IR-4 Project targets specialty crops

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Pesticide applications for "minor" or "specialty" crops — typically those grown on less than 300,000 acres nationwide — often do not get the full support of product registrants because the potential economic benefits are perceived as much more limited than for applications targeting crops grown on large acreages, such as soybeans and field corn. The IR-4 Project is a unique partnership of researchers, producers, the crop-protection industry and federal agencies designed to increase pest-management options for specialty crops, which include vegetables, fruits, nuts, herbs, nursery crops and flowers. (Most of the crops grown in California fit into this category.)

With funding from the U.S. Department of Agriculture, state agencies, commodity groups and other industry sources, IR-4 researchers and cooperators generate field and laboratory residue data, which are submitted to the U.S. Environmental Protection Agency (EPA) to secure regulatory clearances for using safer pest-control techniques on specialty crops. Projects are prioritized based on requests from growers, commodity groups, and USDA and land-grant university researchers. Since 1963, IR-4 has contributed to more than 7,300 regulatory clearances for specialty crops.

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In 1996, IR-4 responded to the federal Food Quality Protection Act (FQPA) by shifting its strategy from product defense (support for older pesticides needing reregistration) to working with reduced-risk/safer chemistries and biopesticides. The program also expanded its Good Laboratory Practices (GLPs) efforts, started a Methyl Bromide Alternatives Program and initiated a pilot program to support new transgenic horticultural crops. Because they are also grown on smaller acreages, transgenic horticultural crops face many of the same regulatory hurdles as uses on conventional specialty crops.

Focus on herbicide tolerance

The IR-4 team initially identified herbicide tolerance and insect resistance as potential opportunities for assisting transgenic specialty crops through the regulatory review process. It then narrowed down the focus to herbicide tolerance, recognizing that the FQPA could possibly limit the use of several key herbicides for vegetables due to regulatory concerns about toxicology and groundwater contamination. The other justification for focusing on herbicide tolerance was that the newer herbicides in the development pipeline for major crops had limited tolerance on specialty crops, prompting companies to restrict their uses on vegetables due to product liability concerns.

Sweet corn. IR-4's first transgenic project was the result of research conducted by Gordon Harvey at the University of Wisconsin, who was looking for alternatives to the use of atrazine — a potential groundwater contaminant — in Wisconsin sweet-corn production. Harvey conducted studies on glufosinate-tolerant (Liberty Link) sweet corn and demonstrated excellent weed control. The commercial varieties linked the Bt gene with the glufosinate-tolerant gene to provide additional protection against corn borer and corn earworm, two major sweet-corn pests.

IR-4 then facilitated the residue assessment programs required by EPA in 1997, 1998 and 1999. As a result, EPA granted Section 18 "emergency use" permits for the herbicide-tolerant sweet corn in Wisconsin, Minnesota and Michigan in 1999 and 2000. However, due to concerns about consumer acceptance expressed by sweet-corn processors, no significant commercial acreages of these varieties were planted in 2001 and 2002. Nonetheless, IR-4 submitted a complete registration package to EPA for glufosinate-tolerant sweet corn in 2003.

Lettuce. IR-4's other herbicide transgenic project was glyphosate-tolerant (Roundup Ready) lettuce. IR-4 staff met with Seminis Vegetable Seeds (licensee of transformation technology) and Monsanto (glyphosate registrant and gene technology licensor) in 1998 to discuss potential technology applications. The project was placed on the IR-4 30-month "fast track," with submission to the EPA scheduled for 2001. The program was a cooperative partnership between Seminis Vegetable Seeds (seeds and technology support), Monsanto (residue analysis and technical support) and IR-4 (field residue program, project management

and petition preparation and submission).

However, in 2000 several grower groups expressed reservations about the program primarily due to concerns about public acceptance, leading the partners to slow the program down. During this period, field results from several university researchers demonstrated excellent weed control in glyphosate-tolerant lettuce, resulting in reduction of hand-hoeing costs. It is still not certain when or if IR-4 will submit a registration package to EPA.

Scott Bauer/USDA-ARS

The interagency IR-4 program evaluates the safety of agricultural chemicals intended for use on specialty crops. In Salinas, Agricultural Research Service agronomist Sharon Benzen displays broccoli grown in test plots, which will be used to determine pesticide residue levels.

Future directions

IR-4 cannot take on additional specialty-crop biotechnology projects without new funding from the USDA (Agricultural Research Service and Cooperative State Research, Education, and Extension Service) and support from IR-4 management and stakeholders. Current funding is just adequate to cover the existing core programs of reduced-risk chemistries, biopesticides, ornamentals and methyl bromide alternatives. Additional funding from Congress or other sources (either public or private) would be necessary. IR-4's core competencies are in field residue studies and chemical laboratory analyses conducted under GLPs. Safety and environmental testing on specialty crops, especially allergenicity testing of newly expressed proteins in transgenic crops, is well beyond IR-4's existing capabilities.

Under current and proposed regulatory guidelines, the best approach for such testing might be to seek approval first in major acreage row crops such as corn, cotton, soybeans and rice, and allow those approvals apply to specialty-crop uses, as was the case for Bt sweet corn following the approval of Bt field corn. Of course, this approach is limited to traits that are applicable in both agronomic and horticultural crops, and will likely exclude many traits directed toward output quality.

IR-4 management and stakeholder support issue is even more difficult, as they are not in unanimous support of developing agricultural biotechnology, principally due to consumer concerns in Europe and to a lesser extent the United States. In the future, the IR-4 framework could be useful to address the pest-control needs of horticultural and other specialty crops via plant biotechnology, once a consensus is reached that they are cost-effective and safe for the environment and consumers.

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range of biotech varieties, each is an independent transformation event subject to all of the regulatory requirements. Because this is prohibitively expensive, developers must transform just one variety, register that event, and then use traditional breeding methods to incorporate the transgene into other varieties. This greatly delays and increases the cost of developing multiple biotech varieties in a given crop. This is particularly restrictive for horticultural crops, in which many varieties are required to meet different seasonal production requirements and diverse consumer preferences, and any single variety has a relatively small market share. For example, dozens of different types and varieties of lettuce (such as iceberg, romaine, leafy) are grown throughout the year as production shifts between summer and winter locations in California, Arizona and Florida.

Some agronomic seed companies budget $50 million for the full commercialization of a new biotech crop, in addition to the standard costs for developing and marketing a traditional variety. Given the small acreage of horticultural crops and their much lower overall value, it is difficult to justify the investment in transgenic horticultural crops. For example, the total U.S. market for iceberg lettuce seed is about $27 million. A typical single variety is worth about $150,000 to $250,000 during its 5-year market lifetime, which suggests that garnering a large market share of lettuce varieties with significant added value would be necessary in order to pay for the additional costs imposed on biotech varieties.

Commercialization opportunities

Despite this gloomy picture, regulatory strategies may be possible that would protect public and environmental safety while decreasing the cost of introducing biotech specialty crops (Strauss 2003). Plant breeding companies employing biotechnology can manage and reduce regulatory costs by carefully and deliberately

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