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From: Ab Basu [mailto:abasu@bio.org]

Sent: Friday, February 06, 2009 4:50 PM

To: Jennings, Henry

Subject: BIO Comments Regarding Maine Board of Pesticides Control Proposed Amendments to Chapter 41-Special Restrictions on Pesticide Use

February 6, 2009

Henry Jennings, Director
Maine Board of Pesticides Control
28 State House Station
Augusta, Maine 04333-0028

On behalf of the agricultural biotechnology industry, BIO is submitting comments opposing the Maine Board of Pesticides Control draft rules to amend Chapter 41 to "Amend the current rule to create a mechanism to regulate Bt sweet corn to prevent pollen drift to other non-Bt-corn crops and to restrict sales of Bt sweet corn seed only to quantities large enough to plant one acre or more".

I would first like to re-submit the attached comments that BIO submitted to the Board on November 27, 2007, when the first draft rules on Plant Incorporated Protectants (PIP) were under review. All of those arguments should be considered as relevant for the newly proposed amendments, along with the following points. In total these arguments reflect our industry's opposition to the newly proposed amendments, while also pointing out the problems inherent in the existing rules on PIPs in Maine. Essentially, BIO questions the existing rules and those drafted for additional inclusion for scientific basis, whether they take into account vast amounts of scientific data on pollen flow or insect resistance management practices, whether they take into account the strong federal regulatory process for PIPs, and also whether there are any documented problems that these rules are intended to address in Maine or elsewhere in the country.

The first proposed amendment is to Chapter 41, Section 5, Part E Subpart I, c: "If no refuge is required, the Bt-corn grower shall maintain at least a 300-foot Bt-corn free buffer to non Bt-corn crops."

BIO objects to this proposed amendment as it arbitrarily sets a buffer length at 300 feet. We do not see any data that supports this number. Additionally, the proposal does not take into account the fact that organic operations (that these rules try and protect) are process-based for certification purposes. No organic certified farm in the entire United States has to our knowledge lost its certification due to any unintentional pollen flow from biotech or conventional neighboring farms. Also, organic farming is, like other identity preserved systems, engaged in producing a crop for which the grower would charge a premium and as such should be the entity that sets into place any required buffers or other protection mechanisms for the integrity of the premium crop. The USDA's National Organic Program rules state this quite clearly. In this case, the proposed rule would require much cost of any grower wanting to plant a Bt corn crop to protect someone else's organic operation from which they would not derive any of the premium benefits that the latter would derive. Furthermore, the existing rule and proposed amendment confuse pollen flow with insect resistance management policies for PIPs. The existing rules and proposal somehow has buffer zones for pollen flow purposes at arbitrary sizes to take the place of required refugia for PIP crops that USEPA strongly regulates for insect resistance management (IRM). While the USEPA requires refugia for IRM purposes for most PIPs, the Agency does not require any refugia area for Bt sweet corn as data shows this is not necessary.

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The second proposed amendment is the Chapter 41, Section 5, Part E new Subsection II: “Dealers distributing Bt-sweet corn shall only sell the seed in quantities large enough to plant one acre or more.”

BIO opposes this proposed amendment with two comments:

First, BIO questions the authority of the Maine Board of Pesticides Control to regulate the marketing standards of PIP products.

Second, BIO is concerned with the potential for unintended consequences from this proposal. There is significant potential harm that this proposal could cause in the long run to small scale growers such as those wanting advanced technology for their sweet corn for small markets or personal consumption. This proposal unfairly, and without any documented data justifying it, places small scale growers at a disadvantage to large farming operations. While this is specific to Bt-sweet corn, it is a precedent that is not in existence anywhere else and for which there is no stated reason or existing problem. The precedent could easily be used for other plants as well. It is unfair and unnecessary.

Thank you for considering BIO's comments regarding the proposed amendments to Chapter 41. Please feel free to call either of the following persons at BIO with any questions you may have:

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November 28, 2007

Maine Board of Pesticides Control
28 State House Station
Augusta, ME 04333-0028

Re: Comments on Proposed Changes to Pesticide Regulations

On behalf of the agricultural biotechnology industry, we are submitting comments opposing the Maine Board of Pesticide Control's (Maine Board) draft rules regarding Bt seeds. The Biotechnology Industry Organization (BIO) and its members strongly urge the Maine Board of Pesticide Control to reconsider the proposed rules in their entirety.

BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and 31 other nations. BIO members are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products. BIO's members have an especially strong interest in food and agricultural products developed through the use of biotechnology. These products include crops improved to resist insect pests through the incorporation of a "plant incorporated protectant" (PIP), e.g. Bt seeds.

BIO and its members will be harmed if the Maine Board promulgates the draft rules as proposed. To establish standing and preserve an appropriate record for potential legal challenge, BIO respectfully requests that the Maine Board not promulgate the draft rules. Should the Maine Board proceed anyhow to promulgate the rules, then BIO also respectfully requests that the Maine Board fulfill all of its administrative duties related to such promulgation. Finally, BIO reserves the right to challenge the legal authority and jurisdiction of the Maine Board to promulgate such rules.

The draft rules, if adopted, could prove to be cumbersome and ambiguous, as well as damaging to Maine agriculture, and place Maine farmers at a competitive disadvantage. More importantly, the draft rules do not take into account numerous scientific conclusions that have found agricultural biotechnology to be safe and beneficial, and instead places this technology under unnecessary, not based on science and burdensome regulations.

Over the course of the last decade, well over one billion acres of biotech crops have been grown worldwide and been eaten by billions of people, without a single documented health problem or environmental concern. Similarly, millions of acres of biotech crops have been grown in the United States over the last several years, successfully co-existing with organic crop production. In fact, the growth of biotechnology in agriculture has been accompanied by a surge in organic acreage and profits derived from organic production in this country.

We encourage the Board to closely consider each of our arguments when deliberating over final rules.

History of Safety and Acceptance of Agricultural Biotechnology

Crops improved through biotechnology have been adopted by farmers in the United States and around the world at rates never before seen by any other advances in the history of agriculture. From the first significant commercial plantings in 1996, double digit growth in each subsequent year has led to more than 252 million acres of biotech crops planted in 2006 in 22 countries.¹ These crops are grown by 10.5 million farmers — 9.5 million of whom are small-scale farmers in the developing world. The reason for such impressive adoption rates is simple — agricultural biotechnology delivers significant and tangible benefits, all the way from farm to fork.

In 2006, U.S. farmers grew eight different biotech crops — alfalfa, canola, corn, cotton, papaya, soybean, squash, and sweet corn — which were primarily of three varieties — disease resistant, pest resistant, and herbicide tolerant which enhances weed control. In 2007, American farmers grew 58.3 million acres of biotech soybean (91 percent of all U.S. soybeans grown). They grew 9.62 million acres of biotech cotton, representing 87 percent of all U.S. cotton grown. And 73 percent of U.S. corn were biotech varieties, or 67.8 million acres.² These traits in biotech crops have delivered widely shared benefits such as increased production, improved quality, increased farmer incomes, and reduction in the environmental impacts of agriculture.

New biotech approaches in pest control have reduced farmers' reliance on pesticide applications, eliminating 69.7 million pounds of pesticide applications in the United States in 2005.³ Globally it is estimated that pesticide applications decreased six percent in the interval from 1996-2004, eliminating 379 million pounds of pesticide applications.⁴

Federal Regulation of Biotech Crops

The regulation of agricultural biotechnology products in the United States is comprehensive, rigorous, and above all, science based — and often misunderstood. Biotech crops undergo intense regulatory scrutiny from the research lab, to field trials, to commercial plantings by farmers, so they are safe for food and the environment.

Three federal U.S. agencies share primary responsibilities for the regulation of agricultural biotechnology products:

1. U.S. Department of Agriculture's Animal and Plant Health Inspection Service (USDA APHIS)
2. U.S. Environmental Protection Agency (EPA)
3. U.S. Food and Drug Administration (FDA)

¹ James, Clive. January 2007. *Global Status of Commercialized Biotech/GM Crops: 2006*. International Service for the Acquisition of Agri-Biotech Applications (ISAAA).

² USDA National Agricultural Statistics Service (NASS), June 2007.

³ Sankula, Sujatha. 2006.

⁴ Brookes and Barfoot. 2005.

EPA is responsible for crops improved to resist insect pests through the incorporation of a “plant incorporated protectant” (PIP),⁵ such as the protein from *Bacillus thuringiensis* (Bt), a bacterium that occurs naturally in soil that can produce proteins that are lethal to certain insects.

Bt alone has been registered by EPA for many years as a bio-pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). As such, Bt is not designated as a restricted or limited use pesticide as human and environmental exposure is benign (aside from affecting target insects only).⁶

In regulating PIPs,⁷ EPA bases their decisions on strict scientific standards and extensive input from academia, industry, other Federal agencies, and the public. Before the first PIP product was registered in 1995, EPA required that PIP products be thoroughly tested against human safety standards before they were used in human food and livestock feed crops. EPA scientists assessed a wide variety of potential effects associated with the use of plant-incorporated protectants, including acute reactions, such as toxicity, allergenicity, and skin and eye irritation, as well as long-term effects including cancer, birth defects, and reproductive and neurological system disorders. PIPs must go through a long and very rigorous scrutiny before they may be marketed.

Further, EPA states that: “Scientists also evaluated these potential effects in light of the public's potential exposures to these pesticides, taking into account all potential combined sources of the exposure (food, drinking water, etc.) to determine the likelihood that a person would be exposed at levels that would pose a health risk. Based on our reviews of the scientific studies and often peer reviews by the Federal Insecticide, Fungicide and Rodenticide Scientific Advisory Panel, EPA determined that these genetically engineered PIP products, when used in accordance with approved label directions and use restrictions, would not pose unreasonable risk to human health and the environment during their time-limited registration.”⁸

In addition to federal regulations, under the Maine Board of Pesticide Control’s own rules, private and commercial pesticide applicators permits are required to apply restricted or limited use pesticides registered with the Board. Several varieties of Bt are registered with the Board and none of the registrations are designated as restricted or limited use. Therefore, under the Board’s own rules, any member of the general public can purchase and apply Bt without any regulatory oversight. However, the proposed regulations being considered by the Board would require that all purchasers, distributors and planters of Bt incorporated seeds be registered as public or private applicators, which is completely inconsistent with how both the Board and EPA has previously regulated Bt. It simply cannot be the intention of the Board to designate Bt registrations as restricted or limited use so that Bt applications would also require special permits.

⁵ EPA's Regulation of *Bacillus thuringiensis* (Bt) Crops, EPA, May 2002, <http://www.epa.gov/oppbppd1/biopesticides/pips/regofbt crops.htm>

⁶ Federal Insecticide, Fungicide, and Rodenticide Act, EPA, 1996, <http://www.epa.gov/region5/defs/html/fifra.htm>

⁷ Plant Incorporated Protectants, EPA, April 2007, <http://www.epa.gov/pesticides/biopesticides/pips/index.htm>

⁸ Ibid.

The agricultural biotechnology industry believes there is no human health or environmental safety concern warranting the promulgation of additional regulation of Bt plants by the Maine Board of Pesticide Control. Our industry believes that the Board may erroneously be considering unnecessary regulations because of unfounded commercial concerns for Maine's organic farming community rather than science based reasoning.

Co-existence of Biotech and Organic Crops in Maine

Activists have repeatedly raised unfounded concerns that pollen from biotech crops may "contaminate" conventional or organic produce, making it un-saleable or somehow less safe. Many years experience growing different crops in close proximity with one another show such concerns do not have scientific merit. Certain crops, including corn and canola, do produce pollen that is capable of carrying genes some distance. But farmers growing different varieties of these crops have long managed pollen flow with little difficulty and fewer problems. Farmers cooperate with their neighbors in considering which fields to use for which varieties, time plantings to stagger dates of flowering and pollination, and use seed produced under quality controlled conditions to ensure they plant what they intend to plant.

Federal organic standards are process-based. If organic farmers follow the processes set forth by USDA, they can obtain organic certification for their operations. If a farmer does not plant biotech seeds, but later some material from a biotech crop is found in their organic crop, it may still be sold as organic under the law, and the organic farmer does not lose his or her organic certification. Moreover, USDA has clearly stipulated that organic standards were established for marketing purposes only and do not suggest – in any way – that organic foods are safer or healthier than foods produced through conventional practices or through biotechnology.

Most importantly, USDA is not aware of any farmers who have ever lost certification for the inadvertent presence of any biotech crop material in their organic crop – despite the claim some activists may make.⁹

USDA's National Organics Standards¹⁰ lay the groundwork for biotech, conventional, and organic crops to co-exist side-by-side without any risk to farmers. Studies have shown that organic, conventional, and biotech crops can co-exist without any economic or commercial problems.¹¹ If concerns over co-existence between biotech and organic crops are the impetus for introducing new regulations for Bt crops, it is important to consider the following:

- The federal National Organics Standards program places the onus on the grower of the organic production system to put in safeguards to reduce risk of prohibited substances, e.g., prohibited chemicals or biotech presence. In contrast, the Board's proposed rules, instead

⁹ Open letter from Bill Hawks, Under Secretary, Marketing and Regulatory Programs, USDA to Gus Douglass, Commissioner, National Association of State Departments of Agriculture, December 21, 2004.

¹⁰ National Organic Program, USDA, <http://www.ams.usda.gov/NOP/NOP/standards.html>

¹¹ Co-Existence in North American Agriculture: Can GM Crops be Grown with Conventional and Organic Crops?, PG Economics, June 2004, <http://www.pgeconomics.co.uk/pdf/CoexistencereportNAmericafinalJune2004.pdf>

places the responsibility to support organic production not on the organic grower but on other abutting growers not necessarily growing organically or deriving those premiums. Is it the Board's intent to purely support organic production over all other forms of agriculture, and furthermore is such a marketing strategy within the scope of jurisdiction for the Board?

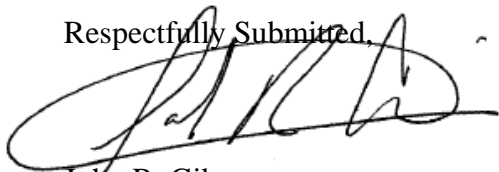
- Bt, whether naturally collected or synthetically produced, is a pesticide that is allowed by USDA's National Organic Standards program to be sprayed on organic crops without jeopardizing certification. In the case of Bt crops, the active ingredient is only a protein from Bt and not the whole organism. So the neighboring crops of a Bt corn field, if organic, likely could be treated with Bt. Unfairly, the Board would not require organic growers benefiting from Bt to treat it as a pesticide with restricted use, as opposed to placing restrictions on farmers growing Bt-incorporated seed. If environmental and health issues are to be considered, shouldn't Bt pesticide sprayed by organic farmers be reviewed for special restrictions?

The Board is responsible for "safeguarding the public health, safety and welfare" and "protecting natural resources of the State" (From the Purpose and Policy Section.) Attempting to regulate pollen flow from plants and impacting commercial marketing strategies regarding organic and other production systems do not appear to be within the Board's mandate and the Board may not have jurisdiction to promulgate and enforce such rules.

BIO and its members are gravely concerned about the origins of the proposed regulations, as there is no evidence that these guidelines protect public health and the environment. It has been repeatedly shown by federal agencies that Bt crops do not pose any unique health or environmental risks that would require additional oversight.

The proposed regulations are cumbersome and would place Maine farmers at a competitive disadvantage. For more than a decade, U.S. farmers have reaped the economic and environmental benefits of planting biotech crops. Maine farmers should have the right to every approved tool available in making decisions about the products and practices that best fit their crop and pesticide control needs – including agricultural biotechnology.

Respectfully Submitted,



John R. Gibson
Biotechnology Industry Organization