
New USDA-ARS Research in Biotechnology Risk Assessment

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The Agriculture Research Service of the United States Department of Agriculture (USDA-ARS) is making many contributions in the field of agricultural biotechnology. These include conserving and improving genetic resources, and developing new genomic information and molecular tools. Increasingly, USDA-ARS research includes biotechnology risk assessment and mitigation.

GENETIC RESOURCES AND GENOME DATABASES

Core responsibilities of the ARS include conserving, safeguarding, and characterizing genetic resources. The ARS manages the US seed and germplasm collections through the National Plant Germplasm System (www.ars-grin.gov/npgs/). These collections, which include over 10,000 plant species of agricultural value, are stored, evaluated, and regenerated at germplasm repositories at over twenty locations. Over 120,000 accessions are distributed annually, many to biotechnologists. Researchers are tapping these germplasm resources to identify valuable genes and to understand crop evolution. High-throughput genomics strategies are providing new, precise methods to identify genes for disease resistance, tolerance of extreme weather conditions, and improved nutritional value. The genetic base of many US crops is narrow, therefore, strategies to integrate novel genes offer the possibility of enhancing genetic diversity.

Much current ARS research uses conventional breeding methods aided by new molecular tools. Genomics information provides molecular markers to accelerate breeding and make it more efficient. Centralized Web sites

providing crop-genome information are supported in cooperation with the National Science Foundation Plant Genome Program. These crop-genome databases include: MaizeGDB (www.maizegdb.org), Gramene (www.gramene.org), GrainGenes (www.graingenes.org), and SoyBase (<http://soybase.agron.iastate.edu/>).

ARS researchers are also protecting US agriculture and food safety by employing molecular tools to develop sensitive detection tests.

ARS BIOTECHNOLOGY RISK-ASSESSMENT RESEARCH

As genetically engineered (GE) crops become more prevalent in the United States, ARS researchers—including geneticists, entomologists, and microbiologists—are increasingly applying their expertise to evaluate their use in farming systems. Much of this work is part of regional evaluation projects that incorporate both conventional and biotechnology methods.

Many of the concerns and questions about GE crops and foods could be asked about any new variety or food product. However, the public has more experience and confidence in conventional plant breeding and food-product development due to many years of largely problem-free experience. Reviews by the National Academy of Sciences have confirmed the safety of GE crops, but have indicated need for more evaluation of environmental effects. Topics identified by the Academy as needing more research attention include:

- development of resistance in pest populations,
- effects on non-target insect species,
- gene flow from crops to surrounding vegetation.

Biosafety research at the USDA addresses priorities identified by the National Academy and by consumer groups. Two agencies are involved: the Cooperative State Research, Education and Extension Service (CSREES) and the ARS jointly administer the Biotechnology Risk Assessment Research Grants Program (www.reeusda.gov/1700/funding/04/rfa_brag_04.htm). This program, authorized in the 1990 Farm Bill, provides 2- and 3-year research grants funded by a 2% set-aside from all USDA biotechnology research projects. In FY 2003, it exceeded \$3 million.

A new initiative to support long-term ARS projects in biotechnology risk assessment was funded by Congress in FY 2002 with additional money in FY 2003. Total funding in FY 2003 was \$5.4 million. Other ARS projects are incorporating biosafety-related research activities into their objectives due to the increasing prevalence of GE crops and increased interest in long-term effects on the environment.

The ARS conducts biosafety research as part of its responsibility to supply needed information to regulatory agencies. All research results are submitted for scientific review and are publicly available. Examples of current ARS biotechnology risk assessment and mitigation research projects follow.

PREVENTING DEVELOPMENT OF RESISTANCE IN PEST POPULATIONS

Cotton farmers have suffered multi-million dollar losses from insect pests, particularly the tobacco budworm and the bollworm. Those losses have been reduced by the use of biotech cotton with *Bacillus thuringiensis* (*Bt*) genes that produce insecticidal proteins. The cotton industry is using strategies to reduce the evolutionary pressure on the tobacco budworm and other pests to acquire resistance to *Bt* cultivars

Researchers at the ARS Southern Insect Management Research Unit, Stoneville, MS, are monitoring tolerance of insect predators of cotton as part of efforts to insure that *Bt* remains an effective means of control (Hardee *et al.*, 2001). They are evaluating caterpillar specimens, collected from cotton-growing areas, that are reared first without *Bt* and then are grown on *Bt*-containing feed. Growth comparisons are made with insects raised on control diets. Changes in susceptibility to *Bt* have not been observed, but monitoring continues; data are used to design and evaluate production practices and federal regulations that will prolong the effectiveness of *Bt* cotton.

Control of the devastating corn rootworm requires extensive use of pesticides. Monsanto has developed a *Bt* corn that is toxic to the rootworm. Wade French and Mike Ellsbury at ARS, Brookings, South Dakota, are partnering with industry researchers to evaluate use of seed mixes as a strategy to slow the evolution of rootworm resistance to *Bt*. Various mixtures of conventional and GE corn are being tested. The advantage of seed mixtures is that rootworms grown on conventional corn plants will not be subject to evolutionary pressure to acquire tolerance, and will continue to mate with rootworm beetles previously exposed to the *Bt* plants. Monitoring includes measuring root damage, plant lodging, and numbers of adult rootworm beetles caught in emergence cages (Anonymous, 2003).

EFFECTS ON NON-TARGET SPECIES AND GENE FLOW INTO THE ENVIRONMENT

Do *Bt* crops harm beneficial insects? ARS researchers are helping to address that question with long-term studies on non-target species. Pitfall traps, with timed daily interval units, are being used to collect ground beetles in corn and soybean research plots and private farms as part of a national pest-management project. The results will alert researchers to any risks to beneficial species (Anonymous, 2003) as well as provide new information about numbers and feeding activities of ground beetles.

Concern over effects of *Bt*-corn pollen on monarch butterflies was raised several years ago. ARS researchers participated in a series of public meetings in 1999 to 2001 to identify research needs to determine if *Bt*-corn pollen is hazardous to monarchs. ARS and industry groups, along with Canadian sources, then provided \$200,000 in grant funding to twenty-nine scientists to

address the biotechnology risk research needs. Entomologists, weed scientists, geneticists and other researchers coordinated experiments to provide comprehensive evaluation of risk. Effects of *Bt*-corn pollen on monarch butterflies in the field were thoroughly evaluated, with little indication of risk. Data were made public and published in six comprehensive papers in the October 9, 2001, *Proceedings of the National Academy of Sciences* (e.g., Hellmich *et al.*, 2001)—a good example of cooperative research by the public sector to evaluate biotechnology risk.

New ARS research projects are being initiated to mitigate and confine the expression of transgenes. Efforts are focused on expression of transgenes only in tissues where they are needed and not in plant organs that are harvested. Priorities include identifying gene promoters and other molecular tools that confer precise and predictable transgene expression. Promoters that confer new pest and disease resistance in the shoots and growing ears of grain crops are needed to withstand devastating diseases of cereals such as scab (*fusarium* head blight). Molecular tools are needed that increase virus resistance in the vegetative tissues of potato without expression in the tubers. A major benefit of this research will be the development methods and tools with public accessibility.

Tissue-specific expression can provide nutritional and health benefits. A project is being developed to enhance calcium levels in potato tubers. And promising new strategies are being used to reduce food allergens. Recently, a transgenic soybean was developed with the major soybean allergen removed (Herman *et al.*, 2003). Reducing allergens in a commodity as widely used as soybean will significantly benefit those with food allergies.

Other ARS projects are focused on precise and predictable transgene expression. Technologies to consistently and precisely insert transgenes are being developed. Such technologies offer the opportunity to stack or combine beneficial genes into one insertion event. Other possibilities are to combine beneficial genes, say for pest resistance, with “domestication” genes that can slow gene flow into wild species.

SUMMARY

The ARS and USDA are increasing research efforts in biotechnology risk assessment and biosafety. Many projects are addressing long-term effects of GE crops in agriculture production systems and on the environment. Other projects are focused on mitigating transgene expression in food and feed. Precise and predictable methods are being developed to express transgenes. These technologies can enhance pest resistance and weather-stress tolerance in plant tissues only when needed. Similarly, nutritional enhancement and allergen reduction can be focused where it will be most beneficial.

New ARS biotechnology risk assessment and mitigation research is addressing biosafety priorities identified by the scientific community and

consumer groups. The results of research by public sector scientists will be made publicly available and will be used for science-based regulation of transgenic crops and food products.

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