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GENETICALLY ENGINEERED RICE

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AGRICULTURAL GENETIC ENGINEERING

Genetic engineering (GE) is a precise and predictable method used to introduce new traits into plants and animals by moving genes and other genetic elements from one or more organisms into another organism.

- GE crops are being produced that have a wide variety of traits that benefit farmers and consumers. For example, GE crops can tolerate drought conditions and herbicides, resist insects and viruses, and provide enhanced quality and nutrition for consumers. GE crops are being developed by private companies, universities, and other researchers.
- GE crops that are currently consumed for food, fiber or feed include corn, soybeans, cotton, canola, alfalfa and squash. Over 70 percent of processed foods on grocery store shelves in the U.S. contain ingredients and oils from biotech crops, according to an industry estimate.
- USDA's National Agricultural Statistics Service estimates that in 2006, 61 percent of the corn, 83 percent of the cotton and 89 percent of the soybeans planted in the United States were biotech varieties.

BIOTECHNOLOGY REGULATORY AUTHORITY

Under a coordinated regulatory framework, USDA's Animal and Plant Health Inspection Service (APHIS), the Food and Drug Administration (FDA), and the U.S. Environmental Protection Agency (EPA) share responsibility for regulating biotechnology products to ensure that approved biotechnology products developed in the U.S. pose no risk to human health or the environment.

- APHIS through its Biotechnology Regulatory Services (BRS) arm is responsible for overseeing the introduction of GE agricultural products in the United States. Since 1987, APHIS has safely deregulated or approved more than 70 GE products.
- Deregulation of GE crops is necessary before they can be produced commercially. The process includes several steps including an initial risk assessment and thorough environmental review.

INVESTIGATION OF REGULATED RICE IN COMMERCIAL RICE SAMPLES

- USDA and FDA have been notified by Bayer CropScience that the company has detected trace amounts of regulated genetically engineered (GE) rice in samples taken from commercial long grain rice.
- Both USDA and FDA have reviewed the available scientific data and concluded that there is no human health, food safety, or environmental concerns associated with this GE rice.
- Bayer has developed many GE herbicide-tolerant products with the protein called Liberty Link, three of which are rice. The regulated line is LLRICE 601 and Bayer

reports finding only trace amounts of it during testing. Bayer conducted field tests of LLRICE 601 between 1998 and 2001. Bayer has indicated it had no plans to market LLRICE 601 and therefore had not petitioned for deregulation.

- Two deregulated rice lines, LLRICE 62 and LLRICE 06, have been through thorough safety evaluations and have been deemed safe for use in food and safe in the environment, although these lines have not been commercialized.
- Based on the available data and information, the FDA has concluded that the presence of LLRICE 601 in the food and feed supply poses no safety concerns and APHIS, through a risk assessment based on the same data and information, concluded that LLRICE 601 is safe in the environment.
- Based on reports that LLRICE 601 is in the marketplace and a petition from Bayer, APHIS will conduct a deregulation process, including an opportunity for public comment.
- Because the line of GE rice in question was regulated, APHIS is conducting an investigation to determine the circumstances surrounding the release and whether any violations of USDA regulations occurred.
- The protein found in LLRICE 601 is approved for use in other products. It has been repeatedly and thoroughly scientifically reviewed and used safely in food and feed, cultivation, import and breeding in the United States, as well as nearly a dozen other countries around the world.
- USDA is in the process of validating a test to provide the marketplace with a tool to detect the presence of the Liberty Link protein in rice. Bayer has made arrangements with several private laboratories to run the tests and will post that information on their website.

U.S. RICE STATISTICS

More than 100 varieties of rice are commercially produced primarily in six states (Arkansas, Texas, Louisiana, Mississippi, Missouri, and California) in the U.S.

- According to estimates for the 2006 crop year, rice production in the U.S. is valued at $1.88 billion, approximately half of which is expected to be exported.
- The U.S. provides about 12 % of world rice trade.
- In 2005, 80% of rice exports were long grain varieties.
- The majority of domestic utilization of U.S. rice is direct food use (58%), while 16 percent is used in processed foods and beer respectively. The remaining 10 percent is found in pet food.

GLOSSARY OF TERMINOLOGY

Agricultural Biotechnology: A range of tools, including traditional breeding techniques, that alter living organisms, or parts of organisms, to make or modify products; improve plants or animals; or develop microorganisms for specific agricultural uses. Modern biotechnology today includes the tools of genetic engineering.

Deregulated: If a GE crop has gone through the regulatory process for USDA to determine that it can be safely commercialized, it is commonly referred to as being a deregulated crop. This is necessary before it is sold and produced commercially. It allows the product to be moved and planted freely without the need for notification or permits. A developer may file a petition for deregulation only after a GE crop has been tested extensively and the developer can show that the product does not pose a plant pest risk.

Gene: The fundamental physical and functional unit of heredity. A gene is typically a specific segment of a chromosome and encodes a specific functional product (such as a protein or RNA molecule).

Genetic engineering: Manipulation of an organism's genes by introducing, eliminating or rearranging specific genes using the methods of modern molecular biology, particularly those techniques referred to as recombinant DNA techniques.

Herbicide-tolerant crops: Crops that have been developed to survive application(s) of particular herbicides by the incorporation of certain gene(s) either through genetic engineering or traditional breeding methods. The genes allow the herbicides to be applied to the crop to provide effective weed control without damaging the crop itself.

Protein: A molecule composed of one or more chains of amino acids in a specific order. Proteins are required for the structure, function, and regulation of the body's cells, tissues, and organs, and each protein has a unique function.

Regulated: If a GE crop has not gone through the regulatory process for USDA to determine if it can be safely commercialized, it is commonly referred to as being in regulated status or a regulated crop.

Variety: A subdivision of a species for taxonomic classification also referred to as a 'cultivar.' A variety is a group of individual plants that is uniform, stable, and distinct genetically from other groups of individuals in the same species.

More information on biotechnology and the USDA regulation of biotechnology can be found at: http://www.aphis.usda.gov/publications/biotechnology/index.shtml

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