



**American Seed Trade Association**  
<http://www.amseed.org/>



<http://www.bio.org/>

**For Immediate Release**

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**The Accord: Generic Event Marketability and Access Agreement Is Now Effective**

Washington, D.C. -- The Biotechnology Industry Organization (BIO) and the American Seed Trade Association (ASTA) announced today that the Generic Event Marketability and Access Agreement (GEMAA) is now effective. Following its launch on October 31, five BIO and ASTA member companies and agriculture biotech providers – BASF Plant Science, Bayer Crop Science, Dow Agro Sciences, DuPont Pioneer and Monsanto Company – have all signed on as signatories.

This landmark agreement driven by the private sector and created within the framework referred to as The Accord was developed to address the transition of commercial biotechnology events as they go off patent. The entire agriculture value chain benefits from the GEMAA by setting 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.

Effective once it received four signatories, the GEMAA will be overseen by a Committee of Signatories that will be formed within three months and will have the duty to carry out the discretionary duties of the GEMAA. Participation on the Committee of Signatories is voluntary, and its first meeting will be held within three months.

“It is 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,” says Cathleen Enright, Executive Vice President, Food and Agriculture, BIO. “To this end, the GEMAA creates a process that is based on binding contractual relationships so that

regulatory and stewardship obligations are maintained.”

“The expiration of patents for biotechnology events not only creates opportunities for growers and the seed industry, but also creates challenges that must be addressed,” says Andrew LaVigne, President and CEO of ASTA. “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. The GEMAA is now effective and addresses this challenge.”

Under the GEMAA section of the Accord, signatories to the agreement that have developed proprietary regulatory information to support the authorizations for events globally would be required to provide notice of patent expiration three years before the last patent on the biotechnology event expires and provide access to the generic event at patent expiration. Additionally, the regulatory data owner must elect to either maintain regulatory responsibility on its own for the whole marketplace for at least four years after the last sale of the product, or share or transition this responsibility with other users. If no interest is expressed by other signatories, the owner could discontinue the event.

In all instances, GEMAA signatories commit to properly steward their commercially available events.

The Accord: GEMAA is the first of two agreements that will make up the Accord. In addition to the GEMAA, the BIO-ASTA group continues to work on a Data Use and Compensation Agreement (DUCA) that complements the GEMAA and will have additional provisions related to structured access to regulatory data, and data compensation, to compliment the bilateral, negotiated process in use today by companies to create novel combination products. The DUCA is targeted to be open for signature in 2013.

More information about the Accord and the GEMAA signature process can be found at:  
[www.AgAccord.org](http://www.AgAccord.org).

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*About BIO:*

*BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products. BIO also produces the BIO International Convention, the world’s largest gathering of the biotechnology industry, along with industry-leading investor and partnering meetings held around the world.*

*About ASTA:*

*Founded in 1883, ASTA, located in Alexandria, Va., is one of the oldest trade organizations in the United States. Its membership consists of about 700 companies involved in seed production and distribution, plant breeding, and related industries in North America. As an authority on plant germplasm, ASTA advocates science and policy issues of industry importance. Its mission is to enhance the development and movement of quality seed worldwide.*