr Ago	4 Wks Ago	10/14/05
Livestock and Products, Weekly Average			
Nebraska Slaughter Steers, 35-65% Choice, Live Weight	$84.65	$86.90	$88.56
Nebraska Feeder Steers, Med. & Large Frame, 550-600 lb	124.27	135.09	134.01
Nebraska Feeder Steers, Med. & Large Frame 750-800 lb	117.93	121.16	121.24
Choice Boxed Beef, 600-750 lb. Carcass	137.28	139.07	143.45
Western Corn Belt Base Hog Price Carcass, Negotiated	67.65	65.45	61.80
Feeder Pigs, National Direct 45 lbs, FOB	49.95	48.67	54.43
Pork Carcass Cutout, 185 lb. Carcass, 51-52% Lean	75.65	71.20	69.47
Slaughter Lambs, Ch. & Pr., 90-160 lbs., Shorn, Midwest	88.50	93.25	92.00
National Carcass Lamb Cutout, FOB	219.88	245.12	*
Crops, Daily Spot Prices			
Wheat, No. 1, H.W. Omaha, bu	3.31	*	*
Corn, No. 2, Yellow Omaha, bu	1.77	1.53	1.49
Soybeans, No. 1, Yellow Omaha, bu	4.74	5.26	5.31
Grain Sorghum, No. 2, Yellow Columbus, cwt	2.84	2.45	2.41
Oats, No. 2, Heavy Minneapolis, MN , bu	1.62	1.79	1.81
Hay			
Alfalfa, Large Square Bales, Good to Premium, RFV 160-185 Northeast Nebraska, ton	115.00	117.50	117.50
Alfalfa, Large Rounds, Good Platte Valley, ton	62.50	37.50	37.50
Grass Hay, Large Rounds, Good Northeast Nebraska, ton	57.50	52.50	52.50

* No market.

Starlink. Monarch Butterflies. Frankenfoods. These words conjure foreboding thoughts of potential catastrophe lurking behind the development of genetically modified organisms, or GMO's. Are they really safe to be released? Are they safe to even experiment with? The purpose here is to describe the federal regulatory system that addresses these issues.

Who Regulates and Why

There are no U.S. laws specifically establishing the regulation of crop biotechnology. It is a stepchild, along with other agricultural biotechnologies, claimed by three parents: United States Department of Agriculture (USDA), Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA).[1]

USDA's Animal and Plant Health Inspection Service (APHIS) claims authority under its obligation to regulate agricultural pests. EPA exercises oversight because it has authority to regulate pesticides under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and toxic substances under the Toxic Substances Control Act (TOSCA). Finally, the FDA enters because of its responsibility for food safety under the Federal Food, Drug and Cosmetic Service Act (FD&C) and for pharmaceuticals under the Federal Health Act (FHA). Under the National Environmental Policy Act (NEPA), all three agencies must conduct environmental assessments for major actions.

This shared parenthood was a deliberate decision in 1986. Discussions led the Office of Science and Technology to reject a new law and new agency for agricultural biotechnology (the "single door" approach), in favor of the "Coordinated Framework for Regulation of Biotechnology Products."[2]

The coordinated approach is still being debated, however, as indicated by the concerns and proposals collated in a recent report by the Pew Initiative on Food and Biotechnology (2004).

The Nature of the Regulations

The USDA and EPA both require advance permits for field testing, while the FDA wields the threat of punitive action if unsafe products were to be released. Regulatory efforts differ for transgenic field crops that produce grain for food and feed, versus those intended to produce pharmaceuticals.

Food and Feed Crops

APHIS defines all transgenic crop organisms as having the potential to be "pests," and they are therefore designated as "regulated articles." A request for a field test permit from APHIS requires extensive descriptions of the organism, the testing, monitoring, disposal and reporting procedures to be followed, and it must disclose any evidence of unusual or harmful aspects of the plant. APHIS provides guidelines for testing and reporting (minimum isolation requirements, etc.), but applications are evaluated on a case-by-case basis. The review process requires several months, except for a one-month "notification process" that is available for substances that are well-understood to be safe.

APHIS contacts regulatory agencies in the states where tests are conducted, to ascertain their approval prior to issuing the permit for testing. Once the permit is issued, APHIS conducts field inspections and monitors reports to verify compliance. Once field tests are completed, over perhaps 2-3 years, if a review determines that the plant *will not become a pest* nor *pose a significant risk to the environment*, APHIS grants the release.

Field trials for plants with "plant-incorporated protectants" also require an Experimental Use Permit (EUP) from EPA. EPA clearance ("registration") is granted if a review of test data and other information submitted by the applicant indicates *no unreasonable adverse health, occupational or environmental risks*. EPA has established pesticide tolerance levels for many substances. They may also require that the developer require farmers to adopt resistance-management borders around commercial fields.

The FDA encourages "voluntary consultation" during the development and testing of plant biotechnology substances, to insure that the ultimate products will be "safe for human health." The FDA asks for a considerable amount of data related to toxicology, allergenicity, nutritional content, etc., and offers guidelines for tests to generate the data. They offer guidelines about GMO labeling, but do not require it unless the nutritional or allergenic content of the product differs significantly from its traditional counterpart.

Pharmaceutical-Producing Crops

Field crops such as corn and soybeans engineered to produce pharmaceutical proteins, vaccines or industrial compounds are subject to a more stringent regulatory process. Isolation and containment requirements are much more demanding than for other crops, with larger perimeter fallow zones, one mile distances from other cornfields in the case of corn, management of all residuals, etc. Dedicated equipment, training programs for workers and specified shipping containers are also required, and compliance inspections are more frequent.

Should This System be Changed?

Some consumer and environmental advocates believe the system permits excessive risks to human health and the environment. Crop producers have expressed fear of potential contamination of their commodity marketing chains. The Pew Initiative has been critical of inter-agency coordination problems. While some critics support new legislation creating a new agency, the Pew report suggests a non-legislated "single door" approach by which super coordination responsibilities would be assigned to one of the current agencies or to the Office of Science and Technology Policy.

Defenders of the current system note that it has so far been successful in protecting human health and environmental safety, and that the continuing evolution of regulations under the coordinated framework is progressing satisfactorily, as compared with the costs and uncertainties associated with a radically altered structure. Indeed, APHIS has established a multi-stakeholder advisory committee to help guide continued evolution of these rules, and over the past year has been developing a new risk-tiered system of oversight and production. Public participation in changes to the regulations is encouraged at the APHIS website below.

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[1] Details on the regulatory procedures of the three agencies can be obtained from their websites: http://www.aphis.usda.gov/brs/index.html; http://www.cfsan.fda.gov/~lrd/biotechm.html#reg; http://www.epa.gov/opptintr/biotech/ and http://www.epa.gov/pesticides/biopesticides/

[2] This framework was established in 1986 by the Office of Science and Technology Policy (51 Fed. Reg. 23302).

[3] Pew Initiative on Food and Biotechnology. Available at