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*GMO*s
Guiding **M**eaningful **O**pinions

The Gene Technology Newsletter for the Horticulture Industry

April 2007

Welcome to the final edition of *GMOs*, the bi-monthly gene technology newsletter for the horticultural industry. *GMOs* has been compiled by Agrifood Awareness Australia Limited in conjunction with HAL since 2000.

If you would like to maintain an interest in gene technology developments in Australia and around the world, see www.afaa.com.au .

Knowledge Bank

ADDRESSING CHALLENGES FOR GM HORTICULTURE CROPS

A workshop was held in the USA in January to identify the regulatory challenges and develop suggestions for enhancing the US regulatory system for GM specialty crops defined as fruits, vegetables, nuts and nursery crops. A workshop report titled *Emerging challenges for biotech specialty crops* is now available.

The US situation in relation to GM horticulture crops is worth investigating as the USA leads the world in GM crop production, has had less consumer resistance towards GM foods and crops, and yet still only has small areas of GM papaya and squash commercialised in the horticultural arena.

According to the workshop report, fruits, vegetables, nuts and nursery crops represent half of the US$100 billion in farm gate receipts. The commodity crops, such as soybeans, corn, canola and cotton, represent the other half. While the regulatory system has generally worked well for GM commodity crops, researchers and developers of GM horticultural crops have struggled to cope with its cost and complexity.

The difficulties faced by GM horticultural crops relate to:

- economies of scale - each horticulture crop occupies a relatively small market niche, compared to the vast acreage of commodity crops;
- the diversity of horticulture crops - just one crop, such as apples, may have dozens of diverse varieties, increasing research and development costs;
- the variety of target traits in specialty crop research - traits that may be especially appealing for horticulture crop producers tend to be more complex than the more “simple” traits of herbicide tolerance or pest resistance utilised in commodity crops.
- The biology of specialty crops - under the current federal regulatory system, each gene-insertion is considered a separate “event” in need of regulatory review. In commodity crops once an event has been fully cleared through the regulatory process it can be transferred through cross-breeding into other varieties of the same crop without additional regulatory review. The biology of horticulture crops usually requires the genetic transformation of each variety – and separate clearance must be sought for each line.

Workshop participants identified a number of regulatory challenges and their potential solutions.

1. Develop a tiered risk-based regulatory system

For a GM crop to clear the regulatory process, it must be proven that it poses no significant risks to the environment. Participants suggested that a tiered risk system could protect the environment while providing some regulatory relief. Risk tiers could be developed based on the scientific assessment of crops, traits, crop-trait combinations and transformation technologies. This would mean lower-tier products would require less data and information than those in higher tiers.

Other suggestions included:

- tiers be developed for field trials and the final federal evaluation process;
- a particular GM crop’s tier could change as it moved through field trials based on information gathered; and,

- a crop undergoing review for the first time might be in a higher tier, than subsequent submissions for the same crop.

2. Move away from event-by-event regulation

Participants suggested that regulation within a tiered-risk assessment framework could allow the system to move away from event-by-event regulation. This would provide considerable regulatory relief to GM horticultural crops, by easing the requirement that each new GM plant line or event in the same crop go through the regulatory system.

3. Increase transparency and condense regulatory timelines

Participants stressed the need for a fully transparent regulatory process, with clear requirements, and a short, predictable timeline for decisions. Some participants commented specifically on the need for clear requirements during field trials in order to pave the way for final regulatory clearance. In particular, some noted a lack of clarity around regulators' concerns and requirements regarding gene flow.

Another major concern was that timelines for decisions from regulators remain uncertain, even where they are stipulated in the regulations. Uncertain timelines add to cost and discourage investors. In addition, timeliness is critical for many horticulture crops, as new varieties may only be marketable for a few seasons before being replaced by others with greater appeal.

4. Develop information modules and white papers for use in applications for regulatory clearance

Scientists have acquired an enormous wealth of new information on the biology of crops, crop traits, genomics and gene transfer techniques. At the moment each applicant must individually research and compile the necessary information. The development of publicly available, standard information and data modules could greatly expedite the writing and evaluation of new submissions. The modules would represent the best available and agreed upon scientific information. In essence, this would help develop and enhance regulatory "memory." Applicants could cut and paste from these modules in preparing their applications, and then consult with regulators regarding what additional data or information would be needed to complete the application in the specific case.

5. Prepare for new types of products and technologies

New types of products and technologies continuously raise new questions for the federal regulatory system which needs mechanisms to anticipate and address emerging questions.

While data and information modules and a tiered risk assessment system would provide frameworks from which to view new products, two other methods were identified to prepare the regulatory system for new products and technologies. The first is to build precedence – very few horticultural crops have actually gone through the system. The second is that hypothetical products could be run through the regulatory process thereby identifying potential bottlenecks, data redundancies, data gaps, and knowledge that must be addressed for an efficient and fair treatment of the new products.

6. Legal concerns

Participants noted that potential applicants' perceptions of high risk associated with liability are hindering scientific progress. Indeed, many said there is a general need for the specialty crops community to better understand their legal risks, for example organic growers have tried to sue GM papaya producers in Hawaii. They also noted the need to address the increasing burden of lawsuits shouldered by APHIS in approving applications for field testing or deregulation.

Participants at the workshop included government regulators and scientific experts, industry representatives and policy makers from the GM specialty crops sector.

For more information:
http://pewagbiotech.org/events/0118/WorkshopReport.pdf

Hot Issues

WAFARMERS POLICY CHANGE ON GMOS

WAFarmers annual GMO policy forum held in February has resulted in a revised policy statement calling on the State Government to lift its moratorium on the commercial release on GMOs.

WAFarmers new GMO policy is as follows:

"WAFarmers supports the lifting of the current State Government moratorium on the commercial release of GMOs.

WAFarmers supports new Australian and State Government tolerance levels of 0.9 per cent in crops and 0.5 per cent in seeds.

WAFarmers supports the Office of Gene Technology Regulator (OGTR) and its charter to protect the health and safety of Australians and the Australian environment."

This policy is subject to further review in February 2008.

For more information:
andymcmillan@waff.org.au

GM CORN SAFETY TO BE REASSESSED

The results of a Greenpeace funded study into the safety of a GM corn (MON863) developed by Monsanto were published this month. The study concludes that the corn cannot be considered a "safe product". The corn is insect-resistant against the corn rootworm, a significant pest of corn crops in certain regions of the United States and Canada. The corn is not grown in Australia, but may be in food imports. It was approved as safe for consumption in Australia by the food regulator Food Standards Australia New Zealand in 2003.

A response to the study has been posted on the FSANZ website and states, "FSANZ assessed food from insect protected MON863 corn as Application A484 and the Final Assessment Report, which recommended its approval for Australia and New Zealand, was released on 8 October 2003. The amendment to Standard 1.5.2 - Food Produced Using Gene Technology - of the Australia New Zealand Food Standards Code (the Code) permitting MON863 corn came into effect in December 2003 in Australia and in April 2004 in New Zealand.

FSANZ completed a comprehensive safety assessment of food derived from MON863 corn as required by Standard 1.5.2. FSANZ evaluated all the available safety data including an acute oral toxicity study using mice and a feeding study in chickens. No potential public health and safety concerns were identified during the assessment and no further data was deemed necessary or requested. No studies on rats were made available to FSANZ.

FSANZ will review the data presented in the recent publication and consider carefully any potential impact this might have on the safety of MON 863 corn. Other regulatory agencies internationally, including the European Food Safety Authority are doing the same."

For more information:
www.foodstandards.gov.au/newsroom/factsheets/factsheets2007/updatemon863cornsafe3508.cfm

Regulatory Updates

OGTR RESEARCH LICENCE APPLICATION UPDATE

The Regulator has granted a licence for the application below.

Reference	Crop/characteristic	Developer
DIR 069/2006	Field trials of herbicide tolerant canola and Indian mustard.	Bayer CropScience Pty Ltd

A risk assessment and risk management plan (RARMP) is currently being prepared for the application below.

Reference	Crop/characteristic	Developer
DIR 073/2007	Field trials of insect resistant cotton and insect resistant /herbicide tolerant cotton.	Deltapine Australia Pty Ltd

For more information:
www.ogtr.gov.au/new/index.htm

Reports of Interest

GM CANOLA FINDING MARKETS - ABARE

An ABARE report titled, *Market Acceptance of GM Canola* released this month concludes that "GM canola is finding ready acceptance in international markets at prices very similar to those received for conventional canola.

Concerns about market acceptance of GM canola led to moratoriums being imposed by governments on the commercial production of GM canola in Australia's key canola producing states. The report found that:

- in the traditional import markets for canola - Japan, Mexico, China, Pakistan and Bangladesh - GM canola is generally accepted as readily as conventional canola and is priced at very similar levels;
- despite perceptions of resistance to GM grains in world markets, countries that are producing GM varieties of soybeans, corn, cotton and canola dominate the world export trade in these grains - for example virtually all Canada's export canola is considered to be GM, but this has not stopped its exports reaching record levels in 2006; and,
- there is already wide use of products from GM crops in the domestic Australian market, particularly with domestically produced GM cottonseed and imported GM soybean products.

For more information:
www.abareconomics.com

Research Updates

CHINA – Researchers have produced an important feed additive enzyme in GM **potatoes**, rather than via the traditional production method using microbial fermentation. Producing the compound in potato is seen as an economical alternative. In addition, the biotech potato can be directly fed to poultry or other animals.

The enzyme, known as xylanase, is used as an additive to animal feeds to help poultry, pigs and horses breakdown xylan, a protein that hampers the rate of digestion and the absorption of nutrients.

USA – University of Florida researchers have published research in the *Proceedings of the National Academy of Sciences* about their development of a folate-packed GM **tomato**.

Folate is one of the most vital nutrients for the human body's growth and development, which is why folate-rich diets are typically suggested for women who are planning a pregnancy or pregnant. Folate deficiencies have been linked to birth defects, slow growth rates and other developmental problems in children, as well as health issues in adults, such as anemia. The vitamin is commonly found in leafy green vegetables like spinach. In developed countries such as the USA and Australia some foods such as cereals are enriched with a synthetic form of folate known as folic acid.

Researchers will also look at applying the technology to cereals and crops for less developed countries.

USA – Monsanto and the Solae Company are combining efforts to develop foods containing higher levels of Omega 3 fatty acids. Omega-3 fatty acids are essential to human health but cannot be manufactured by the body. Omega 3 plays an important role in maintaining health, including heart health, and it is largely found in fish.

Market researchers have projected sales of Omega-3-infused foods will grow at a 60 percent compounded annual rate from 2002 to 2011, prompting concerns that demand could soon outstrip supply and threaten fish stocks. This collaboration seeks to cultivate a new, more sustainable source of Omega-3 products that can be used as ingredients in many different food applications, beginning with soybean products and edible oils.

Market Research

GM FRUIT AND VEGETABLES IN THE EUROPEAN UNION

There is no market research available for this edition of *GMOs*, so instead the focus is on what GM products are not in the marketplace in the European Union.

Like in Australia, there are no GM fruits and vegetables for sale in the EU. However gene technology is being employed in research and development programs across these commodities. Genetically modified fruits and vegetables are still quite a long way from commercial use in the EU.

Chicory – In the past Dutch researchers developed and commenced the regulatory approval process for a herbicide tolerant chicory variety, however this product has been abandoned.

The research focus is now on a unique dietary fibre called inulin which is made in the shoots of chicory. Inulin is gaining attention as a source of fibre for health foods and functional foods as it improves intestinal flora and strengthens the immune system. Chicory is currently the primary source for inulin, but when temperatures are cool, the inulin found

in chicory shoots starts breaking down. A gene derived from the Jerusalem artichoke is expected to stabilise inulin content in chicory shoots.

The first field tests of GM inulin chicory were conducted in the Netherlands in 2004. To-date it is still not available commercially.

Chicory is popular in some regions as a salad green, especially in France and Belgium. It is closely related to red hearted chicory (radicchio).

Papaya – Virus-resistant GM papayas developed and commercially available in the USA and Canada have not been approved for import or marketing in the EU.

Apples - Apple growers in Europe have to deal with dozens of different diseases including fire blight, apple scab, and powdery mildew.

Several institutes are working on developing new possibilities for plant defence using gene technology. Certain genes have been transferred into apples that produce substances that either destroy pathogens or block infection.

Very few of these projects have been tested in the field. Most are still at the laboratory or greenhouse stage. If these gene technology approaches actually prove to be effective and the derived fruit prove to be healthy and safe, a large amount of fungicides and other spraying could potentially be avoided.

As yet, no GM apples have been approved anywhere in the world. This is not likely to change in the next few years. It is expected, however, that the amount of GM apple field trials will increase. At the end of 2006, nine field trials with GM apples were registered in the EU.

Bananas - About four million tonnes of bananas are imported into the EU each year. A fungal disease is now threatening banana plantations globally, and plant breeders have not yet succeeded in developing resistant cultivars. Many hope that gene technology can help.

In the 1950s, the most common banana variety, was completely wiped-out by what was known as Panama disease, also called fusarium wilt. Now Black Sigatoka is the big threat. The only way to treat this new disease is by applying large doses of fungicides - a practice which is losing effectiveness as the fungus is becoming more resistant.

Researchers in Belgium, in cooperation with others, have been working for years to develop improved banana cultivars using conventional breeding methods and gene technology. Resistance genes from various plants including onions and dahlias were introduced into plantains, primarily with the goal of developing resistant plantain cultivars for the Third World. The resulting GM plantains exhibit resistance to the fungus in greenhouses. But before they can be released for use, some toxicological tests still need to be carried out.

Wine grapes - Gene technology offers new possibilities for developing disease resistant grape varieties. The diseases having the biggest impact on wine grapes in the EU are fungal diseases like grey mould, powdery mildew, and downy mildew. They not only cause losses in yield, they also reduce wine quality. Cloudy and persistent fungal residues are a serious problem in the wine cellar. The intensive use of fungicides is still common in many vineyards. When infection is widespread, winegrowers may spray up to eight times per year.

Although years of breeding have resulted in the development of new fungal resistant varieties modern breeding has not yet been able to provide fungus resistant versions of varieties like Riesling, Merlot, or Chardonnay.

Using gene technology, several research teams are working on transferring resistance genes into traditional vine varieties. If scientists succeed in developing fungus resistant vine varieties with gene technology, it would take years until any wine from these varieties would be available on the market.

For more information:
www.gmo-compass.org/eng/grocery_shopping/fruit_vegetables/

Events

CRCA 12th ANNUAL CONFERENCE
Date: 16-18 May, 2007
Description: Investing in science and innovation is critical for countries that want to remain competitive in a globalised world where knowledge acquisition and its use is increasingly becoming the basis for many economies. The 2007 Annual Conference of the Cooperative Research Centres (CRC) Association is an opportunity for Australian science and technology innovators to gain valuable insights from leading bureaucrats, academics and entrepreneurs about their experiences, their successes and their failures in this arena. Topics include: assessing the benefits of cooperative research and innovation; capturing creativity; technology transfer and adoption ; the policy arena; and training and development.
Location: Perth Convention & Exhibition Centre, WA
Telephone: (02) 8850 6796
Email: caroline.jones@optusnet.com.au
Website: www.crca.asn.au/conference/

Gene Technology Contacts

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