American Seed Trade Association
http://www.amseed.org/

http://www.bio.org/

FACTSHEET

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The Accord: Generic Event Marketability and Access Agreement is Open for Signature

Background

The first genetically engineered row crop was commercialized in 1996. Currently, nearly ninety-percent of cotton, corn and soybean acreage in the United States is planted with seed varieties containing biotechnology events. Grain from these crops is traded globally, accounting for over $40 billion annually, making the United States the largest producer and exporter of crops and grain derived from biotechnology globally. The first of the commercial biotechnology events will be going off-patent and becoming "generic" in 2015.

The expiration of patents for biotechnology events creates opportunities for growers and the seed industry, but also creates challenges that must be addressed. The most pressing challenge presented by patent expiration of biotechnology events is the maintenance of global regulatory authorizations for these events as well as associated stewardship obligations so that farmers can continue to cultivate their crops grown from seed varieties containing off-patent events without jeopardizing U.S. export markets.

Beginning in 2010, the Biotechnology Industry Organization (BIO), the American Seed Trade Association (ASTA) and their members engaged key stakeholders to address the opportunities and the challenges associated with patent expiration. The result of this dialogue was the development of a framework, called the Accord, a private-sector driven mechanism that provides for the transition of regulatory and stewardship responsibilities for biotechnology events, after patent expiration.

The Accord: Unique Private Sector Solution

The Accord sets out rights and obligations for signatories involved in commercializing biotechnology seed products containing off-patent biotechnology events to ensure international regulatory and stewardship responsibilities are maintained. The Accord will contain two agreements: The Generic

Event Marketability and Access Agreement (GEMAA) and the Data Use and Compensation Agreement (DUCA). While both of these agreements are voluntary, they are binding contracts among signatories. They promote continued innovation in the seed industry, preserve strong protection for intellectual property rights and potentially provide for new business opportunities.

The GEMAA is complete and is now open for signatures. The DUCA is targeted to be open for signatures the first quarter of 2013.

Scope of the Accord

The scope of the Accord agreements is biotechnology events authorized for cultivation in the United States and U.S. export market authorizations. The agreements will cover all commercialized U. S. patented biotechnology events of Accord signatories that are within 4 years of patent expiration.

Driver of the Accord: Maintaining Agriculture Export Markets

Biotechnology events are highly regulated world-wide. Regardless of the status of event patents, biotechnology events must be authorized for import into our major trading partner countries. Often, these authorizations are time-limited and must be monitored and maintained by companies that developed and are marketing seed containing these events. Following the expiration of patents covering a biotechnology event, companies that are already selling that event may remain in the market, but it is also probable that other seed companies will market seed containing the off-patent event. As companies invest in innovation, they will use these off-patent events in the development of new proprietary seed products.

It is, therefore imperative there be a transparent and predictable mechanism to maintain regulatory authorizations after patent expiration and to obtain any necessary, new authorizations in order to keep U.S. agriculture export markets open. To this end, the Accord creates a process that:

- → Is based on binding contractual relationships
- → Provides for equitable sharing of ongoing regulatory and stewardship costs
- → Maintains obligations for product stewardship practices

Driver of the Accord: Promotion of Innovation and Business Opportunities

A basic principle underlying the Accord is the promotion of continued innovation and business opportunities, while still maintaining the seed industry's high product quality standards. Fundamental components to this principle are:

- → Transparency and predictability in the mechanisms of the Accord
- → Access to generic events after patent expiration
- → Fair compensation for access to proprietary regulatory approvals or data
- → The protection of all intellectual property to maintain incentives for continued investments in innovation

The Accord: The Basic Elements of Both the GEMAA and DUCA

The GEMAA and the DUCA both provide the following basic elements:

- → An opportunity for members of the U.S. agricultural value chain to participate in the process and steer the future direction of the agreements
- → Notice of patent expiration three years prior to that expiration
- → An obligation to provide access to the biotechnology event, in a "usable" form at patent expiration
- → Mechanism for sharing or transitioning of regulatory responsibilities through negotiation with binding arbitration if necessary
- → A predictable process for signatories, or groups of signatories, to become "verified" that they are able to share or take over regulatory responsibilities
- → Stewardship requirements for signatories
- → Process for discontinuation of a biotechnology event

The GEMAA: Path Forward for Generic Biotechnology Events

Under the GEMAA, companies that have developed proprietary regulatory information to support the authorizations for events globally, called "Proprietary Regulatory Property (PRP) Holders", must provide access to the generic event at patent expiration. PRP Holders are required to provide notice of patent expiration three years before the last patent on the biotechnology event expires. At the point of the notice of patent expiration, the PRP Holder has a choice to:

- → Independently maintain regulatory responsibility for the event at no cost to users of the generic event
- → Seek to share regulatory responsibility; or
- → Discontinue regulatory responsibility

<u>Independently Maintain Regulatory Authorizations.</u>

Companies that choose to independently maintain regulatory responsibilities must maintain global regulatory authorizations at no cost to user of the event until they seek to share or choose to discontinue. Under this option, PRP Holders are not mandated to provide access to the proprietary regulatory package for purposes of new product development, such as seed products containing proprietary stacked events.

<u>Seek to Share Regulatory Responsibility</u>

The PRP Holder may seek to share regulatory responsibility for a biotechnology event, in which case the PRP Holder and interested Signatories to the GEMAA would begin negotiation of a "joint responsibility agreement". Once concluded, this agreement would provide full access to the PRP. If there are unresolved issues in this negotiation, they would be submitted to binding arbitration. No party to the negotiation, however, is required to accept the arbitration ruling. If the joint responsibility

agreement is not finalized, the PRP holder must either continue to independently maintain authorizations or announce they will discontinue maintenance of these responsibilities and discontinue the event.

Discontinue Maintenance of Regulatory Responsibility

If a PRP Holder decides to discontinue regulatory responsibilities, a seven year clock is started which concludes when the PRP holder discontinues regulatory responsibilities for the biotechnology event. Like the shared responsibility agreement, the announcement to discontinue begins a negotiation of a "transition agreement" with the same timeline and process as the joint responsibility agreement, including binding arbitration for unresolved issues in the negotiation. Unlike the joint responsibility agreement, the PRP holder must execute the transition agreement. If no other signatory involved in the negotiation signs the transition agreement, the PRP Holder and all other signatories must discontinue the event within the seven year period initiated by the notice to discontinue regulatory responsibilities.

Cost of signing the GEMAA

The agreements were designed to keep operating costs minimal. Costs associated with signing the GEMAA are limited to the annual operating costs of the GEMAA from which small business entities and non-profit 501(c)3 corporations are exempt. If a company signs the GEMAA and currently is involved in utilizing seed products containing biotechnology events, they only take on a commitment to appropriately steward those products. Should a Signatory choose to execute a joint responsibility or transition agreement for a specific event, that Signatory will take on the responsibility to steward that event as well as their share of regulatory costs associated with that event.

Administration of the GEMAA

The GEMAA will be overseen by a Committee of Signatories that will have the duty to carry out the discretionary duties of the GEMAA. Participation on the Committee of Signatories is voluntary. The day-to-day non-discretionary functions of the GEMAA will be managed by an Administrator, who will serve as the point of contact for Signatories, prospective signatories and the public.

Implementation of the GEMAA

The GEMAA will be effective once it has four signatories. Once effective, the Committee of Signatories will be formed within three months, and the first meeting of the Committee will held within three months.

Information on the Accord

Those interested in learning more about the Accord can access information on the website, AgAccord.org, where the GEMAA can be downloaded. Contact information for the Administrator can also be found on AgAccord.org.