For Release
IMMEDIATE (April 7, 2004)

U.S. Grain Industry, BIO Urge U.S. Government to Expedite 'Trace-Amounts' Policy for Biotech Products

WASHINGTON – The nation's two major grain industry organizations and the Biotechnology Industry Organization (BIO) for the first time have jointly urged three U.S. regulatory agencies to expedite the implementation of an overarching, science-based policy governing incidental, trace amounts – or so-called "adventitious presence" – of biotechnology-enhanced events in raw and processed grains and oilseeds, as well as food and feed.

The National Grain and Feed Association (NGFA), North American Export Grain Association (NAEGA), BIO and 17 State and Regional Grain and Feed Associations affiliated with the NGFA said implementation of such a policy for biotech-enhanced commodities is "enormously important" and a "vital" precursor to the United States' providing international leadership to develop a harmonized global approach on the issue.

The organizations' joint statement was precipitated by a request for comment from the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) on whether it should establish a separate component within its regulatory system to address the adventitious presence of biotech-enhanced commodities that have not yet received full regulatory approval for food or feed. APHIS also sought input on whether it should exempt "low-level" occurrences of such biotech-enhanced events in commercial crops, food, feed or seed.

The NGFA, NAEGA, BIO and the other organizations urged APHIS to work with the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) in developing a unified policy approach governing the adventitious presence of biotech events that have been reviewed for food, feed and environmental safety, but have not completed the full regulatory-approval process. In so doing, the groups called on the three federal agencies to adopt a policy proposed by the White House Office of Science and Technology in August 2002.

"Such a policy must be solidly grounded in science, involve all agencies with regulatory responsibilities for biotechnology, and not compromise the safety of the U.S. food and feed supply or the environment," the groups said. The organizations also insisted that such an early safety assessment policy maintain stringent regulatory safeguards and be restricted to those biotech events (specific gene sequences) for which the sponsors seek regulatory approval for use in the general commodity stream for food and feed use. Biotech-enhanced plants intended for pharmaceutical or industrial uses would not be covered by this policy unless they are deregulated for general commodity use in food and feed.

Under the U.S. government's current "coordinated framework" for regulating agricultural biotech-enhanced events, APHIS is responsible for issuing permits for field trials of biotech-enhanced plants, and grants "non-regulated status" to biotech crops if the agency determines they do not pose an adverse risk to other plants, wildlife or the environment. Meanwhile, FDA determines whether biotech-enhanced foods, feed and feed ingredients are safe for human and animal consumption. EPA registers biotech-enhanced events that express their own pesticides and determines whether such products pose unreasonable adverse effects upon the environment.

The NGFA, NAEGA, BIO and other groups noted that trace amounts of biotech-enhanced events in commodity crops that have not completed the regulatory review process can result from a plant's natural physiology (pollen flow) or inadvertent mixing during harvest and transportation. But they noted that the U.S. regulatory system imposes a zero tolerance on the presence of such unapproved biotech-enhanced events in food and feed, regardless of the risk level.

"This 'zero-tolerance' policy exposes grain handlers, food processors and feed manufacturers to the risk that any presence in general commodity crops of biotech-enhanced events that have not been approved for food and feed under the U.S. regulatory process could render such crops adulterated and subject to seizure under federal law," the groups said. Such risks are even more complex for agricultural exporters, which confront a lag time in biotech approvals by foreign governments, they said. Further, the groups subsequently noted that this policy is inconsistent with other food regulations that have established thresholds for trace amounts of unexpected materials.

The NGFA, NAEGA, BIO and other organizations said that once such a policy is established, the U.S. government "must vigorously promote global adoption" of compatible regulatory systems that meet the same standards for being science-based and transparent. "A U.S. policy on adventitious presence is a key element in a much-needed comprehensive and harmonized global approval system for regulation of agricultural products of modern biotechnology," the groups said.

Associations affiliated with the NGFA that signed the joint statement were the Agribusiness Association of Iowa, Grain and Feed Association of Illinois, Grain Elevator and Processing Society, Indiana Grain and Feed Association, Kansas Grain and Feed Association, Michigan Agri-Business Association, Minnesota Grain and Feed Association, Missouri Ag Industries Council Inc., Montana Grain Elevator Association, Nebraska Grain and Feed Association, North Dakota Grain Dealers Association, Ohio Agribusiness Association, Oklahoma Grain and Feed Association, South Dakota Grain and Feed Association, Tennessee Feed and Grain Association, Texas Grain and Feed Association and Wisconsin Agri-Service Association. Also signing was the Iowa Seed Association and the Montana Agricultural Business Association.

The NGFA, established in 1896, consists of 1,000 grain, feed, processing, exporting and other grain-related companies that operate about 5,000 facilities that handle more than two-thirds of all U.S. grains and oilseeds. The NGFA's membership encompasses all sectors of the industry, including country, terminal and export elevators; feed manufacturers; cash grain and feed merchants; end users of grain and grain products, including processors, flour millers, and livestock and poultry integrators; commodity futures brokers and commission merchants; and allied industries. The NGFA also consists of 35 affiliated state and regional grain and feed associations, as well as two international affiliated

associations. The NGFA has a strategic alliance with the Grain Elevator and Processing Society and the Pet Food Institute. The NGFA and NAEGA are co-located and have a joint operating and services agreement.

NAEGA, established in 1912, is a not-for-profit trade association comprised of private and publicly owned companies and farmer-owned cooperatives involved in and providing services to the bulk grain and oilseed exporting industry. NAEGA member companies ship practically all of the bulk grains and oilseeds exported each year from the United States.

BIO represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers and related organizations in all 50 U.S. states and 33 other nations. BIO members are involved in the research and development of health-care, agricultural, industrial and environmental biotechnology products.

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