
A Legal View: Promoting Product Stewardship and Regulation

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With little understanding of how food, feed and fiber products are developed and produced, and even less knowledge of the science of genetics, most consumers are ill prepared to sift through the deluge of misinformation bombarding them on a daily basis. Members of NABC have a unique opportunity to help set the record straight and challenge the myths that are circulated by those who oppose, or question the use of, agricultural biotechnology.

Representatives of land-grant universities and other research institutes have a deservedly high degree of credibility. Without being advocates, they can play a vital role in educating the public, government officials, and the media, on basic agricultural practices and scientific concepts that are critical to an objective analysis of agricultural biotechnology.

Looking to the future, and in light of the rapid rate of adoption of crop biotechnology and the diversity and complexity of products in the development pipeline, I believe that product stewardship and regulation will play an increasingly important role in promoting public confidence in the products of biotechnology. Technology providers, growers, processors, and researchers all have key roles to play in supporting strong governmental oversight of crop biotechnology and implementing proactive product-stewardship programs.

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WHAT WE REALLY KNOW ABOUT THE SAFETY AND BENEFITS OF BIOTECHNOLOGY CROPS

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Myth #1: Lack of regulation—products are rushed to market with little or no government oversight. The reality: unprecedented regulation of plants and plant products. Products are reviewed by at least two federal agencies, the United States Department of Agriculture (USDA) and the Food and Drug Administration (FDA) and often by three, *i.e.* including the Environmental Protection Agency (EPA) (US, 2001) These reviews take place over a period of several years while carefully controlled and monitored greenhouse and field tests are conducted. All of this must occur before a product can ever enter the marketplace. There is no comparable oversight for conventional hybrids and cultivars. The jurisdiction of the regulatory agencies has been exercised since 1986 and universally recognized by regulated parties. The National Institutes of Health (NIH) research guidelines have been followed since 1976 for laboratory and greenhouse research.

Myth #2: No data. The reality: volumes of data. Health, safety and environmental data representing years of laboratory, greenhouse, and field research are routinely submitted to and reviewed by the USDA, EPA, and FDA (NAS, 2000). New data are requested by the agencies as needed.

Myth #3: No public participation. The reality: multiple public participation opportunities. Multiple public participation opportunities have been provided over the past 25 years by EPA, USDA and FDA, including via public meetings, public comment on proposed rules and policies, agency web sites, scientific peer review, and in response to published data.

Myth #4: No benefits. The reality: established benefits. Products have shown clear agronomic, environmental, and health benefits, including high-oleic soybean; slower ripening fruits and vegetables; improved protection from insects and disease (reduced use of chemical insecticides and fungicides, fewer acres cultivated, and less fuel, water, and fertilizer used); and improved tolerance to herbicides (reduced need for chemical applications, promotion of reduced tillage, control of soil erosion, and use of reduced-risk herbicides) (Alliance, 2001; USDA, 2001).

Myth #5: Harm to health and environment. The reality: no evidence of actual harm. With intensive governmental, academic, and commercial oversight for the past 15 years, not a single instance of actual harm to health, safety, or the environment has ever been confirmed for biotechnology crops on the market today (EPA, 2000).

Myth #6: No labeling. The reality: health and safety labeling is required. Federal labeling requirements are identical for all foods. Labeling solely for consumer choice is not required by government in the United States (Federal Register, 1992, 2001).

KEY ISSUES IN PROMOTING PRODUCT STEWARDSHIP AND REGULATION

- To the producer of biotechnology-derived products and others in the chain of commerce, government regulation provides assurance that appropriate safety standards have been met in bringing a product to market. But even the best efforts of regulators may prove inadequate, particularly when dealing with a new technology, without the development and implementation of proactive product-stewardship programs.
- In its broadest terms, product stewardship can be thought of as the legal, ethical and moral obligation to assess products and technologies to ensure that they are safe as well as socially and environmentally responsible. Stewardship includes the assessment—based on sound scientific principles—of the potential impact of a particular product or technology on human health and the environment, as well as those actions and principles necessary to protect the integrity and viability of a particular product or technology.
- Not all stewardship efforts are necessarily confined to individual companies, nor should they be. Many activities are more appropriately industry-wide responsibilities, which are necessary or appropriate for the protection of products or technologies as a class. Many industries operate on the basis of voluntary consensus standards, including a broad array of standards developed by nationally and internationally recognized standard-setting organizations. Government agencies routinely recognize such standards, and federal law requires agencies to use technical standards that are developed or adopted by voluntary consensus standards bodies, unless it would be inconsistent with applicable law or otherwise impractical.
- From a legal perspective, the organizational unit responsible for oversight of product stewardship must be empowered to ensure compliance with the letter and spirit of applicable regulatory requirements and to prevent potential product-related liabilities. Legal obligations in the United States include the submission of applications, notifications, data, and information in order to obtain the appropriate approvals and clearances from the USDA, FDA and EPA under the Coordinated Framework for Regulation of Biotechnology. Those obligations also extend to the post-market surveillance of agricultural biotechnology and crop-derived products and to compliance with appropriate reporting requirements, such as those imposed by EPA for plant-incorporated protectants.
- In addition to biodiversity, examples of crop biotechnology stewardship issues include: risk assessment and risk management plans; seed quality and purity; protein safety, including potential for allergenicity; protein levels in food and feed; insect-resistance-management plans for certain plant-incorporated protectants; outcrossing and open pollination; identity preservation, product channeling and trade.

- A successful risk-management process should be a fundamental part of the product-stewardship program, incorporated into each phase of product development and commercialization. Key elements of the risk-management process include: identifying every potential source of harm (hazard); assessing the probability of occurrence of that harm (exposure); assessing the risk, if any, resulting from the potential combination of hazard and exposure; and the development of alternatives for the minimization and management of the assessed risks.
- For products of agricultural biotechnology, the risks and risk-management alternatives must be evaluated in the context of factors such as health, safety, and environmental and agricultural impacts; regulatory acceptance; public acceptance; market acceptance; and civil liability. Prior to commercialization of any new plant-biotechnology product, the developer would conduct a full, science-based risk assessment to identify and, to the extent possible, quantify every risk presented. Each risk would be reviewed in all relevant contexts and an appropriate management plan would be established, including an effective strategy to mitigate any risk that becomes a reality.
- Regulatory oversight and industry stewardship of crop-biotechnology products, both pre-market and post-market, have occurred notwithstanding the fact that new conventionally bred varieties of food, feed, and fiber crops receive virtually no governmental oversight in the United States or any other nation. Moreover, the National Academy of Sciences (NAS) has repeatedly held—most recently in an April 2000 report on pest-protected plants—that being a product of biotechnology does not make a plant hazardous. Specifically, the NAS has found: (1) no evidence that unique hazards exist either in the use of rDNA techniques or the movement of genes between unrelated organisms; (2) that the risks associated with the introduction of rDNA engineered organisms are the same in kind as those associated with the introduction of unmodified organisms and organisms modified by other methods; and (3) that assessment of the risks of introducing rDNA-engineered organisms into the environment should be based on the nature of the organism and the environment into which it is introduced, not on the method by which it was produced.
- Rigorous, science-based safety assessments must be conducted for each new product or product category, first by the product developers and then by agency scientists. Conditions carefully tailored to address identified risks should be placed on approvals where warranted, and approvals should always be subject to review based on new data and information from any credible source.

- It is the very nature of oversight of a rapidly developing technology that regulation and stewardship must be dynamic processes, always subject to reevaluation and modification based on new information and understanding.
- Proactive product stewardship together with strong regulatory oversight will be critical to the minimization of liability and, ultimately, to domestic and global acceptance of products of modern biotechnology.

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