

How are biotech crop varieties regulated?

Alan McHughen, D. Phil.
Biotechnology Specialist and Geneticist
Department of Botany and Plant Sciences
University of California, Riverside
alanmc@ucr.edu

Introduction

New crop cultivars (i.e., cultivated varieties) undergo a long period of breeding development and evaluation prior to commercial release to be grown by farmers in the U.S. or other countries. In addition to the usual variety registration procedures, crops developed using genetic engineering (GE) to introduce genetic enhancements must face additional regulatory scrutiny. In this paper, the regulatory procedures for commercializing a new crop variety in the U.S. are described briefly. For greater detail of the regulatory process for GE-derived crops, see McHughen and Smyth, 2007.

Question: What is biotechnology and how does it apply to crop breeding?

Answer. Biotechnology is “any technique that uses living organisms or substances from those organisms, to make or modify a product, to improve plants or animals, or to develop microorganisms for specific purposes” (Office of Technology Assessment, United States Congress). In this broad sense, plant and crop breeders have been using biotechnology to modify the genetic makeup of crops for thousands of years. In fact, no currently grown crop varieties are “natural,” in that all arose from human intervention in moving genes around to create new genetic combinations.

A new variety, whether developed using traditional or modern breeding methods, must carry a new combination of genes not present in nature. Recombinant DNA, or genetic engineering, is a more precise form of biotechnology, allowing the breeder to transfer known, desirable genes into crops, instead of moving large groups of mostly unknown genes as in most traditional means of breeding.

Question: How are traditionally bred crops made?

Answer: Plant breeders can spend many years bringing a new crop strain or “cultivar” to market. The breeding process can take 10-12 years or more, depending on the crop type, the breeding method, and the growing and testing conditions. In general, the breeder starts with a current good-quality cultivar, then improves it by introducing some genetic changes. The genetic changes might arise by crossing with a plant of a different cultivar with some desired feature, or perhaps by exposing the cultivar to some chemicals or ionizing radiation to cause genetic mutations, some of which might be beneficial (there are presently more than 2,500 cultivars developed through mutation breeding. See <http://www-infocris.iaea.org/MVD/>).

In either case — or with any of the dozens of other methods breeders use to change the genetic makeup of a plant — these “traditional” forms of genetic modification can give rise to a new cultivar, combining many of the good features of the parent, along with some additional beneficial trait(s). Much of the required time occurs in testing the new cultivar after the genetic changes have taken place to ensure the new cultivar really is superior to earlier cultivars and remains of high quality with no loss of yield or other agronomic features.

Question: Does anyone “own” these new cultivars?

Answer: Eventually, when the breeder is ready to release the new cultivar to farmers, he or she seeks a plant variety protection certificate from USDA. A variety certificate allows the breeder (or, usually, the breeder’s employer) to market the new cultivar, with its designated name, to farmers and provides legal claim on ownership of the variety and the name. It is not a health or environmental safety assurance, but rather an identification of “intellectual property” ownership. In order to secure a certificate, the breeder must show the new strain meets three criteria: 1) the new strain must be genetically different from all other varieties or cultivars, 2) that a population of plants is uniform in appearance and performance, and 3) that the new trait is stably inherited from one generation to the next. This “DUS” (**D**istinct, **U**niform, genetically **S**table) standard is applied around the world. A prospective new cultivar failing in any of these criteria cannot be certified. Details of the USDA-administered Plant Variety Protection Act (PVPA) are available online at http://ams.usda.gov/science/PVPO/PVPO_Act/PVPA2005.pdf.

Question: Do the same regulations apply to cultivars developed through biotechnology?

Answer: New crop cultivars developed using rDNA (recombinant DNA), or GE (genetic engineering), or GM (Genetic Modification) also must adhere to these standards. In addition, GE cultivars must undergo mandatory safety assessments, something traditionally bred crop cultivars — even those developed using ionizing radiation as a mutagenic source — are exempt from.

Question: What agencies regulate biotech crops?

Answer: Three main U.S. federal agencies are responsible for the safety assessments of biotech crop cultivars. The U.S. Department of Food and Agriculture (USDA), the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA) all have authority over portions of the process.

USDA. The Biotechnology Regulatory Services (BRS) office of the Animal and Plant Health Inspection service (APHIS) branch of USDA regulates all new biotech crop cultivars, focusing on environmental safety. BRS demands data from the breeder on such issues as the kind of trait added, where the trait originated, and how the new biotech plant compares to the non-biotech parent plant, in terms of environmental fitness. That is, the concern is whether the new plant will become invasive or “weedy,” and become a pest of agriculture and native ecosystems. Questions and concerns relate to how the new crop disperses seed or pollen, and how the spread of seed or pollen compares with that of

traditional plants of the same species. For more information on the USDA/APHIS regulatory procedures for products of biotechnology, see http://www.aphis.usda.gov/biotechnology/brs_main.shtml.

The **FDA** is primarily concerned with food and feed safety, so it ensures that new biotech crops destined for our dinner tables or animal feeds carry no additional toxic or allergenic substances. FDA must approve all new crops or foods if substances new to the food supply are present. Because most biotech crops and foods carry no new ingredients, FDA conducts a voluntary or optional review of the new crop, food, or feed developed using biotechnology to provide assurance to the developer and the consumer at large that the new product is safe to eat. While the FDA review is, technically, voluntary, it is effectively compulsory, for the simple reason that no company wishes to release a harmful food or feed without such review. Any company bypassing the FDA review risks a huge liability if its new product harms consumers, and because the FDA conducts a science-based investigation of potential hazards, every biotech food on the market has undergone the FDA review. The FDA web pages carrying information about biotechnology are available at <http://vm.cfsan.fda.gov/~lrd/biotechm.html>.

The **EPA** has responsibility for safe use of pesticides and pesticidal products. As many biotech-derived crops involve pesticidal properties such as a new herbicide resistance, EPA also needs to ensure the safety of the new cultivar before it can be commercially released. The majority of biotech crop cultivars on the market invoke EPA regulatory scrutiny. EPA procedures are available on the internet at <http://www.epa.gov/scipoly/biotech/pubs/framework.htm>.

In some cases, the biotech-derived crop cultivars might pose special hazards, and those attract special regulatory scrutiny. For example, some plants modified to produce certain pharmaceutical substances or industrial chemicals face greater scrutiny, as some of these could pose a potential hazard if they find their way into the food or feed supply in large quantities.

Question: What is the take-home message for crops developed through biotechnology?

Answer: Overall, the crop cultivars developed using biotechnological methods undergo the most stringent regulatory oversight of any agricultural product in history and, because of that, the level of safety assurance is higher than any other form of breeding. Even then, the risk of breeding is extraordinarily low to begin with, and traditional breeding has a history of safe use that extends back many centuries. Nevertheless, when adverse incidents attributable to the breeding method have occurred, they have invariably been on crops developed using traditional breeding methods (NAS/IOM, 2004).

Biotech crops were first released in 1994, and since then have grown to over 250 million acres each year all over the world (James, 2007). According to a study conducted by the U.S. National Academy of Sciences and Institute of Medicine, there are no documented ill effects from eating a biotech food (NAS/IOM, 2004), and no verified reports of harm have emerged since.

References and further reading

James, C. 2007. Highlights of ISAAA Brief No. 35-2006; Global Status of Commercialized Biotech/GM Crops: 2006. Online at <http://www.isaaa.org/kc/cropbiotechupdate/2007/01/18.html>.

McHughen, A. and S. Smyth, 2007. U.S. regulatory system for genetically modified (genetically modified organism (GMO), rDNA or transgenic) crop cultivars. *Plant Biotech Journal*, 5: (in press; online at: <http://www.blackwell-synergy.com/doi/pdf/10.1111/j.1467-7652.2007.00300.x>).

National Academy of Sciences and Institute of Medicine. 2004. *Safety of Genetically Engineered Foods*. Washington DC: National Academies Press. Online at <http://www.nap.edu/openbook.php?isbn=0309092094>.