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

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 open for signature. The GEMAA is a landmark agreement created within the private sector-driven framework, referred to as The Accord. The Accord was developed to address the transition of commercial biotechnology events as they go off patent.

When implemented, the GEMAA will provide confidence to growers, breeders and grain handlers in the use of generic biotechnology events. The GEMAA is intended to benefit the entire agriculture value chain by ensuring the maintenance of foreign regulatory authorizations and stewardship obligations following the expiration of patents for biotechnology events utilized in seed varieties.

Beginning in 2010, BIO, ASTA and their technology provider and seed company members engaged a wide range of stakeholders including grower groups, grain handlers and government officials to identify and create solutions that would provide clarity and enable ongoing farmer choice of biotechnology events (often referred to as biotech traits) following patent expiration. The result of this 2 year dialogue was the development of the GEMAA as a component of the Accord.

The GEMAA is a contractually binding agreement among signatories which provides a clear set of procedures to manage patent expiry for the benefit of the entire value chain. The agreement will promote continued innovation and competition in the seed industry, while respecting the intellectual property rights essential to stimulate the innovation needed to meet the growing global demand for food, feed and fuel.
“The clear message we heard from our stakeholders was the importance of a reliable plan to maintain U.S. export markets,” says Cathleen Enright, Executive Vice President, Food and Agriculture, BIO, “The GEMAA provides a predictable and transparent process that ensures global regulatory authorizations are maintained during and after these transitions so that farmers can continue to realize the benefits of these products.”

“Innovation is the basis upon which the seed industry can provide farmers with a wide array of high quality seed,” says Andrew LaVigne, President and CEO of ASTA, “Providing business opportunities is one of the principles behind the Accord. It assures access to off-patent, biotech events and a path by which these events can be confidently utilized by the broader seed industry.”

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 the first quarter of 2013.

More information about the Accord and the GEMAA signature process can be found at: 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 750 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.