



## Oral Presentation Abstracts

**MONDAY 9 NOVEMBER 2009**

### Workshop 1: Legal frameworks for coexistence

**Chairs: Bernhard Koch, Stuart Smyth**

The legal frameworks that exist to govern coexistence represent a myriad of options, alternatives and outcomes. Legal frameworks to govern coexistence in North America are market based, where the state has no mandate to regulate past the point of variety approval. In Europe, regulators have more extensive mandates and the legal frameworks that govern coexistence are state led initiatives. This session will provide insight on how Europe and the European states have approached the challenge of establishing legal frameworks for coexistence.

#### Current developments of EU coexistence legislations

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Measures ensuring coexistence of genetically modified (GM) crops with conventional and organic agricultural production provides for choice for European Union (EU) consumers and agricultural producers and, thus, reconcile individual preferences and economic opportunities. Whilst environmental and health aspects of GM crop cultivation are to be addressed beforehand during the EU authorisation procedure, coexistence measures have their focus on the economic impact. The segregation measures applied under coexistence rules enable the cultivation of GM crops, while protecting farmers of non-GM crops from adverse economic consequences of accidental mixing of crops with GMOs. Following the European Commission Recommendation of 2003, coexistence measures shall be science-based and proportionate and must not generally forbid the growing of GM crops.

EU experience with the cultivation of GM crops remains extremely limited in comparison with other regions of the world. The only GM crop currently cultivated in the EU is GM maize which is resistant to certain lepidopteran pests. In 2008, GM maize was produced in the Czech Republic, Germany, Spain, Portugal, Romania, and Slovak Republic on a cultivation surface of about 104 000 hectares equalling 1.2 percent of the EU's total maize area.

On 2 April 2009, the European Commission issued a second report on coexistence, outlining the activities undertaken in response to the European Council's request and providing an update of the state of implementation of national coexistence measures. Fifteen Member States have adopted legislation on coexistence, 11 more than in 2006 when the first coexistence report was published. Another 3 Member States have notified draft legislation to the European Commission. The coexistence approaches applied in Member States differ with respect to administrative procedures and the technical specifications of segregation measures. These differences reflect the regional variation of agronomic, climatic and other factors determining the likelihood of GMO admixture to non-GM crops. In view of further enhancing the efficiency of national coexistence measures, the European Coexistence Bureau (ECoB), created by the European Commission, is developing, in collaboration with the Member States, crop specific Best Practice Documents.

The European Commission is convinced that the subsidiarity-based approach on coexistence has been the right choice, which leaves the legislative competence on coexistence with the Member States, and it sees no need to develop further harmonisation on this matter.



## Measures of coexistence in Germany

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In Germany two important measures of coexistence are established: (1) the GMO location register and (2) the German regulation of good agricultural practice on production of genetically modified plants.

The GMO location register was launched in February 2005 by the Federal Office of Consumer Protection and Food Safety (BVL) after amendment of the German Genetechnology Act implementing the European Directive 2001/18/EC. One purpose of this register is to support the monitoring of potential adverse environmental effects of GMO cultivation. However, another intention of the location register is to support the coexistence and transparency measures. The register provides data on the intended locations for GMO cultivation three months ahead of sowings. Further, the effective cultivation area per year as well as area maps are publicly available via the internet. After five years of experience we will review notification statistics, public interest, and implementation problems encountered with the GMO location register.

In 2008, the German Genetechnology Act was amended and supplemented by a regulation of good agricultural practice on production of genetically modified plants (GMP). This regulation implies special rules for the general handling of GMP. Farmers need to inform their neighbors about their GMP cultivation plan and are requested to comply with special rules for storage, transport, and harvest of GMP, as well as volunteer control. Furthermore, species specific guidelines are accomplished for maize, the only GMP authorized for cultivation in the EU at present. In this respect, isolation distances from GM maize to conventional maize of 150 m and to organic maize of 300 m are determined. These distances can be reduced by reaching an agreement between affected neighbors. However, other EU Member states apply variable coexistence measures compared to Germany.

## The regulatory approach towards coexistence in Flanders, Belgium

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Belgium is a federal state which consists of three regions (Flanders, Wallonia and Brussels Capital) and agriculture is a responsibility of the regions. In Flanders, the Dutch speaking northern part of the country, the first discussions on the creation of a draft legislation on coexistence measures started more than five years ago. Today the decree has arrived at its final stage for adoption in the Flemish Parliament, after being notified to the European Commission in 2008. It provides a legislative framework that lays down the basic principles to be met for the cultivation of GM crops.

The following elements are foreseen. Firstly, farmers and contractors who want to work with GM crops need to follow specific training. Secondly, such farmers are requested to notify the competent authority, the neighbouring farmers, the owner of the plot and other persons, e.g. mediating contractors, intervening in the crop. Neighbouring farmers within the isolation distance have the right to object to the GM crop on the basis of a reasoned economic interest. Moreover, GM farmers pay a contribution into a fund for each GM crop they grow, that is used to compensate possible economic damage to conventional and organic harvests within the notification distance. A committee, composed of members from the administration, scientific institutions and the agricultural sector, will oversee the objections by neighbouring farmers and demands for compensation. Other issues addressed in this decree are liability, GM-free zones (on a voluntary basis of all farmers concerned), a register, monitoring and supervision by the competent authority. Finally, it is provided for that infringements are penalised with an administrative fine and that the legislation will be evaluated within two years after its entry into force.

The crop-specific measures (isolation distances etc.) to be taken are still under discussion either on a scientific, administrative as well as political level and will be embedded in an order of the Flemish Government together with all other implementing rules, regulating the timing and technical provisions and conditions of all the procedural steps. These measures will be based on scientific data and may be differentiated between professional and non-professional GM growers.

## **Brazilian GMO free areas experiment and the release of RR soybean**

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This article aims to examine how the release and commercialisation of the Roundup Ready™ soybeans in Brazil has been done and the resistance of the organised society to this fact. To do so, the Brazilian legislation on Biosafety is considered, as the application for release and commercialisation of Monsanto's GM soy is processed by the National Biosafety Technical Commission (CTNBio). Lawsuits made by consumer organisations to prevent such release as well as the resulting court decisions were also examined. In 1998, Monsanto asked CTNBio for commercial release of herbicide tolerant soybean Roundup Ready™, and in response to this request, the Brazilian Institute for Consumer Protection (IDEC), Greenpeace and the Brazilian Institute of Environment and Natural Resources (IBAMA), intend action to prevent the commercialisation and prohibit any activity related to transgenic soybeans.

The Brazilian Courts suspended Monsanto's application but, in December 1998, CTNBio accepted it concluding that there was no evidence of risk to human, environmental or animal health. In August 1999, the Judiciary again suspended activities related to transgenic soybeans and several states of the Federation attempted to become "GMO free areas", editing their own laws. However, farmers in southern Brazil continued to grow transgenic soy pirated or illegally imported. In 2000 the Brazilian Federal Government backed the production of RR Soybean and, in January 2002, decided to accelerate the commercial release of GMOs. Laws published in 2003 and 2004 allowed commercialization of RR Soybean, disregarding the precautionary principle adopted by the Brazilian Federal Constitution.

In conclusion, although organised society and various states of the Federation tried to prohibit the use of GMOs and/or create GMO-free areas, the pressure from farmers and industry and the lack of effective supervision from the Federal Government has resulted in the adoption of RR soybean by farmers across the country.

## **Regulating the coexistence of GM and non-GM farming: the missing link in the EU regulatory regime for agricultural biotechnology**

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The creation of a comprehensive EU regulatory regime for agribiotech has proved a lengthy and arduous affair. Following the 1990s disintegration of the initial legal framework, major revisions were undertaken in recent years. By 2004, the Commission declared the regime-overhaul complete, and lifted the longstanding *de-facto* moratorium on GMO import authorisations. Moreover, it resumed the authorisation process for EU-wide cultivation of GM crops, despite unrelenting deep political divide between Member States. With this reopening of the floodgates to Europe's internal market to GMO-imports, and with imminent commercial-scale cultivation of GM-crops on EU soil, the regulatory regime will be put to the test once again.

The pressing question emerges whether the revised regime will prove complete and adequate, and whether repeat of the 1990s political stalemate can be avoided. This paper argues that, in fact, the regime is still incomplete, and that lack of a consistent, coherent, integral approach threatens to undermine the effectiveness of, or render redundant, legislation that was adopted.

Serious omissions will be identified in the arsenal of regulatory instruments and definitions of pivotal legal concepts, with the ultimate potential to paralyse the regime, again. The most vital missing link lies at the heart of the regulatory/production cycle of GMO-products: the cultivation stage. Applications of biotechnology span across all stages of the GMO product-cycle: from seedling to final product. From an EU regulatory perspective, three cycle stages are distinguishable: (i) authorisation, (ii) cultivation, (iii) distribution. It appears evident that any regime aiming to regulate this technology should equally span this entire cycle. However, analysis of past and present laws/policies on agribiotech demonstrates that, throughout two decades, the EU regime has not attained this objective.

It is evident that a regulatory gap is left in this crucial intermediate stage, involving thorny issues of coexistence between GMO and non-GMO farming. The anomaly this regulatory gap creates is a regime which allows for authorisation of GMOs for cultivation, and sets qualitative end-of-cycle targets/requirements for final cultivated products, but fails to provide any substantive prescriptions for how cultivation itself should be operationalised in practice.



This paper analyzes the Commission strategy to fill this regulatory lacuna, with specific reference to implications thereof for environment and health, consumer choice, EU internal market, and for the viability of the current regulatory regime. Finally, makes recommendations for an alternative, more consistent and integral, approach to regulating the coexistence between GM and non-GM agriculture in Europe.

## **The non-scientific base of coexistence legislation in the European Union**

**Mathias BOYSEN**

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The European Union legislation on coexistence basically attempts to achieve two objectives which are not based on a (natural) scientific risk-assessment but rather on socio-scientific principles.

First, consumers should gain the freedom of choice to buy or not to buy food produced from GM plants. In doing so, consumers can apply their individual risk perception. They might make their decision on individual moral grounds or on personal basic beliefs, which are not necessarily connected with actual scientific risk assessment. Thereby, the EU coexistence guideline seamlessly follows the EU labeling regulation on GMO, because it should ensure implementation of a 0.9% threshold for labeling GMO ingredients.

Second, the precautionary principle should be implemented due to the fact, that some risk always exists, which neither can be proofed accurately, nor can it be disproved completely based on today's knowledge. Since such risks are inherent for all kind of technical innovations they do not reason a total ban of GM plants. However, they give reason for surveillance of GM plants to detect unexpected effects after their approval. Coexistence of GM and non-GM based agricultural supply chains is essential for this purpose.

Once the precautionary principle is established, its vague nature allows space for political decision making, which is only partly based on scientific evidence about the known risks of GM plants. The EU has only enacted a guideline on the development of national strategies for coexistence leaving the implementation of rules to its Member States. Consequently, national coexistence regulations vary widely – including laws defining the liability in cases of economic losses due to a dispersal of GM plants. For example, the distance requirements between GM maize and non-GM maize range from 25 meters (Netherlands) to 800 meters (Luxembourg).

Furthermore, it is highly questionable to what extent coexistence measures could appease the public or might even increase the acceptance of GM plants and GM food; it might increase skepticism instead. This could happen, if coexistence regulations are misleadingly considered as an instrument to prevent negative health effects or ecological harm, which would inevitably occur above a threshold of zero percent. Such counterfactual public perception on the function of coexistence easily results in the conclusion, that coexistence is not possible at all. Moreover, this might enforce opposition to GM plants and GM food in general.

The presentation describes these political and socio-scientific elements of the regulation on coexistence in the EU in more detail and gives further examples.



## **Workshop 2: Workshop on Technical Challenges Related to GMO Analysis Along the Food and Feed Production Chains**

**Please refer to program grid for details**

## **Workshop 3: Communication on GMOs**

Communication on GM crops is a constant challenge and an integral component to ensuring that consumers are aware of the facts underpinning the science when they consider whether to buy GM or pay more for non GM. The workshop will share best practice experiences of coexistence experts from all over the world, and will try to find communication examples and lessons.

## **TUESDAY 10 NOVEMBER 2009**

### **Plenary 1: GM Crops in the World Today**

#### **The GM crop pipeline - contributing to sustainability of global food, feed and fibre productivity**

**Gerard BARRY**

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The adoption of GM crops has continued worldwide, with annual growth rates in acreage exceeding 10%. In addition, the adoption of GM crops in developing countries is expanding, in acreage and in new countries: the rapid adoption of GM maize in Brazil, building on experiences with soybean and cotton; the adoption of Bt crops in Egypt and Burkina Faso, and the planned expanded field trials of GM maize in Mexico are testament to the growing recognition of the value of technology. India, other countries in Asia, and Brazil are advancing the evaluation of new crops. These represent a new large wave of indigenous products, in food crops such as eggplant (brinjal) and rice, for example, and in meeting the growing needs for food and fuel in Brazil by improving the productivity of sugarcane. In the case of India and China, these new GM crops also demonstrate the evolution of the commercialisation of the technology from the first products imported from other countries to those now being developed by the national private and public sectors. These advances recognize the national policy and support for the use of modern biotechnology for development. In Japan, especially, the exploration of the use of GM crops as sources of vaccines or antigens is an existing area of research and represents examples of important societal goals that may be achieved with GM crop technology. In the European Union, Spain remains in the forefront of research and cultivation of GM crops, but heartening statements from government ministers of Denmark and the United Kingdom suggest that the impediments to the acceptance, if not the adoption of GM foods and crops, are being evaluated from new perspectives, including from those of 15 years of experience worldwide and of food and feed security.

#### **GM crops for food, feed and energy**

**German SPANGENBERG**

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Significant progress has been made in the development and exploitation of plant biotechnologies derived from genomic discoveries. These will find applications in food, feed, health, bioenergy and bioindustry and contribute to addressing challenges for global food security in a climate of change. Recent advances and applications of high-throughput methodologies for plant functional genomics – from genome to phenome – in crops and pastures that provide the knowledge base for these developments will be described. Selected examples of current approaches on the molecular genetic dissection of biosynthetic pathways and developmental processes in plants will be presented. Strategies for application of molecular methodologies to plant improvement addressing high impact outcome scenarios for productivity, environmental and societal benefits will be outlined.



## Plenary 2: The Global Status of Coexistence

### Overview of coexistence practices contrasting different approaches in different countries and touching on specific challenges in the developing world

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Coexistence practices differ between countries. The coexistence practices observed depend on the property rights regime. In general, coexistence policies can be divided into *ex ante* regulations and *ex post* liability rules farmers' have to comply with resulting in responses by farmers' depending on the specific policies. This paper provides an overview of coexistence practices in different countries, namely the EU member states, Canada and the United States and discusses implications for the planting of transgenic crops and the specific challenges for developing countries. The overview shows coexistence policies in the EU are dominated by *ex ante* minimum distance requirements for transgenic crops growing farmers discriminating against smaller farms. If minimum distance requirements are combined with flexible adjustment possibilities at farm level, farm size will be less relevant for adoption. In Canada and the United States the "property right" is with the transgenic crop growing farmer and coexistence policy is dominated by *ex post* liability. Challenges for countries intending to introduce transgenic crops include choosing the appropriate property rights regime as well as the degree of flexibility of specific coexistence policies.

### Legal responses to the risks of GM farming as a challenge to coexistence

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Professor of civil and comparative law, University of Innsbruck, Austria

Apart from setting standards for GM farming and requiring safety checks for GM products, legislators also provide for the case that a risk that should have been prevented by such measures materialises. These are not necessarily novel solutions – classic tort law already offers remedies for such losses. Sometimes these traditional solutions are enhanced or replaced by alternative redress schemes. Either way, potential risks of GM farming have a significant impact upon its coexistence with conventional or organic agriculture. This paper will present a comparative overview of how the legal systems in Europe have addressed these hazards.



## Implementing coexistence into global food and feed supply chains

### Randal GIROUX

*Cargill Incorporated, Wayzata, Minnesota, USA*

Effective coexistence is one measure to assure the production and processing of abundant supplies of safe and nutritious foods on a sustainable basis, while allowing customers and suppliers to be free to choose whether to use *conventional, organic, or agricultural biotechnology* products consistent with underlying consumer preferences and choices. To enable effective commercial coexistence, there must be a recognition that this is a dynamic, evolving, and complex marketplace involving diverse agricultural systems.

Several countries have adopted all three agricultural systems and each has evolved towards some form of coexistence that is commercially-relevant and effective for their needs. It must be recognised that the concurrent use of different production systems can sometimes limit individual choices of both farmers and retail consumers. While true consumer demand eventually influences what farmers grow, sometimes there are temporary market failures in meeting emerging demand for a particular crop or product.

In developing coexistence, some markets have discovered commercial realities that can either enable or inhibit coexistence. If the desire to develop coexistence continues, markets will continue to evolve towards enabling key features and addressing the inhibitors. Key features enabling coexistence include:

The development and availability of identity-preservation (IdP) systems and test methods to meet *market-based thresholds* for adventitious presence that are appropriate to specific applications and needs;

- The willingness of customers and retail consumers to pay a premium for differentiated food products, e.g. organic, non-GM, and other specialty products; and,
- Commercial agreements (contracts) based on clear, verifiable and achievable specifications with limited government mandate;

Several key factors also pose a challenge to coexistence including:

- Failure to adequately contain regulated GM events or products being developed through breeding programs and/or field trials associated with product development.
- Adventitious Presence (AP) policies for LLP and food/feed labeling that are not commercially-achievable.
- Asynchronous approvals and zero tolerance policies can have significant upstream and downstream effects. Exports of an entire crop (GM, organic, and non-GM) can be placed at risk.
- Compliance and enforcement protocols that are not based on consistent standards and have not been suitably validated or demonstrated they are fit for purpose as the product moves through the food and feed supply chains

This presentation will provide a general overview of commercial perspectives on managing coexistence and some lessons we have learned in implementing these systems into both domestic and global food and feed supply chains



## Plenary 3: The Socioeconomics of Coexistence

### The economic incentives for coexistence: availability and sustainability of price premiums for non-GM crops

Phillip GLYDE

*Australian Bureau of Agricultural and Resource Economics, Canberra, Australian Capital Territory, Australia*

World markets for grains have become differentiated into GM, certified non-GM and organic segments, creating opportunities and challenges for grain market participants. Price premiums for non-GM grains are the market signals guiding the evolution of the markets for non-GM grains.

This paper contains an analysis of the reasons for the existence of price premiums for non-GM grains and a summary of the evidence to date of the extent of price premiums for non-GM products throughout the world. An assessment is made of the sustainability of the price premiums for non-GM grains into the future.

The key conclusion of the analysis is that world markets for grains for which there are GM variants (soybeans, corn, canola and cottonseed) are dominated by GM grains, but there are niches for certified non-GM and organically produced grains, paying significant price premiums. Apart from consumer attitudes, the key drivers of price premiums are mandatory labeling of GM products in key grain consuming countries; higher production costs for non-GM crops; and the costs of identity preservation.

There is some evidence of global markets for certified non-GM grain contracting, as consumer acceptance of GM grains grows, but significant niches are likely to be sustained into the future. World markets for organic grains appear to be expanding, but this is only partly related to consumer aversion to GM grains.

The paper draws on some recent ABARE research on market acceptance of GM grains; identity preservation costs; and the potential impact of the introduction of GM canola on organic production systems in Australia.

### The size and distribution of the benefits from the adoption of biotech crop varieties

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We used data on actual adoption patterns and farm-level impacts on costs and yields to parameterise a global market simulation model and estimate the total global benefits from the adoption of biotech varieties of maize and soybeans over the period 1996-2006. Using these results and other data we also estimated the distribution of those benefits (a) between technology suppliers (biotech companies and seed companies) and others, and (b) among those others including farmers and consumers in the United States and in the rest of the world.

### Coexistence as a problem of market-making

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Peter W.B. Phillips's research is supported by VALGEN (Value Generation through Genomics and GE<sup>3</sup>LS), a project sponsored by the Government of Canada through Genome Canada and Genome Prairie.

Coexistence, as defined by the EU, involves simultaneous GM and GM-free crop and food production, assuming both products have passed regulatory risk evaluation. Much of the recent discussion about co-existence focuses on how governments can create it, or in some cases how to do it more efficiently and effectively. At one level, the issue of coexistence is a problem of market-making. Economic theory and commercial practice suggest that there are challenges with leaving market-making to private initiative. This paper reviews the economic rationale for involvement by governments and other non-market actors and assesses the evidence of the impact of various interventions on practical coexistence.

## Plenary 4: Managing Coexistence in Farming Systems

### Biology matters: seed and pollen-mediated gene flow in three oilseed crops, safflower, flax and oilseed rape

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Quantification of seed- and pollen-mediated gene flow (SMGF and PMGF) was conducted in two oilseed crops: flax (*Linum usitatissimum* L.) and safflower (*Carthamus tinctorius* L.) and compared to published studies in oilseed rape (*Brassica napus* L.). Safflower is being examined as a platform for plant made pharmaceuticals, while flax may be developed as a source of  $\omega$ -3-fatty acids. For all three species, pollen-mediated gene flow decreases rapidly with distance but oilseed rape averaged <2.0 % outcrossing within 10 m of the source plot. Safflower and flax had more limited dispersal immediately adjacent to source plots, outcrossing 0 to 3 m ranged from 0.48 to 1.67% and <0.6 %, respectively. With mitigation, PMGF in safflower and flax is unlikely to hinder coexistence. Harvest losses in all three crops were significant and highly variable between fields and growers, with losses in oilseed rape averaged 3,600 seeds m<sup>-2</sup>, safflower between 231 and 1069 seeds m<sup>-2</sup>, and flax between 53 and 1986 seeds m<sup>-2</sup>. Harvest losses are difficult to manage, being influenced by weather and crop maturity at harvest. However, persistence of seed over winter and seedling emergence over time can be influenced with tillage practices. While tillage tends to establish secondary dormancy in canola and increases seed and volunteer persistence, safflower and flax lack primary and secondary dormancy. In these species, seed burial increased lethal fall germination, diminishing the seedbank. Volunteer populations of all species were highest in the year following the crop. In field surveys, volunteers of oilseed rape and flax were intermittent and reduced to low densities by the third year following the crop, while safflower volunteers were rare in the second year. In these three oilseed crops, SMGF was a source of adventitious presence in subsequent crop seed and challenges the ability of GM growers to produce conventional crops, or to revert to conventional crops on the same land base. Vigilant herbicide control of volunteers was required in the year following GM crops to prevent AP and reduce seed bank replenishment. In safflower and flax, low PMGF limits the impact of volunteers and ruderal populations. Coexistence between adjacent GM and conventional growers should be achievable. Knowledge of the biological and agronomic factors contributing to seed- and pollen-mediated gene flow can inform coexist and mitigation practice.

### Ex ante evaluation of gene flow in oilseed rape with cropping system models

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Oilseed rape (OSR) genes can escape fields in space via pollen and seeds and in time via volunteers resulting from seeds lost before or during oilseed rape harvests. Several national and European research projects aim to evaluating the risk of gene flow and the adventitious presence of GM seeds in non-GM harvests (AGMP) and to propose strategies at various spatio-temporal levels for managing co-existence. The present paper presents several complementary approaches for studying gene flow at different scales, focusing on modelling and simulations for ex ante evaluation of local measures and cropping systems in agricultural landscapes.



## **Is GM and non-GM crop coexistence possible in perennial, outcrossing species? An investigation with alfalfa (*Medicago sativa*, L.) in North America**

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Genetically Modified Glyphosate Resistant (GM-GR) alfalfa was deregulated in the U.S. in 2005 and shortly after it was returned to regulated status following a court moratorium. In Canada, it was authorized for environmental release but not yet for commercial cultivation. GM-GR alfalfa is the first perennial, highly outcrossing, insect pollinated species to receive authorization for deregulation in the US. Alfalfa is an important forage crop and an integral part of organic systems both as a livestock field and for restoring soil fertility. The deregulation of GM-GR alfalfa raised serious concerns among conventional and organic alfalfa farmers due to potential market and environmental risks resulting from transgene escape. There exist discrepancies among the stakeholders as to whether or not co-existence is possible in highly diverse alfalfa production systems. Long distance landscape level gene flow occurs in a metapopulation context and for agricultural landscapes, the metapopulation consists of cultivated crops, volunteers and feral populations. Our work in western Canada revealed that alfalfa is capable of establishing self-sustaining feral populations. A detailed survey indicated the widespread occurrence of feral alfalfa populations in roadside habitats, particularly in alfalfa growing regions. The ecology and biology of alfalfa is favorable for successful establishment even under resource poor conditions. Feral alfalfa populations could serve as sources and sinks for novel traits and facilitate long-distance transgene dispersal. As such, feral alfalfa populations could act as potential barriers for the establishment of co-existence between GM and non-GM alfalfa. Our results suggest that total confinement of novel traits within alfalfa production fields is highly unlikely, although strict adherence to stewardship practices, including the management of feral populations in roadsides, would help reduce the level of gene flow and the risk of adventitious presence. Therefore, maintenance of zero tolerance, as is often required in organic production systems, could become very difficult, if not impossible. Human error and unfavorable weather conditions are inevitable and might potentially impede co-existence. The success of co-existence depends ultimately on the establishment of threshold levels above zero. Landscape level gene flow models will help determine realistic thresholds and feral populations will be an essential component of such landscape level models.

## **The challenges of GM coexistence to the seeds industry – a European perspective**

**Michael LEADER**

*European Seed Association, EuropaBio, Monsanto, Melbourne, Victoria, Australia*

GM varieties make up around 15% of today's global commercial seed trade. Yet the only legal threshold in Europe today is that food products containing less than 0.9% of GM products authorized for import and/or cultivation in the EU do not need to be labeled as GM. This does not address the reality of the global situation, especially when the number of commercialized genetically modified crops in the world is foreseen to multiply by four from about 30 today to over 120 in 2015 (according to a recent report of the European Commission's Joint Research Centre), and Europe continues to lag behind the rest of the world in granting GM product approvals. The seed industry is ready and able to ensure coexistence of their products throughout the entire life cycle. Thresholds for adventitious presence are an integral part of making this work. These thresholds must be proportionate, up-to-date, non-discriminatory, harmonized and clearly communicated by governments. The rules governing trade must be able to be understood by all parties. Most importantly, these rules must not put the European seed industry at a competitive disadvantage. European industry demands access to, and use of, modern biotechnology in plant breeding and variety development.



## **Workshop 4: The International Society for Coexistence in Agricultural Systems**

A key issue for continuity of the GMCC conference series is 'ownership'. The first three events were strongly supported by the European Commission and managed by key research establishment within the European Union. Though there is a major ongoing commitment from the EU research establishments, new structures and support have to be established to run future GMCC conferences in a world wide context.

At GMCC-07, the Scientific Committee met and decided to pursue the very successful model of the International Society for Biosafety Research (ISBR). The origins of the ISBR have parallels with the GMCC series in arising from a 'once-off' conference in 1990. The committee that planned the initial conference formed the ISBR 'learned society' which has run biennial ISBGMO conferences since then. Since 2002, the society also publishes a quarterly journal 'Environmental Biosafety Research'. Based on the ISBR model, it is proposed to establish the International Society for Coexistence in Agricultural Systems (ISCA) to progress the interests of the GM coexistence research community.

The Workshop will look at models for the society and identify a path forward to set up an effective organisation to deliver GMCC-11 and to lead future research in the area. It is aimed to clarify the expectations, needs and potential contribution of different interest groups in ISCA. After a short introduction, individuals representing different interest groups (regulators, traders, academia, capacity builders, as well as developers from developing countries and from industry) will provide their personal view. This will be followed by a constructive exchange between all participants. At the workshop some conclusions should be formulated which will be circulated amongst the GMCC-09 participants for further discussion.

## **WEDNESDAY 11 NOVEMBER 2009**

### **Plenary 5: Managing Coexistence in the Marketplace**

#### **The global GM trade in grain – an overview**

**Geoff HONEY**

*CEO Grain Trade Australia, Sydney, New South Wales, Australia*

There is now over 120 million hectares of GM crop being grown global each year. The major grain exporting nations of Canada, United States, Brazil, Argentina and Australia all grow GM crops. This presentation will discuss the adoption of this technology and highlight the challenges faced by the global grain trade, both exporters and importers alike. Regulatory issues such as the Biosafety Protocol and the approval process of GM crops will be mentioned as a lead to further explanation by following presentations.

#### **The challenges and opportunities in trading GM grain and oilseeds – a trade perspective**

**Gary MARTIN**

*President, North American Export Grain Association, Washington DC, USA*

Safe, sustainable, reliable food and energy security are dependent upon efficient global trade of agricultural products. The innovation of crop biotechnology continues to significantly impact international supply chains. Reflecting on 15 years of experience from North America, this examination of regulatory and commercial issues related to biotechnology and the trade of grains and oilseeds merges the practical and the political to deliver a direction for a successful future.



## **Asynchronous GM approval: impact on feed security and competitiveness of the EU feed and livestock sector**

**Alexander DÖRING**

*Secretary General of the European Feed Manufacturers Federation (FEFAC), Brussels, Belgium*

In his introduction, the author will provide a brief overview on the history of market access problems to imported feed materials for EU feed manufacturers due to asynchronous GM approval starting with the loss of Canadian oilseed rape meal in 1997 and US soybean and Canadian linseed in 2009.

He will recall the feed chain partner commitments to ensure compliance with EU rules regarding imports of feed materials containing GM events, prior and after the lifting of the de-facto EU moratorium on GM approvals and the adoption of the GM labeling legislation 1829/2003 and GM traceability rules laid down in Regulation 1830/2003.

The second part of the presentation will summarise the main economic impact studies conducted by industry consortia, European and national authorities including the recent JRC GM pipeline study report published in September 2009. The author will point to the key lobbying actions undertaken by feed and food chain partners in the EU starting in 2007 with the loss of US corn gluten feed and DDGS due to the presence of Pioneer's Herculex RW event.

In his conclusions and outlook he will discuss the various options for risk managers to deal with legal 'zero tolerance' requirements underlining the need for an urgent reform of global GM approval regulatory systems regarding the need to recognize the concept of adventitious presence of non-approved GM events in importing countries by referring to the CODEX LLP Risk assessment guideline adopted in 2008 in order to avoid major feed and food security challenges in the near future resulting from the rapidly growing global acreage of GM plants and the steadily rising number of GM approvals and GM crops.

## **Parallel Session 1A: The Socioeconomics of Coexistence – Market Driven Examples**

### **The economics of cotton coexistence in Australia**

**Richard HAIRE**

*CEO of Queensland Cotton, Brisbane, Queensland, Australia*

Genetically modified cotton was first released in commercial quantities in the late nineteen nineties following an exhaustive and at times exhausting testing and approval regime. And the technology achieved instant adoption by growers. Its creation was to control the heliothis which had become as destructive to cotton as it was resistant to conventional chemistry and other crop protection practices.

Today, the big three of China (with 67 percent of its production being GM), the United States (86 percent of its production) and India (76 percent of production) account for more than ninety percent of the world's GM cotton.

Ninety five percent of Australia's cotton is GM and ten percent of Brazil's cotton is estimated to be GM. Modern traits include enhanced inbuilt insecticides and herbicide tolerance allowing over crop herbicide applications without causing crop damage.

There have been numerous assessments done of its economic, social and environmental merit and they all share common conclusions. The net economic, social and environmental benefit has been unambiguously positive. That the industry has avoided much of the adverse publicity faced by other GM crops is testament to the universal recognition of these benefits.

The primary products are cotton planting seed, cotton lint, cotton seed oil and cotton seed meal. There is no evidence of material market bias against the products emanating from this technology.



## **The economics of canola coexistence in Canada**

**Stuart SMYTH**

*Department of Bioresource Policy, Business and Economics, University of Saskatchewan, Saskatoon, Canada*

Coexistence is one of the product differentiation options that gained prominence in the late 1990s as consumer demands for product and process attributes increases. Product differentiation systems previously existed in the supply chain industry (e.g., malting barley, organic products), but the application of product differentiation systems based on process was unique. The commercialization of transgenic crops created the first use of product differentiation systems to distinguish between the process methods used to create the crop varieties. Scientifically, transgenic, conventional and organic crops are indistinguishable, but the power in supply chains lies with consumers and they are demanding greater levels of knowledge about the products they are purchasing.

After several years of increased use of product differentiation systems, Smyth and Phillips (2002) offered a detailed examination of three forms of product differentiation and the corresponding supply chain attributes. They offered definitions of identity preservation, segregation and traceability and used supply chain attributes to demonstrate how the various systems are driven by different rationals. Smyth and Phillips argue that the driver of identity preservation is product premiums, the driver of segregation is product safety and the driver of traceability is processing and production knowledge in the event of a food safety failure. The drivers for each of the three systems are unique to the system and while there is some attribute overlap between the systems, the systems are not interchangeable.

Use of product differentiation systems has grown throughout the decade and as a result, the functioning requirements of the systems have been refined. Initial interests were in the cost of such systems, but as the systems have evolved, interest is now piqued in the governance structures of the systems. Sustainability of product differentiation ultimately depends on the quality of the product, whether it be a tangible food product or knowledge about specific attributes, therefore, to ensure that quality is the top priority the various product differentiations systems have to be flexible enough to adjust to changing market and regulatory demands.

This paper will compare and contrast a market-based identity preservation system with a state mandated segregation system. The focus of the comparison will be on quality assurance and two-way flows of information. This analysis will provide information on the fundamental underlying structures of these systems and highlight the importance of how product differentiation systems need to be able to respond to the demands that drive the system.

## **The economics of sugar beet coexistence in the US**

**William WILSON**

*University Distinguished Professor, Department of Agribusiness and Applied Economics, North Dakota State University, Fargo, North Dakota, USA*

GM technology (specifically Roundup Ready) has been available for sugar beets in the United States since the mid-1990s. However, due to apparent consumer resistance, as conveyed by food companies, the technology was not commercialized. After about 10 years, a concerted effort on the part of growers, processors, technology and food companies worked to develop a plan to commercialize this trait in the United States. As a result there was a very rapid penetration reaching 95% of the area planted after just 2 years. The commercialization has resulted in substantial cost savings for growers, minimal problems requiring segregation and no apparent commercialization problems. However, there have been intermittent legal interventions that have affected the production of crops with this trait. These developments are reviewed in this paper.



## Coexistence of conventional and Roundup Ready soybean in Parana State, Brazil

Michel FOK<sup>1</sup>, Jean-Louis Le GUERROUE<sup>2</sup>, Josemar Xavier de MEDEIROS<sup>2</sup>

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In Brazil, in spite of strong resistance, the Government of Parana State has had to comply with the Federal Union's decision in 2005 and allow the production of Genetically Modified Soybean (GMS) rendered tolerant to glyphosate. This communication reports and analyses the outcomes of interviews and of a survey conducted in the campaign 2007/08, covering 232 producers, to clarify the current situation of coexistence in this State.

Globally, there still is a rather balanced coexistence between GMS and conventional soybean (CS). GMS covers 43% of total soybean area and 41% of total production. An original result of the conducted survey pertains to the cohabitation of three producer types according to the extent of GMS adoption: 0%, 100% and intermediate percentage for producers managing intra-farm coexistence. This third type represents more than 50% of soybean producers. This specific coexistence leads to observe that more than 70% of producers have adopted GMS, as many as those who have maintained producing CS.

Many factors impacting on coexistence have been identified, but they have varying influence on the continuation of CS. This latter mainly benefits from higher yield because GM varieties eventually are not yet as much productive as previously announced. It is also relevant where fields are little infested by weeds. The decision on choosing GMS or CS is frequently based on the level of weed infestation. As this infestation may vary between plots, the decision criteria mentioned above explains both the feature of intra-farm coexistence and the possibility of coming back to CS after "cleaning" the field by one or two years of GMS use.

The yield superiority of CS should not last very long. The extensive research dedicated to GMS is upon reducing the yield gap. If so, the unique advantage of CS growing will disappear and this will make the convenience of GMS to manage weeds furthermore attractive. Yet, this convenience seems to account more than production cost reduction in adopting GMS. Indeed, price premium for CS is seldom obtained, and only at limited extent when it does. This is pushing elevators to question the relevance of keeping on segregating. Their withdrawal from segregating will in return discourage farmers from growing CS. The pursuance of soybean coexistence in Parana State will depend upon better transmission of market premium to producers.

## Economic impact and the traceability costs in the case of banning the cultivation of GM soybean in Romania

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Genetically modified soybean (GMS), resistant to glyphosate was introduced into cultivation in Romania in 1999.

Since 2002, the areas cultivated with soybean have grown constantly through the increase in the interest in GMS due to the advantages exhibited by this crop: a production increase of up to 30%, protection against problem weeds *Phragmites* and *Sorghum*, the decrease in the costs for fighting weeds in the basic crop and in the following crops, the reduction in fuel consumption for the entire cultivated area due to the possibility to adopt the minimum tillage system, the increase in the nitrogen reserve in the soil by about 30-40 kg of active substance as a result of the more intense activity of the symbiotic bacteria, larger incomes due to the plus in production and in the quality of the beans which attract bigger selling prices. As a result of these advantages, in 2006 199.8 thousand ha of soybean were cultivated, 137.3 thousand ha of which were declared GMS.

From the analysis of the balance account of the trade in soybean and derived products in the interval 2001-2008, we notice that, except for 2002, Romania supplies itself with the necessary soy oil and arrived to export over 42000 t of soybeans in 2005 and 2006 after a long period in which it was a net importer of this product. In the entire period, Romania has been a net importer of soy meal.

In value terms, the balance account of the trade in the three products is negative. If we compare the years 2007 and 2006 at the level of the difference between the balance account for the trade in the three products, we notice that in 2007 the processing industry in Romania had to make foreign currency efforts amounting to €60.5m to make up for the lack of these products, €30m of which for soybeans, almost €20m for the surplus of meal and about €10m for the soy oil it could not export.

For the lack of nitrogen resulting from the activity of the symbiotic bacteria we can estimate the level of losses at €1.1m in 2007 and €1.725m in 2008. The expenses on the supplementary mechanical work are of about €30/ha which means losses of €2.3m in 2007 and €4.14m in 2008. The expenses on fighting weeds are difficult to estimate since they depend directly on the crop and fighting method adopted.

## Parallel Session 1B: Managing Coexistence in Farming Systems 1

### Pollen-mediated gene flow in wheat (*Triticum aestivum* L.): How low is too high and what can R\* say about it?

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Transgenic wheat is currently being field tested with the intent of commercialization. The development of wheat genotypes with novel traits has raised concerns regarding the presence of volunteer wheat populations and the role they may play in facilitating transgene movement. Field experiments and empirical modeling conducted between 2005 and 2006 revealed varying rates of pollen-mediated gene flow (PMGF) between volunteer and cropped spring wheat that were dependent on volunteer and cropped wheat densities, emergence times, and height.

The frequency of PMGF in spring wheat decreased exponentially from a high of 0.31% to a low of 0.0002% with increasing crop (receptor) plant population density, but showed no dependence on either crop genotype or height. A 125 growing degree day hybridization window was also identified that produced dramatic declines in PMGF from a high of 0.51% to a low of 0.0003%, and will serve to temporally isolate a given wheat crop from neighboring transgenic crops or from volunteers growing within. Although maximum observed PMGF was always less than 0.6% and did not exceed a 0.9% EU-labeling threshold in any case, the question remains is this low enough?

Mechanistic modeling demonstrated that these seemingly low rates were indeed large enough to become problematic. For example, selection pressure of 95% (similar to that imposed by many herbicides) would produce a volunteer population in which half of the individuals possessed the transgene in just 2-4 generations. Continuously imposed selection pressure of only 30% (as may be the case for yield increases associated with enhanced nitrogen or water use efficiency) would result in 50% of the volunteer wheat population possessing the transgene in just 15 generations with PMGF rates of 0.55%. What's more, resource-based ecological traits such as enhanced water and nutrient use could theoretically shift zero net growth isoclines (rate of population growth is zero) for species which possess the transgene, potentially altering the competitive dynamics among weed communities. Thus, even the relatively low PMGF rates that we observed in wheat could have a profound influence on population structure and the long term fate of the transgene in the agricultural system.

Future models coupling resource-ratio theory (R\*) with population genetics are needed and may prove a useful tool in predicting the spread of second-generation transgenes.

### Management of herbicide-resistant weed beet: A simulation study

Yann TRICAULT<sup>1</sup>, Mathilde SESTER<sup>2</sup>, **Henri DARMENCY**<sup>1</sup>, Frédérique ANGEVIN<sup>3</sup>, Nathalie COLBACH<sup>1</sup>

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In regions of sugar beet cultivation, weed beet infestations are responsible for economic losses. Weed beet belongs to the same species as the cropped plant, thus rendering herbicide control impossible in conventional sugar beet where costly practices such as manual weeding of bolters must be carried out instead. Genetically-modified herbicide-tolerant (GMHT) sugar beet varieties might provide an alternative in fields heavily infested with weed beet. However, accidental bolting of GMHT plants would result in pollen-mediated transgene flow towards weed beets. The objective of the present paper was to use a spatio-temporal simulation model for comparing three production systems with different cultural practices to evaluate the risk of herbicide-tolerant weed beet populations in a small agricultural region where GMHT and conventional sugar beet coexist.

The GENESYS-Beet simulation model was used in a case study of a French sugar beet production region where three types of intensive production systems had been identified: (1) "potato grower"; (2) "beet grower"; and (3) "cereal grower". The three production systems were successively simulated on a real 149 field map extracted from the studied region. Our simulation results show that gene flow is inevitable, both in time and in space, but that it varies considerably with the cropping system. Similar results were obtained for oilseed rape.

Simulation models proved to be powerful tools for predicting the effect of alternative methods on gene flow to and from weed populations. However proposals still require economic feasibility studies.



## **Estimation of both rice pollination rates under normal conditions at Tsukuba Japan and mixture rates between simulated GM rice and non-GM rice by co-use of harvester machine**

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Rice is a major crop in Asia and supports the majority of the population. Now GM rice is about to be under commercial target. Although rice is principally autogamous, a certain level of pollination exists between GM and non-GM rices. Different from EU regulation of 0.9% threshold (an example is maize whose pollen pollinate in farther fields), it may be expected that lower threshold can be set for rice. To reveal environmental impacts of GM rice, it is necessary to understand pollination processes through modelling. Through intensive studies supported by Ministry of Agriculture, Forestry, and Fisheries are now being run and a model (Kawashima-Shibaike model) whose basic structure consists of a plume diffusion model is developed to simulate pollination processes for 4 years of intensive field investigations. Application of the model to normal conditions at Tsukuba where intensive studies were conducted showed that threshold pollination level 0.1% can be achieved under normal conditions without any measures being taken, when areas of GM rice and non-GM rice are between 0.1ha and 1ha. This paper suggests higher pollination rates are expected when wind blows at 2m/s in the direction from GM rice to non-GM rice. In this scenario, measures such as isolation distance or staggered flowering period were necessary to achieve the threshold pollination level.

At the same time, mixture between simulated GM rice and non-GM rice during harvesting processes with co-usage of harvester was investigated. Three years of investigations show that the mixture rates in regard to harvested amount of rice were functioned by a power function. The mixture rates after cleaning of harvesters were one tenth of those without the cleaning.

## **LPIS (Land Parcel Identification System) to manage GM/conventional maize coexistence in the EU intensive agricultural region of Lombardy**

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Lombardy is a region of Northern Italy, located in the wide and flat Po Valley where arable crops are widespread and agriculture is very intensive. Within this region, the GIS system SIARL (Sistema Informativo Agricolo Regione Lombardia), is used for the registration and management of farmer declarations when applying for EU subsidies.

According to provisions under EU law, land use history referring to the past 5 years is required to be documented. Therefore, land use is registered on the basis of the declaration at the time of its introduction. In particular, farmers applying for public subsidies and growing GM crops are obliged to declare the GM seeds or plants cropped.

The aim of the simulation is to quantify in a real agricultural context, the potential GM cropping area in 3 different intensively cropped areas (municipalities) of Lombardy region. This simulation will take into consideration the historical cropping systems, farming systems and size and rotation schemes.

Simulations using 3 different cropping distances, allow for gauging the three municipalities' availability of agricultural land suitable to for the expansion of maize cropping to GM cultivars. Results indicated area suitability is very limited in 2 simulations out of 3, but the establishment of an ad hoc procedure for crop declaration prior neighbors' authorization could extend the suitable area in all simulations. This suggests that land use distribution, more than cropping distances and relative maize area percentage, is the most significant variable.

These results can assist in outlining the management control strategy and features of the control program to be triggered as well as the budget repartition between the control bodies. This system is diverse in nature as it can be adapted to other crops.



## Relative impacts of closest fields and background pollen on GM adventitious presence in non-GM harvests

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In Europe, isolation strategies are the most common rules proposed to ensure the coexistence of GM and conventional crops. Spatial strategies are usually based on distance from the closest GM field, and on empirical data from two-plot experiments. However, long distance pollen dispersal produces a background pollen cloud in numerous plant species. In natural populations, its impact depends on a complex interaction between the spatial distribution of pollen sources and the short- and long-distance components of dispersal. We thus investigated under which conditions there would be a need to account for the multiplicity of pollen sources over landscapes in the case of maize.

We characterised five real French landscapes thanks to spatial descriptors. We used these descriptors as input data of a model, GenExP-Landsites, which simulates neutral agricultural landscapes. This model is based on Voronoï tessellation method. We generated 10 6 km x 6 km landscapes. For each of them, 8 combinations of amount of maize fields / percentage of GM varieties / maize crop allocation were defined. We simulated pollen dispersal on these landscapes either via a Normal Inverse Gaussian (NIG, currently used for European coexistence studies) or a bivariate Student (2Dt) kernel. These kernels differ in their amount of short- and long-distance dispersal. We analysed the impact of local and landscape variables on GM rates in conventional fields with linear models and quantified the increase of these rates due to dispersal from farther than the closest GM field.

Average landscape impurity rates increased linearly with the proportion of GM maize over the landscape. The increase was twice faster with the NIG and was governed by the short-distance dispersal component. Variation in rates of adventitious presence mostly depended on distance to the closest GM field and size of the receptor field. However, rates were generally largely underestimated when only dispersal from the closest GM field was considered.

The short-distance component of dispersal had a major impact on adventitious presence (through a local protection effect and the impact of the closest GM field). However, intermediate- to long-distance dispersal from GM sources farther than the nearest GM field had a significant impact, thereby precluding the establishment of isolation distances directly from two-plot experiments. We propose directions to quantify the impact of long distance dispersal on rates of GM adventitious presence in conventional harvests.

## Parallel Session 1C: Managing Coexistence in the Marketplace

### Closed loop identity preservation systems and successful coexistence

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Canada has a stringent science-based regulatory system designed to evaluate and manage food safety, livestock feed safety and environmental safety risks associated with novel plants prior to approval. Economic and market implications are not considered in this regulatory process. This means that consumer concerns about genetically modified (GM) plant products and the associated market sensitivities have the potential to result in market loss and disruptions for conventional and organic supply chains.

With the emergence of the non-GM soybean market and the development of identity preserved supply chains to meet the demands of that market, Canada has experienced successful co-existence in soybeans. However, the conditions that allowed for this successful co-existence are not likely to be replicated in all other crop types. Where these conditions do not exist, closed-loop production and handling systems may contribute to successful coexistence.

A three year cooperative government-industry pilot project involving a new and unique wheat variety that was not eligible for unrestricted commercial registration in Canada due to its non-conforming end-use quality characteristics was carried out to determine if it could be successfully contained within a closed-loop identity preserved (IP) system. While the variety itself was



considered low risk because its quality was not significantly different than varieties registered for commercial production, it provided an opportunity to determine what factors contribute to successful confinement and whether they are feasible within Canada's grain handling and transportation system.

The pilot project included the development of a risk assessment framework designed to allow for comparison of relative risks of new and unique varieties and identify potential risk mitigation practices, and a determination and an evaluation of the quality management system requirements for a closed-loop IP system. During the three years that this variety was produced, handled, stored and transported, shipments of conventional bulk wheat were monitored for the presence of this variety to assess whether it was successfully contained.

The results of this pilot study demonstrate that closed-loop IP systems can be difficult and costly to maintain and do not guarantee 100 percent containment.

## **Modelling coexistence between GM and non-GM supply chains: the starch maize simulation model**

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Coexistence between GM and non-GM supply chains is a complex issue, because adventitious mixing of GM material with non-GM product can occur at any one of the stages of production, from the field where the crop is grown to its handling and processing.

In this paper, we present a simulation model of the coexistence between GM and non-GM products along supply chains, focusing on the starch maize supply chain. The aim of this model is to assess the ability of the supply chain to provide final non-GM product compliant with a required threshold (0.9% labelling threshold for example). The model simulates GM and non-GM flows, and takes into account "real" admixture and dilution functions between GM and non-GM batches at field, collection, and wet-milling process levels.

The input data of the model are the proportion of GM in the supply chain, the distribution of non-GM purity rate in the raw material (calculated using the MAPOD<sup>®</sup> gene-flow model), strategy of scheduling of non-GM and GM batches, and scenario of controlling the GM purity rate of non-GM batches. Indeed, for non-GM batches, uncertainty remains about the GM adventitious content, due to various sources of commingling between GM and non-GM material. In the model, non-GM batches can be automatically downgraded, or testing can be used to gather information on the non-GM batches. Measurement error in testing is taken into account in the model.

Various simulations were carried out with the model to assess the probability of compliance as a function of non-GM purity rate in the raw material and the scheduling and control scenarios.

The results suggest that, in spite of the variability of the upstream distribution of GM adventitious presence in non-GM harvest at field level, the downstream supply chain is crucial on the capacity to provide non-GM product. There is a trade-off between number of non-downgraded non-GM batches and compliance of these batches with the threshold. The capacity of stakeholders to provide non-GM products compliant with the labeling threshold depends on strategies (scheduling of the batches and control rules).

## **Analysing the repartition and coexistence means used in maize in France in 2007**

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We studied how coexistence was managed in maize in the South of France at the farm level by surveying 23 contrasted farms in a region where nearly half of the maize cropped in 2007 was GM. Using semi-directive interviews, we identified factors explaining the choice of GM or NGM maize cropping like: presence of maize specialty crops, presence of technical scope of progress for maize yield, perception of corn borer as a risk or return time of maize. We will use these results to build a multicriteria model of maize allocation.

## Elaboration of coexistence scenarios from fields to primary grain collection

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Developing management scenarios for coexistence requires assembling heterogeneous knowledge on chain food, actors' decision making and of course gene flow. For this purpose and under the European research program SIGMEA (Sustainable Introduction of GMOs Into European Agriculture), we used the "role playing game" method to see how farmers, grain collection companies and advisers, were able to manage coexistence in the cases of maize in Alsace (France), and oilseed rape in Beauce (France). Placed in the context of their grain collection area, they played their own role during the key moments of sowing (decision for crop allocation), harvesting (organization and delivery to silos) and grain collection (assembling harvests from different fields in grain batches). The results of these decisions, expressed as percentages of GM grain in conventional harvest and subsequent achievement of purity standards, were obtained through a meta-model incorporating gene flow at the field level and further admixture in harvest machineries and silos. Four major scenarios have been identified. If the admixture risk is low to moderate and information is easily available, a segregation strategy based on separated grain collection slots in time or dedicated silos is enough to achieve purity standards. If the admixture risk is high, farmers will coordinate to implement preventive measures (isolation distance or buffer strips), or corrective measures in case of failure (for example downgrading field edges of conventional OSR as GM OSR). However, this would not be possible when information becomes less available, and some farms will be then classified as "risky", leading to make downgrading conventional OSR easier. In the latter scenario, the risk of admixture is so high and access to information so low that no coexistence is possible.

These results suggest that the problem of coexistence is not to define what the "good" measure is, but rather to make access to information easier in order to ensure efficient management, i.e. adapting management practices according to the diversity of the risks and to the objectives of the different stakeholders. Another issue is more political: how to articulate the rigidity of the legislation and the diversity of the strategies used by professional actors when they manage grain quality?

## Collective strategies and coordination for the management of coexistence: the case studies of Alsace and western south of France.

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In France, organizing the coexistence of GM and non-GM crop requires to set up a land governance that involves all the concerned parties. At farmland level, for seed or food production, the grain merchants have a key position. Their position upstream of and downstream from farmers gives them a strong position to manage the agricultural land. The governance has to allow coordination between rival grain merchants to enable coexistence.

For these companies, coexistence gives rise to two kinds of constraint, those involving the segregation of products and those involving the risk management of admixture. These constraints encourage rival grain merchants to collaborate and to coordinate their activities. The management of segregation requires sharing resources (division of the landscape, machinery used for each product). The risk management of admixture requires sharing information (such as GM location) between rival companies.

We made several case studies on two regions (the Alsace region and the western South of France). Two zones concerned by GM and non GM coexistence and contrasted from the point of view of the relations between grain merchants as well as the types of markets of these companies.

The study shows that there are already such relations between grain merchants. But there is a strong regional disparities in the organization methods and the form of these relations.

In Alsace case, grain merchants took a collective decision to produce only non-GM maize. These companies persuade farmers to do so. It appears that the small number of grain merchant, their average size, the local culture, characterized by a strong regional identity, favored the development of close informal relationships. These relationships allowed these companies to manage the absence of GM products in their territory, rather than managing the coexistence between GM and conventional crops.

In the case of south-western France there are numerous different-sized companies. This prevents informal coordination and favored the development of a common organization which manages a charter of good practices. These practices consist of developing collaborative management arrangements to share information, machinery and infrastructure between rival grain merchants so as to manage the coexistence of GM crops at minimal cost.



## **Cost-benefit analysis of a traceability and certification system for non-genetically modified soybeans: the experience of Imcopa Co. in Brazil**

Victor PELAEZ<sup>1</sup>, Dayani AQUINO<sup>2</sup>

<sup>1</sup>Federal University of Parana, Curitiba, Brazil, <sup>2</sup>Federal University of Parana, Curitiba, Brazil

This paper analyses the economic costs and benefits of a family-owned Brazilian soybean crusher (Imcopa) in adapting its production system for selling soy and its derivatives with non-GM certification. This was Brazil's first soybean crusher to implement a non-GM soybean traceability and certification system, in 1998. It is now held to be the world's largest non-GM lecithin exporter. Three fundamental elements of reasoning were set to guide the analysis of the company experience in the non-GM chain: the information asymmetry; the rationality of actors; and the growth of the firm. Access to information about company was initiated through a workshop organized in November 2005 with the support of the Agricultural Secretariat of Parana State.

The subsequent interviews, carried out in 2006 and 2008, were based on semi-structured questionnaires aiming at obtaining a background of the company's growth trajectory, its structure of production, investment and operational costs of the traceability and certification system, and the productive opportunities identified by company's managers which led to the decision of setting up the non-GM segregation system. Such a decision procured for Imcopa an increasing of its annual sales by 18 times in ten years, from US\$ 70 millions in 1998 to nearly US\$ 1,3 billion in 2008. Furthermore, the possibilities of commercialization of non-GM soy and its derivatives in the international market have provided Imcopa with a wider insertion into a commercial network of feed and food products. This has allowed for the company a better rationale to diversify its activities by identifying and exploring new market niches. Meanwhile, after the definitive legalization of GM soy production in Brazil, in March 2005, this kind of culture has been quickly expanding all over the territory, which has enhanced the costs of segregation and also the primes paid for maintaining farmers interested in cultivating non-GM soy.

The main conclusion of the paper states that the main reason for the creation and maintenance of a non-GM soy chain, whereby Imcopa participates, has been the demand created by international food companies which are not been willing to take the risk of relating their labels with GMOs.

## **Plenary 6: Coexistence Case Studies - New Crops, New Countries**

### **Coexistence challenges and opportunities for wheat**

**William W. WILSON**

*University Distinguished Professor, Department of Agribusiness and Applied Economics, North Dakota State University, Fargo, North Dakota, USA*

Development of Genetically Modified (GM) wheat is continuing on a number of fronts and in several countries. Even though prospective GM traits are years away from commercialization, there are important challenges related to commercialization of future traits. One challenge of importance is the form and terms of contracts that would be used to facilitate a dual marketing system to accommodate needs of both GM and non-GM customers. In this paper, a principal-agent model was specified to define the equilibrium solution of a contracting strategy for a supplier exporting non-GM wheat to meet traceability requirements. The buyer (principal) offers a contract, the supplier (agent) accepts the contract, and then the supplier decides whether to offer a subsequent contract to the farmer. There is uncertainty throughout the supply chain due to adventitious commingling and imperfect information. Results indicate farmers would require \$3.31/mt and suppliers \$2.94/mt to induce their participation in the contracting strategy.



## **Coexistence challenges and opportunities for rice**

**Gerard BARRY**

*Program Leader, IRRI Program 4: Rice and Human Health, International Rice Research Institute (IRRI), Los Banos, Laguna, Philippines*

As with any GM crop, GM rice will be released following the appropriate biosafety risk evaluation. While not generally recognized as an out-crossing crop, the low level of this biological occurrence will be a fact. The effect of the movement of transgenes from rice to rice will have been assessed as part of the approval processes. While GM rice has been approved for commercialization in the US, it is likely that broad cultivation of the GM crop is likely to occur first in Asia. In China, at least one GM event has been awaiting final approval and release since 2004 and co-existence issues, such as the effect on the limited rice exports from the country, have been evaluated. For India, the current decision to avoid introducing GM traits into the official Basmati varieties and to not grow GM rice in the Basmati producing areas recognizes a practical approach to managing both the adoption of modern technology to improve the productivity of the crop and to separate the domains of biosafety processes from those of trade and export. Many important rice producing countries are still formulating their biosafety regulations or at the beginning of the process. A number of other products under development, such as for vaccine production are likely to grown in very small and isolated acreages and in some cases may be managed in containment facilities; risk management procedures for such products will rely heavily on temporal and physical isolation. For all products, the widespread recognition and adoption of procedures in accord with the Low Level Presence Annex of the *Codex Alimentarius* is highly desired.

## **Coexistence challenges and opportunities for fruit crops**

**Dennis GONSALVES**

*Director, USDA Pacific Basin Agricultural Research Center, Hilo, Hawaii, USA*

The Hawaiian transgenic papaya is the only transgenic fruit crop that has been commercialised in the US and in the world. The dominant transgenic cultivar 'Rainbow' is resistant to papaya ringspot virus (PRSV), which is the most important virus disease of papaya worldwide. 'Rainbow' was commercialised in 1998 and saved Hawaii's papaya industry from devastation by PRSV. Resistance of 'Rainbow' and other commercial derivatives of the original transgenic line have held up well for over decade. Today, transgenic papaya accounts for about 80% of the papaya crop in Hawaii. Yet, Hawaii still needs to grow nontransgenic papaya to export to Japan, which has not yet deregulated the Hawaiian transgenic papaya. Ironically, transgenic and nontransgenic fruit crop commercially 'co-exist' since they both are grown in the Puna district of Hawaii Island, where about 90% of Hawaii's papaya are cultivated. Often times, nontransgenic and transgenic cultivars are grown in close proximity, with the nontransgenic papaya being exported to Japan. This presentation will discuss the protocols that are used to enable 'co-existence' and also provide information on our efforts to get the Hawaiian transgenic papaya deregulated in Japan. The Hawaiian papaya case provides a realistic and unique opportunity to investigate challenges and opportunities of 'co-existence' of transgenic fruit crops.

## **GM coexistence development in China**

**Yufa PENG**

*National Key Laboratory for Biology of Plant Diseases and Insect Pests, Institute of Plant Protection, Chinese Academy of Agricultural Sciences, Beijing, P. R. China*

During 1997 to 2009, China has reviewed more than 2700 applications for field testing (> 50 species of crops involved) and/or production, and approved seven kinds of GM crops for local production and four kinds for imports. In this paper, current situations and challenges ahead will be addressed with a focus on the government attitude as well as the needs from producers, traders and consumers as relevant to GM and non-GM coexistence.



## Parallel Session 2A: Managing Coexistence in Farming Systems 2

### Some aspects influencing the quantification of gene flow in maize fields: flowering heterogeneities and simplified field sampling methods

Joaquima MESSEGUER<sup>1</sup>, Montserrat PALAUDELMÀS<sup>1</sup>, Joan SERRA<sup>2</sup>, Jordi SALVIA<sup>2</sup>, Anna NADAL<sup>3</sup>, Maria PLA<sup>4</sup>, Enric MELÉ<sup>1</sup>

<sup>1</sup>Plant Genetics Department, IRTA, Centre de Recerca en Agrigenòmica, CSIC-IRTA-UAB, Barcelona, Spain, <sup>2</sup>Mas Badia, IRTA, La Tallada de l'Empordà, Girona, Spain, <sup>3</sup>IBMB-CSIC and Molecular Genetics Department (Centre de Recerca en Agrigenòmica CSIC-IRTA-UAB), <sup>4</sup>INTEA Girona University, Campus Montilivi, Girona, Spain

Quantification of GM content in conventional maize fields is a complex process that may be influenced by more than one surrounding GM field. In this regard, the Global Index is a useful tool to estimate the % of GM material due to cross-fertilization in a conventional maize field. However, this percentage needs to be confirmed by sampling, and establishing an accurate and cheap field sampling system can be very difficult. Furthermore, field irregularities produced by environmental conditions that affect plant growth and flowering dynamics have to be taken into account when modelling gene flow.

### Coexistence in maize: field trials to assess measures for keeping the GM-content in maize kernel harvest below the EU labeling threshold of 0.9%

Gerhard RÜHL, Maren LANGHOF, Bernd HOMMEL, Alexandra HUSKEN, Charles NJONTIE, Peter WEHLING

*Institute of Crop and Soil Science, Julius Kühn-Institute (JKI), Federal Research Centre for Cultivated Plants, Braunschweig, Germany*

It could be shown that in most cases 50 m isolation distance will effectively keep the GM-content of non-GM kernel maize harvests below the EU labelling threshold of 0.9 % and discarding 3 to 12 m of the non-GM field edge additionally can reduce this GM-rate. However, modest and constant wind blowing from GM to non-GM maize can increase GM-rates of non-GM maize fields in spite of these measures considerably. Barley stubble in comparison to clover-grass as crop species grown between GM and non-GM maize did not result in a different extent of pollen mediated gene flow.

### Biological measures for gene flow mitigation

Alexandra HÜSKEN, Joachim SCHIEMANN

*Julius Kuehn Institute, Federal Research Centre for Cultivated Plants (JKI), Institute for Biosafety of Genetically Modified Plants, Braunschweig, Quedlinburg, Germany*

An EU-funded project (Co-Extra, WP1) is aimed at analysing and validating methods for restricting gene flow during cultivation. It focuses on methods like cytoplasmic male sterility (CMS) in maize, cleistogamy in oilseed rape and plastid transformation in tobacco. Parameters of gene flow of CMS-maize and cleistogamous oilseed rape has been studied under field conditions located at different sites in Europe. Moreover, data mining was performed to gain information about the suitability of chloroplast transformation as a containment strategy. An experimental system with tobacco plants was developed in order to have the ability to evaluate the biosafety of transplastomic plants. Our data demonstrates that the used biological mitigation techniques provide an effective tool to increase the biosafety of transgenic plants and to reduce dramatically for instance implemented isolation distances. However, in cases where pollen transmission must be prevented altogether (e.g. PMPs), stacking with other containment methods will be necessary to eliminate the residual outcrossing risk.



## Mesoscale dispersal of pollen and implications for gene flow

Yves BRUNET<sup>1</sup>, Sylvain DUPONT<sup>1</sup>, Stéphanie DELAGE<sup>1</sup>, Magali DE LUCA<sup>1</sup>, Pierre TULET<sup>2</sup>, Jean-Pierre PINTY<sup>2</sup>, Christine LAC<sup>2</sup>, Juan ESCOBAR<sup>3</sup>, Xavier FOUEILLASSAR<sup>4</sup>

<sup>1</sup>INRA Ephyse, Gironde, France, <sup>2</sup>XCNRM, Météo-France, <sup>3</sup>Laboratoire d'Aérodologie, <sup>4</sup>Arvalis

In order to better understand long-range dispersal of maize pollen the mesoscale Meso-NH model has been modified to calculate the trajectories and dehydration of pollen grains. Simulations were performed over South-West France during the maize pollination period. As compared with airborne measurements, the model provides good estimates of pollen concentration throughout the atmospheric boundary layer, whereas pollen viability is slightly overestimated. The simulations allow the pollen plume to be characterized on each day and deposition maps of viable pollen to be produced. Our results provide quantification of long-distance pollen deposition and show that background fortuitious contamination is unavoidable at regional scale.

## Impact of gene stacking on gene flow – the case of maize

Lénaïc PAUL<sup>1</sup>, Cécile COLLONNIER<sup>2</sup>, Frédérique ANGEVIN<sup>1</sup>, Antoine MESSEAN<sup>1</sup>

<sup>1</sup>INRA, Eco-Innov, Thiverval-Grignon, France, <sup>2</sup>GEVES, SEV La Minière, Guyancourt, France

The number of GM crops bearing more than one trait started increasing over the past few years and is expected to keep growing in the future. There are different ways of introducing several effect genes into a plant, but for the European Food Safety Authority, "stacked events" only refers to plants obtained by conventional crossing between transgenic lines. Under the European regulations, GM food and feed has to be traced and labelled above a threshold of 0.9% of adventitious presence of authorised GMOs due to gene flow. GM material is mainly detected by real-time PCR, which targets transgenic DNA marker sequences and measures their copy number relative to the number of copies of species specific endogenous DNA marker sequences. This measurement unit is of great consequence when dealing with stacked events, as the GM content expressed as haploid genome of a seed carrying N stacked GM-traits is N times bigger as the one of a seed carrying only one GM trait, although both of them count as one transgenic seed only. This is at the disadvantage of conventional farmers willing to comply with the legal thresholds, as the risks of exceeding the thresholds of adventitious GM presence are consequently higher if the GM varieties surrounding conventional fields include stacked ones.

This study aims at giving an overview of the impact of gene stacking on the rate of adventitious presence of GM seeds in non-GM harvests due to pollen flow in the case of maize. For each genetic structure we have established a relationship between the percentage of non-GM female flowers fertilised by a pollen grain from a GM field and the percentage of resulting transgenic seeds in the non-GM harvest, taking into account transgene segregation in pollen grains according to their relative location on chromosomes. We have also established intervals of percentage of transgenic pollen grains considering recombination frequencies comprised between 0 and 50%.

These relationships can be used to assess the risks of gene flow regarding to the stacking structure and to adapt isolation measures for GM and non-GM crops coexistence. They are also a basis for the calculation of a percentage of GM-DNA as it could be obtained by PCR assays from a percentage of GM seeds as it could be obtained by counting or by simulation. Finally, they will be useful to adapt the MAPOD gene-flow model (Angevin et al., 2008\*) to different situations of gene stacking.



## Parallel Session 2B: Coexistence Case Studies - Wheat

### Pollen-mediated gene flow from genetically modified wheat plants

**Dmitry MIROSHNICHENKO**, Gregoriy POROSHIN, Sergey DOLGOV

*'Biotron', Branch of Institute of Bioorganic Chemistry RAS, Pushchino, Moscow Region, Russia*

Wheat is primarily self-pollinated; however, some cross-pollination can occur depending on biological, agronomic, and environmental factors. Potential risks of gene escape from transgenic crops through pollen and seed dispersal have slowed down full utilisation of gene technology in crop improvement. Although no transgenic wheat varieties have yet been officially approved for extensive commercial cultivation in the world, it is apparent that, as an important world cereal crop, transgenic wheat varieties could be released into the environment for commercial production, and probably within the near future.

In 2004, 2005 and 2008 crop-to-crop gene flow in spring wheat was investigated. Field experiments were established in Orel region, European part of Russia. As the pollen source, transgenic homozygous line expressing recombinant DNA encoding two marker genes, such as bar and gfp genes was used. Among the marker genes available, the bar gene, encoding phosphinothricin acetyl transferase and conferring resistance to herbicide ammonium glufosinate, are particularly suitable for investigating gene flow in controlled experimental field trials. Green fluorescent protein marker gene gfp was used to monitor in vivo foreign gene expression at different stages of experiments and for segregation study. Analysis of phenotypic and molecular data showed that gene flow was greatly affected by the direction of the dominant wind and the distance between the targets.

The overall outcrossing rate of non-transgenic receptor wheat plants growing at one meter from transgenic plants varied year after year from 0,15% (2004) to 0,41% (2005). Pollen-mediated gene flow tended to occur more often in years with lower temperature and higher humidity during pollination (2004, 2008). When non-transgenic receptor plants were grown in plots at three or five meter from transgenic plants, only a few seeds were produced from fertilisation with transgenic donor plants (less than 5% from total amount of transgenic hybrids). A strong asymmetric distribution of the gene flow was detected in different parts of plots and the maximum outcrossing in individual samples (0.80-0.90%) were recorded following the direction of the dominant wind.

### Wheat coexistence issues for Australia

**Peter FLOTTMANN**

*CEO Grain Growers Association Ltd, North Ryde, New South Wales, Australia*

In 2007, the Australian grains industry came together to produce a statement entitled "Delivering Market Choice with GM canola". Endorsed by 29 industry organisations, the statement recognised the grains industry's capacity, backed by rigorous protocols and processes, to deliver market choice for GM canola. In 2009, three Australian entities joined Canada and the USA to sign and release a GM Wheat Trilateral statement. As Australian GM wheat R&D progresses, the Australian grains industry will work with local and international organisations, to address the market and trade considerations for GM wheat, to ensure a predictable global path to commercialisation.

### Wheat coexistence issues from a processing perspective

**John MILLER**

*Chairman, North American Millers' Association, President, Miller Milling Company, Bloomington, Minnesota, USA*

The author presents the North American Millers' Association's (NAMA) perspective on issues surrounding the coexistence of biotech wheat and conventional wheat. He describes why he believes the industry needs biotech wheat, the consequences of not having it, the current landscape surrounding its commercial acceptance, what US millers are doing to encourage it and challenges that may confront us once it is commercially available.



## Toward the commercialization of GM wheat

**Stephen VANDERVALK**

*Alberta Vice President, Western Canadian Wheat Growers Association, Fort Macleod, AB, Canada*

The Wheat Growers Association support introduction of GM wheat as a means to improve the profitability and long-term sustainability of our farms, based in part on our generally positive experience with GM canola in Canada. Many GM wheat traits could offer significant benefits to farmers, including improved nutrient utilization, fusarium resistance, insect tolerances, and drought tolerance to name a few. The main hurdles to overcome in the introduction of GM wheat include market acceptance, market access, segregation and liability issues. The Wheat Growers Association do not believe GM wheat can be successfully introduced unless all players in the value chain derive some benefit. The conditions for the successful introduction of GM wheat do not exist in Canada today, however we expect they will within the next decade.

## THURSDAY 12 NOVEMBER 2009

### Plenary 7: Coexistence Case Studies – Australian Canola

#### Genetically modified canola in Australian farming systems: opportunities, challenges and segregation

**Christopher PRESTON<sup>1</sup>**, Jeanine BAKER<sup>2</sup>

*<sup>1</sup>School of Agriculture, Food & Wine, University of Adelaide, Glen Osmond, South Australia, Australia*

Herbicide tolerance is an important attribute in canola cultivars in Australia, helping make canola the third most important grain crop in Australia. The introduction of genetically modified (GM) canola to Australia provides two additional herbicide modes of action for use in canola. There are several potential on-farm risks to co-existence of GM and non-GM canola in Australia. These include: adventitious presence of GM traits in sowing seed; gene flow between canola crops; GM canola volunteers; farm hygiene; and roadside canola volunteers. Current research indicates farm hygiene and poorly-managed canola volunteers represent the highest risks for adventitious presence in Australia.

#### Pollen flow in canola: 2008-9 trials and results

**Rick ROUSH<sup>1</sup>**, Chris PRESTON<sup>2</sup>, Hanwen WU<sup>3</sup>

*<sup>1</sup>Melbourne School of Land and Environment, University of Melbourne, Australia, <sup>2</sup>Faculty of Sciences, University of Adelaide, Glen Osmond, South Australia, Australia, <sup>3</sup>NSW Department of Primary Industries, Wagga Wagga, New South Wales, Australia*

Pollen flow among commercial canola crops was measured in the year 2000 through the use of varieties resistant to acetolactate synthase (ALS)-inhibiting herbicides. This "Clearfield" canola was grown commercially in Australia for the first time in 2000, and seed from these crops was used to assess pollen dispersal into neighboring ALS-herbicide sensitive crops. In these experiments, we examined pollen movement on a real-world scale, testing over 48 million individual plants that were the potential progeny of hybridized with resistant canola to assess where the pollen had traveled. The results showed that pollen flow was low (averaging less than 0.01%) but appeared to extend over a few km. Resistance was not detected in fields more than 3 km from the sources, although the number of fields sampled was not large (Reiger et al. 2002, *Science* 296: 2386-2388).

Such trials can only be effectively run in the first year of the release of a novel herbicide resistance to avoid the issue of possible impurity in the non-GM crops in later years. With the introduction of Roundup Ready (RR) canola in Victoria and New South Wales in 2008, it was possible to repeat the experiments from 2000 using resistance to glyphosate as a marker. Similar trials are planned in Western Australia under the leadership of Professor Steve Powles.

Parallel to the trial in 2000, we collected more than 1 kg of canola (at least 200,000) from 35 conventional canola within 1 m to 4 km from GM paddocks during October and November 2008.

Collected seed samples were thoroughly labeled by paddock and location within the paddock, and shipped to the University of Melbourne's Dookie Campus, where they were planted in separate plots across approximately 5 ha in December 2008. Also planted were 4 glyphosate resistant and several susceptible canola controls. All plots were multiply irrigated, sprayed twice



with glyphosate, and scored for surviving plants. Samples of nearly 1000 plants were also tested via PCR to double-check their resistance status, and showed that field scoring of resistance was very accurate.

Results show that the frequency of resistance, and therefore pollen flow, declined sharply with distance from the Roundup Ready source canola paddocks, but was very low overall. As part of the project, samples of ryegrass and wild radish seeds were collected for resistance testing in and near GM and conventional paddocks. Ryegrass plants were much less common in GM than in non-GM paddocks.

## **Maintaining market choice with the commercial release of Roundup Ready® canola.**

### **James NEILSEN**

*Canola Systems Specialist Monsanto Australia Limited, Melbourne, Victoria, Australia*

The Australian grains industry is committed to maintaining market choice, to deliver both GM and non-GM canola, with the commercial introduction of Roundup Ready® canola. To enable this Monsanto has worked closely with technology partners and industry to develop stewardship plans and has implemented programs to allow both canola segregations to operate concurrently.

These programs including a Crop Management Plan that describes measures that can be implemented to maintain separation between Roundup Ready canola and non GM canola production, technical publications for control of Roundup Ready canola volunteers, technical publications for clean-down of machinery and equipment involved in the handling or harvest of Roundup Ready canola. These processes have been put in place to ensure that compliance with the Australian grain industry adopted adventitious presence level of 0.9% for CS01–A non-GM canola is maintained. In addition, the broader industry has various processes in place to allow both GM and non GM canola to be produced, handled and sold in the marketplace.

Monsanto has also implemented a two part grower agreement, including the Licence & Stewardship Agreement and a separate Technology User Agreement, that stipulate regulatory and stewardship requirements and commercial obligations.

Before growers are able to grow Roundup Ready canola they must undertake an accreditation course, which informs growers about the potential issues associated with segregation including seed handling, delivery and in paddock segregation. Minimum separation distances, based on research in to canola pollen flow, between Roundup Ready and non-GM canola, are contained within the crop management plan. There is also a requirement that Roundup Ready canola seed is stored separately to CS01-A non-GM canola.

Grain delivery of Roundup Ready canola is also segregated; growers are only allowed to deliver grain to approved grain handlers that provide storage for CS01 canola. Segregation is not an issue unique to GM canola, as grain handlers manage a number of segregations between different crops including grades within crops as a normal practice every season.

## **Grower perspective on the GM canola test market**

### **Andrew WEIDEMANN**

*Weidemann Pastoral Co, Rupanyup, Victoria, Australia*

Weidemann Pastoral Company farms 2700 ha in the Wimmera region of Victoria. Over the past 20 years, adoption of new technology to provide greater sustainability and profitability of our farm has completely changed the way we farm. Our farm now employs no-till seeding and stubble retention for crop seeding, guidance systems and controlled traffic for farm equipment. We grew Roundup Ready GM canola in 2008 and found it suited our farming system, providing excellent weed control and yields at least as good as those of non-GM canola.



## **Grain handler/market perspective of the test market**

**Robert GREEN**

*President Australian Oilseeds Federation, Melbourne, Victoria, Australia*

Following the removal of the moratoria on GM canola production in NSW and Victoria in 2008 the area under cultivation has grown rapidly. The Industry has focussed on providing market choice to the consumers of the oil and meal and has developed protocols and practises. To achieve this, trading standards have been developed by the AOF for CSO1 (Canola) and CSO1-A (non gm canola with allowable AP).

## **Plenary 8: Testing Methodologies and Traceability Systems**

### **The development of detection methods for the monitoring of GMO in Japan**

**Kazumi KITTA<sup>1</sup>, Junichi MANO<sup>1</sup>, Satoshi FURUI<sup>1</sup>, Satoshi FUTO<sup>2</sup>, Hiroshi AKIYAMA<sup>3</sup>, Reiko TESHIMA<sup>3</sup>, Akihiro HINO<sup>1</sup>**

*<sup>1</sup>National Food Research Institute, Tsukuba, Japan, <sup>2</sup>FASMAC Co., Ltd., Atsugi, Japan, <sup>3</sup>National Institute of Health Science, Tokyo, Japan*

The Japanese government introduced a labelling system for genetically modified (GM) foods. To ensure the authenticity of the system, detection methods for newly approved GM events have been developed and validated. One was the development of quantitative analytical methods utilizing plasmid DNAs as calibrators, which enabled us to obtain an unlimited supply of calibrators of consistent quality and also to obtain a stable standard curve to quantify GM organisms (GMO) in samples. In addition, we have developed time- and cost-effective detection methods, such as a screening method utilizing multiplex real-time polymerase chain reaction (PCR), and qualitative multiplex PCR detection methods

### **Environmental multipurpose monitoring**

**Yves BERTHEAU<sup>1</sup> and Arne HOLST-JENSEN<sup>2</sup>**

*<sup>1</sup>NRA Research Unit for Plant Pathology and GMO Detection Methods, Versailles, France, <sup>2</sup>National Veterinary Institute, Ullevalsveien, Oslo, Norway*

The need of environmental monitoring of agricultural and natural ecosystems is increasing in importance through global climate changes, pathogens, pollen flows, invasive species, UGM (e.g. experimental testing of GMO), bio-preparedness, etc. The required tools are available: meteo and pathogen facilities, GIS and national versus European centralization of data, filters, on site detection, data registration and data base for long term studies. This paper will examine experiences from Norwegian and German studies and other experiences.



## **Detecting unauthorised GMOs**

Arne HOLST-JENSEN<sup>1</sup>, Yves BERTHEAU<sup>2</sup> Allain CHAPON<sup>2</sup>, John DAVISON<sup>2</sup>

<sup>1</sup>National Veterinary Institute, Oslo, Norway, <sup>2</sup>Institut National de la Recherche Agronomique, (INRA), Versailles, France

Genetically modified organisms (GMO) and derived products have been on the market for more than one decade. The acreage and diversity (taxonomically and with respect to the genetic composition of inserted sequences) of GMOs is constantly increasing (James 2008) and detection is gradually becoming more and more challenging.

Based on European legal requirements, the enforcement laboratories have primarily focused on testing for compliance with labelling requirements, i.e. on detection and quantification of EU authorised GMOs and derived materials. Recently unauthorised GMOs (according to the EU approval regulatory frame) have been repeatedly detected and reported in various European countries. Examples of unauthorised GMOs recently found on the European market include 55-1/63-1 papaya, LL62, LL601 and Bt63 rice, MIR604 and MON88017 maize and A2704-12 soybean. The sources of unauthorised GMOs in the EU may vary from GMOs authorised in other countries but not in the EU, via unintended mixing of pollen from field trials into commercial fields to unexpected release of experimental GMOs or even GMOs issued from biohacking and bioterrorism.

Moreover, while the number of countries producing and releasing GMOs has been constantly increasing for more than one decade, the regulations, monitoring and enforcement is highly variable among responsible jurisdictions.

Various initiatives, including the EU-funded granted research programs Co-Extra project (GM and non-GM supply chains: their CO-EXistence and TRAceability: [www.coextra.eu](http://www.coextra.eu)) are working to formalise ways of thinking about unauthorised GMOs and to rationalise approaches that would facilitate the detection of unauthorised GMOs.

This talk will briefly summarise the state of the art in relation to unauthorised GMOs with particular focus on detection methods and approaches.

## **Coexistence in supply chains: the view point of a grain trader**

**Randal GIROUX**

*Cargill Incorporated, Wayzata, Minnesota, USA*

In developing coexistence, some markets have discovered commercial realities that can either enable or inhibit coexistence. One key feature is the development and availability of identity-preservation (IdP) systems and test methods to meet market-based thresholds for adventitious presence that are appropriate to specific applications and needs. Once market based thresholds are enacted, industry (and sometimes governments) require analytical methods to monitor supply chains, certify product compliance, and enable enforcement. To test for the presence of transgenic events or to measure the %GM requires validated methods that are fit for the purpose and are suited to the testing environment. These methods need to perform across a wide range of material compositions and product types. To meet this need, the food and feed supply chain are adopting different strategies to make %GM determinations, including protein and DNA-based testing (PCR). During this presentation, several of the approaches that have been implemented will be shared. In addition, discussion of emerging information on the impacts of genetics, processing, and method performance on these measurements will be discussed.



## Parallel Session 3A: The Socioeconomics of Coexistence – Regulatory Driven Examples

### Macroeconomic impact of GM crop adoption in the European Union

**Morten GYLLING**, Henning Tarp JENSEN, Hans Grinsted JENSEN

*Institute of Food and Resource Economics, University of Copenhagen, Frederiksberg, Denmark*

Bio-safety issues and food-safety concerns have delayed the adoption of GM crop varieties in the food chain of the European Union (EU). Previous studies have focused on analyzing possible changes in consumer preferences. The point of departure for the current study is that consumer preferences are invariant. Instead, policy-relevant limitations for the adoption of GM crop varieties in the EU are considered to include (i) lack of (approval of) appropriate GM varieties for the EU area, (ii) lack of marketing of GM products due to first mover issues among commodity retailers, (iii) country-specific insurance problems related to coexistence regulation of GM varieties, and (iv) lack of a concerted effort by national and EU institutions including technical support and farmer-to-farmer interactions. A set of simulations are carried out to analyze the potential macroeconomic EU-wide gains from dealing with the above issues. A sensitivity analysis is used to measure the impact of variation in (i) the potential adoption of GM varieties among agricultural producers, and (ii) the potential demand for GM-containing processed foods among consumers.

### The impact of coexistence measures on the process of adoption of GM crops by EU farmers

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Despite the extensive adoption world-wide of genetically modified (GM) crops, cultivation in the EU remains very low and controversial. Understanding the extent of adoption of new GM crops, (other than the already grown *Bt* maize), as well as the technical and socioeconomic factors affecting this adoption by farmers is essential for policy-makers. Based on survey data from 1214 farmers in six EU countries this paper analyses *ex ante* the potential adoption of three crop/trait combinations, not yet authorized for cultivation in the EU but widely grown elsewhere, under different policy scenarios (with and without coexistence strategies). Results show that on average there is very high potential adoption of HT oilseed rape, HT maize, as well as *Bt*/HT maize. On average, forty-one percent of the farmers surveyed in the six countries are prepared to plant these GM crops. This figure nevertheless depends to a large extent on the coexistence measures put in place by EU member states. According to the survey, the measures with the strongest negative impact on the potential adoption of GM crops are the obligation to pay compensation to nearby farms in case of unintended admixture, the creation of a GMO tax and the introduction of an insurance mechanism to cover dissemination risks. Regarding technical coexistence measures, the introduction of mandatory isolation distances between GM and conventional crops to avoid admixture is being considered or established by most EU member states. Our research reports on the influence of such distances on the willingness to adopt GM crops and identifies values for these distances above which farmers would prefer to abandon GM crops. Statistic analyses are used to find factors influencing the potential adoption of HT oilseed rape and GM maize. The education level, household income and the farmers' specialization in rape are variables found to be positively related to the adoption of HT rape. Regarding *Bt*/HT maize, the country, farm size, and household income are variables that might influence the adoption.

Disclaimer: The views expressed are purely those of the author and may not in any circumstances be regarded as stating an official position of the European Commission.



## Costs of coexistence and traceability systems in the food industry in Germany and Denmark

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In contrast to the increasing use of GM plants in world-wide agriculture, the acceptance of GM food is still low in the European Union (EU). In order to ensure freedom of choice for consumers and users of GM and non-GM products, GM food and feed products have to be labeled to contain GMOs or GM material in case a tolerance threshold of 0.9 % is exceeded for EU authorized GMOs.

This paper aims to quantify the cost of traceability and co-existence systems for GM food from the seed to the retail level for sugar, wheat starch and rapeseed oil for human consumption in Germany and Denmark respecting the 0.9 % threshold for labeling of GM food. The cost calculation for traceability and co-existence measures are done with a specific model which follows the principle of aggregating all incurred cost for cultivating and transporting crops or processing of the raw material crop on the different levels of the value chain and of increasing the price of the final product at each level. Thus all co-existence and traceability costs emerging in the value chain are transferred to the final end products.

Altogether the measures to ensure co-existence and traceability lead to 5 % to 8 % higher price for GMO-free rapeseed oil in Germany and 8 % to 10 % higher prices in Denmark. In case of GMO-free sugar the price loading amounts to 2 % to 5 % and in case of GMO-free wheat starch to 8 % to 11 % each related to the current price of the respective product in Germany. In Denmark the price loading for non-GM wheat flour for baking will be at the level of 7 % to 8 %. For GMO-free sugar the analog figure lies between 0.3 % and 2 % in Denmark. At the end of the paper the differences in the organization and costs of co-existence measures in the two analyzed countries will be highlighted as well as recommendations for practical implementation and handling of such systems.

## How do coexistence regulations affect markets and welfare?

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This paper presents a theoretical economic model assessing the effect of the level of mandatory coexistence regulations on market and welfare outcome (prices and market shares of GM and non-GM products; profit levels and utility obtained by different types of producers and consumers).

The model is designed to represent in a stylized fashion the effects of isolation distances, which are the most widely used or envisioned coexistence policy instrument in European Union member states at the time being.

We assume that when implementing isolation distances, GMO producers incur costs due to foregone productivity gains on the isolation distance (that has to be planted with a non-GM seed) and additional handling costs (separate sowing). We model these GMO farmers' costs as heterogeneous, because they depend on the size and location of their fields; as increasing with the size of the non-GM supply stream, because the higher the size of this channel, the higher the likelihood that GMO producers' neighbors are willing to grow non-GM crops; and as increasing with the regulation level, because higher isolation distances are more costly to meet.

For simplification matters, we assume that non-GMO producers are not able to take any measure on their own to prevent GMO commingling. Every of them faces a probability that his non-GM harvest may be downgraded, in case it does not comply with the (exogenous in our paper) non-GM purity threshold defined by law. We model this downgrading probability as heterogeneous among non-GM farmers (depending on where they are located, how large are their fields); as increasing with the size of the GM supply stream; and as decreasing with the regulation level (higher isolation distances diminish commingling risks).

All farmers have the same productivity increase from GMO adoption and only differ with respect to their costs of implementing isolation distances (if they grow GMOs) or to their probability of having their harvest downgraded (if they produce non-GMOs). Unit profits are linear and crop choices are endogenous. We model a classical vertical differentiation model on the consumer side.

We solve this model to study the optimal arbitrage between a strict regulation (that does not cause much downgrading but constrains heavily GMO adoption), and a loose regulation (that does not constrain much GMO adoption but causes much non-GMO downgrading). Next, we analyze the effects of ex-post regulation in the form of a compensation scheme towards downgraded crops depending on market-level (endogenously determined) prices.



## On the proportionality of EU spatial *ex ante* coexistence regulations (SEACERs)

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Europe and its member states are currently struggling to implement coherent coexistence regulations on genetically modified (GM) and non-GM crops in all EU Member States. Proposed spatial *ex ante* coexistence regulations (SEACERs) include isolation distances and pollen barriers. The European Commission (EC) has clearly emphasized the proportionality condition of SEACERs. So far the question whether the SEACERs currently proposed by the EC satisfy the proportionality condition has received limited attention in the literature. To address this question, we propose a measure for assessing the spatial impact of SEACERs on the coexistence of a theoretical GM crop with its non-GM counterpart based on a real geographical dataset.

We interpret SEACERs as creating protective halos around non-GM crops in a landscape. Where a halo overlaps with a field where a GM crop is intended to be planted, a shadow is created on the field. Complying with SEACERs implies that shadows are exempt from GM crop planting of a particular crop species. In constraining farmers' planting options, shadows induce opportunity costs which, according to EC regulations, are to be financially borne by GM crop farmers and amortized over the remaining GM crop area. To summarize this effect, we define the shadow factor of a SEACER as the ratio of the total area of the shadow induced by the SEACER to the remaining total area planted with the GM crop assuming perfect compliance with the SEACER. The shadow factor is a measure for the opportunity costs borne by GM crop farmers per planted hectare of the GM crop as a result of complying with a SEACER. The shadow factor can be used to assess the impact of alternative SEACERs in different landscapes under given market conditions as it summarizes the interaction between SEACERs and the spatial configuration of the landscape.

We illustrate the shadow factor by simulating alternative planting scenarios and distance requirements in ArcView® on a sample square in Central France. Our findings show that pollen barriers are more likely to satisfy the proportionality condition than wide isolation distances. In densely planted areas, wide isolation distances may unleash a domino-effect, which further raises their shadow factor and their non-proportional character. These findings are timely for EU policy makers, who are currently struggling to implement coherent coexistence regulations in a heterogeneous landscape of European agriculture.

## Parallel Session 3B: Coexistence Case Studies – New Crops, New Countries

### Towards the development of a coexistence regime for the production of GM potato in Ireland

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The commercialisation of GM potato crops in Europe has called for improved understanding for both producers and consumers with regard to the effectiveness of existing co-existence procedures. As there is no national legislation in place to prevent Irish farmers from securing GM potato seed once authorization has been approved at the EU level, the future availability of transgenic potato crops has set new challenges for policymakers to develop coexistence procedures that minimize gene flow and ensure the efficient segregation of GM, conventional and organic potato systems through all stages of production, in accordance with the 0.9% threshold as outlined by the European Union. The goal of this 4 year research project is to develop a robust protocol for the coexistence of GM and non-GM potato from a whole chain perspective.

Two commercial systems were surveyed and production practices highlighted which could compromise effective coexistence. These included a) seed impurities pre-sowing, b) inadequate machine hygiene, c) pollen and seed dispersal from neighbouring and volunteer plants, d) mixing of crops post-harvest e) waste management and f) inadequate record keeping and labeling. In parallel, the potential for pollen mediated gene flow and the monitoring of the post harvest emergence and persistence of volunteers through a rotation were assessed and traced in field-based trials using two conventional potato varieties (Désirée, pollen donor and British Queen, male sterile pollen receptor).

The extent of pollen mediated gene flow was determined by scoring for berry development on receptor plants and the determination of the paternity of the progeny was completed via microsatellite analysis. This data, modeled on a commercial production layout, will be used to determine the appropriate co-existence barriers to preserve the genetic integrity of non-GM potato crops. Also, the emergence in the field of true potato seed volunteers and ground-keepers, derived from Désirée



post harvest allows for the assessment of appropriate volunteer control practices. Thus, the determination of the minimum segregation distances and the appropriate volunteer control measure, in conjunction with the critical assessment of existing production practices, will assist in the development of a 'whole chain' standard operation procedure to negate the potential of GM admixture in non-GM potato crops, once the cultivation of GM potatoes commences in Ireland.

## **Coexistence challenges for Brazil**

**Roseli ROCHA DOS SANTOS**

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The foundations of the current Brazilian agro biotech research and its applications were established by molecular biology research groups in the mid 70s. Both public agricultural system and many private seed industries have developed new technologies for the varieties research and were responsible for fundamental improvements on Brazilian agriculture, as the spread of soybeans and the successful utilisation of biofuels, among others. These developments associated to the regulations recognising rights have attracted investments from large international groups as Monsanto, Syngenta, Dupont and Bayer. After a long period of political debates and a legal moratorium, the effective possibility of the cultivation of GM seeds in Brazil was assured by new Law on Biosafety of March 24, 2005, which established that CTNBio was responsible for the analysis, processing and decision on the requirements for any activity related to GMO in Brazil. After the Biosecurity law, legalising GMO, the biotechnology take a new impulse, as can be observed by the number of experimental fields release approvals by CTNBio. Until 2008, the only GM food crop authorized for commercial utilisation was the RR soy, which had largely spread in Brazil even during the legal prohibition. The experiments with GM crops, in more recent years presents a clear trend shift from soybeans to maize, being the experimental phenotypes mainly herbicide tolerance and insect resistance (combined). The most important bet of biotech companies in Brazil now is the GM maize is and their next step is to make inroads into the biofuels market, as all the big traders are already doing. The number of requests to CTNBio for planned release of new GM crops has also been growing, among them the GM soy variety tolerant to the 2,4-D herbicide, the GM rice and the GM eucalyptus. With the spread of GM crops the coexistence became an important issue. Greater government controls, enforcing the regulations already in place must to be implemented. On the producer's side, is increasing the demand for a "premium" for conventional crops, which could cover segregation costs and encourage farmers to adopt measures to ensure coexistence more effectively.

## **Gene flow studies for the release of alfalfa mosaic virus resistant transgenic white clover**

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White clover (*Trifolium repens* L.) is the major forage legume species sown in temperate dairy pastures in Australia, and a key pasture legume in temperate climates throughout the world. However, viruses such as alfalfa mosaic virus (AMV) costs Australian farmers approximately \$AU 110 million annually with AMV incidence of up to 35 per cent in white clover dairy pastures.

We have developed, selected, molecularly bred and field evaluated generations of transgenic AMV resistant white clover since 1998 to generate virus-resistant white clover synthetic varieties. Field testing and biosafety assessments of transgenic white clover were conducted first under the non-statutory Genetic Manipulation Advisory Committee (PR64, PR64X) and later licensed through the federally regulated Gene Technology Act 2000 (DIR 047/2003 and DIR089/2008) regimes.

White clover is an obligate cross-pollinated species. Understanding the dynamics of gene flow is therefore an important consideration for the release of transgenic white clover. Outcomes from extensive field evaluation of transgenic white clover, and associated biosafety research, including gene flow modelling using phenotypically distinct non-transgenic genotypes, will be presented and discussed.



## Coexistence between GM and non-GM cotton in India

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The only GM crop commercialized so far in India is the insect tolerant Bt cotton which was approved in 2002 after seven years of regulatory work. Cotton accounted for about 48% of the insecticides consumed in India. The profitability of the cotton farmer with an average yield of 306Kg of kapas/ha was very poor. The technology increased cotton yields to 560Kg kapas/ha by 2006 and reduced insecticide consumption by more than 50%. By 2009 about 90% of the cotton acreage got converted to Bt cotton hybrids from the traditional non-Bt hybrids and OPVs. Cotton oil is used as a cooking medium in certain parts of India. Neither the Government nor the consumers differentiated between GM and non-GM cotton oil. No labeling requirements are prescribed by the Government.

The success of Bt cotton has encouraged the Government to come out with a Biotech policy that encourages the use of technology in many crops including the food crops. The first GM food crop Bt Egg Plant is slated for approval in 2009. More GM crops like rice, corn, sorghum, vegetables, etc are under various stages of trials. Shortage of labour and water and increasing salinity of soil will make other traits like herbicide tolerance, drought tolerance, salt tolerance, etc, crucial for enhancing the productivity of Indian agriculture. The Government is expected to take time in carrying different stakeholders in the approval process. The introduction of output traits will test the system with regard to segregated supply chain.

## Parallel Session 3C: Testing Methodologies and Traceability Systems

### Harmonising GMO analysis in Europe: A ready-to-use multi-target analytical system for GMO detection for European control laboratories

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This presentation describes the development, production and testing of a high-throughput analytical system, a screening tool for the unequivocal simultaneous identification of all currently EU approved and all unapproved GMOs known to the Community Reference Laboratory for GM Food and Feed (CRL-GMFF) established according to Regulation (EC) No 1829/2003. Further it illustrates the rationale and comparative advantage of the strategy selected as well as the formulation, potentiality and flexibility of the system.

The approach, developed in response to the constantly growing testing needs throughout the world, allows the event-specific simultaneous detection of 39 single-insert GMOs and of stacked events derived from them. System performance (specificity, efficiency etc) has been successfully confirmed by experimental testing conducted within the CRL-GMFF and in collaboration with European control laboratories. The limit of detection (LOD) has been determined to be at least 0.045% expressed in haploid genome copies, thus in full compliance with EU requirements for method LOD.

The methodology and format allow immediate implementation since RT-PCR based on 96-well platforms is used worldwide and adopted by most EU control laboratories. The use of ready-to-use plates, guaranteed to avoid variability within the same batch, improves comparability of results.

Finally, the approach presented is flexible and constitutes the starting point for a whole new set of applications: inclusion of new GMO targets as methods become available, formulation of crop-specific or screening pre-spotted plates, or even 96-well pre-spotted plates for quantitative determination of GM content.

The 'Real-time PCR based ready-to-use multi-target analytical system for GMO detection' developed by the Joint Research Centre, is the first analytical tool worldwide allowing the detection of so many GM events simultaneously using event-specific targets.



## **GMO testing in seed – An overview of current international activities and harmonization efforts**

**Kevin G. BOYCE**

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Since 1924, the International Seed Testing Association (ISTA) is the international body for defining parameters determining seed quality, standardizing the sampling and testing methodologies and monitoring the performance of laboratories analyzing seed quality. Since 2001 ISTA is actively working on GMO detection in seed lots. Sampling systems for seed lots have been developed, calculation programs for calculating laboratory sample sizes have been realized (SeedCalc), 12 rounds of international proficiency tests have been executed and an international accreditation system following a performance based approach has been established on international level.

Today ISTA is of the opinion that any obligation to the use of a single technique in the detection could impair the capability to detect and quantify GM seeds and that in order to cope with the different aims and situations where quantification of GM seed is required, more than one unit is acceptable for reporting quantitative results of GM seeds in conventional seed lots. The presentation in a comprehensive overview highlights the latest achievements and explains the current positions in GM seed testing.

## **Qualitative and quantitative molecular testing methodologies and traceability systems for Bt crops commercialized or under field trials in India**

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The global area under genetically modified (GM) crops has continued to grow tremendously in 2008 reaching 125 million hectares. Despite the high adoption rate and future promises pertaining to GM crops, there are a multitude of concerns related to environmental and food safety along with socio-ethical issues about the impact of GM crops. However, the employment of transgene technology in food crops has led to public concern pertaining to their potential risks to the environment and human health. The novel traits incorporated in transgenic crops should be evaluated and detected for environmental safety, food security, ethical and other related aspects.

As the number of GM crops is increasing, it is necessary to use appropriate qualitative and quantitative methods for detection of GM crops. Hence, the development of reliable methods of GM detection, identification, tracing and quantification has become a challenging task. In India, so far, five events of Bt cotton, viz., MON531 with *cry1Ac* gene, MON15985 with *cry1Ac* and *cry2Ab* genes, GFM-*cry1A* with fused *cry1Ac-cry1Ab* gene, Event1 with *cry1Ac* and BN-Bt with truncated *cry1Ac* gene have been commercialized and also other Bt crops such as Bt brinjal with *cry1Ac/cry1Ab* genes, Bt cauliflower, Bt rice, Bt okra with *cry1Ac* gene are under different stages of field trials. It is imperative to develop diagnostic tools for the different Bt crops and polymerase chain reaction (PCR) is the most widely used and accepted analytical method for GM detection.

The present study reports on the development of PCR based qualitative and quantitative testing assays for detection of Bt cotton events, Bt brinjal, Bt cauliflower, Bt rice and Bt okra. The multiplex PCR assays for simultaneous detection of specific *cry* gene, *Cauliflower Mosaic Virus* 35S promoter, *nos* terminator and selectable marker gene, viz., *nptII* (*neomycin phosphotransferase*) or *aadA* (*aminoglycoside-3'-adenyltransferase*), in different Bt crops were developed.

The quantitative real time PCR assays have also been reported for estimation of copies of specific transgene integrated in the different Bt crops. In India, to meet the regulatory obligations, as per the Supreme Court of India's stipulations for conducting field trials of GM crops, a protocol for testing contamination upto 0.01% has to be established. In order to develop an efficient traceability system, the assays for detection of specific GM trait/transgene upto 0.01% have also been developed and validated. The present study reveals that the developed PCR assays provide a robust, cost-effective and sensitive method that can be used to qualitatively and quantitatively to detect different Bt crops.

## Quantification of copy number ratio in maize MON810 by digital PCR

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Quantitative analysis of genetically modified (GM) foods is a measurement that requires estimation of the amount of the transgenic event relative to an endogenous gene. Regulatory authorities in the European Union have defined the labelling threshold for GM food on the copy number ratio between the transgenic event and an endogenous gene. Real-time polymerase chain reaction (PCR) is currently being used for quantification of GMOs. Limitations in real time PCR applications to detect very low number of DNA targets has led to new developments such as the digital PCR which allows precise and accurate measurement of DNA copies.

Digital PCR involves splitting the PCR solution into a very large number of individual assays. In the case of the instrument used in this study, the digital array splits the sample into 765 individual partitions of 6 nL volume each. The concentration of DNA in the PCR assay is adjusted so that when the DNA molecules are delivered across the 765 partitions, not all partitions will contain a DNA molecule. Following amplification of the DNA in the partitions, the number of partitions that contain amplified DNA is counted. Based on the proportion of positive partitions, statistics can then be used to estimate the number of DNA molecules present in the original solution. The read-out from the instrument provides real-time data (Ct values) and amplification curves for each partition. One of the major strengths of digital PCR is that it allows investigation of the behaviour of single molecule templates in PCR. This is difficult to achieve on a large scale using conventional real-time PCR.

The present study focused on quantifying the GM target sequence from Maize MON 810 by digital PCR. Kernels from MON810 hybrids which differ only in the transgenic locus originating from the female and male parents (provided by Monsanto) together with certified reference materials (ERM-BF413 and BF413 0%, 0.1%, 1%, 2%, and 5%) from the Institute for Reference Material and Measurements (IRMM, Geel, Belgium) were used in this study. Based on the obtained results, the GM seeds used for preparing the MON810 ERM-BF series were indeed hemizygous hybrid seeds with the GM allele carried by the female parent. These results agree with Zhang et. al, 2008 who estimated empirically the GM percentage per haploid genome taking into account the type of tissue and GM parental origin in MON810 certified reference materials. Using digital PCR it was possible to determine the GM copy number ratio for the all ERM-BF series without the use of an external calibrant.



## **Multiplex DNA detection system for identification of genetically modified organisms (GMOs) in food and feed chains**

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The adoption of GM crops has continuously increased over the last decade with 125 million hectares of these crops grown in 2008 worldwide. There is a great demand from both the general public and the organic farming community for the possibility to choose from genetic modification (GM) free or GM-containing foodstuffs and for the ability to grow GM-free crops. Coexistence is a way of allowing farmers to choose between conventional, organic and GM crop production and demands a traceability system. In Europe, such traceability is legally mandated for food and feed originating from or containing GMOs. In order to monitor and enforce compliance with coexistence regulations, authorities require the ability to trace, detect and identify GMOs.

Conventional real time PCR reaches a 0.1% detection level for most targets. However, the numbers of different approved and unapproved GM plants make detection and identification of GM material in food a time-consuming and expensive puzzle in cases when many subsequent real time PCR reactions have to be performed for a final identification. There is a clear need for a method that can identify many DNA targets within a limited set of experiments and at a sensitive level.

Padlock probe (PLP), ligation-based multiplex detection provides a promising method to meet all the demands of GM detection. This method is based on the detection of a unique DNA sequence by a PLP in isolated plant DNA. Only when both ends of the PLP hybridize juxtaposed to their specific complementary target sequence, ligation can occur and will result in a circular molecule. Universal primer sites in the PLP then enable amplification of only the circularized probes. Only amplified probes will yield a signal when the pool of PCR products is hybridized to a microarray.

PLPs have been developed for 29 targets already, including GM plant species and several GM events, elements and constructs. We have detected positive targets in mixtures up to 13 DNA targets. During the PLP experiments 0.1% detection level has been reached so far in case of elements, and 1% in case of events. Similar results were reached during transfer of the method to another institute. Further aims are to design padlock probes for more targets and to lower the detection level. An alternative, so called rolling circle amplification method is also being explored. The latest results will be presented.