The Importance of Stewardship in Agricultural Biotechnology

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An important issue that concerns us at BIO is that the biotechnology industry be good stewards. We expect that this will be important for a long time to come. Good stewardship relates to regulatory policy and—contrary to the philosophy that we need less regulation—at BIO we understand the role that regulatory policy plays and we embrace it. It is the backbone for all that we do to ensure biotechnology's success.

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BIO is a trade association representing all facets of biotechnology. We have over 1,100 member companies—90% of which are small entrepreneurial entities—academic institutions and state centers here in the United States. We have members in all fifty states and in thirty-four nations, and we are involved in R&D across all of the sectors, including food and agriculture, healthcare and industrial manufacturing. Our 2005 annual meeting in Philadelphia had close to 19,000 attendees, a record number indicating how this technology is growing in importance.

It can be hard to tell where food and agriculture ends and healthcare and industrial aspects begin, particularly in terms of plant-made pharmaceuticals (PMPs) and industrial products (PMIPs). It is appropriate, therefore, for BIO to examine all facets of biotechnology, particularly in terms of synergisms across these sectors.

2005 marked the tenth anniversary of commercial planting of biotech crops. This, the most rapidly adopted technology in the history of agriculture, now plays an extremely important role for soybean, cotton, corn and canola, representing well over two thirds of all of the varieties that are being planted. 2005 also marked the cumulative planting of one billion acres of biotech crops around the world, the achievement of which all of us who are part of this industry may be proud.

Ten years ago, we focused on agronomic traits. We have begun to move into quality traits and are now developing plants as factories for synthesis of pharmaceuticals and industrial products and materials—the third wave.

The United States has evolved an elaborate regulatory system that we refer to as the Coordinated Regulatory Framework. There is a lot of history here, going back to the late 1980s. It is a science- and risk-based regulatory system and is transparent, and we are working with the regulatory agencies—USDA, EPA and FDA—to ensure that it will become more transparent in the future. The biotech industry has always embraced strong regulatory policy and oversight; we cannot overstate how important this is to us in terms of promoting consumer confidence.

In 2004, BIO released a containment analysis and critical control point (CACCP) plan for PMP and PMIP production.

Stewardship Areas

Within BIO, we have a robust training program and an active group is laying out principles for development and confinement of PMPs and PMIPs. And late in 2004, BIO released a containment analysis and critical control point (CACCP) plan for PMP and PMIP production. These areas constitute a strong stewardship program to help ensure that we are meeting all federal requirements.

Compliance Training

A couple of years ago, the author met with the NABC board to discuss aspects of training deemed mutually important. We have now developed educational workshops dealing with compliance aspects affecting genetically engineered (GE) corn, cotton and soybeans. These workshops will be offered in conjunction with professional society meetings and conferences such as those organized by NABC. Not only do we want those in our industry to participate in these training courses, they will be offered also to universities and federal research agencies to help ensure that all abide by the federal requirements and understand the legal implications involved in conducting field trials with GE crops.

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Furthermore, we are planning to provide accreditation as part of the incentive to participate in these training programs. We are optimistic that we will be able to offer continuing education credits (CECs). We hope to begin offering classes and workshops in the fall of 2005 in conjunction with professional society meetings and be fully operation throughout 2006 and beyond.

What will be involved? The courses will cover notification and permitting procedures, compliance and enforcement, transport and storage, trial-site management, harvest disposition and post-harvest management. An important aspect is auditing and verification, particularly by third parties, also requirements to be met with pesticidal products with regards to Environmental Use Permits. One-day workshops are envisioned; in some cases a half-day or two-thirds of a day may suffice.

CACCP

Within the PMP/PMIP arena, we have been working on drawing up principles for development and confinement. A reference document that we published looks at two areas. One is the principle for controlled exposures to PMPs and PMIPs, and the other describes development practices for PMPs and PMIPs, which examines confinement systems that control exposure and cross-pollination, confirmation of confinement and the use of identity preservation systems. In 2004, we finished the second phase of this project; the principles document was reduced down to a confinement analysis and critical control points (CACCP) approach to PMP and PMIP production. This terminology resonates with people in the food industry who understand the hazard analysis and critical control point (HACCP) system (which relates to risk analysis and food safety) which has many elements in common with risk assessment and management of PMPs and PMIPs.

The CACCP system entails seven principles: how the critical control points are determined, how limits are established, how the process is monitored (a very important aspect), how corrective actions are to be initiated, how verification procedures are establish, and record keeping and documentation. Whether in industry, at a university or within a federal research agency, all of these principles apply.

Commitment of top management is essential. Prerequisites include GMPs and other good Q&A protocols, facility standards, supplier control, cleaning and sanitation, *etc.* Of primary importance are education and training, and as our compliance training programs evolve, we will include modules covering the CACCP system, for example. Participants in the training courses will return to their universities, companies or research agencies and develop institutional standard operating procedures to fit specific home-base needs.

For biotechnology to continue to evolve, commitment to good stewardship on the part of the industrial sector will be essential, together with embracement of federal regulatory policies.

Summary

Stewardship is an extremely important aspect of the development of biotechnology, one that BIO's membership takes very seriously. Our goals include the highest standards of performance, to demonstrate transparency, openness and commitment to regulatory compliance. For biotechnology to continue to evolve, commitment to good stewardship

on the part of the industrial sector will be essential, together with embracement of federal regulatory policies.

More information is available at http://www.bio.org or from the author at mphillips@bio.org.

Michael Phillips is vice president for Food and Agriculture, Science and Regulatory Policy of the Biotechnology Industry Organization (BIO). With over 1,000 members, BIO is the largest trade organization to serve the life sciences industry, representing biotech companies, academic institutions, state biotechnology centers and affiliated organizations in all fifty states and thirty-four nations. BIO members are involved in R&D on health care, agricultural, industrial and environmental biotechnology products.

Prior to joining BIO in 1999, Dr. Phillips was the executive director of the Board on Agriculture and Natural Resources at the National Academy of Sciences. Before working for the Academy, he was director of the W.K. Kellogg Foundation program for Food, Agricultural and Natural Resource Issues for the 21st Century. He was also director of the Food and Agriculture program of the Office of Technology Assessment (OTA) of the United States Congress. Prior to his OTA service, he was a faculty member at Purdue University and was a senior staff member in the Secretary's office at the USDA.

Phillips has an MS and PhD in food and agricultural policy from Ohio State and Purdue Universities, respectively. He has authored and supervised numerous studies and reports on food and agriculture with a special focus on agricultural biotechnology.