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Conducting public-sector research on commercialized transgenic seed

In search of a paradigm that works

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The following statement has been submitted by 24 leading corn insect scientists working at public research institutions located in 17 corn producing states. All of the scientists have been active participants of the Regional Research Project NCCC-46—Development, Optimization and Delivery of Management Strategies for Corn Rootworms and Other Below-ground Insect Pests of Maize and/or related projects with corn insect pests. The statement may be applicable to all EPA [Environmental Protection Agency] decisions on PIPs [plant incorporated protectants], not just for the current SAP [scientific advisory panel]. It should not be interpreted that the actions and opinions of these 24 scientists represent those of the entire group of scientists participating in NCCC-46. The names of the scientists have been withheld from the public docket because virtually all of us require cooperation from industry at some level to conduct our research.

Statement:

Technology/stewardship agreements required for the purchase of genetically modified seed explicitly prohibit research. These agreements inhibit public scientists from pursuing their mandated role on behalf of the public good unless the research is approved by industry. As a result of restricted access, no truly independent research can be legally conducted on many critical questions regarding the technology, its performance, its management implications, IRM

[insect resistance management], and its interactions with insect biology. Consequently, data flowing to an EPA Scientific Advisory Panel from the public sector is unduly limited. Given the importance of the FIFRA [Federal Insecticide, Fungicide and Rodenticide Act] SAP process to an effective and credible assessment of new PIPs on behalf of the American public, we urge EPA to require registrants to remove the prohibition on research on their products and specifically allow research by public-sector scientists.—Shields et al. public comment to EPA FIFRA Scientific Advisory Panel.

Docket: EPA-HQ-OPP-2008-0835.

The Issue

The National Agricultural Statistics Service has estimated that more than 50% of US corn planted in 2008 expressed a *Bacillus thuringiensis* (Bt)-derived toxin protecting the plant against targeted insect pests. Glyphosate-tolerant corn and soybeans occupy over 50% and nearly 100% of US acreage, respectively. Increasingly, transgenic seed contains multiple stacked or pyramided genes in one product. The development of such transgenic seed is time-consuming, highly technical and expensive, and it represents a tremendous investment in intellectual property by seed companies. Safeguarding this intellectual property is just as critical to business success as the innovative research underlying these technological advances. Successful

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companies must prevent competitors from exploiting their technological secrets, and maintain perceived relative value of their own products versus those of competitors.

Transgenic crops are also the focus of public controversy, with some segments of society expressing an agenda to discredit these products through legal and public-relations campaigns against companies marketing transgenic seed. This creates an emotionally-charged atmosphere, with these elements poised to take advantage of negative publicity, studies lacking scientific rigor and societal fears about technology. Thus, seed companies have a strong motivation to limit access to their products by unqualified researchers, and to control research direction and possibly transmission of research results.

Caught in the middle of these conflicting forces are public-sector scientists employed by state or federally-supported institutions, such as land-grant universities and USDA, who have a long standing mandate to impartially investigate agricultural products that are available in the open market to North American farmers. To fulfill this mandate, scientists must be able to conduct objective, comparative and independent research on transgenic seed. For this research to be credible with the public and government regulators, public scientists must be free to formulate the questions, design and conduct the necessary experiments to answer those questions, and follow unexpected leads. Ultimately, their research must pass scientific muster and be freely shared with colleagues in conferences and the refereed literature, and the results communicated with regulators, the agricultural community, and the public.

However, company policies designed for the high-stakes world of transgenic seed production and marketing create an environment that precludes public scientists from meeting their obligations to the American crop producer and ultimately the consumer. The key obstacle to conducting research is a tag attached to every bag of transgenic seed available for purchase, in both the US and Canada, outlining a Technology/Stewardship Agreement. Signing the agreement is required to purchase the product, and in so doing the buyer agrees that the seed will

not be used to conduct research. Because of this “bag-tag” agreement, these commercially-available, highly impactful and widely-adopted products cannot be evaluated in any way by public scientists unless legal permission is expressly granted by the company. This represents a fundamental shift in the paradigm of agricultural research, where heretofore any public-sector researcher could purchase and test any commercially-available product (seed, pesticides, fertilizers, equipment, etc.), independent of company agreements and restrictions.

The need to seek permission to conduct research on commercially available transgenic seed is fraught with logistical hurdles and ethical ramifications. Negotiation of agreements on a case-by-case basis is expensive for universities and government research agencies. The process is slow as the institution seeks to protect its scientists’ rights, including the right to publish the results, while the company, from its perspective, seeks to ensure appropriate research design and reporting of results. The resulting delay is a serious bottleneck that can impede timely conduct of promising research.

Even with a successfully negotiated agreement in place, the current system sets up an uneven relationship where industry partners may unduly influence the way research is designed and disseminated. Projects are vulnerable to company-imposed restrictions at multiple levels. This creates uncertainty, which dampens scientific inquiry for a number of reasons. Public-sector scientists do not know if a research project will be allowed to finish that year, if a multi-year study will reach completion, or if publication of results will be permitted. Many scientists will not initiate, and their institutions often will not allow initiation of, important experiments in the absence of a guarantee against possible interruption by the industry partner. Furthermore, researchers are very cautious about proposing such experiments in federal grant applications because they cannot guarantee execution.

Some important paths of inquiry are particularly vulnerable. In our experience, these most often include attempts to determine levels of plant incorporated protectants (e.g., Bt toxins) in different

plant tissues at different ages, to measure off-target effects (e.g., on non-target and beneficial insects, decomposer communities and aquatic environments), to investigate secondary-pest issues in transgenic fields, and to compare competitors’ products. Comparative studies using seed from multiple companies are especially problematic, because they require separately negotiated agreements with all parties, any of which can withdraw their product from the experiment if the results of the comparison appear to be unfavorable. The freedom to follow up on unexpected research results during the course of planned experimentation, which reflects the very essence of scientific inquiry, is nearly impossible because of the requirement to again seek and receive permission before doing so.

In formulating regulations, the EPA depends heavily on recommendations from Scientific Advisory Panels (SAPs), independent panels of experts assembled by EPA for the express purpose of answering scientific questions bearing on regulatory issues. The success and appropriateness of regulatory decisions depends on the quality of data used to formulate strategies, e.g., for insect resistance management in transgenic crops. This quality reflects the novelty and pertinence of the questions asked and the rigor of experimental design. Furthermore, the quality of recommendations from SAPs to EPA relies on the quality of interpretation of the data presented. One of the unfortunate side-effects arising from the need for direct cooperation of public scientists (via legal agreements, seed or other materials) with seed companies is that many of the most-experienced scientists—those with first-hand knowledge of the target organisms, the crop, and their interactions—are disqualified by EPA from serving on SAPs because of their perceived “ties” to industry. If research was allowed on commercialized products without company permission, many scientists would not be forced into formal agreements with industry.

All of this is having a negative effect on public research within our scientific community. We do not wish to imply that public-sector research to date on transgenic crops is anything less than high

quality. Our point is that the public is not served by policies that preclude research unrelated to legitimate intellectual property concerns, influence the scientific approach, and potentially create biases in the availability of data (or even the perception thereof). Nor is it served when circumstances allow only a subset of public-sector scientists to conduct company-approved research to provide data for submission to regulatory agencies.

Regardless of whether the power of a given company to influence future data flow is exercised, the very fact that such power exists and has been exercised in the past has the potential to call the independence of any study related to transgenic crops into question. We are concerned that these circumstances jeopardize the credibility of all public scientists working on these products, open the process of product evaluation to a perception of potential abuses, and could further fuel public mistrust regarding transgenic technology, regulatory decisions and information issuing from seed companies.

In Search of a New Paradigm

Scientific Advisory Panels rely heavily on independent, public sector studies as the scientific foundation for recommendations to EPA. In February of 2009, a broad cross-section of public-sector corn entomologists submitted two public comments to EPA, one of which is presented as a preamble to this article. These statements were meant to alert two SAPs to the situation described above.

The issue outlined in the public statements is crucial, because the public sector's ability to counterbalance a company's freedom to exercise discretion, both in how in-house experiments are performed and in deciding which internal datasets are submitted to EPA, is in jeopardy. If the public sector is constrained in conducting research, then the suite of questions being addressed and the datasets providing the answers are largely vetted and selected directly or indirectly by industry solely, without the truly independent public-sector input that is generally assumed and relied upon. The statements to the SAPs and EPA were meant as a warning that the assumption of independence is no longer

valid under current company-imposed restrictions on public-sector research. Although composed by corn entomologists, the warning is relevant to all transgenic crops and all public-sector scientists of any discipline who seek to conduct research on transgenic crops.

Following the public comments to EPA, ensuing stories in the press, and public questioning of a panel convened by the National Academy of Science's Committee on Science, Technology and Law, industry has recognized and acknowledged the seriousness of the problem. We view this as an extremely positive step. Public scientists are very familiar with intellectual property issues and secrecy agreements associated with research on products in development, and have worked with companies for years to ensure that company rights are protected when studying materials in the development pipeline, such as plant varieties and pesticides. However, the extension of intellectual property protection to commercialized transgenic seed presents a dramatic change in industry policy. Nevertheless, both groups are optimistic that an amicable, mutually-acceptable solution can be identified.

A concrete step toward resolving this issue was taken in late June 2009, when the American Seed Trade Association (ASTA) invited company representatives and university-based and government corn entomologists to a meeting in Ames, Iowa. As a professional trade organization for seed companies, ASTA brokered a draft set of principles, designed to protect the legitimate property rights of companies while affording public scientists independence to conduct research on commercialized transgenic seed (Table 1).

Because of anti-trust laws, ASTA cannot require uniform implementation of these principles by all company players. Member companies nevertheless participated in drafting the principles, and the public scientists were assured that each firm is serious about implementing change and will adopt a set of company-specific policies reflecting the spirit of the principles. There remains disagreement on some points. For instance, scientists expressed a preference for removal of the bag-tag restriction on research, but the companies were unwilling to do this for reasons of

competitiveness in the marketplace. In the future, we hope that it is possible to alter the wording on the bag-tag to allow public sector research without jeopardizing any company's competitive position.

After much discussion and minor wording changes, scientists agreed that the new principles would address most of the current public sector research issues if adopted by the companies and implemented in a cooperative way. From our perspective, success means that:

- Public scientists are free to design, conduct and report studies involving commercialized transgenic seed, including comparative studies across products and companies, without industry oversight or the need to obtain permission.
- Companies relinquish control of those public-sector research activities on their products that do not infringe on patent rights, in a way which is authentic and transparent to the public.
- All commercial GM crops, including corn, soybeans, cotton, sugar beets, canola and alfalfa, are covered under the new principles and resulting policies.
- The principles apply not only to studies of insects, but also to those of weed control, plant pathology, nematology, ecology and potential off-target effects.

The Future

Although each company has the freedom to act independently, implementation most likely would involve multiyear blanket agreements between each firm and public institution. In the past, companies occasionally negotiated such agreements with individual institutions, delineating acceptable research activities by all institutional scientists on certain transgenic products. Although not widely known or used, these earlier limited agreements represent a precedent for broader scale implementation of multiyear blanket agreements.

The scientists at the meeting in Ames were assured that, in the case of public institutions, the restrictive language on the bag-tag would be superseded by the blanket agreements, and these agreements would be based on the principles brokered by ASTA. Thus, as long as a multi-year blanket agreement with their institution is in place with his/her university, an

Table 1. Types of research on transgenic seed that may be included and types that are not addressed by the statement of principles and objectives as recommended by ASTA, “to enable the public sector research community to independently conduct research studies on commercially available seed products in laboratory, greenhouse and field settings for the purpose of understanding the technology, education, extension and the safe and effective use of these products”

Research may include:	Statement does not address:
Agronomic and yield comparisons	Breeding with plants produced from the seed
Testing for compositional profile such as oil content	Reverse engineering or characterizing the genetic composition of patent-protected traits in seed
Studies related to end-use such as animal feeding	Development of methods for detecting the presence or absence of patent-protected traits in seed
Comparative efficacy studies	Use of non-commercial methods to detect the presence or absence of patent-protected traits in seed
Studies on interactions of the trait with pest biology and pest management practices including interactions related to resistance management	Research on modifications or improvements to the patent-protected traits
Studies on interactions of introduced traits with the environment	

From “Research with Commercially Available Seed Products”, internal ASTA document, September 2009, with permission.

individual scientist will be able to conduct most types of transgenic crop research without obtaining prior permission or facing restrictions.

There is cautious optimism among the public entomologists involved in this process that, while not perfect, this plan represents a major step forward, mitigating the most negative effects of the current restrictions. We applaud ASTA and the seed companies for taking the initiative to formulate the research principles and reach out to public-sector entomologists. A number of potential pitfalls and concerns nonetheless remain. For example, each company is free to decide how fully it will adopt the principles. Even one non-player could limit or prevent comparisons of all products across all companies, severely compromising the ability of public scientists to fully serve the public interest. Alternatively, one non-player could restrict entire categories of research that other companies permit.

Although the principles specifically recommend that ASTA members allow certain categories of research, we are aware that many studies do not fit neatly into categories. The intentionally, and commendably, broad language of the principles simultaneously leaves them open to interpretation. This could be a significant stumbling block. For example,

since the unveiling of the principles in Ames, two of the major industry players have stated informally that development of resistant insect colonies is specifically allowed, while two other companies have stated informally that they interpret the same wording as not including development of resistant insect colonies. Other important research areas potentially open to interpretation include cross-resistance studies and studies of non-target organisms. Additional examples are likely to surface.

If this new paradigm is to be successful, it is critical that companies adopt, interpret and enact the principles to allow all research by public-sector scientists that does not truly and obviously impinge on intellectual property rights, viz. the kind of significant research that the public demands and EPA requires. The protection of intellectual property while conducting independent research is neither a new nor an intractable problem, and there is no reason to believe we cannot effectively work with this next generation of pest management tools—tools that are yearly gaining market share, acceptance and prominence in the agricultural landscape—without compromising industry property rights.

Transgenic crops are now the norm for many large-acreage commodities in the US

and Canada. Industry and the public sector have more similarities than differences in how we want to see these powerful tools evaluated, implemented and preserved over the long term. Despite the many potential pitfalls, public scientists are hopeful that the new paradigm will be viable because of good faith efforts of all. The principles were approved in September 2009 by both the ASTA Executive Committee and the Biotechnology Industry Organization’s Food & Agriculture Section Governing Board, and they will be presented at ASTA’s annual meeting in December 2009, where public scientists and industry representatives have been invited to a special session for updates and further discussion.

We hope that approval of these principles will allow timely formulation of new policies by each company in the spirit of the principles, with uniform implementation across crops and geographical regions, in time for scientists and companies to negotiate blanket agreements in advance of the 2010 growing season. Both groups recognize the need for continued discourse between scientists and company representatives at appropriately high administrative levels, and we look forward to a future of continued productive dialogue with our industry colleagues.