By Kent J. Bradford, Ph.D.

Biotech Seed Traceability & Labeling:
Hindrance or Asset to Marketing & Trade?

Traceability – the ability to document the history of the origin, production, participants, and handling steps involved in the production of seed, food or feed products – is a familiar concept in the seed industry as it is the basis of seed certification programs. Documentation of the pedigree of the seed planted to verify its identity is the starting point of the seed certification process. In addition, seed certification guidelines specify measures, such as previous crop history and isolation from related crops, which must be taken to minimize the commingling of undesired varieties, other crops or weed seeds. Protocols for cleaning the equipment used for harvesting and processing seed are designed to preserve genetic and physical purity during conditioning, handling and packaging. Finally, labeling of certified seed ensures the customer that specific quality standards have been met.

Traceability Systems

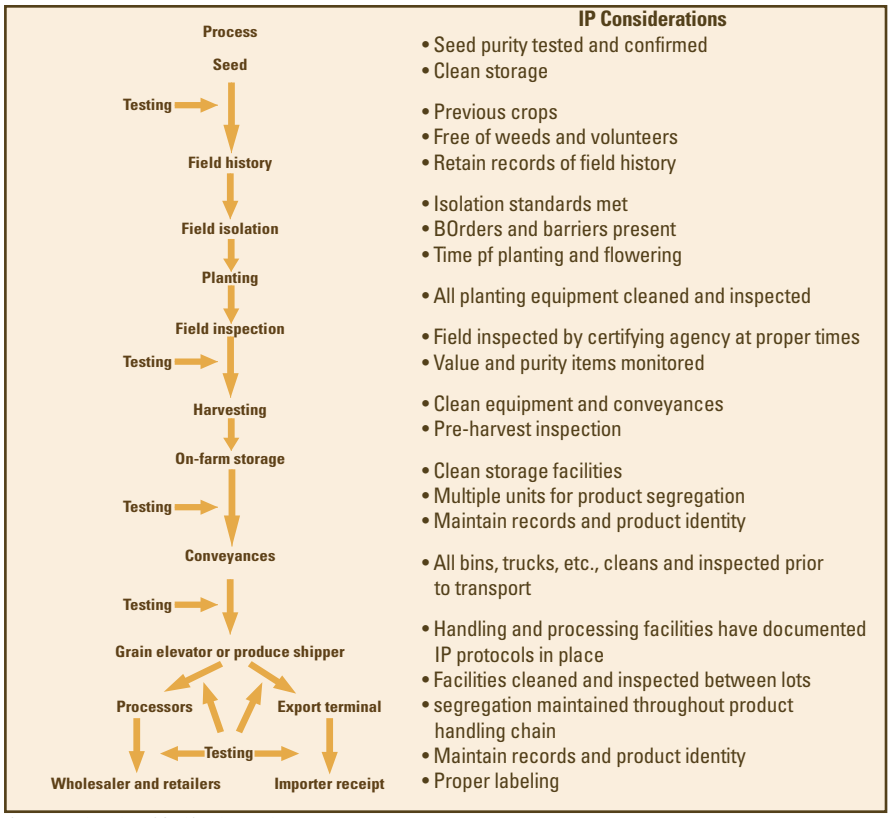
Traceability can be achieved through various systems. Process traceability focuses on documentation and auditing of the process by which the seed or commodity is produced, often involving a third-party agency, as for certified seed. Origin traceability is more concerned with where a product came from and the handling steps involved in getting it to market. The intent would be to develop a cumulative record of what was delivered or blended together at each step in the marketing chain. For food products, traceability may be primarily focused on safety verification or lot identification should recalls be necessary. Depending upon the intent of the system, labeling may or may not be included. For value-added products, such as certified seeds, labeling may be advantageous. In other cases, labeling is not desired or necessary, as when undesired components are maintained below established threshold levels via the certification or traceability system.

These elements are components of traceability and labeling regulations that are being adopted in some countries for seeds and commodities developed by recombinant DNA (rDNA) techniques, also termed transgenic or biotech varieties. There is as yet no consistency or harmonization among these regulations. In the United States, once a particular biotech trait (a specific "event") has been approved and deregulated for commercial production and sale, there are no further requirements for traceability solely based on the fact that it was developed using modern biotechnology. Specific markets or distribution channels may impose identity preservation (IP) requirements during production and handling to either ensure (e.g., value-added traits) or exclude (e.g., organic systems) the presence of biotech materials, but these requirements are not mandated by law. In contrast, the European Union (EU) has enacted regulations requiring both traceability and labeling for all agricultural materials derived from biotech varieties, including those in which the engineered DNA and protein may no longer be present or detectable, such as for extracted oils. Other countries may have no regulations (as yet) or may require biotechnology-specific labeling, but not traceability.

Fragmented Global Regulations

The diversity and lack of harmonization of labeling and traceability regulations worldwide creates supply and marketing issues for the seed and commodity industries. A given biotech variety or event may be approved in the country of origin but not by potential trading partners. Currently, most biotech varieties have been first developed and approved in the U.S., but most countries have a zero tolerance policy for events unapproved through their own regulatory systems, including the U.S. However, once a biotech variety of a commodity is grown widely in a particular location, the likelihood of some level of admixture or adventitious presence (AP) in other varieties of the same crop increases. Allowable thresholds for such undesired AP also vary widely among countries, even for approved varieties (from 5% to 0.1%). In some cases, documentation of production under an IP system designed to meet specific purity standards can result in an exemption from labeling or testing requirements. However, requirements for IP record-keeping differ among regulatory systems.

IP and traceability systems are evolving to provide mechanisms for capturing the value associated with biotech traits without disrupting marketing channels. IP relies on documentation, communication, and coordination of all parties involved in the production and marketing process, often with external verification by certification agencies. IP systems are often process- based, meaning that they focus on establishing standard operating procedures to minimize contamination and verify that those procedures are followed by external auditing and inspection. If accepted by the marketing chain and end users, this approach avoids costly and repeated testing of products. It can also be used for products for which tests are not



Source: University of California, Davis.

available or practical like organic foods. However, if the IP system is used to exclude specific products, such as those for biotech-free markets, issues can arise if testing is done and AP of undesired materials is detected. It is possible that a product could have been produced in compliance with all procedures throughout the IP system and still have a low level of AP that, if detected, might not be acceptable to a customer or trigger labeling requirements.

Biotech Testing and Labeling Systems

Testing for biotech components in seed and food products is also problematic. Diverse testing methods can be used (e.g., DNA-based, protein-based, bioassays, etc.), and sampling and testing protocols are not standardized nor universally recognized. Simply due to the statistics of random sampling, different tests could give different results, even if the testing procedures themselves were reliable and standardized. This lack of predictability of test results increases the risk and liability of each participant in the marketing chain, which encourages additional testing at each point where the seed or commodity changes hands. Such testing can result in significant additional costs. And as noted above, the EU regulations require labeling of products derived from biotech crops even if the product has been processed and no genetically engineered material (i.e., DNA or protein) is present or detectable.

Labeling requirements for biotech products are often justified on the basis of the consumers' "right to know" the origin and composition of their foods, irrespective of safety or health issues. However, food manufacturers currently do not wish to label products as containing biotech ingredients for fear of losing market share. Thus, in countries where labeling of biotech components is required, food manufacturers commonly use non-biotech ingredients to avoid the labeling requirement. This has further emphasized IP and traceability systems to enable such non-biotech sourcing, although market premiums for non-biotech commodities have remained small.

These traceability and labeling regulations, though targeted primarily to food products, have significant implications for the seed industry. Commodities can only be as "pure" as the seeds from which they are

"pure" as the seeds from which they are grown, so seeds destined for biotech-free markets require exceptional levels of genetic purity. Channeling programs can direct specific biotech varieties to markets where they are approved and accepted, such as the Market Choices® certification program of the American Seed Trade Association, which utilizes a distinctive symbol on seed bags to alert growers of potential restrictions on crop sales due to lack of regulatory approval in certain markets.

INCONGRUITY OF INTERNATIONAL AGREEMENTS

Seeds, as living biological material, also face restrictions associated with the Cartagena Protocol on Biosafety, developed under the auspices of the Convention on Biological Diversity. The Protocol was adopted in January 2000 and went into force in late 2003, although the U.S. has not ratified the Convention on Biological Diversity and thus, cannot be a Party to the Protocol. A central component of the latter is the establishment of an advance informed agreement (AIA) procedure to ensure that countries are provided necessary information to make informed decisions before importing a "living modified organism" (LMO) for intentional release. As an AIA is not required for LMOs intended for food, feed or processing, it applies primarily to seeds or propagative materials. A Meeting of the Parties (MOP-2) to further develop agreements for LMO transboundary (international) movement will be in Montreal 30 May-3 June, 2005. Documentation that may be required for the transboundary movement of LMOs depends upon the intended use (www.biodiv.org). The most requirements pertain to the use for uncontrolled release into the environment (i.e., crop planting).

As additional regulations based upon the Precautionary Principle, such as the Cartagena Protocol, are woven into international agreements, a unique status for biotech products will likely be perpetuated. While the stated policy of the U.S. government is that regulations should be driven by the end product, not the process by which the product was developed (this concept has been repeatedly affirmed by the U.S. National Academy of Sciences), the U.S. Department of Agriculture and Environmental Protection Agency consider biotech crops to be "regulated articles" based solely on whether rDNA methods were used in their development. This policy results in situations like the current marketing and commercial acceptance (and low regulatory scrutiny) of herbicide-tolerant wheat developed through mutagenesis, but high regulatory burden for and market rejection of herbicide-tolerant wheat developed by rDNA technology.

Regulating Based on Process Versus Product

The "event-specific" basis of biotech regulatory systems is also a significant source of problems in seed traceability that will likely worsen in the future as more products are introduced into the marketplace. Biotech traits are currently regulated as specific "events" or insertions into a host plant genome. A specific insertion event may be deregulated, while the insertion of a gene for the same trait in a different location in the genome may not. This situation was highlighted recently by Syngenta's disclosure that a corn variety containing the *Bt*11 event conferring insect resistance contained low levels of a second event (*Bt*10) that was not deregulated, even though their phenotypes were indistinguishable. While regulatory agencies in both the U.S. and EU agreed that there is no health and safety risk from the presence of the *Bt*10 event, the EU is nonetheless instituting special testing measures to detect it in U.S. corn products. This is an example of a traceability and regulatory compliance failure that has no unique phenotypic, product performance, end product use, safety, or environmental consequences and would never have drawn any attention (or even been detected) if it had occurred in a conventional variety.

A recent review of the scientific literature and past experience with biotech and conventional crop breeding argued that continuing to base regulatory decisions on specific genetic insertion events, rather than on phenotypic characteristics (i.e., process rather than product) has little scientific justification (Bradford et al., 2005[1]). A tiered regulatory system based upon phenotypic expression of the engineered trait and having different stringencies associated with true risk levels would be a more rational approach and would obviate many of the traceability issues that arise due to the overly cautious and inconsistent international systems regulating biotech crops. A voice that has been largely absent from the discussions regarding the Cartagena Protocol and

[1] Bradford, K.J., Van Deynze, A., Gutterson, N., Parrott, W., Strauss, S.H. (2005) Regulating transgenic crops sensibly: lessons from plant breeding, biotechnology and genomics. *Nature Biotechnology* 23: 439-444.

other regulatory schemes is that of public scientists involved in the research and development of biotech crops. To address this absence, a Public Research and Regulation Foundation has been established to channel input from public scientists into the international biotech regulatory process (see www.pubresreg.org).

Traceability and labeling are well-established, integral parts of seed production and marketing systems. They can serve to maintain product quality, capture value, inform the consumer, and ensure the safety of agricultural products. However, when they are based on distinctions that do not affect final product quality or safety, as many current biotech regulations are, they can become a hindrance, rather than an asset, to marketing and trade.

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