



**14th INTERNATIONAL SYMPOSIUM ON THE  
BIOSAFETY OF GENETICALLY MODIFIED  
ORGANISMS**

**Environmental Risk Assessment (ERA) of Genetically Modified  
Organisms (GMOs): Past, Present and Future**

**Guadalajara, México, 4–8 June 2017**

## Sponsors

*We would like to thank the following sponsors for providing support to organize the ISBGM014 in Guadalajara, Mexico*



## Welcome Note

### Foreword from the Chair of the Local Organizing Committee of ISBGMO14

I would like to welcome you all to ISBGMO14 in June 2017, in the beautiful city of Guadalajara, in central Mexico. Even though in Mexico we started early to use biotechnology –we had our first experimental field trial in 1988– we have not really been able to fully benefit from the advantages of this technology as can be seen from the fact that we use GM-cotton, some GM soybeans, but in the case of maize, certainly our most important crop, we have only been able to carry out field releases at the experimental and pilot phase stage, but never reached commercial releases. Unfortunately, this is not an isolated occurrence as many other countries are still debating whether or not to use the technology, mainly because unfounded fears and distrust of the technology. Therefore, the ISBGMO14 symposium, with its theme "***Environmental Risk Assessment of Genetically Modified Organisms: past, present and future***", may shed some light into the ways we need to move forward, and use the new and exciting technologies being developed. During the symposium we will be listening to experts talk about the lessons from the past, review our current status, and discuss exciting new tools such as genome editing, gene drives, and the use of iRNA technology, this in turn may help us ensure that this time we will be riding the wagon of biotechnology instead of just looking it move away from us.

**Ariel Alvarez-Morales – LOC Chair**

A handwritten signature in black ink, appearing to read 'A. Alvarez-Morales'.

### Foreword from the President of International Society for Biosafety Research (ISBR)

In welcoming you all to ISBGMO14 in Guadalajara, I am prompted to remind you of the ISBR mission, part of which reads '*to promote the practice and application of science in the fields of agricultural biotechnology and environmental risk analysis*'. I can think of no time during my career when the need to defend the practice and application of sound science has been more important, or the threat to evidence-based action and policy has been greater. Last Sunday my newspaper, under the headline '*Standing Up For The Facts*' showed pictures of a huge rally in London, part of a global march against what the demonstrators see as the promulgation of 'alternative facts' by populist politicians who ignore scientific evidence. To quote further from the ISBR mission, '*promoting scientifically sound research*' and '*fostering communication and technical exchange among experts*' has, in these times of 'fake news', taken on a renewed urgency and a more crucial significance. And of course, the relevance and importance of ISBR in providing a platform for constructive dialogue between scientists, regulators, policy-makers and others involved in the safe application of biotechnology, has never been greater. So, if you are not a member, do join us. Help us to strengthen the role of high quality research in biosafety assessments – you could begin by really getting involved in ISBGMO14; challenge assumptions and ask questions (however naïve you feel them to be, no-one will mind). I look forward to meeting you.

**Alan Gray - ISBR President**

A handwritten signature in black ink, appearing to read 'Alan Gray'.

## Committees

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## Schedule

### Day 1 – 5 June 2017 – Morning

<b>Welcome Addresses</b>	
09:00	Chair of the ISBGMO14 Local Organising Committee (LOC) <b>Ariel Álvarez</b> , <i>Cinvestav Unidad Irapuato</i>
09:10	President of International Society of Biosafety Research (ISBR) <b>Alan Gray</b> , <i>Centre for Ecology and Hydrology (CEH)</i>
09:20	Student travel grant awards offered by the Agricultural Biotechnology Stewardship Technical Committee (ABSTC) <b>Pamela M Bachman</b> , <i>Monsanto</i>
09:30	Challenges and opportunities: A Latin American perspective <b>Sol Ortiz García</b> , <i>Comisión Intersecretarial de Bioseguridad de los Organismos Genéticamente Modificados (CIBIOGEM)</i>
<b>Plenary Session I: Advancing ERA of GMOs – Learning from the Past to Further Advance ERA</b>	
<i>Organisers: Sarah Davis, Canadian Food Inspection Agency (CFIA) &amp; Yann Devos, European Food Safety Authority (EFSA)</i>	
09:50	Introduction
09:55	Keynote: Environmental effects of GM crops: Findings of a National Academy of Sciences, Engineering and Medicine (US-NASEM) report <b>Fred Gould</b> , <i>North Carolina State University (NCSU)</i>
10:25	Weeds or wimps? 30 years of experience from evolving ERA, deliberate release, experimental research, the development of theory, unintended free-living transgenic plants, unanticipated products – and a century of experience of non-engineered crops gone wild <b>Norman Ellstrand</b> , <i>University of California (UC)</i>
10:45	<b>COFFEE BREAK</b>
11:15	Assessing effects of GM plants on valued non-target organisms <b>Jörg Romeis</b> , <i>Agroscope</i>
11:35	Modernizing risk assessment for GM crops – Learning from experience <b>Phil Macdonald</b> , <i>Canadian Food Inspection Agency (CFIA)</i>



11:55	Resistance evolution in insect pests and weeds in GM crop systems <b>Nick Storer</b> , <i>Dow AgroSciences</i>
12:15	Panel discussion <b>Christine Tibelius</b> , <i>Canadian Food Inspection Agency (CFIA)</i>
13:00	<b>LUNCH</b>

## Day 1 – 5 June 2017 – Afternoon

Parallel Sessions I, II & III			
14:30	<p><b>Parallel Session I: Effects of vertical gene flow between GM plants and sexually compatible relatives – Dangerous liaisons?</b></p> <p><i>Organisers: Sol Ortiz García, Comisión Intersecretarial de Bioseguridad de los Organismos Genéticamente Modificados (CIBIOGEM) &amp; Yann Devos, European Food Safety Authority (EFSA)</i></p>	<p><b>Parallel Session II: Types of evidence and efforts necessary to inform the safety assessment of unintended effects in GM plants</b></p> <p><i>Organisers: Sarah Davis, Canadian Food Inspection Agency (CFIA) &amp; Jörg Romeis, Agroscope</i></p>	<p><b>Parallel Session III: Biosafety research, risk assessment experiences and capacity building in Latin America</b></p> <p><i>Organisers: Jaime E Padilla-Acero, AgroBio &amp; Juan Manuel de la Fuente Martínez, Monsanto</i></p>
14:30	<b>Introductions</b>		
14:35	<p>When vertical gene flow matters</p> <p><b>Norman Ellstrand</b>, <i>University of California (UC)</i></p>	<p>Experience gained on the assessment of unanticipated unintended changes in GM plants</p> <p><b>Wayne A Parrott</b>, <i>University of Georgia (UGA)</i></p>	<p>Argentina's experience on the regulated use of GM crops</p> <p><b>Martín Lema</b>, <i>Ministry of Agro-industry &amp; Quilmes National University</i></p>
14:55	<p>Assessment of consequences associated with potential gene flow from transgenic maize to landraces</p> <p><b>Silverio García Lara</b>, <i>Tecnológico de Monterrey</i></p>	<p>Science informing policy – A study of insertional effects and implications on Canada's approach to environmental safety</p> <p><b>Heather Shears</b>, <i>Canadian Food Inspection Agency (CFIA)</i></p>	<p>The work of IICA and the status of Central American countries on biosafety</p> <p><b>Pedro J Rocha</b>, <i>Inter-American Institute for Cooperation on Agriculture (IICA)</i></p>
15:15	<p>Potential for gene flow from transgenic maize (<i>Zea mays</i> L.) to eastern gamagrass (<i>Tripsacum dactyloides</i> L.)</p> <p><b>Duška Stojšin</b>, <i>Monsanto</i></p>	<p>Unintended effects of gene insertions into plants and their impact on commercialisation as agricultural biotechnology products</p> <p><b>Laura S Privalle</b>, <i>Bayer</i></p>	<p>Brazil's experience on the regulated use of GM crops</p> <p><b>Flavio Finardi-Filho</b>, <i>University of Sao Paulo</i></p>

15:35	<p>Across time and space: Transgene flow between oilseed crops and weedy relatives</p> <p><b>Linda M Hall</b>, <i>University of Alberta</i></p>	<p>Rodent feeding trials with whole food/feed – Summarising experiences from the EU-funded projects GRACE and GTwYST</p> <p><b>Joachim Schiemann</b>, <i>Julius Kühn-Institute (JKI)</i></p>	<p>CIAT GM research in Colombia to address agriculture sustainability and micronutrient malnutrition</p> <p><b>Joe Tohme</b>, <i>International Center for Tropical Agriculture (CIAT)</i></p>
15:55	<b>COFFEE BREAK</b>		
16:25	<p>GM gene flow in sugar beet: Regulatory experience in the United States</p> <p><b>Subray Hegde</b>, <i>US Department of Agriculture's Biotechnology Regulatory Services (USDA- BRS)</i></p>	<p>The value of <i>in planta</i> data for the non-target risk assessment</p> <p><b>Jörg Romeis</b>, <i>Agroscope</i></p>	<p>An environmentally friendly GM technology to effectively decrease the use of fertilisers and herbicides in agriculture</p> <p><b>Luis Herrera-Estrella</b>, <i>Centro de Investigación y de Estudios Avanzados</i></p>
16:45	<p>22 years and 22,979 trees later: Lessons from field- testing GM trees in the USA</p> <p><b>Amy L Klocko</b>, <i>Oregon State University (OSU)</i></p>	<p>Future avenues and developments: Omics technologies as part of risk assessment strategies</p> <p><b>Esther J Kok</b>, <i>RIKILT Wageningen University and Research (UR)</i></p>	<p>The use of GM crops in México: Experiences in biosafety, institutional capacity, and the effect of regulations on the evolution of national policies</p> <p><b>Natalhie Beatriz Campos Reales Pineda</b>, <i>Comisión Intersecretarial de Bioseguridad de los Organismos Genéticamente Modificados (CIBIOGEM)</i></p>
17:05	<p>Formulating and testing hypotheses about the likelihood of GM crops and hybrids becoming harmful weeds</p> <p><b>Alan Raybould</b>, <i>Syngenta Crop Protection</i></p>	<p>Evaluating biotech potatoes, one variety at a time</p> <p><b>Susan Collinge</b>, <i>JR Simplot Company</i></p>	<p>Biosafety regulatory systems overseeing the use of GMOs in the Latin America and the Caribbean region</p> <p><b>Ayrton André Rosado Huaynasi</b>, <i>International Centre for Genetic Engineering and Biotechnology (ICGEB)</i></p>
17:25	<p>Panel discussion</p> <p><b>Alan Gray</b>, <i>Centre for Ecology and Hydrology (CEH)</i> (moderator)</p>	<p>Panel discussion</p> <p><b>Phil Macdonald</b>, <i>Canadian Food Inspection Agency (CFIA)</i> (moderator)</p>	<p>Panel discussion</p> <p><b>Ariel Álvarez</b>, <i>Cinvestav Unidad Irapuato</i> (moderator)</p>
18:10	Poster Session I		

## Day 2 – 6 June 2017 – Morning

### Plenary Session II: Advancing ERA of GMOs – Learning from the Past to Further Advance ERA

Organisers: **Mònica García-Alonso**, *Estel Consult Ltd* & **Jörg Romeis**, *Agroscope*

09:00	<b>Introduction</b>
09:05	Keynote: Science and values in governing GMOs: Facts, fictions, and fantasies <b>Sheila Jasanoff</b> , <i>Harvard University</i>
09:35	Assessment of environmental risks to ecosystem services. Where are we now, and where are we going? <b>Lorraine Maltby</b> , <i>University of Sheffield</i>
09:55	Problem formulation: Identifying data that are relevant to ERA <b>Alan Raybould</b> , <i>Syngenta Crop Protection</i>
10:15	Development of a construct-based risk assessment framework for GM crops <b>Clara Rubinstein</b> , <i>Monsanto</i>
10:35	<b>COFFEE BREAK</b>
11:05	When science meets policy: The undoing of the Guidance on risk assessment developed under the Cartagena Protocol for Biosafety <b>Karen Hokanson</b> , <i>University of Minnesota (UM)</i>
11:25	Beyond the OECD Blue Book: Building consensus on environmental considerations for risk/safety assessment for the release of transgenic plants <b>Phil Macdonald</b> , <i>Canadian Food Inspection Agency (CFIA)</i>
11:45	Identifying surrogate environments to facilitate data transportability for ERA <b>Andrew Roberts</b> , <i>International Life Sciences Institute (ILSI) Research Foundation</i>
12:05	Panel discussion <b>Mònica García-Alonso</b> , <i>Estel Consult Ltd</i> (moderator)
12:50	<b>LUNCH</b>

## Day 2 – 6 June 2017 – Afternoon

Parallel Sessions IV, V & VI			
14:20	<p><b>Parallel Session IV: ERA vs. ecological research – The relevance of a good problem formulation to ensure that gathered data are useful for ERA</b></p> <p><i>Organisers: Wendy Craig, International Centre for Genetic Engineering and Biotechnology (ICGEB) &amp; Mònica García-Alonso, Estel Consult Ltd</i></p>	<p><b>Parallel Session V: Plant genome-editing – Any novel features to consider for ERA and regulation?</b></p> <p><i>Organisers: Nina Duensing, Federal Office of Consumer Protection and Food Safety (BVL) &amp; Detlef Bartsch, Federal Office of Consumer Protection and Food Safety (BVL) &amp; Thorben Sprink, Julius Kühn-Institute (JKI)</i></p>	<p><b>Parallel Session VI: GMOs in IPM</b></p> <p><i>Organisers: Jennifer Anderson, DuPont Pioneer &amp; Michael Meissle, Agroscope</i></p>
14:20	<b>Introductions</b>		
14:25	<p>An introduction to problem formulation</p> <p><b>Wendy Craig</b>, <i>International Centre for Genetic Engineering and Biotechnology (ICGEB)</i></p>	<p>What is unique about genome editing?</p> <p><b>Wayne A Parrott</b>, <i>University of Georgia (UGA)</i></p>	<p>The principles of Integrated Pest Management – How do GM crops fit?</p> <p><b>Michael Meissle</b>, <i>Agroscope</i></p>
14:45	<p>Regulatory use of problem formulation – GM mustard</p> <p><b>Vibha Ahuja</b>, <i>Biotech Consortium India Limited</i></p>	<p>ERA challenges associated with genome-edited crops from a public risk assessor perspective</p> <p><b>Thorben Sprink</b>, <i>Julius Kühn-Institute (JKI)</i></p>	<p>The role and value of regulation of IPM programs for <i>Bt</i>-crops</p> <p><b>Graham Head</b>, <i>Monsanto</i></p>
15:05	<p>Taking stock of the ERA of GM higher plants</p> <p><b>Patrick Rüdelsheim</b>, <i>Perseus</i></p>	<p>CRISPR-Cas gene editing and similarities to conventional breeding outcomes: A product developer perspective</p> <p><b>Maria Fedorova</b>, <i>DuPont Pioneer</i></p>	<p>Implementing best practices to complement biotech resistance management guidelines</p> <p><b>Timothy Dennehy</b>, <i>Bayer</i></p>

15:25	<p>The use of a problem formulation approach to focus the nutritional assessment of food and feed originating from a novel GM crop</p> <p><b>Phil Brune</b>, <i>Syngenta Crop Protection</i></p>	<p>Regulatory challenges: Technology-based vs. product-based regulations and potential impact on product monitoring</p> <p><b>Martín Lema</b>, <i>Ministry of Agro-industry &amp; Quilmes National University</i></p>	<p>Implementing IPM for <i>Bt</i>-eggplant: Meeting the challenges or dreaming the impossible dream?</p> <p><b>Anthony M Shelton</b>, <i>Cornell University</i></p>
15:45	<b>COFFEE BREAK</b>		
16:15	<p>For GM breeding stacks, crop composition and transgene expression are predicted by the single component events</p> <p><b>Rod Herman</b>, <i>Dow AgroSciences</i></p>	<p>Preparing for future biotechnology products – Perspectives on the National Academies of Sciences, Engineering and Medicine (US-NASEM) report</p> <p><b>Jeffrey D Wolt</b>, <i>Iowa State University (ISU)</i></p>	<p>Implementing IPM for bean golden mosaic virus in common bean in Brazil</p> <p><b>Josias Correa de Faria</b>, <i>Embrapa Rice and Beans</i></p>
16:35	<p>The use of problem formulation in Mexico</p> <p><b>Sol Ortiz García</b>, <i>Comisión Intersecretarial de Bioseguridad de los Organismos Genéticamente Modificados (CIBIOGEM)</i></p>	<p><b>World Café session</b> – Three interactive table discussions (each of 20') on novel features to consider for plant genome editing, focusing on:</p>	<p>IPM and weed management for the future</p> <p><b>Micheal DK Owen</b>, <i>Iowa State University (ISU)</i></p>

16:55	<p>Using expert panels and problem formulation to inform risk assessments for gene flow from GM crops to wild relatives</p> <p><b>Karen Hokanson, University of Minnesota (UM)</b></p>	<p>Café table 1: ERA – Novel demands?</p> <p><b>Thorben Sprink, Julius Kühn-Institute (JKI)</b></p> <p>Café table 2: Monitoring – Detection and identification of new products/traits after placing on the market</p> <p><b>Nina Duensing, Federal Office of Consumer Protection and Food Safety (BVL)</b></p>	<p>Implementing IPM for cotton in Arizona and Mexico</p> <p><b>Peter Ellsworth, University of Arizona (UA)</b></p>
17:15	<p>Panel discussion</p> <p><b>Alan Gray, Centre for Ecology and Hydrology (CEH) (moderator)</b></p>	<p>Café table 3: Global harmonisation of regulation</p> <p><b>Detlef Bartsch, Federal Office of Consumer Protection and Food Safety (BVL)</b></p> <p>Panel discussion</p> <p><b>Detlef Bartsch, Federal Office of Consumer Protection and Food Safety (BVL) (moderator)</b></p>	<p>Panel discussion</p> <p><b>Jennifer Anderson, DuPont Pioneer &amp; Michael Meissle, Agroscope (moderators)</b></p>
18:00	Pecha Kucha Session		
19:00	Poster Session II		
20:30	Membership Meeting		

### Day 3 – 7 June 2017 – Morning

Parallel Sessions VII, VIII & IX			
08:30	<b>Parallel Session VII: ERA of RNAi-based GM plants &amp; data transportability</b>  <i>Organisers: Pamela M Bachman, Monsanto &amp; Joachim Schiemann, Julius Kühn-Institute (JKI)</i>	<b>Parallel Session VIII: ERA studies/tools</b>  <i>Organisers: Adinda De Schrijver, Scientific Institute of Public Health &amp; Michael Meissle, Agroscopie</i>	<b>Parallel Session IX: Regulatory issues &amp; data requirements</b>  <i>Organisers: Christine Tibelius, Canadian Food Inspection Agency (CFIA) &amp; Karen Hokanson, University of Minnesota (UM)</i>
08:30	<b>Introductions</b>		
08:35	Safety assessment for potatoes with traits based upon RNA interference  <i>Cathy Zhong, JR Simplot Company</i>	<i>Bt</i> -rice in China – Focusing the non-target risk assessment  <i>Yunhe Li, Chinese Academy of Agricultural Sciences (CAAS)</i>	Suppression gene drives for non-insect pests and conservation biology  <i>Allison Snow, Ohio State University (OSU)</i>
09:05	Assessing the impact of transgenic RNAi plants on non-target organisms: Current knowledge and future directions  <i>Xuguo Zhou, University of Kentucky (UKY)</i>	Resistance risk assessment of target pests to <i>Bt</i> -rice in China  <i>Lanzhi Han, Chinese Academy of Agricultural Sciences (CAAS)</i>	Draft ERA of a hypothetical gene drive <i>Aedes aegypti</i> for population suppression  <i>Paulo Paes De Andrade, Universidade Federal de Campina Grande</i>
09:35	Environmental fate of an insecticidal, double-stranded RNA in two Brazilian soils  <i>Daniella PV Braga, Monsanto</i>	Biosafety aspects in the pre-commercialisation phase of developing GM sugarcane in South Africa  <i>Sandy Snyman, South African Sugarcane Research Institute (SASRI)</i>	Regulating gene drives: Are African regulators up to the task?  <i>Olalekan Akinbo, NEPAD African Biosafety Network of Expertise (ABNE)</i>
10:05	Research on modifying plants to produce interfering RNA: iPlanta a new EU scientific network  <i>Jeremy Sweet, JT Environmental Consultants</i>	Non-pesticidal R-proteins: A case study of late blight protected potato  <i>Cathy Zhong, JR Simplot Company</i>	ERA: Does science matters?  <i>Marlene Keese, Therapeutic Goods Administration (TGA)</i>
10:35	<b>COFFEE BREAK</b>		



11:05	The recent tendency in the ERA of GM crops in Japan <b>Ryo Ohsawa</b> , <i>University of Tsukuba</i>	Can systematic reviews inform GMO risk assessment and risk management?  <b>Ralf Wilhelm</b> , <i>Julius Kühn-Institute (JKI)</i>	Refining data requirements for risk assessments of GM plants  <b>Heidi Mitchell</b> , <i>Office of the Gene Technology Regulator (OGTR)</i>
11:35	Data transportability of non-target arthropod field data for GM traits across crops and geographies  <b>Peter Asimwe</b> , <i>Monsanto</i>	Use of species sensitivity distributions to characterise hazard for insect control traits  <b>Chad Boeckman</b> , <i>DuPont Pioneer</i>	Transgenic <i>Agrostis stolonifera</i> : Gene flow, establishment and abandonment  <b>Carol Mallory-Smith</b> , <i>Oregon State University</i>
12:05	Data transportability of confined field trials from cultivation country to import country  <b>Shuichi Nakai</b> , <i>Monsanto</i>	Interactions between stacked <i>Bt</i> -maize and herbivorous aphids and spider mites  <b>Yinghua Shu</b> , <i>South China Agricultural University</i>	The limited value of agronomic and phenotypic characterisation for the risk assessment of GM crops intended for import in the EU  <b>Lieselot Bertho</b> , <i>Monsanto</i>
12:35	Evaluating the transportability of ecological risk assessment on transgenic crops to associated breeding stacks  <b>Justin McDonald</b> , <i>Syngenta</i>	Characterisation of the differences between natural <i>Bt</i> -toxins and commercialised GMO <i>Bt</i> -toxins  <b>Jonathan Latham</b> , <i>Bioscience Resource Project</i>	Future introductions of GM microbial biocontrol agents in the EU – Is current legislation and risk assessment fit for purpose?  <b>Boet Glandorf</b> , <i>National Institute of Public Health and the Environment (RIVM)</i>
13:05	<b>LUNCH</b>		
13:00	<b>FIELD EXCURSION</b>		
18:30	<b>DEPARTURE FROM HOTEL TO HOSPICIO CABAÑAS</b>		
19:00	<b>GALA DINNER</b>		
22:00	<b>RETURN TO HOTEL</b>		

## Day 4 – 8 June 2017 – Morning

Parallel Sessions X, XI & XII			
09:00	<b>Parallel Session X: Gene drive systems and GM insects for pest control</b>  <i>Organisers: <b>Anthony Shelton</b>, Cornell University &amp; <b>Andrew Roberts</b>, International Life Sciences Institute (ILSI) Research Foundation</i>	<b>Parallel Session XI: Biosafety and ERA of GM algae</b>  <i>Organiser: <b>Tomal Dattaroy</b>, Reliance Industries Ltd</i>	<b>Parallel Session XII: Capacities for the risk assessment of GMOs: challenges to build sustainable systems</b>  <i>Organiser: <b>Carmen Enriqueta Vicién</b>, Universidad de Buenos Aires</i>
09:00	<b>Introductions</b>		
09:05	Trialing gene drives to control invasive species: The what, where and how?  <b>Tim Harvey-Samuel</b> , Pirbright Institute	Algal biology – Technological advancements to harness potential benefits and regulatory implications  <b>Tomal Dattaroy</b> , Reliance Industries Limited	CONABIA as FAO Centre of reference for biosafety of GMOs  <b>Martín Lema</b> , Ministry of Agro-industry & Quilmes National University
09:25	Biosafety for gene drive research  <b>Paul De Barro</b> , Commonwealth Science and Industrial Research Organisation (CSIRO)	Overview of guidance and data needs for ERA of GM algae  <b>Carolina Peñalva-Arana</b> , US Environmental Protection Agency (US EPA)	Capacity building support program for Paraguay  <b>Danilo Fernández Ríos</b> , Universidad Nacional de Asunción
09:45	Policy and regulatory issues for use of gene drives to control insect-borne human disease and insect agricultural pests  <b>Robert Friedman</b> , J. Craig Venter Institute (JCVI)	Evaluation of phenotype stability and ecological risk of a GM alga in open pond production  <b>Stephen Mayfield</b> , University of California San Diego (UCSD)	Managing agricultural biotechnology research for food security in Africa: Capacity building efforts for research, innovation and application  <b>Ruth Mbabazi</b> , Michigan State University (MSU)
10:05	Problem formulation for the use of gene drive in <i>Anopheles gambiae</i> to control malaria transmission  <b>Andrew Roberts</b> , International Life Sciences Institute (ILSI) Research Foundation	Environmental and biotechnological risk assessment of GM algae  <b>Jeremy Sweet</b> , JT Environmental Consultants	e-Learning courses: Providing a sustainable and interactive resource  <b>John Teem</b> , International Life Sciences Institute (ILSI) Research Foundation

10:25	<b>COFFEE BREAK</b>		
10:55	<p>ERA of GMOs with engineered gene drives – Lessons from non-GM ERAs?</p> <p><b>Peter Thygesen</b>, <i>Office of the Gene Technology Regulator (OGTR)</i></p>	<p>Using algae biotechnology to develop high-value colostrum proteins as formula ingredients</p> <p><b>Xun Wang</b>, <i>Triton Algae Innovations</i></p>	<p>A curriculum-based approach to teaching biosafety through e-learning</p> <p><b>Dennis O Ndolo</b>, <i>International Centre for Genetic Engineering and Biotechnology (ICGEB)</i></p>
11:15	<p>Challenges for the regulation of gene drive technology</p> <p><b>Detlef Bartsch</b>, <i>Federal Office of Consumer Protection and Food Safety (BVL)</i></p>	<p>Biosafety assessment for environmental release of GM algae: An Indian perspective</p> <p><b>Abhijit Poddar</b>, <i>Biosafety Support Unit</i></p>	<p>Brazilian capacity building experiences in biosafety: Impacts in governance and supporting decision-making</p> <p><b>Deise Maria Fontana Capalbo</b>, <i>Brazilian Agriculture Research Corporation (EMBRAPA) – Environment</i></p>
11:35	<p>Friendly™ Aedes” and the challenges for the regulation of genetically modified insects in Brazil</p> <p><b>Fabiano dos Santos Ferreira</b>, <i>Oxitec</i></p>	<p>Risk assessment of GM algae</p> <p><b>Richard Sayre</b>, <i>New Mexico Consortium (NMC)</i></p>	<p>Institutional capacity strengthening to overcome systems challenges towards building functional biosafety systems in Africa</p> <p><b>Samuel Edudzi Timpo</b>, <i>NEPAD African Biosafety Network of Expertise (ABNE)</i></p>
11:55	<p>Panel discussion)</p> <p><b>Hector Quemada</b>, <i>Donald Danforth Plant Science Center</i> &amp; <b>Andrew Roberts</b>, <i>International Life Sciences Institute (ILSI) Research Foundation</i> (moderators)</p>	<p>Panel discussion</p> <p><b>Patrick Rüdelsheim</b>, <i>Perseus</i> (moderator)</p>	<p>Panel discussion</p> <p><b>Clara Rubinstein</b>, <i>Monsanto</i> (moderator)</p>
12:40	<b>LUNCH</b>		

## Day 4 – 8 June 2017 – Afternoon

### Plenary Session III: Advancing ERA of GMOs – Looking Ahead to Future Opportunities and Challenges

Organisers: **Jennifer Anderson**, *DuPont Pioneer* & **Yann Devos**, *European Food Safety Authority (EFSA)*

14:10	<b>Introduction</b>
14:15	Keynote: Future for food systems <b>Tim Benton</b> , <i>University of Leeds</i>
14:45	Emerging products of agricultural biotechnology for sustainable agriculture, food security and climate change mitigation <b>Jim Gaffney</b> , <i>DuPont Pioneer</i>
15:05	Opportunities to prepare the US regulatory system for future biotechnology products: Findings from a US National Academies of Sciences report <b>Steven P Bradbury</b> , <i>Iowa State University (ISU)</i>
15:25	Enabling sound scientific decision-making for novel and familiar traits with the existing ERA framework <b>Pamela M Bachman</b> , <i>Monsanto</i>
15:45	<b>COFFEE BREAK</b>
16:15	Gene drives on the horizon – Challenges in science, ethics, and governance <b>Elizabeth Heitman</b> , <i>University of Texas Southwestern Medical Center</i>
16:35	Impact of synthetic biology and the implications of ERA <b>Maria Mercedes Roca</b> , <i>Tecnologico de Monterrey</i>
16:55	ERA and regulatory challenges – Alternative approaches <b>Paul Keese</b> , <i>University of Ghana</i>
17:15	<b>Patrick Rüdelsheim</b> , <i>Perseus</i> (moderator)
18:00	<b>CLOSING SESSION</b>

## Day 1 – 5 June 2017 – Evening

Poster Session I	
18:10	<b>Regulatory considerations</b>
PO I-1	Establishing biodiversity damage resulting from GMOs <b>Claudia Colmenarez Ortiz, Ghent University</b>
PO I-2	Inspired eyes: The current biotechnology legislation in the international landscape from a student's perspective <b>Daniel Gómez Domínguez, Instituto Tecnológico y de Estudios Superiores de Monterrey</b>
PO I-3	New biotechnologies and innovation: A challenge for the Mexican regulatory system <b>Diana Priscilla Bonilla Ruelas, Instituto Tecnológico y de Estudios Superiores Monterrey</b>
PO I-4	Problem formulation approach to assess the risk of GM maize use in Mexico: A preliminary exercise using the proposed Official Mexican Standard (NOM) <b>Sol Guerrero-Ortiz, Cornell Alliance for Science</b>
PO I-5	Regulated field trials in Mexico. Planning and implementation through interdisciplinary approach <b>Carlos Patiño-Echeverri, Monsanto</b>
PO I-6	ERA studies for biotechnology-derived products in Brazil <b>Daniella PV Braga, Monsanto</b>
PO I-7	The joint evolution of institutional organisation and GMO risk analysis in Argentina <b>Agustina Whelan, Ministry of Agro-industry</b>
PO I-8	Government support for deregulation of public sector GMOs in Argentina <b>Agustina Whelan, Ministry of Agro-industry</b>
PO I-9	Uruguayan biosafety framework for developing and/or handling GM vegetables under confined conditions <b>Alejandra Ferenczi, Ministry of Livestock, Agriculture and Fisheries</b>
PO I-11	20 years of biosafety in Bolivia. Lessons learned <b>Cecilia González Paredes, Instituto Boliviano de Comercio Exterior</b>
PO I-12	Biotechnology and biosafety in Africa: Building functional regulatory systems for safe deployment of GM crops in Africa <b>Olalekan Akinbo, NEPAD African Biosafety Network of Expertise (ABNE)</b>

PO I-15	<p>Technical specifications and procedural scope of the new Mexican official standard (NOM) for the ERA of GMOs</p> <p><b>Jaime E Padilla-Acero</b>, <i>AgroBIO Mexico</i></p>
PO I-16	<p>Rethinking regulatory policy and practice for effective GMO oversight in Uganda: A perceptive treatise</p> <p><b>Gumisiriza Gilbert</b>, <i>Uganda Biosciences Information Center (UBIC)</i></p>
PO I-17	<p>Complementarity or contradiction: Application of ERA and SECs for GM crops deregulation in Africa</p> <p><b>Francis Nang'ayo</b>, <i>African Agricultural Technology Foundation (AATF)</i></p>
PO I-18	<p>GMO regulation in New Zealand: Unique features, first GMO release and recent changes in the “not GMO” regulations</p> <p><b>Tim Strabala</b>, <i>Environmental Protection Authority (NZ EPA)</i></p>
	<b>ERA considerations</b>
	<b>General Considerations</b>
PO I-19	<p>Regulatory science versus research science: Decision making for environmental release of GM plants</p> <p><b>Peter Thygesen</b>, <i>Office of the Gene Technology Regulator (OGTR)</i></p>
PO I-22	<p>ERA of RNAi-based crops in Argentina</p> <p><b>Germán Ceizel Borella</b>, <i>Ministry of Agro-industry</i></p>
PO I-23	<p>Biosafety strategies for tropical tree (<i>Cedrela odorata</i>) transformation</p> <p><b>Yuri Jorge Peña-Ramirez</b>, <i>El Colegio de la Frontera Sur</i></p>
PO I-24	<p>Relevance of environmental safety assessments of individual biotechnology-derived traits for products combining multiple traits through conventional breeding</p> <p><b>Ernest L Clawson</b>, <i>Monsanto</i></p>
PO I-25	<p>Regulatory assessment of breeding stacks of approved parental events: Case study in Argentina and Paraguay</p> <p><b>Magdalena López Olaciregui</b>, <i>Dow AgroSciences</i></p>
PO I-27	<p>Risk assessment of GM potato with the <i>erf</i> gene for bacterial wilt resistance in Uruguay</p> <p><b>Federico Boschi</b>, <i>National Seed Institute</i></p>

	<b>Tools</b>
PO I-29	Data transportability for field trial research <b>John Teem</b> , <i>International Life Sciences Institute (ILSI) Research Foundation</i>
PO I-30	How to detect synergism among <i>Bacillus thuringiensis</i> insecticidal proteins without <i>a priori</i> assumptions Regarding the mode of action <b>Jianhong Wu</b> , <i>Syngenta Crop Protection</i>
PO I-32	CADIMA: An online tool supporting the reporting and conduct of the evidence synthesis process <b>Ralf Wilhelm</b> , <i>Julius Kühn-Institute (JKI)</i>
PO I-33	Research with GM plants in a government-funded protected field site in Switzerland <b>Jörg Romeis</b> , <i>Agroscope</i>
	<b>Studies</b>
PO I-34	Effects of Cry1Ab <i>Bt</i> -rice straw return on the earthworm <i>Eisenia fetida</i> <b>Yinghua Shu</b> , <i>South China Agricultural University (SCAU)</i>
PO I-35	Testing insecticidal proteins and GM plant material on a surrogate dipteran species <b>Michael Meissle</b> , <i>Agroscope</i>
PO I-36	The risk assessment of Cry1Ie protein on <i>Chrysoperla sinica</i> larvae <b>Kanglai He</b> , <i>Chinese Academy of Agricultural Sciences (CAAS)</i>
PO I-37	Levels of Cry1Ac protein in herbivorous and predatory arthropods in <i>Bt</i> -soybean <b>Young-Joong Kim</b> , <i>Seoul National University</i>
PO I-38	Impacts of sugarcane expressing Cry1Ab protein on non-target arthropods in Brazilian field conditions <b>Adriana Cheavegatti Gianotto</b> , <i>Centro de Tecnologia Canavieira</i>
PO I-39	Change of <i>Bt</i> -protein in the process of eight-times continuous <i>Bt</i> -corn planting and straw returning to soil and its effects on soil nutrient content <b>Jianwu Wang</b> , <i>South China Agricultural University (SCAU)</i>
PO I-40	Effect of Cry1Ab <i>Bt</i> -maize straw return on greenhouse gases emission and nitrogen cycle in soil <b>Jianwu Wang</b> , <i>South China Agricultural University (SCAU)</i>

PO I-41	<p>Transgenic overexpression of EPSPS in <i>Arabidopsis thaliana</i> can enhance fecundity in the absence of glyphosate</p> <p><b>Zachery T Beres</b>, <i>Ohio State University (OSU)</i></p>
PO I-42	<p>Crop wild relatives of cultivated eggplant (<i>Solanum melongena</i> L.) in the Philippines – Does <i>Bt</i>-eggplant pose a real threat?</p> <p><b>Desiree M Hautea</b>, <i>University of the Philippines Los Baños</i></p>
PO I-43	<p>Assessment of impact of gene flow on biodiversity: Experience with GM mustard</p> <p><b>Pranjali Vishwakarma</b>, <i>Biosafety Support Unit</i></p>
PO I-44	<p>Agronomic, ecological and genetic-segregation assessment of GM traited landraces: Evidence for the safe coexistence of maize landraces with modern GM maize hybrids</p> <p><b>Bill Duncan</b>, <i>Monsanto</i></p>
PO I-45	<p>Assessing the risk of GM sugarcane outcrossing with a related wild species using phylogenetic and pollen viability studies</p> <p><b>Khanyi Hlobisile</b>, <i>North-West University</i></p>
PO I-46	<p>Conservation and biosafety alternatives for productive coexistence of conventional and GM maize in its center of origin and genetic diversity</p> <p><b>Jaime E Padilla-Acero</b>, <i>AgroBIO Mexico</i></p>
PO I-47	<p>Evaluating the risks of possible adverse effects of glyphosate on human and environmental health</p> <p><b>Robert McDowell</b>, <i>Consult MRS</i></p>
PO I-48	<p>Genetic engineering for environmental restoration? Transgenic American chestnut shows heritable resistance to chestnut blight with minimal non-target impacts.</p> <p><b>Andrew Newhouse</b>, <i>State University of New York College of Environmental Science &amp; Forestry (SUNY-ESF)</i></p>
PO I-49	<p>GM cotton impact after 20 years of cultivation in Mexico</p> <p><b>Martha Graciela Rocha Munive</b>, <i>Universidad Nacional Autónoma de México</i></p>



## Day 2 – 6 June 2017 – Evening

### Pecha Kucha Session

Organisers: **Mònica García-Alonso**, *Estel Consult Ltd* & **Sol Ortiz García**, *Comisión Intersecretarial de Bioseguridad de los Organismos Genéticamente Modificados (CIBIOGEM)*

18:00	Introduction
18:05	Risk assessment of GM potato with the <i>erf</i> gene for bacterial wilt resistance in Uruguay <b>Federico Boschi</b> , <i>National Seed Institute</i>
18:10	The risk assessment of Cry1Ie protein on <i>Chrysoperla sinica</i> larvae <b>Kanglai He</b> , <i>Chinese Academy of Agricultural Sciences (CAAS)</i>
18:15	Levels of Cry1Ac protein in herbivorous and predatory arthropods in <i>Bt</i> -soybean <b>Young-Joong Kim</b> , <i>Seoul National University</i>
18:20	The interplay of gene editing regulation and social impacts <b>Martín Lema</b> - <i>Ministry of Agro-industry &amp; Quilmes National University</i>
18:25	Impact assessment of genome editing in plants <b>Dominik Modrzejewski</b> , <i>Julius Kühn-Institute (JKI)</i>
18:30	Alternate hosts of eggplant fruit and shoot borer, <i>Leucinodes orbonalis</i> Guenee in the Philippines: Implications for resistance management with <i>Bt</i> -eggplant <b>Lourdes D Taylo</b> , <i>University of the Philippines Los Baños</i>
18:35	New biotechnologies and innovation: A challenge for the Mexican regulatory system <b>Diana Priscilla Bonilla Ruelas</b> , <i>Instituto Tecnológico y de Estudios Superiores Monterrey</i>
18:40	Inspired eyes: The current biotechnology legislation in the international landscape from a student's perspective <b>Daniel Gómez Dominguez</b> , <i>Instituto Tecnológico y de Estudios Superiores de Monterrey</i>
18:45	Establishing biodiversity damage resulting from GMOs <b>Claudia Colmenarez Ortiz</b> , <i>Ghent University</i>
18:50	Readiness of the Nigerian public for the introduction of GM crops into the food market <b>Oluwakemi Hannah Oladipo</b> , <i>National Biotechnology Development Agency</i>

18.55	Public awareness and the Asian BCH roadmap: The Philippines experience <b>Julieta Fe L Estacio</b> , <i>National Committee on Biosafety of The Philippines</i>
<b>Poster Session II</b>	
19:00	<b>Molecular, agronomic/phenotypic, compositional, toxicological and nutritional characterisation of GM plants</b>
PO II-1	Southern-by-Sequencing (SbS) for molecular characterisation of GMOs and gene edited varieties <b>Kent Brink</b> , <i>DuPont Pioneer</i>
PO II-2	Molecular characterisation of transgenic events for safety assessment using Next Generation Sequencing approaches <b>Satish Guttikonda</b> , <i>Dow AgroSciences</i>
PO II-3	Next-Generation Sequencing tools for molecular characterisation of new traits <b>Kent Brink</b> , <i>DuPont Pioneer</i>
PO II-4	Meta-analysis of data on the expression of Cry proteins and field performance of <i>Bt</i> -cotton hybrids approved in India <b>Govind Kumar Rai</b> , <i>Biosafety Support Unit</i>
PO II-5	Salt/drought tolerant and higher yielding aromatically prized Kalijeera rice by downregulating the Drought and Salt Tolerant Transcription factor, DST <b>Ar-Rafi Md Faisal</b> , <i>University of Dhaka</i>
PO II-6	Jasmonic acid induced defence responses in conventional and transgenic corn seedlings expressing <i>Bt</i> -insecticidal proteins <b>Yuanjiao Feng</b> , <i>South China Agricultural University (SCAU)</i>
PO II-7	Reduced caterpillar damage benefits <i>Lygus hesperus</i> on <i>Bt</i> -cotton <b>Jörg Romeis</b> , <i>Agroscope</i>
PO II-8	Brazilian industrial processing of GM sugarcane produces sugar and ethanol indistinguishable from products derived from conventional sugarcane <b>Adriana Cheavegatti Gianotto</b> , <i>Centro de Tecnologia Canavieira</i>
PO II-9	Compositional assessment of GM traited landraces: Evidence for the safe co-existence of landraces and modern maize hybrids <b>Elisa Leyva-Guerrero</b> , <i>Monsanto</i>

PO II-10	<p>Comparative assessment on key component compositions between imported GM soybeans and local non-GM soybeans from Taiwan</p> <p><b>Huan-Yu Lin</b>, <i>Food Industry Research and Development Institute (FIRDI)</i></p>
PO II-12	<p>LC-MS/MS based methods for <i>in vitro</i> digestibility and quantification of transgenic membrane proteins</p> <p><b>Xue-Rong Zhou</b>, <i>Commonwealth Science and Industrial Research Organisation (CSIRO)</i></p>
PO II-13	<p>Safety evaluation and approval status of GM foods in Korea</p> <p><b>Yun-Sook Kang</b>, <i>Ministry of Food and Drug Safety</i></p>
PO II-14	<p>The International Life Sciences Institute Crop Composition Database (ILSI-CCDB)</p> <p><b>Laurie Bennett</b>, <i>International Life Sciences Institute (ILSI) Research Foundation</i></p>
PO II-16	<p>Analysis of two varieties of transgenic soybean and a conventional variety by the Micronucleus Test, in mice</p> <p><b>Edith Alba Segovia Corrales</b>, <i>Universidad Nacional de Asunción</i></p>
PO II-17	<p>Comparison of nutritional composition between the transgenic rice varieties and conventional comparators using univariate and multivariate analysis</p> <p><b>Soo-Yun Park</b>, <i>National Institute of Agricultural Science</i></p>
PO II-18	<p>Nutritional safety assessment of GM rice (insect resistance) using the database of commercial rice varieties</p> <p><b>Seon-Woo Oh</b>, <i>National Institute of Agricultural Science</i></p>
	<b>Insect resistance monitoring/management</b>
PO II-19	<p><i>Diatraea saccharalis</i> resistance to Herculex<sup>®</sup> maize in an isolate area in San Luis in Argentina: Detection, characterisation and management</p> <p><b>Ana Maria Signorini</b>, <i>Dow AgroSciences</i></p>
PO II-20	<p>Differential gene expression among Philippine populations of Asian corn borer (<i>Ostrinia furnacalis</i> Guen.) (Lepidoptera: Crambidae)</p> <p><b>John Carlo Medrano Marasigan</b>, <i>University of the Philippines Los Baños</i></p>
PO II-21	<p>Development and characterisation of the Asian corn borer resistance to <i>Bt</i>-toxin Cry1Ie</p> <p><b>Kanglai He</b>, <i>Chinese Academy of Agricultural Sciences (CAAS)</i></p>
PO II-23	<p>Seed industry management of field-evolved resistance to <i>Bt</i>-corn in a population of <i>Diatraea saccharalis</i> in Argentina</p> <p><b>María Fabiana Malacarne</b>, <i>Asociación Semilleros Argentinos</i></p>

PO II-24	<p><i>Spodoptera frugiperda</i> resistance to Cry1F <i>Bt</i>-protein in maize in Argentina: Detection, characterisation, and management</p> <p><b>Ana M Signorini</b>, <i>Dow AgroSciences</i></p>
PO II-25	<p>Alternate hosts of eggplant fruit and shoot borer, <i>Leucinodes orbonalis</i> Guenee in the Philippines: Implications for resistance management with <i>Bt</i>-eggplant</p> <p><b>Lourdes D Taylo</b>, <i>University of the Philippines Los Baños</i> Co-author: Desiree M Hautea</p>
	<b>Monitoring</b>
PO II-28	<p>Strategy to assess the quality of DNA extracts used in the monitoring of GMOs by the q-PCR technique. An alfalfa seeds case</p> <p><b>Daniela Tosto</b>, <i>National Institute of Agronomic Technology (INTA)</i></p>
PO II-29	<p>Developing and implementing a national post-market environmental monitoring framework for GMOs in South Africa</p> <p><b>Tlou Masehela</b>, <i>South African National Biodiversity Institute (SANBI)</i></p>
	<b>Capacity building</b>
PO II-30	<p>Technology transfer and capacity building in biotechnology and biosafety for a sustainable and intensified agriculture in Africa</p> <p><b>Marc Heijde</b>, <i>International Plant Biotechnology Outreach (IPBO)</i></p>
	<b>Public perception and risk communication</b>
PO II-31	<p>Risk communication – The understated game changer in biosafety policy development and implementation in Africa</p> <p><b>Samuel Edudzi Timpo</b>, <i>NEPAD Agency African Biosafety Network of Expertise (ABNE)</i></p>
PO II-32	<p>The dismal failure of risk communication for GMOs</p> <p><b>Robert McDowell</b>, <i>Consult MRS</i></p>
PO II-33	<p>Stakeholders' attitudes towards implementing risk assessment and risk management for GMOs in Uganda</p> <p><b>Barbara Mugwanya Zawedde</b>, <i>National Agricultural Research Organisation (NARO)</i></p>
PO II-34	<p>Communication and public perception of GM crops: The experiences of South-South LA projects shaping a communication strategy</p> <p><b>Deise Maria Fontana Capalbo</b>, <i>Brazilian Agriculture Research Corporation (EMBRAPA) – Environment</i></p>

PO II-35	<p>Readiness of the Nigerian public for the introduction of GM crops into the food market</p> <p><b>Oluwakemi Hannah Oladipo</b>, <i>National Biotechnology Development Agency</i></p>
PO II-36	<p>Public awareness and the Asian BCH roadmap: The Philippines experience</p> <p><b>Julieta Fe L Estacio</b>, <i>National Committee on Biosafety of The Philippines</i></p>
	<b>Socio-economic and ethical considerations</b>
PO II-37	<p>The interplay of gene editing regulation and social impacts</p> <p><b>Agustina Whelan</b>, <i>Ministry of Agro-industry</i></p>
PO II-38	<p>Impact assessment of genome editing in plants</p> <p><b>Dominik Modrzejewski</b>, <i>Julius Kühn-Institute (JKI)</i></p>
PO II-39	<p>Biosafety regulators' challenge: Measuring and monitoring the socio-economic impacts of GMOs in The Philippines</p> <p><b>Leonardo A Gonzales</b>, <i>Philippine Department of Science and Technology Biosafety Committee (DOST-BC)</i></p>
PO II-40	<p><i>Ex-ante</i> assessment of the potential impact of transgenic banana resistant to BXW disease in East Africa</p> <p><b>Leena Tripathi</b>, <i>International Institute of Tropical Agriculture (IITA)</i></p>
PO II-41	<p>Quantification of GM soybean pollen in Mexican honey using digital PCR</p> <p><b>Amanda Galvez</b>, <i>Universidad Nacional Autonoma de Mexico</i></p>
PO II-42	<p>The advantages of glyphosate-resistant corn production in China</p> <p><b>Xiangju Li</b>, <i>Chinese Academy of Agricultural Sciences (CAAS)</i></p>
PO II-43	<p>Evaluation of weed control efficacy and safety of glyphosate in herbicide tolerant transgenic maize</p> <p><b>Huilin Yu</b>, <i>Chinese Academy of Agricultural Sciences (CAAS)</i></p>

## Plenary Session I – Abstracts

### Advancing ERA of GMOs - Learning from the Past to Further Advance ERA

This session will review the weight of scientific evidence on environmental risks accumulated and familiarity gained with the deliberate release of GM plants into the environment over the last three decades, and build on this experience to further advance pre-market environmental risk assessments (ERAs). Experience gained with the assessment of potential risks will be reviewed critically to assess: its scientific foundation; how potential adverse environmental effects may be best evaluated within the frame of current ERAs; and whether specific data requirements necessitate re-evaluation. Environmental risks associated with the cultivation of GM plants will also be put into the perspective of those of current agricultural systems, so as to contextualise ERAs more.

Session organisers: **Sarah Davis** - *Canadian Food Inspection Agency (CFIA)* & **Yann Devos** - *European Food Safety Authority (EFSA)*

## PL I-1

### **Environmental effects of genetically modified crops: Findings of a National Academies of Sciences, Engineering and Medicine (US-NASEM) report**

**Fred Gould** - *North Carolina State University (NCSU)*

From 2014 through 2016 our US National Academies committee developed a report titled “Genetically modified Crops: Experiences and Prospects”. This report examined health, environmental, agronomic, and socio-economic impacts of currently commercialized genetically modified (GM) crops. It also examined potential impacts of GM crops that may come on the market in the future. In this presentation I will focus only on our findings regarding the assessment of environmental impacts. Among the environmental impacts that we examined are effects on beneficial insects, crop relatives, as well as plant and animal biodiversity within and beyond agricultural fields. The committee “found no conclusive evidence of cause-and-effect relationships between GM crops and environmental problems. However, the complex nature of assessing long-term environmental changes often made it difficult to reach definitive conclusions”. We illustrate using the case of decline in overwintering monarch butterfly populations.

The committee points out those personal and cultural values are important in assessing environmental impacts because one person’s weed is another person’s flower. The committee addressed the critical need for an analytic-deliberative approach in development of regulations for crop varieties with novel characteristics whether developed by genetic engineering or conventional breeding. When there is a preliminary finding of a potential environmental effect, the committee recommends that rigorous, publicly funded studies follow-up on the preliminary finding. The committee makes a strong recommendation that “regulatory agencies responsible for environmental risk should have the authority to impose continuing requirements and require environmental monitoring for unexpected effects after a GM crop has been approved for commercial release”.

I will end by explaining the process that the committee used to ensure that we heard from diverse, interested parties and made our findings accessible beyond the printed report.

## PL I -2

### **Weeds or wimps? 30 years of experience from evolving environmental risk assessment (ERA), deliberate release, experimental research, the development of theory, unintended free-living transgenic plants, unanticipated products – and a century of experience of non-engineered crops gone wild**

**Norman C. Ellstrand** - *University of California (UC)*

Concern about whether engineered plants could become nasty weeds or invasives dates to the 1980's. Two pathways were posited:

1. The transgenic plant itself might have a phenotype sufficiently altered that it would persist and spread as a new weed or invasive.
2. Hybridization between crops and their wild/weedy relatives would deliver transgenic traits that would lead to increased weediness or invasiveness.

Relevant data were scarce; those that existed were in need of synthesis. Needed expertise was divided among scholars in diverse and isolated fields. The science of weed evolution was in its infancy. "Evolution of invasiveness" was a phrase yet unspoken.

Early risk assessments starting bridging expertise, sometimes painfully. Risk identification was refined. Gene flow was identified as the exposure component of risk, rather than a hazard per se. Field trials and full deregulation allowed for experimental field work that often yielded surprising results. The rise of the integrative evolutionary study of weeds and invasiveness started to inform theory. Non-engineered crops and crop/wild/weed hybrid lineages that had evolved invasiveness or weediness (and those that had not) have emerged to serve as model systems. Furthermore, unintended free-living transgenic populations have been documented; they can serve as examples for assessing persistence (so far, not uncommon) and environmental impacts (so far, quite rare). A more thoughtful, informed, integrative, and nuanced approach to ERA has evolved. The fact that novel transgenic traits, from pharmaceutical-production to seed-sterility to gene drive have stimulated the identification of new potential hazards that transcend the simple ones originally hypothesized suggests that ERA for problematic plants will continue to evolve.



## PL I -3

### Assessing effects of GM plants on valued non-target organisms

Jorg Romeis - *Agroscope*

Arthropods form a major part of the biodiversity in agricultural landscapes and contribute to important ecosystem services or are of conservation value. Therefore, it is legally required to assess the potential impacts that genetically modified (GM) plants may have on valued non-target arthropods (NTAs) in the environmental risk assessment (ERA) that is conducted prior to the cultivation of a GM plant. This risk to NTAs is particularly evident for plants producing insecticidal compounds for pest control such as Cry proteins from *Bacillus thuringiensis* (Bt). Using Bt-transgenic crops as an example, this talk describes how to assess the risks of GM crops to NTAs. This includes in particular the use of problem formulation to generate plausible and testable risk hypotheses, the application of the tiered risk assessment framework to test these risk hypotheses, the selection of the most appropriate test species, and the design of robust laboratory test systems. The relevance and quality of the collected data are important to ensure the safety of GM plants released into the environment, and facilitate data transportability across jurisdictions. The developed frameworks will also help to perform a robust ERA for future GM plants and applications.

## PL I -4

### Modernizing risk assessment for GM crops – Learning from experience

**Phil Macdonald** - *Canadian Food Inspection Agency (CFIA)*

Co-author: Sarah Davis

The first GM crops were commercialized in Canada in 1995, and since that time more than 100 have been assessed for environmental safety. A key principle, that the potential risks posed by a GMO can be most effectively assessed by a comparison to its familiar counterpart, has served very well for the risk assessment of genetically modified (GM) crops, and in Canada, has underpinned the risk assessment of plants with novel traits (PNT) that have received commercial authorization. Worldwide, there is growing familiarity with GM crops, foods and feeds, coupled with a growing body of research on genetic engineering and fueled by the rapid advancements in molecular analysis techniques that has provided an unprecedented understanding of plant genomes and genetic change. Molecular characterization of a GM crop is usually considered as a component of the risk assessment for environmental, food and feed safety. Canada has looked at the molecular characterization component as an important area for refinement. In keeping with the comparative approach, Canada has evaluated the potential outcomes of inserting a new gene or genes into a plant in the context of the changes that will occur in a plant genome either spontaneously or through other more conventional forms of plant breeding (Schnell et al. 2015). The outcomes of that project have been considered and applied to the risk assessment process for GM crops, and Canada continues to look to apply experience and science to ensure that risk assessments are fit for that purpose.

## PL I -5

### Resistance evolution in insect pests and weeds in GM crop systems

**Nick Storer** - *Dow AgroSciences*

Co-authors: Mark A Peterson, Dwain M Rule, Robert A Masters

Management of agriculturally important pests has been dramatically enhanced through use of genetically modified (GM) crops. In-plant insect protection traits control or suppress target pests feeding on the GM crop throughout the whole plant and season long. Herbicide-tolerance traits increase flexibility to apply herbicides during the cropping season to minimize the effects of weed competition and to protect crop yield. These tools can be deployed in ways that are protective of the agricultural environment and human health, and have been enthusiastically embraced by growers in countries where GM cultivation has been approved.

As with any highly effective pest management tool, whether chemical, biological, or cultural, repeated use can select target pest genotypes that are resistant to the tool, such that over time resistance evolution in pest populations can diminish the effectiveness of the management tool. In this sense, GM cropping systems encounter the same resistance issues as any other cropping system. This presentation will review the current extent of management challenges due to resistant insect and weed populations in GM cropping systems, examine the factors that have contributed to the emergence of resistance, and discuss the roles of farmers, researchers, extension services, governments and the seeds and crop protection industry in delaying and managing resistance.

## Plenary Session II - Abstracts

### Advancing ERA of GMOs – Present Challenges

Pre-market ERA is an important analytical scientific tool that helps regulatory decision-making. Robust ERAs begin with an explicit problem formulation where plausible and relevant exposure scenarios and the potential adverse effects from those exposures are identified. Risk is then characterised by testing specific hypotheses about the likelihood and severity of adverse effects. Although significant advances have been made, ERA of GMOs faces a number of challenges. Potential avenues to overcome some of these challenges and further increase coherence in the ERA methodology will be considered, focusing on: the ecosystem services approach to make protection goals operational; problem formulation to enhance the relevance of ERA studies; clear quality criteria to warrant the reliability of ERA studies; data harmonisation and transportability to ensure consistent and coherent generation and use of scientific data across regulatory jurisdictions to support ERAs; and approaches to ensure ERAs remain proportionate to the level of risk or uncertainty.

Session organisers: **Mònica García-Alonso** - *Estel Consult Ltd* & **Jörg Romeis** - *Agroscope*

## PL II -1

### Science and values in governing GMOs: Facts, fictions, and fantasies

*Sheila Jasanoff - Harvard University*

In the early days of genetic engineering, the food and agriculture industries enthusiastically greeted a new technology carrying the halo of precision and promising correctives to nature's mistakes and deficiencies. Human beings had bred plants for thousands of years. Now, it was thought, new biological knowledge would permit a short-circuiting of centuries through rapid and targeted modification and the unprecedented ability to build new traits into existing genomes. Yet, within relatively few years, this promising technology became one of the most contested inventions in modern industrial history. As genome editing holds out the hope of still cheaper, quicker, and more precise interventions to remake biological organisms, a revisiting of that earlier history with an eye to better integration of science, technology, and politics, seems urgently necessary.

Drawing on nearly four decades of experience with the manufacture, risk assessment, and introduction of GMOs throughout the world, and on relevant theorizing from the field of science and technology studies, this talk will focus on three sets of issues, each of which has attracted its share of factual analysis, fictional story-telling and fantastical projections into the future. First, how scientific is risk assessment? Second, what accounts for the observed cross-cultural divergences between scientific and political assessment of GMOs? Third, what should be done to ensure adoption of valuable technological advances without sacrificing legitimately different social values concerning the protection of nature, the acceptability of risk, and the limits of human technological manipulation?

## PL II -2

### **Assessment of environmental risks to ecosystem services. Where are we now, and where are we going?**

**Lorraine Maltby** - *University of Sheffield*

Genetically modified organisms, chemicals and other regulated products may have positive or negative effects on human well-being. The challenge facing decision makers is how to balance the wellbeing benefits provided by the use of regulated products with the potential wellbeing costs due to habitat degradation and loss of biodiversity. Many environmental policies aim to protect biodiversity, but as its not possible to protect everything, everywhere, forever, and, therefore, generic biodiversity protection goals must be translated into more specific protections goals to make them operational. One approach to setting specific protection goals is to consider what aspects of biodiversity are to be protected in different ecosystems and why. Ecosystems services (ES) are the direct or indirect contributions of ecosystems to human well-being and are underpinned by biodiversity. Ecosystem services provide a useful vehicle for setting specific protection goals and ecosystem services approaches are being explored within several risk assessment frameworks. Assessing the environmental risk of regulated products to ecosystem services requires the development of tools and approaches for:

1. identifying clear protection goals that stipulate what needs to be protected within a landscape context
2. translating ecotoxicological exposure and effects information into risks for ecosystem services delivery.

The recent CARES project brought together stakeholders from government, business and academia to develop a common understanding of the merits and feasibility of an ecosystem services approach to environmental risk assessment (ERA) and the implications for implementation within current European regulatory frameworks. The project assessed the current state of knowledge and identified key information gaps and challenges; explored the use of novel approaches from ecology, ecotoxicology and ecological modelling to address key information gaps; explored how an ES approach could be implemented; and considered the implications for regulatory risk assessment. The issues and outcomes from this project will be discussed.

## PL II -3

### Problem formulation: Identifying data that are relevant to ERA

**Alan Raybould** - *Syngenta*

Risk assessment provides estimates of the likelihood and seriousness of harmful effects that may occur after taking a course of action. Such estimates help decision-makers to decide whether or not to undertake or permit certain activities. In the field of GM crops, risk assessments contribute to decisions by, for example, product developers and regulatory authorities.

Risk assessment is scientific in that it creates objective knowledge by testing hypotheses. There are, however, important non-scientific elements that guide risk assessment, the most important of which are definitions of what to regard as harmful effects and the amount of risk that is acceptable.

With these considerations in mind, we can devise a simple scheme for planning a risk assessment for cultivation of a GM crop; this scheme is problem formulation:

1. Decide what would constitute harmful effects from cultivating the crop
2. Consider what events would have to happen for the harmful effects to occur (a “pathway to harm”)
3. Formulate hypotheses that events on the pathway to harm will not occur
4. Test the hypotheses with existing data
5. Decide what, if any, new data are needed to test the hypotheses in order to make a decision

Viewed in this way, problem formulation helps us to identify relevant data for risk assessment:

- Data should test a hypothesis that specified events on a pathway to harm will not occur
- New data ought to be required only if hypotheses are corroborated insufficiently rigorously (of if all the hypotheses are refuted)
- New data that provide greater precision in a prediction should be required only if decision-making criteria are similarly precise

I will illustrate the above points with examples from regulatory risk assessments.

## PL II -4

### Development of a construct-based risk assessment framework for GM Crops

Clara Rubinstein - *ILSI Argentina/ Monsanto Argentina*

Co-author: Carmen Enriqueta Vicién

Experience gained in the risk assessment (RA) of genetically modified (GM) crops since their first experimental introduction in the early 1990s, has increased the level of familiarity with these breeding methodologies and has motivated several agencies and expert groups worldwide to revisit the scientific criteria underlying the RA process. Along these lines, the need to engage in a scientific discussion for the case of GM crops transformed with similar constructs was recently identified in Argentina. In response to this need, the Argentine branch of the International Life Sciences Institute (ILSI Argentina) convened a tripartite working group (WG) to discuss a science-based evaluation approach for transformation events developed with genetic constructs which are identical or similar to those used in previously evaluated or approved GM crops. This discussion considered new transformation events within the same or different species and covered both environmental and food safety aspects. A construct-similarity concept was defined, considering the biological function of the introduced genes. Factors like environmental and dietary exposure, familiarity with both, the crop and the trait, as well as the crop biology, were identified as key to inform a construct-based RA process. The purpose of this work is to discuss the principles for the risk assessment of identical or similar constructs using accepted methodologies and available knowledge, and does not intend to present a detailed, prescriptive process, as these situations would be expected to be considerably diverse.



## PL II -5

### **When science meets policy: The undoing of the Guidance on risk assessment developed under the Cartagena Protocol for Biosafety**

**Karen Hokanson** – *University of Minnesota (UM)*

At the fourth Meeting of the Parties serving as the Conference of the Parties to the Cartagena Protocol on Biosafety (MOP4) in 2008 (Bonn), the MOP requested an Ad Hoc Technical Expert Group (AHTEG) and the use of an openended online forum to develop guidance on the necessary steps to conduct a risk assessment in accordance with Annex III to the Protocol. Over the eight years that followed, multiple face-to-face meetings of two different AHTEGs, and many open-ended online forums were convened by the Secretariat to the Convention on Biological Diversity, where different views emerged regarding the purpose for, approach to and content of such guidance. Between MOP6 and MOP7, the Secretariat facilitated a testing of the guidance where there were also divergent opinions expressed by parties, non-party governments, and other organizations about the practicality and usefulness, the consistency with the Protocol, and the appropriate level and types of experience upon which the guidance was based. After MOP 7, there was a significant effort by the Secretariat and the AHTEG to address the differences of opinion noted through the testing process, yet the MOP decided at MOP8 in 2016 (Cancun) to end the work of the AHTEG on risk assessment, and to only “take note of” the resulting guidance document. The MOP did not agree to “endorse”, “welcome” or even “acknowledge” the guidance as an official document, although the guidance remains available as a resource for those who might choose to use it. This presentation will discuss some reasons why this attempt to develop a commonly accepted guidance was unsuccessful, and will consider the shortfalls of the guidance as identified during a discussion among a group of risk assessment practitioners from several countries where risk assessments for general release into the environment have been applied to various GM crops.

## PL II -6

### **Beyond the OECD Blue Book: Building consensus on environmental considerations for risk/safety assessment for the release of transgenic plants**

**Phil Macdonald** - *Canadian Food Inspection Agency (CFIA)*

Co-author: Sarah Davis

The Organisation for Economic Co-operation and Development (OECD) Working Group on the Harmonisation of Regulatory Oversight in Biotechnology promotes international harmonisation in environmental risk/safety assessment and regulation of organisms produced through modern biotechnology. It works to ensure that the information used in environmental risk/safety assessment, as well as the methods used to collect such information, is as similar as possible among countries. This is to improve mutual understanding, increase the efficiency of environmental risk/safety assessment, avoid duplication of effort, and reduce barriers to trade. The main outputs of the OECD Working Group are agreed upon “consensus documents,” which are intended to be a “snapshot” of current information for use during the regulatory assessment of products of biotechnology. A current project, entitled Environmental Considerations for Risk/Safety Assessment for the Release of Transgenic Plants (Environmental Considerations), focuses on a set of environmental considerations routinely considered by risk assessors. They are meant to facilitate the identification of potential adverse effects associated with the release of a transgenic plant, the identification of potential pathways to harm, the formulation of testable risk hypotheses, and the identification of information elements which can be used to inform the testable risk hypotheses. This is congruent with the so-called “Problem Formulation” approach to assessment. This project builds upon the work begun by the OECD with the Recombinant DNA Safety Considerations (the so-called “Blue Book”; 1986), Safety Considerations for Biotechnology: Scale-up of Crop Plants (1993), and other documents that first articulated key concepts and safety issues used for conducting an environmental risk/safety assessment. In this presentation, the chair of the project will provide an overview of the activities of the OECD Working Group with respect to environmental risk/safety assessment of a transgenic plant, including how its early foundational work helped to shape the nearly completed consensus document on Environmental Considerations.

## PL II -7

### Identifying surrogate environments to facilitate data transportability for ERA

**Andrew Roberts** – *International Life Science Institute (ILSI) Research Foundation*

It is a practical reality that countries require in-country confined field trials prior to regulatory authorizations for cultivation of genetically modified crops. There are multiple reasons for this, but frequently such requirements are justified with the idea that the crop must be tested within the environment where it will be used. The result of these requirements is massive duplication of studies, particularly for crops that are intended to be planted on a global scale. This duplication places a heavy burden on developers and a nearly insurmountable barrier to the development and dissemination of public-sector GM plants. Many have asked whether these studies are necessary or informative for ERA. In order to address this question, the ILSI Research Foundation has convened multiple expert working groups to first address the question of what environmental characteristics influence the results of confined field tests. And then to see if these characteristics can be used to identify surrogate environments that would be expected to produce similar results under confined field trial conditions. The results, current status and future directions of this work will be presented here.

## Plenary Session III – Abstracts

### Advancing ERA of GMOs – Looking Ahead to Future Opportunities and Challenges

The ERA of GMOs faces a number of challenges. Among these are the questions posed by rapid advances in the science of genetic modification resulting in an expanding range of GMO applications. Emerging new breeding technologies, their applicability to crop improvement and animal breeding, and the technical and regulatory challenges they may present will be discussed. This session will explore new developments in GM technology; future opportunities and challenges new GMO applications may present, and put those into the context of agricultural innovation, agronomic sustainability, the need to feeding the growing world population and climate change.

Session organisers: **Jennifer Anderson** - *DuPont Pioneer* & **Yann Devos** - *European Food Safety Authority (EFSA)*

## PL III -1

### Future for food systems

**Tim Benton** - *University of Leeds*

We all know the key challenges of the future for food systems: meeting (or limiting) demand to feed more people, whilst mitigating and adapting to climate change, and managing the environment sympathetically (especially ensuring restoration of degrading soils, and managing biodiversity). As the future unfolds, what might our food system look like? Two big uncertainties are:

1. The extent to which people will move increasingly towards healthy diets (as now over 50% of the world's population are malnourished, and the health bills are mounting) and ones that have a lower environmental footprint (e.g. changing patterns of consumption of animal products, more "sustainably produced")
2. The degree to which the world will move further or away from liberal, free-trade policies.

If regions move towards more self-sufficiency and lower dependence on trade, it will impact commodity crop production, as will, potentially, changing diets. Having set the scene of possible futures, I'll explore the role of, and potential for, GM technologies to deliver production that is economically profitable and meets policy and consumer demand and preferences. I'll examine reasons for and against, and explore some of the notions for "evidence-based" regulation and what counts as evidence. Together, thinking about different futures and the challenges for food in each one, and the extent to which consumers and policy will or will not embrace new technology sets the context of the research agenda over the next decades, and therefore the extent to which modern molecular technologies will contribute to sustainable food security in the future.

## PL III -2

### **Emerging products of agricultural biotechnology for sustainable agriculture, food security and climate change mitigation**

**James F Gaffney** - *DuPont Pioneer*

Co-author: Jennifer Anderson

The global agricultural production system faces greater challenges than simply producing enough food, feed, and fiber for a growing and more prosperous population. Maintaining fragile and often highly diverse ecosystems, improving water quality and lowering greenhouse gas emissions, and producing more food in the region where it is consumed are other important considerations often viewed as intractable problems of productivity. At the same time, sustainable agriculture, food security, and climate change mitigation often have broadly different interpretations dependent upon personal experiences, views of technology, and political and economic situations. Potential solutions to the challenges may be controversial with wide-ranging opinions, creating an atmosphere of “paralysis by analysis” in the face of very time-limited problems. The longer we wait to take action, the greater the challenges become. A brief review of definitions of sustainable agriculture, food security, and climate change mitigation will be included as a baseline for discussion followed by where implementation of solutions are most needed and will have the greatest impact in the short-to medium-term. Select products of agricultural biotechnology are available, or in development, and include

1. new systems for developing hybrid crops more efficiently,
2. transgenic traited crops for increased yield and yield stability under challenging environmental conditions,
3. genome editing to more quickly develop disease and insect resistance in crops that may be difficult with traditional breeding.

Combinations of technologies, including developing sound and complimentary agronomic practices, will also be discussed, along with ideas for reducing controversy and implementing the most promising solutions.

### PL III -3

## **Opportunities to prepare the US regulatory system for future biotechnology products: Findings from a US National Academies of Sciences report**

**Steven P Bradbury** - *Iowa State University (ISU)*

In July 2015, the Office of Science and Technology Policy in the Executive Office of the President initiated an effort to modernize the U.S. government's regulatory system for biotechnology products. As part of this effort, a committee of the National Academies of Sciences, Engineering, and Medicine was tasked to forecast likely products of biotechnology over the next 5 to 10 years (excluding human drugs and medical devices) and the scientific capabilities, tools, and expertise that would be needed by the regulatory agencies to ensure efficient and sound risk analyses.

The committee's information-gathering efforts included dialogue with the U.S. Department of Agriculture, Environmental Protection Agency, Food and Drug Administration, and other federal agencies; product developers and interested publics; and an overview of the literature, including recent Academies' reports on gene drives, genetically-modified crops, and industrialization of biology.

The committee evaluated technological, economic and social drivers to the bioeconomy and concluded the number and complexity of future products are growing rapidly, as is the diversity and number of new product developers, which has the potential to overwhelm the U.S. regulatory system. The report observed that establishing a single point of entry to the U.S. regulatory system would be beneficial for federal agencies, developers and the public. The committee concluded that risk-assessment endpoints for future products will not be new, but the pathways to these endpoints have the potential to be very complex, especially for products released to the environment. The report provides fourteen specific recommendations that fall into three broad areas:

1. Enhance scientific capabilities and tools in the natural, social and regulatory sciences;
2. Develop prototype approaches for assessing risks and benefits, with public participation and external peer review, for future unfamiliar and complex products identified through horizon scanning;
3. Connect biotechnology research and development pipelines with proactive advances in regulatory science.

**PL III -4****Enabling sound scientific decision making for novel and familiar traits with the existing ERA framework**

**Pamela M Bachman** - *Monsanto*

Questions have surfaced in recent years regarding the suitability of the current ecological risk assessment (ERA) testing and assessment paradigm for assessing modes of action (MOAs) that depart from the traditional *Bt*-derived traits, citing greater uncertainty with novel traits. Consequently, additional studies that are not triggered in the existing tiered approach have been requested of registrants. New products, derived with biotechnology, in registrant pipelines may include new MOAs, new protein classes, and/or other innovations with limited history of safe use. To promote public trust in regulatory decisions and guidance for developing regulatory systems, it is critical that science-based decision-making is based on a product's risk assessment and registration is maintained and reinforced. The current ERA framework is sufficiently rigorous and flexible to allow registrants to develop testing programs that can support a broad range of biopesticides and has enabled scientifically sound regulatory decisions with adequate certainty of acceptable risk. This presentation will provide case studies on how the ERA framework is adaptable to a new MOA, the corn rootworm active DvSnf7 RNA, as well as for an unregistered Cry protein, Cry51Aa2.834\_16 with activity against piercing and sucking pests.



## PL III -5

### Gene drives on the horizon – Challenges in science, ethics, and governance

**Elizabeth Heitman** – *University of Texas Southwestern Medical Center*

The fast-growing ability to modify, edit, and engineer genetic changes in a wide variety of life forms increasingly outpaces the capability of professional ethics and regulatory systems to govern these new techniques. Since 2015, researchers exploring the phenomenon of gene drive have used CRISPR-Cas9 to develop gene drive modifications in four models: yeast, fruit flies, and two species of mosquito, providing proof of concept for the efficient introduction of specific genetic traits throughout an entire population in the laboratory. Gene drives have been proposed as a means to address various complex and persistent problems in public health, agriculture, and conservation. Most research to date has focused on controlling or altering organisms such as mosquitoes that transmit infectious diseases to humans, but conservationists are now also exploring the use of gene drives to control or eliminate invasive species.

A range of questions about responsible science—from whether, why, and how research should be conducted to whether, when, and where a gene-drive modified organism should be released into the environment—rest on human values at every step. Who gets to decide what is developed, and how it might be used, are pressing questions to address now, before the technology is widely developed or applied.

This session examines the June 2016 report from the National Academies of Sciences, Engineering, and Medicine on the science, ethics, and governance of gene drives. Following an introduction to the Academies' study process, it will examine the ethical concerns that gene drive research raises, the need for multifactorial risk assessment, the role of public engagement throughout the process, and the Committee's recommendations for general principles to guide responsible practices in and governance of gene drive research.

## PL III -6

### Impact of synthetic biology and the implications of ERA

**Maria Mercedes Roca** – *Tecnologico de Monterrey*

Co-author: Paulo Paes Andrade

With the advent of genome editing technologies such as CRISPR and gene drives, coupled with the digital and nanotechnology revolutions, humanity has embarked on a powerful genomic revolution. The possibility of eradicating diseases such as malaria, dengue, and zika by deploying GM mosquitos, or using of genetic engineering to manage agricultural pests currently targeted by chemical pesticides, is now within reach. "Synthetic biology" is an umbrella term, without an internationally agreed definition, that refers to a set of powerful genetic engineering techniques with applications in health, agricultural and food processing, energy and industry environmental protection. The development and deployment of these generic technologies, collectively referred to as biotechnologies, are blurring the borders between fields of applications and raise profound questions for society as their intended impacts unfold, and their unintended consequences are not yet known. These rapid technological advances will increase the pace of change and create new opportunities. Yet, they will also aggravate divisions between stakeholders, as they sharpen ideological, moral and philosophical differences.

Most biosafety systems require Environmental Risk Assessments (ERAs) before a GMO is released into the environment. Furthermore, the Cartagena Protocol on Biosafety specifically regulates transboundary movements of Living Modified Organisms (LMOs). However, GM mosquitos or GM insect pests, won't respect national borders. The future success of biotechnologies depends to a large extent on well-crafted public policies. The all-important safety aspects of policy must be guided by scientifically defensible, risk-based approaches rather than by public opinion, especially when the latter is driven by activists groups and political agendas. Choosing a flawed paradigm has critical implications for a technology.

This paper explores the implications of considering synthetic biology as a separate field from modern biotechnology when conducting ERAs. It also examines if current products of synthetic biology are sufficiently different from GMOs derived from modern biotechnology, requiring different or more sophisticated ERA approaches.

## PL III -7

### ERA and regulatory challenges – Alternative approaches

Paul Keese - *University of Ghana*

Co-author: Peter Thygesen

GMOs are not the only biological threat. All types of organisms have the potential to cause harm, as indicated by monikers such as weed, pest, parasite or pathogen. Indeed, organisms introduced into a new environment are considered to be a major source of risk to biodiversity and ecosystem functioning. Even organisms designed to provide part of the solution (e.g. biocontrol agents) pose risk. We propose a new approach, termed biorisk, which uses a common risk assessment methodology that encompasses all forms of biorisks, including those from GMOs, and meets international obligations for risk assessment as required under the IPPC (International Plant Protection Convention), OIE World Organisation for Animal Health, WTO-SPS (World Trade Organization Sanitary and Phytosanitary Measures), CODEX (Codex Alimentarius) or Cartagena Protocol. The potential benefits of a generic risk assessment framework for biorisks include:

- Provide regulatory efficiency and consistency of decision-making using common risk criteria
- Reframe regulatory decisions such that known weeds, pests and pathogens provide the baseline comparators for risk assessment (e.g. risk from a GM crop could be evaluated against the level of risk from all weeds).
- Provide in-built future proof that maintains coverage regardless of advances in new technologies, including synthetic biology, or new threats arising from factors such as climate change or bioterrorism.
- Render obsolete the product vs process debate as risk-based irrespective of product or process.
- Provide a more useful communication platform that encompasses shared interests and concerns regarding biological threats, both nationally and regionally.

## Parallel Session I – Abstracts

### Effects of Vertical Gene Flow Between GM Plants and Sexually Compatible Relatives – Dangerous Liaisons?

Gene flow between crops and their cross-compatible wild/weedy relatives is a well-documented phenomenon. Evidence indicates that 22 of the world's 25 most important crops exchange genes with their relatives. The consequences of such vertical gene flow are variable, and can be difficult to predict. Although crops and certain wild/weedy relatives have exchanged genes for centuries, the concern with GM plants is that the acquisition of transgenes by their relatives may alter their capacity for persistence or invasiveness, affecting their abundance, and potentially resulting in impacts on other organisms, the abiotic environment, biogeochemical cycles or ecosystem services. Depending on which plant and which transgenes are involved, and on the characteristics of the receiving environment, this may enable wild/weedy relatives to go extinct, exacerbate a weed problem, or to expand and invade new habitats. Although such dramatic outcomes are rarely observed, the persistence of crop genes in populations of wild/weedy relatives has been documented, with emerging evidence for introgression. This session will therefore consider the probability and consequences of transgene flow to wild/weed relatives, and means to mitigate gene flow, focusing on various GM plants. Participants to the session will share their views and experience gained with the deliberate release of GM plants into the environment over the last three decades. This information will then be used to determine the data that are necessary to characterise risk and clarify the risks that may arise from the cultivation of GM plants.

Session Organisers: **Sol Ortiz García** - *Comision Intersecretarial de Bioseguridad de los Organismos Genéticamente Modificados (CIBIOGEM)* & **Yann Devos** - *European Food Safety Authority (EFSA)*

## PS I -1

### When vertical gene flow matters

**Norman Ellstrand** - *University of California (UC)*

Gene flow is a common and natural phenomenon. While it is often of evolutionary significance, most gene flow has little impact on human affairs. Nonetheless, in certain well-documented cases, gene flow from crops to their sexually compatible relatives has resulted in both positive and negative impacts. When does gene flow matter? A necessary, but not sufficient, condition is that gene flow must be evolutionarily significant for an immigrant gene to persist in a recipient population. Persistence depends on

1. The gene flow immigration rate,
2. Whether gene flow is recurrent or unique,
3. The fitness effect of immigrant gene in its new population.

Whether or not persistence has an environmental, economic, or other social impact depends on the recipient plant, the recipient population, the recipient ecosystem, and the values of the human system interacting with those plants. To date, there have been more than two dozen reports of spontaneous transgene flow by seed and pollen into unintended populations. These case studies are informative, illustrating the types of impacts to date. Like natural gene flow, transgene flow has had and is anticipated to have sporadic effects on human affairs. Whether rare negative effects are realized will depend on mindful decision making prior to environmental release. Models of risk assessment for unintended transgene flow may serve as a starting point for risk assessment of intended gene flow, such as in the case of planned “gene drive” technology.

## PS I -2

### **Assessment of consequences associated with potential gene flow from transgenic maize to landraces**

**Silverio García Lara** - *Tecnológico de Monterrey*

Co-author: Juan Manuel de la Fuente Martínez

Numerous scientific works have concluded that commercialized genetically modified (GM) crops are safe for human consumption and the environment. The use of GM maize and its comparison to conventional maize have been documented extensively, supporting this technology. Between 2009 and 2013, pilot field trials with GM maize were conducted in Mexico - the center of origin and genetic diversity of this important crop, confirming its biological efficacy and environmental safety.

The objective of this project was to address the potential impacts of GM traits in maize landraces by a comparative analysis of landraces with and without GM traits in relation to its agronomic and phenotypic characteristics, ecological interactions and grain composition.

In 2013, a backcross breeding program was begun that introgressed GM traits that confer insect resistance and herbicide tolerance (MON89034×MON88017) into two different Mexican landrace accessions: Tuxpeño (PI 479072) and Tabloncillo (PI 515340). Landraces with and without the GM traits were developed to be used in this study. In 2015 and 2016, field trials were established at locations in the USA that are comparable to the ecoregions in which the landraces are grown in Mexico. These field trials were used to obtain data on agronomic and phenotypic characteristics, ecological interactions and to generate materials for grain compositional analysis. Furthermore, Mendelian segregation analysis of the GM traits was completed for segregating generations of both maize landraces.

Results of this study support that expressed GM traits do not alter measured agronomic and phenotypic characteristics, ecological interactions or variation in grain composition of the landraces compared to near-isogenic controls. Moreover, these genes of interest segregate across multiple generations following expected Mendelian segregation ratios like any nontransgenic allele. These results provide strong evidence for a safe coexistence between GM maize hybrids and landraces in Mexico.

**PS I -3****Potential for gene flow from transgenic maize (*Zea mays* L.) to eastern gamagrass (*Tripsacum dactyloides* L.)****Duška Stojšin - Monsanto**

Co-authors: Moon-Sub Lee, Eric Anderson, Marc McPherson, Baltazar Baltazar, Michael J Horak, Juan Manuel de la FuenteMartínez, Kungsheng Wu, James H Crowley, Lane Rayburn, DK Lee

Eastern gamagrass (*Tripsacum dactyloides* L.) belongs to the same *Poaceae* family as maize (*Zea mays* L.) and grows naturally in the same region where maize is commercially produced in the USA. Although no evidence exists of gene flow from maize to eastern gamagrass in nature, experimental crosses between the two species were made using specific techniques. As part of the environmental risk assessment (ERA), the possibility of transgene flow from maize to eastern gamagrass populations in nature was evaluated with the objectives: (1) to assess the seeds of eastern gamagrass populations naturally growing near commercial maize fields for the presence of a transgenic glyphosate-tolerant gene (cp4 epsps) that would indicate cross-pollination between the two species, and (2) to evaluate the possibility of interspecific hybridization between transgenic maize used as male parent and eastern gamagrass used as female parent. A total of 46,643 seeds from 54 eastern gamagrass populations collected in proximity of maize fields in Illinois, USA, were planted in a field in 2014 and 2015. Emerged seedlings were treated with glyphosate herbicide and assessed for survival. An additional 48,000 seeds from the same 54 eastern gamagrass populations were tested for the presence of the cp4 epsps gene markers using TaqMan<sup>®</sup> Polymerase Chain Reaction method. No seedlings survived the herbicide treatment and no seed indicated presence of the herbicide tolerant cp4 epsps gene, even though these eastern gamagrass populations were exposed to glyphosate-tolerant maize pollen for years. No interspecific hybrids were produced from hand-pollination attempts involving 1,529 eastern gamagrass spikelets exposed to maize pollen. These results indicate that there is no evidence of gene flow from maize to eastern gamagrass in nature. The outcome of this study should be taken in consideration when assessing for environmental risks regarding the consequence of gene flow from transgenic maize to its wild relatives.

**PS I -4****Across time and space: Transgene flow between oilseed crops and weedy relatives**

Linda M Hall - *University of Alberta*

Co-author: Hugh J Beckie

The *Brassicaceae* contains numerous transgenic field crops, cultivated or being developed (*Brassica napus*, oilseed rape; *B. juncea*, Indian mustard; *B. carinata*, Ethiopian mustard; and *Camelina sativa*, camelia) and weedy species (*Sinapis arvensis*, wild mustard; *Raphanus raphanistrum*, wild radish; *C. microcarpa*, little pod false flax; and *Capsella bursa-pastoris*, Shepherd's purse), that frequently grow close together. Intra- and inter-specific gene flow via pollen has been demonstrated in small plot and field trials in western Canada. This pollen-mediated gene flow can lead to seed contamination and transgene stacking. Specifically, gene flow between crop types may allow transgenes incorporation into seed exported to jurisdictions where they are not permitted, while crop to weed hybridization could result in introgression of genes conferring herbicide resistance in weeds. Seed-mediated gene flow resulting from anthropogenic dispersal of *Brassicaceae*'s small, round, and difficult-to-contain seeds allows crop "volunteers" to occur in fields and ruderal areas, providing additional sources of transgenes for dispersal. The transient populations that result are common and seed dormancy or production may allow survival across seasons, compounding the risk of gene flow. The multifarious sources and pathways for gene flow make transgenes difficult to contain and can result in transgene movement across local, regional and international scales.



## PS I -5

### GM gene flow in sugar beet: Regulatory experience in the USA

**Subray Hegde** - *US Department of Agriculture's Biotechnology Regulatory Services (USDA-BRS)*

Co-authors: John Turner, Sally McCammon

Gene flow is considered one of the powerful evolutionary forces shaping the genetic structure among sexually compatible genetically distinct populations (Grant 1981; Rieseberg 1997; Ellstrand 2003; Hegde et al. 2006). However, a certain type of gene flow is considered either harmful or undesirable for the environment, i.e. when a genetically modified (GM) trait escapes into a sexually compatible wild plant, making it a weedy plant. In the United States, APHIS USDA is responsible for regulating certain genetically modified plants. A key protection goal of APHIS USDA is to protect plant health from pests, including weeds. So far, USDA has approved three GM sugarbeet events for the unconfined field release since 1997. The potential environmental risk of GM sugarbeet-wild beet gene flow on the environment became a contentious issue during the unconfined field release of a genetically modified (GM) herbicide-resistant sugarbeet. Although no sugarbeet species are known to be native to the U.S. (Panella and Lewellen 2007), three introduced sugarbeet species (*B. procumbens*, *B. vulgaris* ssp. *vulgaris*, *B. vulgaris* ssp. *maritima* and *B. macrocarpa*) are present in the United States (USDA ARS 2011). The only location where feral sugarbeets are recorded is in California (Bartsh and Ellstrand 1999) and data suggest that their formation was due to gene flow that occurred either among wild sugarbeet populations or between cultivated and wild sugarbeets at some point (Richardson 2016). Based on the APHIS USDA's analysis, escape of GM traits into weed beet populations is possible if they are grown in close proximity to feral sugarbeets. However, APHIS concludes that the potential for pollen-mediated gene flow is low from the GM sugarbeet to wild SCRs due to the use of male-sterile GM plants for seed production and/or lack of proximity between the two types.

## PS I -6

### **22 years and 22,979 trees later: Lessons from field-testing GM trees in the USA**

**Amy L Klocko** - *Oregon State University (OSU)*

Co-author: Steven H Strauss

Trees play numerous important roles in human-dominated and wild ecosystems. They provide a wide variety of wood, fiber, energy and chemical products, as well as diverse ecosystem services, such as wildlife habitat and climate change mitigation. They are also grown in extremely diverse production systems, ranging from ornamental and horticultural plantings to lightly managed plantations and wild forests. The roles that biotechnology, including genetic engineering (GM), can play are therefore also highly diverse, ranging from protection or restoration of wild species to improvement of economics and sustainability of high intensity clonal systems. Genetic engineering has special appeal for many tree systems because breeding by conventional means is slow and high-value clonal varieties that are widely used can be “tweaked” by GM to improve specific characteristics while leaving the large majority of the genotype intact. Important traits that have been studied in the field, and well-documented in peer review literature, include pest and herbicide resistance, wood chemistry, coproduct synthesis, containment, and accelerated flowering. In a recently published book chapter that reflected on our two decades-plus experience conducting USDA-authorized field trials in the USA (*Biosafety of Transgenic Forest Trees*, Springer, 2016), we discussed several biological and management lessons. These will be discussed in more depth, but three major conclusions are:

1. Compliance with regulatory standards is often costly and challenging, and is a major impediment to use of GM for field research or breeding.
2. Field studies often reveal major surprises when compared to laboratory or greenhouse studies. They are essential for understanding the practical and physiological significance of GM modifications.
3. When produced by overexpression or RNA interference, traits are highly stable over many years, including genetic containment/sterility traits. Once a tree is out of the Petri dish, any unexpected phenotypic changes have been seen very rarely.

## PS I -7

### **Formulating and testing hypotheses about the likelihood of GM crops and hybrids becoming harmful weeds**

**Alan Raybould** - *Syngenta Crop Protection*

The purpose of risk assessment is to predict the likelihood and seriousness of harm resulting from a course of action. Such predictions help in decision-making, such as whether to permit the cultivation of a particular GM crop in a given location. An important part of risk assessment for the cultivation of GM crops is a determination of the likelihood that a crop, or its hybrids with wild species, will become harmful weeds of agriculture or damage non-agricultural habitats. This activity may appear complicated owing to attempts to make assessments quantitative and to incorporate ideas from evolutionary ecology. Research intended to help risk assessment has often measured gene frequencies, hybridization rates, population growth rates, or “fitness.” A much better approach is to test simple hypotheses that a particular GM crop or its hybrids show no greater weediness or invasiveness potential than non-GM plants of the same species, or that the crop will have no greater weediness and invasiveness potential compared than other introduced species that have not become weeds. In this talk, I will illustrate how to derive and test such hypotheses.

## Parallel Session II – Abstracts

### **Types of Evidence and Efforts Necessary to Inform the Safety Assessment of Unintended Effects in GM Plants**

As GM plants intended for commercialisation were developed, procedures were introduced to ensure they were as safe for food, feed and the environment as their conventional counterparts. These procedures were developed to address two types of potential changes to be considered in a GM crop safety assessment: intended and unintended. An intended change occurs as a consequence of the introduced transgene altering the crops phenotype. An unintended change could also occur as a consequence of the gene insertion, from random mutations that take place during the transformation and tissue culture process, or from pleiotrophic effects. Unintended effects might have an impact on potential agronomic performance, but they do not necessarily pose safety threats for human health, animal health or the environment. After 20 years of regulatory oversight and commercial use of GM plants, no adverse unintended effects have been discovered during regulatory reviews. Consequently, a re-evaluation of the original premise is merited. The objectives of the session are to explore the types of information that are necessary to inform the safety assessment of unintended effects in GM plants, and to explore the opportunity for revised approaches. The session will conclude with a panel discussion with subject matter experts.

Session organisers: **Sarah Davis** - *Canadian Food Inspection Agency (CFIA)* & **Jörg Romeis** - *Agroscope*

## PS II -1

### Experience gained on the assessment of unanticipated unintended changes in GM plants

**Wayne A Parrott** - *University of Georgia (UGA)*

Changes at the DNA level underpin most changes in crop appearance, composition, and behavior. The concern is that any of these changes could affect food or environmental safety adversely in unintended and unanticipated ways. Unanticipated means unpredictable because similar changes/effects have never been seen in that species, nor can they be expected from the transgene(s) being added. Accordingly, the potential of DNA changes to affect safety can be assessed using conventional plant breeding as a base line. While breeders have been inducing mutations and adding traits to crops from their wild relatives and related species for the better part of a century, the corresponding DNA-level changes remained mostly unknown. Advances in sequencing and genome assembly are finally providing answers; natural DNA insertions, rearrangements, and horizontal gene transfer are far more common than ever imagined. It is now recognized that all members of a species share a core genome, but, individuals have their core genome supplemented with assorted genes from the expendable genome of the species, such that individuals within a species can vary from each other by hundreds or thousands of genes. Thus, there are parallels between a plant breeder adding genes from wild relatives and engineering with cisgenes, if not transgenes. While conventional breeding has resulted in unintended changes with adverse results, none of these unintended effects were unanticipated. The inference is that DNA-level changes per se are not a source of unanticipated safety concerns. Accordingly, it is not surprising that commercialized engineered crops have been as safe as their conventional counterparts. The conclusion is that the probability of unanticipated effects with adverse effects from transformation itself is immeasurably low, and efforts should center on assessing the risks from hazards associated with the transgenes.

## PS II -2

### **Science informing policy – A study of insertional effects and implications on Canada's approach to environmental safety**

**Heather Shearer-** *Canadian Food Inspection Agency (CFIA)*

Co-author: Cindy Pearson

In 2015, the Canadian Food Inspection Agency (CFIA) and Health Canada (HC) jointly published a review of what is known about insertional effects and their potential for adverse unintended environmental, food and feed phenotypes, and how this compares to the spontaneous genetic changes that occur in plants developed through mutagenesis or conventional breeding methods. This paper concludes that the effects and thus the potential risks that arise from inserting a new gene(s) into a plant are comparable to the changes that occur spontaneously from plant breeding. This conclusion provides scientific basis for certain CFIA policies, such as policies on the environmental release of plants with novel traits (PNTs) in Canada. This presentation will focus on how the science of insertional effects has informed policy direction at the CFIA in terms of ensuring that data requirements for the pre-market assessment of PNTs are fit-for-purpose. Examples will include policies on intra-specific crossing as well as re-transformation and remutation. A critical assessment of the science-policy interface helps ensure that the regulatory burden is appropriate for applicants, while still maintaining scientific rigour in the pre-market assessment process.

## PS II -3

### **Unintended effects of gene insertions into plants and their impact on commercialisation as agricultural biotechnology products**

**Laura S Privalle** - *Bayer*

One of the questions evaluated when bringing an agricultural biotechnology product to market is whether the insertion of the newly introduced gene into the plant genome has resulted in unintended effects. Every transformation event does not result in a suitable commercial candidate. Unintended effects, such as lack of fertility, inability to regenerate, yield drag, stunting, abnormal color, etc., have been observed. A brief description of the development process of a biotech product will be presented to explain why hundreds of events (each insertion is defined as an event) are screened before the commercial event is identified. Efficacy is the primary consideration for commercial event selection, with agronomic performance and molecular characteristics of the insertion being other key parameters. These commercial events have to be shown to have similar agronomic performance and comparable composition to their conventional counterparts prior to receiving regulatory approvals. An outcome is that only events that have been demonstrated not to have any adverse unintended effects are considered for regulatory approval and commercialization. The plasticity and size of the genomes of crop plants reduce the frequency of unintended adverse effects, but nevertheless, a large number of events need to be considered before identifying the one that becomes the commercial product. Beneficial unintended effects, such as reduced mycotoxin presence as a result of insect resistance in the *Bt*-crops, have also been observed.

## PS II -4

### **Rodent feeding trials with whole food/feed – Summarising experiences from the EU-funded projects GRACE and GTwYST**

**Joachim Schiemann** - *Julius Kühn-Institute (JKI)*

Co-author: Ralf Wilhelm

The EU-funded projects GRACE (7/2012-11/2015) and G-TwYST (4/2014-4/2018) explore(d) the added value of rodent feeding trials with whole food/feed with transgenic maize (MON810 and NK603). This research was triggered by the EU Implementing Regulation 503/2013 mandatorily demanding the performance of a 90-day whole food/feed trial with rodents for the risk assessment of transgenic plants. There is an ongoing controversy on the necessity and added value of such feeding trials. While the GRACE project finished at the end of 2015 and published a series of papers on subchronic and chronic feeding studies with MON810 maize as well as concluding recommendations (<http://www.grace-fp7.eu/>), the project G-TwYST is still ongoing, studying potential impacts of whole food/feed on the health status of rats with NK603 maize in subchronic and combined chronic and carcinogenicity trials. The talk will summarize the results, conclusions and recommendations derived from both projects to the actual date



## PS II -5

### The value of *in planta* data for the non-target risk assessment

Jörg Romeis - *Agroscope*

Co-author: Michael Meissle

The genetic modification of plants could lead to unintended changes that potentially raise safety concerns. Such effects are thus addressed in premarket risk assessments of genetically modified (GM) plants. In respect to non-target organisms (NTOs) and the ecosystem services they contribute to, the guidance on the environmental risk assessment (ERA) of GM plants of the European Food Safety Authority (EFSA) requests applicants to conduct NTO studies using GM plant material (whole plants, plant parts, or ground plant material). These studies aim to support the risk assessment by gathering additional information on the interactions of the GM plant with NTOs. This data request is only required for GM plants for cultivation and is unique to the European Union. The presentation will address whether such *in planta* studies are of value to the NTO risk assessment, i.e., if they can help to reduce uncertainties. Examples of *in planta* NTO studies will be presented, and their pros and cons regarding the NTO risk assessment will be discussed.

## PS II -6

### **Future avenues and developments: Omics technologies as part of risk assessment strategies**

**Esther J Kok** - *RIKILT Wageningen University and Research (UR)*

There is to a large extent global agreement on risk-assessment procedures for new plant varieties obtained by the use of recombinant-DNA techniques. The main lines formulated by FAO and OECD have been implemented in most countries. Differences between countries can nevertheless also be observed in the implementation of the guidelines. In recent years we have seen some important developments in plant and animal breeding with upcoming powerful new technologies, of which Crispr-Cas is the most important, that will allow relatively rapid changes in the physiology of plants and animals that may meet the interests of producers as well as consumers. These developments will require adjustments to the risk assessment paradigm developed two decades ago that were primarily aimed at the introduced genetic construct and at a premarket risk assessment to evaluate the safety for humans, animals and the environment as the last step prior to market introduction. Here we propose to make safety considerations an integral part of the development of new varieties, according to the safe-by-design concept, using omics technologies to monitor new varieties for intended as well as unintended changes in the physiology of the new variety or breed. A model will be presented that can be used by risk assessors based on more informative data provided with lower costs by plant and animal breeders compared to the current approach of targeted (compositional) analyses based on extended field trials. The model can be used to evaluate, for example, transcriptomics, proteomics, or metabolomics profiles. The model has been applied in the European GRACE project, where maize materials were analysed in animal feeding trials with whole foods as well as in comparative compositional analyses, including omics approaches. Results will be presented, as well as an outlook on future application.

## PS II -7

### Evaluating biotech potatoes, one variety at a time

Susan Collinge, *JR Simplot Company*

Co-authors: Jeff Habig, Tracy Rood, Muffy Koch

Regulatory frameworks were developed to assess the safety of novel proteins that provide insect protection in crops like corn and soybean. Following a single regulatory approval of such traits, the insect protection was then bred into many varieties for commercial purpose. Potatoes, being tetraploid and highly heterozygous, are difficult to breed and commercial varieties tend to be consistent for many years. For example, the Russet Burbank was discovered by Luther Burbank in 1914 and remains the most popular potato variety in North America. Recently, biotech potato varieties have been introduced in the US and Canada, first emphasizing quality traits and more recently protection against late blight. To introduce biotech traits to potatoes, each variety must be transformed separately, resulting in a unique event. Because most regulatory systems are event-based, a separate approval is required even when introducing already approved traits. Streamlined evaluations in the US and Canada allow for faster clearance and market access for traits already evaluated in other varieties. Because there is a 20-year history documenting the absence of adverse unintended effects from approved biotech crops, consideration should be given to trait-based rather than event-based approval for vegetatively propagated crops like potatoes. Quality traits based on gene silencing of native transcripts with RNAi to reduce endogenous proteins should be evaluated based on the evidence of RNAi safety and of the history of safe consumption of RNA. Studies to show efficacy throughout the plant life cycle, in multiple tissues, and over multiple generations, provide little pertinent information for traits that only reduce endogenous substances, rather than produce new proteins. A weight of evidence approach using risk-assessment principles is recommended as an alternative to the traditional data packages for all biotech crops.

## Parallel Session III - Abstracts

### Biosafety Research, Risk Assessment Experiences and Capacity Building in Latin America

Latin America is a very contrasting region in terms of the use and development of GM plants. Both, Brazil and Argentina have been leaders in the growing of these plants, with Brazil being a Party to the Cartagena Protocol, while Argentina and Chile (together with the USA and Canada in the continent) have not signed the protocol and therefore are No-Parties. There are countries which currently import GMOs to be used for food and feed or processing, but do not allow local cultivation of these despite having legislation in place, while other countries have decided for a complete moratorium on the use of these materials. Also, there are instances where countries are still working on the establishment of a regulatory framework, while others that have such framework are unable to use the technology because of legal constraints such as lawsuits. Furthermore, there are wide differences in terms of capabilities for developing products of their own, therefore some countries see themselves as only recipients of this technology, while others have begun to develop their own products, not only to address national problems, but also to compete with the large transnational companies and therefore avoiding the monopolic practices. Participants to the session will share their stories concerning regional or national experience with GMOs, and will set the framework to discuss the path to be followed that may best suit the needs and expectations of such a diverse group of countries, such that the challenges of the future may be solved, at least partially, by the use of a technology that so far has proven to be safe and reliable.

Session organisers: **Jaime E Padilla-Acero** - *AgroBio* & **Juan Manuel de la Fuente Martínez** - *Monsanto*

## PS III -1

### Argentina's experience on the regulated use of GM crops

**Martín Lema** - *Ministry of Agro-industry & Quilmes National University*

The Argentinean regulatory system for genetically modified organisms was established in 1991; it is the second oldest in Latin America. The country is third in the rank of hectares planted each year with GM crops. There is plenty of activity pertaining to development and testing of new traits and crops derived from modern biotechnology. Its National Advisory Commission in Agricultural Biotechnology (CONABIA) was recognized as FAO Reference Center for the biosafety of genetically modified organisms. At the same time, Argentina maintains a high degree of regulatory harmonization with other leading regulatory systems, an intense trade of products derived from genetically modified crops with a diverse array of importing and exporting countries, a passionate contribution to international efforts for capacity building in biosafety, and a significant degree of intervention in relevant international fora such as Cartagena Protocol, CODEX, OECD, etc. The regulatory system routinely deals with applications for genetically modified plants, animals and microorganisms. Approximately twice a year there are significant updates to the regulation that modernizes preexisting regulatory criteria and proactively introduces approaches for emerging issues such as new breeding techniques, repeated use of constructs, second-generation traits, socioeconomic considerations, etc. In brief, it would be interesting to review a case where it was possible to maintain a functional regulatory system and conciliate an intense pace of innovation with a vigorous trade while caring for worldwide compatible regulatory standards. Current expectations and challenges for one of the leading regulatory systems in Latin America also will be depicted.

## PS III -2

### **The work of IICA and the status of Central American countries on biosafety**

**Pedro J Rocha** - *Inter-American Institute for Cooperation on Agriculture (IICA)*

The Inter-American Institute for Cooperation on Agriculture (IICA) is a 75-year-old institution acting as the agriculture-specialized agency of the Inter-American System. As a result of the orientations given by the Ministers of Agriculture of the 34 member countries at the Inter-American Board of Agriculture (IABA) during the last 11 years, IICA has been working in biotechnology and biosafety (B&B).

Three main groups of activities have been carried out: Institutional support, training and communication. Institutional support has been offered both at national and regional levels. For instance, in the framework of a UNEP-GEF project, IICA proposed the strategy for education and communication of biotechnology for Costa Rica. Similarly, the Institute has reviewed Honduras' biosafety regulatory framework as a requirement from the Ministry of Agriculture, and by doing so a technical basis was provided to support the advance of the bilateral customs agreement between Guatemala and Honduras.

At the regional level, IICA supported the creation of the Initiative for Central America in Biotechnology and Biosafety (ICABB), a technical platform that allows for the open discussion of biosafety issues involving countries of Central America and Dominican Republic. Regarding training and communication, IICA has organized courses, seminars and meetings on different topics aligned to Cartagena Protocol on Biosafety, including risk assessment, synthetic biology, low level presence, and biotech communication courses. In addition, IICA has participated in several communication activities on biotechnology in all countries of Central America.

Biotechnology and biosafety are very important issues for Central American countries; IICA recognizes that and will continue responding to the broad spectrum of requirements from its member countries.

### PS III -3

#### **Brazil's experience on the regulated use of GM crops**

**Flavio Finardi-Filho** - *University of Sao Paulo*

Ten years after the beginning of the Brazilian biosafety law, the country approved 112 GM products, including plants (62.5%), vaccines (24.1%), microorganisms (11.6%), drug (0.9%), and insects (0.9%). CTNBio – National Technical Commission on Biosafety is the regulatory agency in charge of controlling the effective use of good practices on the genetic modification of living organisms in order to protect the human and animal health and environmental protection. A regular petition of a new GM plant follows several administrative and evaluation steps from the official report in the governmental newspaper, to the permission to import a small lot of seeds to fulfill field trials, to the report of the agronomic behavior after trials through to the request for commercial release. Once approved, the process must wait for a final decision of the CNBS – National Council of Biosafety, an inter-ministerial organism to receive the governmental agreement for commercialization. Despite the long way and time expended on the legal procedures, the fast adoption of the GM crops by the seed producers was driven by the companies and research institutions to propose new events, most of that to facilitate the agricultural practices on different biomes of this tropical country. Now the CTNBio has a new task: how to regulate the events obtained by the use of NBTs.

## PS III -4

### **CIAT GM research in Colombia to address agriculture sustainability and micronutrient malnutrition**

**Joe Tohme** - *International Center for Tropical Agriculture (CIAT)*

Co-author: Paul Chavarriaga

The International Center for Tropical Agriculture (CIAT), with its headquarters in Palmira, Colombia, works in collaboration with partners to reduce hunger and poverty and to improve human nutrition in the tropics through research aimed at increasing the eco-efficiency of agriculture. CIAT develops more resilient, productive and nutritious varieties of common bean, cassava and rice, together with improved tropical forages. As part of its effort to improve crop nutrition and productivity, CIAT has permission from the Colombian National Biosafety Committee to carry out research on transgenic rice and cassava under biosafety-confined field trials. CIAT Biosafety Guidelines were developed to strictly adhere to all of the Colombian regulations in place. CIAT has developed standard operating procedures (SOPs) that include strict biosafety regulations for confined field trials. CIAT has been a member since 2014 of Excellence Through Stewardship (ETS) – a global organization that promotes universal adoption of best management practices for developing products through plant biotechnology. Current research work focuses on proof of concepts to develop 1) rice genotypes with improved nitrogen use efficiency; 2) rice genotypes with higher level of iron – high zinc to address micronutrients malnutrition; and 3) genome editing for quality traits. Results from these projects, as well as lessons learned for conducting confined biosafety, regulatory compliance plans, and capacity building will be described.



### PS III -5

## **An environmentally friendly GM technology to effectively decrease the use of fertilisers and herbicides in agriculture**

**Luis Herrera-Estrella** - *Centro de Investigación y de Estudios Avanzados*

Co-author: Damar Lopez-Arredondo

Poor soil fertility and aggressive weeds pose major constraints to meeting the increasing demand for global food production. Phosphorus (P) is a nutrient that limits crop yield in over 60% of the world's arable land. Therefore, to increase plant productivity in soils with low P availability, several million tons of P-fertilizer is applied every year. Low phosphate (Pi) availability in the soil is mainly due to its high reactivity with soil components and rapid conversion by soil bacteria into forms that are not readily available for plant uptake. These factors cause only 20-30% of the Pi applied as fertilizer actually to be used by cultivated plants. The inefficient utilization of Pi is further aggravated by the competition of weeds with crops for soil resources. Because Pi cannot be substituted in plant nutrition, other chemical forms of P have received little attention to formulate more effective fertilizers. Phosphite (Phi), a reduced form of P, was proposed as a promising alternative fertilizer after the Second World War, owing to its distinct chemical and biochemical properties compared with Pi. However, plants cannot metabolize Phi, limiting its use as a fertilizer. Previously, we reported on the development of a novel fertilization and weed control system by engineering plants to metabolize Phi, achieved by expressing a phosphite oxidoreductase that converts Phi into Pi. When grown in soil with native microflora and fertilized with Phi, engineered plants achieve maximum productivity with 30-50% less P than that required to reach the same productivity using Pi-fertilizer. Since nonengineered plants are unable to use Phi as a P source, when fertilized with Phi, the engineered plants easily outcompete weeds, reducing or eliminating the need for herbicides. Here we present the application of this technology in maize, soybean, and cotton, species in which the system has been successfully implemented. These metabolically engineered plants allow the design of a dual fertilization and weed control system with both potentially important economical and ecological benefits.

### PS III -6

#### **The use of GM crops in México: Experiences in biosafety, institutional capacity, and the effect of regulations on the evolution of national policies**

**Natalhie Beatriz Campos Reales Pineda** - *Comisión Intersecretarial de Bioseguridad de los Organismos Genéticamente Modificados (CIBIOGEM)*

Co-author: Sol Ortiz García

Establishment of coherent biosafety policies is complex in nature. Abundance of genetic and biological resources, productive systems, and potential biotech developments pose biosafety challenges that most likely require strategic vision and diversified solutions. In the Mexican context, biosafety policies have to apply to a megadiverse, multicultural nation.

The first release of a GM crop was approved in 1988. Since then, different events have been tested through the regulatory scheme. In contrast with the efforts for increasing local capacities in biosafety over the past two decades, a significant reduction on field trial requests has been observed. This effect is due in part to the biosafety regulatory constraints, but also because of political and legal issues.

Mexico differs in the type of crops and the receptor environments across its vast territory. This represents important challenges for the enforcement of policies on a case by-case basis. Therefore, scientifically based decisions are sought in order to ensure the safe and responsible use of the novel technologies, and biosafety research is encouraged. Framed by the Law of Biosafety for Genetically Modified Organisms, the national framework is comprehensive and has evolved complementary regulations and national standards for risk assessment, labelling, monitoring and inspecting strategies. Specific regulations for areas determined as centers of origin of relevant species or the protection regime for maize crops are of interest. Social awareness activities and other participation procedures have also been established.

In this work, we review progression of institutional capacities, policy milestones, and coordinated actions towards a consolidated operational system, along with the description of the best practices and main challenges.

### PS III -7

## Biosafety regulatory systems overseeing the use of GMOs in the Latin America and the Caribbean region

**Ayrton André Rosado Huaynasi** - *International Centre for Genetic Engineering and Biotechnology (ICGEB)*

Co-author: Wendy Craig

Most developing countries require biosafety regulatory systems to ensure the safe use of Genetically Modified Organisms (GMOs) within their territories. The development of a legal framework and the establishment of an administrative system are two fundamental elements in such regulatory systems. Further, the ability to process applications to authorise GMOs to be used with different degrees of containment (from zero to total) is a good indicator of an operational biosafety regulatory system. In the Latin America and the Caribbean (LAC) region, some obvious countries, such as Argentina, Brazil, Cuba, Honduras and Mexico, have had operational biosafety regulatory systems for a significant time and have accumulated extensive experience in regulating GMOs for a multitude of diverse purposes, while other countries have little, or are yet to gain such, experience. Based on the results of Araya-Quesada et al. (2012), our study provides an update of the progress made by countries in the LAC region to the end of 2015 in establishing biosafety regulatory systems and enhancing the regulation of four key types of GMO use (e.g. contained use, confined use, unconfined use and importation of GMOs or their derived products for strictly food, feed or processing purposes). It demonstrates that nine countries in the LAC region have operational biosafety regulatory systems with regulatory experience in all four key types of GMO use. In addition, only eight countries located in the Latin American sub region have gained experience in the regulation of one or two key types since the end of 2015. Significantly however, the majority of countries in the LAC region have little or no experience in the regulation of GMOs; in fact, this study identified common limitations experienced by biosafety regulatory systems in these countries and proposes specific capacity building support in the region.

## Parallel Session IV - Abstracts

### **ERA vs. Ecological Research – The Relevance of a Good Problem Formulation to Ensure That Gathered Data are Useful for ERA**

Every deployment of a GMO can trigger hundreds of imaginable risks in the minds of stakeholders (e.g. applicants, regulators, academia, the wider public, etc.). The use of problem formulation assists the identification of significant risks to important and valued resources, and as a consequence, helps direct the generation and analysis of high-quality data relating to the identified risks. In addition, when a transparent and inclusive approach is taken with regard to problem formulation, consistent, thorough and efficient ERAs are promoted, which in turn leads to the identification of key areas for ecological research relevant to GMO use. Moreover, such an approach, when communicated to stakeholders, helps the wider understanding of how the scope of each ERA was determined and which data were key to the conclusions. The use of problem formulation therefore helps ensure that each ERA is successful and effective. In this session, it will be demonstrated how the use of problem formulation can help drive ERA and related ecological research to be more focused on significant risks.

Session organisers: **Wendy Craig** - *International Centre for Genetic Engineering and Biotechnology (ICGEB)* & **Mònica García-Alonso** - *Estel Consult Ltd*

## PS IV -1

### An introduction to problem formulation

**Wendy Craig** - *International Centre for Genetic Engineering and Biotechnology (ICGEB)*

Problem Formulation has become increasingly acknowledged by the GMO regulatory community as an integral component of environmental risk assessment (ERA) since its early adoption by the USA's EPA (1992). In this context, problem formulation constitutes a systematic or strategic approach that establishes the goals, breadth, and focus of the ERA. When properly used, it results in the articulation of specific important and valued environmental entities to be protected (based on both scientific and policy considerations), proceeds to how they may be plausibly impacted through interaction with the GMO, and concludes in the identification of the necessary information and data to determine the degree (if any) of likely impact. This short introductory presentation will draw together highlights from the previous plenary session describing present challenges to the advancement of the ERA of GMOs, and will contextualise how the various approaches described in the present parallel session help to promote consistent, thorough and efficient ERAs. Additionally, when these approaches are embraced, they can strengthen the justification of key areas of ecological research relevant to GMO use to be funded or undertaken, as well as achieve a greater, more informed involvement of wider stakeholders in GMO regulation.

## PS IV -2

### Regulatory use of problem formulation – GM mustard

**Vibha Ahuja** - *Biotech Consortium India Limited*

Safety assessment of a GM plant is the most important step in its development process. Developers of GM plants (both public and private sector) test their products according to regulatory requirements. Regulatory authorities undertake thorough analysis of the data and the protocols used before granting approvals for various activities, such as confined field trials and environmental release. Additional information and additional testing may be asked by the regulatory agencies at various stages of the development process. Process of data submission and approval of *Bt* cotton, the only approved GM crop in India, indicates that the assessment protocols were developed on a case-by-case basis, and data requirements were stipulated at various steps. Though the case-by-case requirements and protocols always will be required in the safety assessment process due to the difference in host plants, traits and several other factors, applying a structured problem formulation framework can reduce the inconsistencies and harmonize the regulatory approval process.

Keeping in view the above, problem formulation approach was used in regulatory evaluation of GM *Brassica juncea* (mustard) in India. To begin with, available information on mustard was collected, including preparation of a biology document. Knowledge gathered through past experience on GM canola and decision documents by the regulatory agencies in other countries were also reviewed. The use of a problem formulation approach has helped greatly in systematic generation of data and also in addressing concerns raised during review process. The presentation would share experience in applying problem formulation approach in the development and regulatory approvals for GM mustard.

## PS IV -3

### Taking stock of the ERA of GM higher plants

Patrick Rüdelsheim – *Perseus*

Co-author: Greet Smets

When legislation addressing environmental effects of activities with genetically modified organisms was established, knowledge on these effects was limited. Commissioned by the Dutch National Institute for Public Health and the Environment (RIVM), the authors reviewed information gained, identifying elements for which an Environmental Risk Assessment (ERA) can be conducted with acceptable confidence and without requiring additional information. The presentation provides a summary of the study and its main conclusions:

- The comparative assessment builds on knowledge of the nonmodified host/parental organism. When the host organism has a history of safe use, the ERA can focus on the potential impact resulting from the modification.
- It is questioned whether genes and gene constructs that were independently and repetitively assessed, leading to authorisation, should be subjected to a full assessment when deployed in new events. Similarly, experience obtained with stacked events should allow limiting the review to those cases where the stack is potentially leading to an interaction between the inserted traits.
- Major field crops are well documented and provide a model for other plant species.
- Traits like specific herbicide tolerances and insect resistance have been elaborated and can serve as models for other traits.
- Mechanisms such as spread in the environment (seeds, pollen) and transfer to other organisms (pollen flow) have been documented in detail. Further accumulation of information is unlikely to provide new insights for the ERA.
- The hypothetical concern for horizontal gene transfer can be neglected unless the trait would indicate a special safety issue.
- The interaction with nontarget organisms (NTO) has been studied in great detail for *Bt* proteins. Additional scientific research and experience increases the level of confidence, but there is no justification to expand the requirements for preauthorisation NTO testing.
- Evaluating changes in management is largely influenced by the choice of the reference management regime.

## PS IV -4

### **The use of a problem formulation approach to focus the nutritional assessment of food and feed originating from a novel GM crop**

**Phil Brune** - *Syngenta Crop Protection*

The compositional equivalence study is one of the key study types that comprise the overall safety assessment of a novel genetically modified (GM) crop. The main purpose of the composition study is to assure the nutritional status of food and feed originating from the new GM crop is comparable to food and feed present in the commercial market. Because nutritional components are metabolites or end products of major plant metabolic processes, a secondary purpose of composition studies is to look for evidence of hypothetical unintended effects. However, the body of work conducted over more than 20 years has not shown substantial, unintended departures in nutrition, nor have they provided evidence for biologically impactful unintended changes in plant metabolism. To date, most traits incorporated through recombinant DNA techniques have been for insect control or herbicide tolerance, and the current approach has provided successful evaluation of crop safety. Because the technology has proven to be safe, this untargeted approach to compositional analysis may no longer be warranted. As the science moves forward, the types of traits involved will become more complex, and plant metabolic pathways may be more likely to be affected. Rather than continue with an open-ended evaluation of nutritional safety that does not have a well-defined hypothesis, a problem formulation approach is a tactical way to evaluate the safety of these new GM crops. Problem formulation is a process to clearly identify and clarify the problem (or question) and define the most appropriate means of addressing the problem. This presentation will discuss how this process can be used to evaluate nutritional safety and will work through an example of how it has been used to evaluate GM soy with tolerance to the herbicide mesotrione.



## PS IV -5

### **For GM breeding stacks, crop composition and transgene expression are predicted by the single component events**

**Rod Herman** - *Dow AgroSciences*

Co-authors: Satyalinga Gampala, Brandon J Fast, Kimberly Richey, Zhifang Gao, Greg Bradfisch

Crop-composition and transgene-expression levels are measured for genetically modified (GM) crops to investigate unintended and expected effects, respectively, in part, to support environmental risk assessment (ERA). The composition and transgene expression in GM breeding stacks should be predictable from the single component events based on our scientific knowledge around plant breeding. We investigated the effects of GM stacking versus non-GM hybrid development on maize grain composition to determine relative risks for unintended effects, and we evaluated the power of single events to predict stack transgene-expression levels in maize, soybean, and cotton to assess expected effects. Scatter plots allowed visual comparisons between crop lines to be made, and the fit of data to the line of identity ( $y = x$ ) quantified the amount of variability accounted for by predictions. Transgenesis and stacking were found to change crop composition less than traditional non-GM hybrid development in maize, and transgene expression levels were predicted well by expression in component single events in maize, soybean, and cotton. Results indicate that composition and transgene-expression data on breeding stacks are unnecessary for assessing risk if such data are available for the single component events.

## PS IV -6

### The use of problem formulation in Mexico

**Sol Ortiz García** - *Comisión Intersecretarial de Bioseguridad de los Organismos Genéticamente Modificados (CIBIOGEM)*

Mexican Biosafety regulation for GM plants started 20 years ago with the publication of an Official Mexican Standard (NOM) dealing with field trials of genetically modified crops. In 2005 a Biosafety Law for GMOs was published that included general principles for risks assessment and a general methodological approach based on Annex III of the Cartagena Protocol on Biosafety. After few years of discussions and negotiations among relevant stakeholders, recently a new NOM has been consulted for publication. This new Standard includes Problem Formulation (PF) in its approach for contextualizing risk assessment and complementing its general methodology. In this paper we present a preliminary analysis of the components in the NOM for ERA, how it fits under description of the PF approach, and how it could fulfill its purpose to guide applicants as well as regulators under a harmonized framework. A main indicator of its applicability could be how effectively the process allows for discriminating between data that informs that assessment and “nice to know” information.

## PS IV -7

### Using expert panels and problem formulation to inform risk assessments for gene flow from GM crops to wild relatives

**Karen Hokanson** - *University of Minnesota (UM)*

Co-authors: Norman C Ellstrand, Alan Raybould

Problem formulation is the process of identifying possible adverse effects and formulating plausible scenarios that might lead to them. As part of this process, experts with relevant knowledge and experience are often called upon to help clarify the available information about the crop, the introduced trait, and the environment where it will be grown, in order to inform the risk assessment. This presentation will describe three cases where a panel of experts was convened to essentially use problem formulation to consider the risks associated with gene flow from a GM crop to "wild" (naturally occurring) relatives of that crop. The three cases considered were a nutritionally enhanced sorghum, an insect-resistant cowpea, and a virus-resistant cassava, all to be grown in Africa. In each case, the respective panel of experts identified possible adverse effects and steps in the pathway that could lead to them, and then discussed what information is known to determine whether each of the steps in the pathway is likely or not to occur. The process of problem formulation was extremely useful to focus and facilitate these expert panel discussions. However, one important observation from all of these examples is that, even following problem formulation, there still was a debate among experts about which information is "nice-to-know" and which is "need-to-know." This distinction is the challenge for decision-makers involved in GM crop approvals. Problem formulation can make risk assessment of GM crops more clear and transparent by helping to effectively communicate science-based risk assessments among all interested parties, including the scientific community, the product developers, the regulators, the decision-makers, and the concerned public.

## Parallel Session V - Abstracts

### Plant Genome Editing – Any Novel Features to Consider for ERA and Regulation?

New genome editing techniques (e.g., TALEN, Zinc Finger) open the gate to a so far unknown spatially and functionally precise surgery of genes to the end of a controlled mutagenesis. Moreover, even entire genes can be placed into the genome at desired loci using these techniques. At the same time decisions on whether organisms created by these developments do require legal regulation lags behind in numerous jurisdictions. The progress on genome editing may challenge both risk assessment and regulation: There is a need to balance the public's need for food, feed and environmental safety and the costs for developers, growers, shippers and processors, without wasting resources in a proportionate way. This session will bring together developers, risk assessors and regulators to promote a knowledge-based discussion by summarising technological developments of the last years, identifying knowledge gaps, analysing scenarios for the introduction of selected edited organisms in the environment, and creating awareness about benefits and risks of the new techniques by connecting regulatory approaches, ethical aspects and decision-making.

Session organisers: **Nina Duensing** - *Federal Office of Consumer Protection and Food Safety (BVL)* & **Detlef Bartsch** - *Federal Office of Consumer Protection and Food Safety (BVL)* & **Thorben Sprink** - *Julius Kühn-Institute (JKI)*

## PS V -1

### What is unique about genome editing?

**Wayne A Parrott** - *University of Georgia (UGA)*

Genome-editing technologies are making it possible to target preselected sequences for modification. The current stage of technology permits efficient gene inactivation, analogous to what happens with induced mutations. In the future, genome editing will enable the replacement of one allele with another (analogous to what breeding does) or inserting genes into predetermined locations. Nevertheless, editing tools are not perfect and can result in unintended changes elsewhere in the genome. Software that predicts the potential for unintended changes in other parts of the genome makes it possible to select targets that are unlikely to result in unintended changes, particularly in diploid, self-pollinated plants. Avoiding off-target effects in polyploids and heterozygous plants is more challenging, but software is continuously improving. Regardless, parts of the genome likely to experience off-target changes are reasonably easy to evaluate. Even if an unintended change were to escape detection, there is no evidence that DNA-level changes affect safety adversely. Furthermore, the normal background mutation rate can be comparable to the off-target rate. In addition, changes induced by mutagenesis—which can be far greater than changes from editing—have a solid safety record. Although whole-genome sequencing has been recommended as a safeguard, whole-genome sequencing is not an effective approach because the sequencing error rate can be higher than the off-target rate, and because even the best sequencing protocols do not provide whole-genome coverage. Thus, changes in parts of the genome that remain unsequenced or get filtered out will not be detected. While using genome editing for allele deletion or replacement does not pose risks different from those posed by conventional breeding and mutagenesis, gene insertion will present the same set of hazards posed by current transgenes. As such, hazard identification and risk assessment need to focus on the new gene.

## PS V -2

### **ERA challenges associated with genome-edited crops from a public risk assessor perspective**

**Thorben Sprink** - *Julius Kühn-Institute (JKI)*

Co-author: Ralf Wilhelm

The new breeding techniques and essentially genome editing will have substantial impacts on breeding efforts and agriculture in the next years. Associated with new breeding methods, new products and traits may arise on the global markets if the regulatory framework permits this. There is an ongoing controversy if such products or the techniques themselves require specific legal regulation and, neither any judgment, nor any regulation at the national or international levels has been passed so far. Nevertheless, several authorities and organizations have explored this issue. We will introduce suggested guidance from different organizations, such as EFSA, discuss knowledge gaps, and will put the different genome-editing techniques in the regulatory context. Additionally, we will discuss the possible assets and drawbacks of national and international harmonized regulations and guidance from the view of a public risk assessor.

**PS V -3****CRISPR-Cas gene editing and similarities to conventional breeding outcomes: A product developer perspective**

**Maria Fedorova** - *DuPont Pioneer*

Traditional plant breeding historically has relied on a plant's genetic variability to develop new varieties with improved characteristics. Favorable allelic variations, spontaneous mutations and induced random mutations have been a source of genetic diversity carried forward into commercially valuable genotypes. The ability to induce genetic variation in a targeted and more efficient fashion has been viewed as a much needed breakthrough and a challenge until recently. Gene editing, enabled by tools such as ZFN, TALEN or CRISPR-Cas, provides that breakthrough. Gene editing can be defined as targeted modification of a plant's own genes without introducing any foreign genetic material. This distinguishes gene-edited varieties from GMOs. This presentation will focus on the use of CRISPR-Cas as a gene-editing tool, which is considered a major advancement in precision plant breeding due to its versatility, efficiency and ability to work across species. Examples of technology applications and plant characterization methodologies will be provided to show that gene editing can produce plants indistinguishable from those that could arise from spontaneous or induced classical mutagenesis or be developed by introgressing the desired allele through a series of breeding crosses, i.e., tools deployed in conventional breeding. The specificity of gene editing can be evaluated using molecular diagnostic tools, and potential off-target cutting, if needed, can be segregated away through traditional breeding crosses. However, risk assessment considerations associated with potential off-target cutting should be viewed in the context of well-documented dynamic nature and plasticity of plant genomes. The frequency of any potential off-target cutting is expected to be significantly lower than the frequency of meiotic recombinations, spontaneous mutations, or collateral mutations from classical induced mutagenesis in conventional plant breeding, which has a long history of safe use.

## PS V -4

### **Regulatory challenges: Technology-based vs. product-based regulations and potential impact on product monitoring**

**Martín Lema** - *Ministry of Agro-industry & Quilmes National University*

Gene-editing techniques comprise recent innovations in plant breeding using molecular biology. They provide the capability of introducing a site-directed mutation or deletion in the genome; and in some cases these techniques can be further refined to also achieve site-directed insertion of DNA constructs also. Crops improved with these technologies are approaching the market; this has raised an international debate regarding how they are to be regulated. Some argue they should be considered genetically modified crops, some others consider them to be just another form of mutagenesis, and therefore to be regulated as products of conventional breeding. In this regard, many argumentation avenues follow a comparative approach regarding, for instance, the possibility of generating the same kind of genetic modifications by other means, or the detectability of gene editions for the purpose of control and monitoring, or the relative safety of these products, *inter allia*. However in the end, governments have to establish the regulatory requirements for these crops from the legal definitions applicable to defined categories of regulated products. Existing legal definitions applicable to genetically modified crops (or related categories) are diverse, although many of them are derived from the Cartagena Protocol. Quite often, these definitions include “triggers” for regulatory classification that are based both on product characteristics and the process to obtain them. In regards to products derived from gene editing, initial pronouncements by some regulatory agencies or official expert bodies in different countries include examples referring either to certain technologies or to isolated products. Technology-based decisions in this area may be more attractive to the developers; however, product-by-product judgments may be more feasible and also facilitate product monitoring later if necessary. Finally, finding the adequate regulatory approach not only entails issues pertaining to safety information and legal definitions; it also interplays with international trade and innovation in agriculture.



**PS V -5****Preparing for future biotechnology products – Perspectives on the National Academies of Sciences, Engineering and Medicine (US-NASEM) report**

**Jeffrey D Wolt** - Iowa State University (ISU)

The U.S. Office of Science and Technology Policy (OSTP), in 2015, initiated an effort to modernize the U.S. regulatory system for biotechnology products. This effort included commissioning an external, independent analysis of the future landscape of biotechnology products, with a focus on potential new risks and risk assessment frameworks for biotechnology products expected to emerge in the marketplace in the next 5 to 10 years. This task was undertaken by a committee of science and policy experts convened by the U.S. National Academies of Sciences, Engineering and Medicine, which will report their findings in 2017. The committee's deliberations are anticipated to reflect recognition of rapid growth in the bioeconomy and the need for the U.S. regulatory system to keep pace. This is especially true given the variety and number of biotechnology products expected to emerge in future years. The safe use of new biotechnology products requires rigorous, predictable, and transparent risk-analysis processes that mirror future biotechnology applications. The committee's findings are expected to align with those of OSTP's internal analysis reflecting a modernized regulatory system that effectively anticipates and addresses emerging products of biotechnology. This contribution examines the findings of this report in terms of the biotechnology products envisioned and the regulatory and governance structures that will support their safe development and use.

## PS V -6

### World Café session

#### PS V-6

##### **Café table 1: ERA – Novel demands?**

**Thorben Sprink** - *Julius Kühn-Institute (JKI)*

#### PS V-7

##### **Café table 2: Monitoring – Detection and identification of new products/traits after placing on the market**

**Nina Duensing** - *Federal Office of Consumer Protection and Food Safety (BVL)*

#### PS V-8

##### **Café table 3: Global harmonisation of regulation**

**Detlef Bartsch** - *Federal Office of Consumer Protection and Food Safety (BVL)*

Co-authors: Georg Leggewie, Thorben Sprink

New genome-editing techniques open the gate to an unknown spatially and functionally precise surgery of the genome to the end of a controlled mutagenesis. Moreover, even entire genes can be placed or deleted at desired loci using these techniques. However, so-called "off target" effects are unlikely to vanish from the engineered genomic landscape. With either diverse legal interpretations in some countries or even a current lack of legal guidance in others, a debate has started on whether the legal status of plants with edited genomes has to be based on the process used to create the organism or on the trait/final product obtained by the process. This has implications for potential novel demands on the Risk Assessment (RA). It is also discussed whether point mutations created by genome-editing techniques have the same legal status as point mutations created by conventional mutagenesis. Last, in various countries, tracing requirements are in use to detect and to identify a modified organism. Yet, point mutations do not carry a tag displaying the technique used to create them. In case it is decided that genome-edited organisms are to receive regulation, how shall they be monitored? Finally, asynchronous or even divergent regulation in different states may disturb world trade and collide with standards of the World Trade Organisation. RA and regulation need to balance the public's need for food, feed, and environmental safety and the costs for developers, growers, shippers, and processors without wasting resources and while allowing innovation in a proportionate way. An interactive World Café will be used as a well-known communication tool to invite session participants for their feedback on three Challenge Station. At the end of the exercise, a session summary may define sticking points in the legal debate and point at solutions for legal interpretation.

## Parallel Session VI - Abstracts

### GMOs in IPM

As the global population continues to expand, utilising an integrated approach to pest management will be important for food security and agricultural sustainability. GM crops with resistance to insects, tolerance to herbicides, and enhanced agronomic performance can contribute as an important set of tools in a diversified integrated pest management (IPM) plan. Current developments in IPM and in insect resistance management (IRM) will be highlighted. The purpose of this symposium is to provide a venue for scientists from academia, private organizations, public research institutes, and industry to present innovative research in the development of robust IPM plans. A series of presentations will be followed by a panel discussion, highlighting advancements in the field and discussing the role of agricultural biotechnology in IPM development

Organisers: **Jennifer Anderson** - *DuPont Pioneer* & **Michael Meissle** - *Agroscope*

## PS VI -1

### The principles of Integrated Pest Management – How do GM crops fit?

Michael Meissle - *Agroscope*

The concepts of Integrated Pest Management (IPM) and Integrated Production (IP) are approximately 40 years old but more timely than ever since the goal is to enhance the sustainability of modern agricultural systems. In this presentation, the principles of IP will be introduced using the concept promoted by the International Organisation for Biological and Integrated Control (IOBC). Genetically modified (GM) crops are grown in increasing areas globally. The majority of them are tolerant to broad-spectrum herbicides or resistant against certain Lepidoptera and Coleoptera pests. Studies with both types of GM crops have shown that they can be used in integrated systems to improve sustainability. In particular for insecticidal crops producing Cry proteins from *Bacillus thuringiensis*, a range of environmental benefits has been reported on the field and landscape scale. For a sustainable use of GM crops, however, the evolution of resistance in target pests or weeds has to be mitigated. To ensure a responsible use of GM crops with reduced environmental impact, multiple stakeholders have to make a joint effort. A high proportion of growers need to comply with the implemented regulatory obligations with support from effective product stewardship programmes established by the companies. In addition, agricultural systems can be improved further with clear incentives from governments, label organizations, grower associations, and support from the market, including the supply chain, the agricultural and food processing industry, retailers, and consumers.

## PS VI -2

### The role and value of regulation of IPM programs for *Bt*-crops

Graham Head – *Monsanto*

Co-author: Samuel Martinelli

Transgenic crops that express proteins from *Bacillus thuringiensis* (*Bt*) for the control of insect pests (*Bt*-crops) were first approved for commercialization in 1995 and since have been commercialized in more than 15 countries. Their primary application has been for control of important lepidopteran pests in corn and cotton, and more recently in soybeans, with approximately 200 million hectares planted annually across these three crops. As such, *Bt*-crops have become an important part of integrated pest management (IPM) programs in these crops. These programs benefit from the efficacy and specificity of *Bt*-crops but must adequately address non-target pests i.e., non-lepidopteran pests of these crops. As part of ensuring the safe use of *Bt*-crops, regulators in a number of countries have included IPM and insect resistance management (IRM) practices in *Bt*-crop registrations. This presentation will review how IPM for *Bt*-crops has been considered by regulators and the degree to which regulation has been helpful in achieving adoption of appropriate IPM and IRM practices by farmers.

## PS VI -3

### Implementing best practices to complement biotech resistance management guidelines

Timothy Dennehy - *Bayer*

Co-author: Clinton D Pilcher

Resistance management (RM) for biotech crops continues to receive considerable attention globally. Historically, there are numerous examples of successful deployment and adoption of RM plans for specific product x pest combinations. There are equal numbers of examples where RM plans have failed to achieve their intended outcomes. Industry continues to explore potential opportunities to improve RM adoption by growers globally. Recent initiatives will be addressed along with discussion of the contributing factors that may explain why some initiatives are successful and others are not. Socio-economic factors play a key role in understanding what best practices should be used to ensure successful RM implementation.

## PS VI -4

### Implementing IPM for *Bt*-eggplant: Meeting the challenges or dreaming the impossible dream?

Anthony M Shelton - Cornell University

Co-authors: Joseph E Huesing, Gour Pada Das, Desiree M Hautea, Karen E Hokanson, Srinivas Parimi, Vijay Paranjape, Nicholas P Storer, Arif Hossain

EE-1, an eggplant expressing Cry1Ac, was developed by Maharashtra Hybrid Seeds Company Private Limited (Mahyco), a major Indian seed company, to control the eggplant fruit and shoot borer (EFSB), the primary insect pest of eggplant in Asia and Africa. Mahyco provided EE-1 to the Bangladesh Agricultural Research Institute (BARI) and the University of the Philippines Los Baños to incorporate into their breeding lines. On October 30, 2013, the government of Bangladesh approved four varieties of *Bt* eggplant (brinjal) for limited release to control EFSB. The following year 20 farmers grew *Bt* eggplant in demonstration trials, and the number of demonstration trails increased to 108 in 2015 and 230 in 2016. Because growers were allowed to save their seed, the number of farmers actually growing *Bt* eggplant was far higher. Research trials and demonstration trials indicated that *Bt* eggplant provided excellent control of EFSB. Although not yet commercialized in the Philippines, research trials there also indicated nearly complete control of EFSB with their lines derived from EE-1.

The long-term sustainability of *Bt* eggplant will require stewardship of lines derived from EE-1. This includes ensuring the integrity of seeds, field implementation of insect-resistance management strategies, and proper training of farmers about the technology and how it can fit into an overall IPM program. In the Philippines, farmers have had access to *Bt* maize since 2003, so they have considerable experience with *Bt*-crops and IPM, but in Bangladesh *Bt* eggplant is the first such crop, so this presents challenges. In both countries production is done by small-scale farmers, and there is a need to provide them with appropriate information to take the technology forward successfully. In this presentation, we discuss the integration of *Bt* eggplant technology into existing IPM programs.

## PS VI -5

### Implementing IPM for bean golden mosaic virus in common bean in Brazil

Josias Correa de Faria - *Embrapa Rice and Beans*

Co-authors: Thiago Thiago Lívio Pessoa Oliveira de Souza, Eliane Dias Quintela

Bean golden mosaic virus (BGMV) is the causal agent of the most destructive viral disease of common beans in Brazil. It is efficiently vectored by the whitefly *Bemisia tabaci*, which is also a significant insect pest for this crop. With the commercial approval of the first genetically modified (GM) common bean resistant to BGMV, using RNAi technology, by the Brazilian National Biosafety Committee, the next challenge became the insertion of the trait into commercial varieties and thereafter the food chain. Keeping BGMV under control has brought about the so far hidden whitefly-borne pathogen Cowpea mild mottle virus (CPMMV), a Carlavirus. Eventually, other geminiviruses not present yet may appear. Therefore, the GM crop with resistance to a disease will help to diversify the toolbox for Integrated Pest Management (IPM) in common bean. An integrated approach to pest management including this novel technology became a challenge and is considered essential to achieve both agricultural and environmental sustainability, in addition to contributing to food security and grower profitability. The tools analyzed include whitefly host-free period, elimination of hosts for both virus and whitefly, GM resistance to BGMV and conventional resistance to Bean common mosaic virus/Bean common mosaic necrosis virus, planting time, the use of sentinel areas (early common bean planting to check in advance whitefly population and the degree of virus incidence), chemical control, building professional capacity (training), and an innovative alert system. There are encouraging results with the required adoption of whitefly host-free period and adoption of regular crop-pest survey to evaluate the real need for chemical control. The associated use of whitefly monitoring/reporting system and the alert by the sentinel may help growers to make the correct decision on growing common beans or an alternative crop to maximize income with lower risk of crop losses.



## PS VI -6

### IPM and weed management for the future

**Micheal DK Owen** - *Iowa State University (ISU)*

There is a critical need to adopt diverse tactics, in addition to herbicides, to more effectively and robustly manage herbicide-resistant weeds and to mitigate the selection for evolution of herbicide resistance where it has not yet become a problem. The burgeoning issues of evolved herbicide resistances in key weeds reflect agricultural systems where herbicides have been the principle tactic for more than 45 years. The inclusion of alternate strategies for weed control has declined steadily over the same time frame, and the loss of weed management diversity has resulted in evolved resistance to a number of herbicide groups. For the last decade, glyphosate was used in a majority of the row crop acres in the United States. There are many reasons and justifications for this, including, but not limited to time management efficiency, cost, effectiveness, and the simplicity and convenience of herbicide-based weed control. Not unexpectedly, the ecologically narrow focus of this approach has resulted in widespread evolved resistance to glyphosate within important weed populations to the extent that it should be clear that weed management in row crops is not sustainable if based primarily on a single herbicide in the absence of other management practices. However, it must be understood that herbicides will continue to play a significant role in weed management. Consider that new crop cultivars with genetically modified resistance to auxinic (Group 4) herbicides and other herbicide groups in the future will bring other technological concerns into play. Cultural and biological tactics that can supplement mechanical and herbicide-based weed management approaches will be important components of successful herbicide-resistant weed management programs in the future. The key will be for all entities involved in weed management, private, commercial and government, to consider more diverse approaches for weed management.

## PS VI -7

### Implementing IPM for cotton in Arizona and Mexico

Peter Ellsworth -University of Arizona (UA)

Co-author: Steven E Naranjo

GM plants alone are not tactical solutions to entire systems of IPM, and their uptake by producers should not be treated as such. GM plants can, however, become important if not critical and enabling technologies for integration into IPM systems. *Bt* cotton was introduced into the Arizona system in 1996. Prior to introduction, ample ecological research was conducted within the Arizona system, and farmers were prepared through organized programs of Cooperative Extension. The proper integration of both “soft” and “hard” technologies is critical to the successful uptake of innovations. The Arizona IPM model was shaped by this foundational tactical element of resistant varieties that prevented any economic damage by the principle lepidopteran pest, the pink bollworm (*Pectinophora gossypiella*). However, the cotton system had two other primary insect pests: the invasive whitefly, *Bemisia tabaci* biotype B (a.k.a. Middle East - Asia Minor 1 or *B. argentifolii*), and the mirid plant bug (*Lygus hesperus*). This presentation documents the introduction and integration of both hard (e.g., *Bt* cotton) and soft technological advances into a stable IPM strategy. Enabled by *Bt* cotton, this IPM program resulted in 1) the broad-scale reduction in broadly toxic insecticide use in Arizona cotton; 2) the adoption by growers of the keystone tactic of natural enemy conservation as a key ecosystem service; 3) the eradication of the primary lepidopteran pest, the pink bollworm; and 4) >US \$500,000,000 in cumulative savings to Arizona’s cotton growers. In a rare opportunity to examine a counterfactual system, this presentation will also examine *Bt* cotton and IPM uptake in the nearby eco-region of northwestern Mexico, where this full suite of benefits was not realized until major educational programs were put in place to support the proper integration of this and other key tactics into their overall cotton IPM program.

## Parallel Session VII - Abstracts

### ERA of RNAi-based GM Plants & Data Transportability

Session Organisers: **Pamela M Bachman** - *Monsanto* & **Joachim Schiemann** - *Julius Kühn-Institute (JKI)*

## PS VII -1

### Safety assessment for potatoes with traits based upon RNA interference

Cathy Zhong - *JR Simplot Company*

Co-author: Jeffry Habig, Aaron Rowland

Biotechnology has enabled introduction of traits with consumer, grower, and processor benefits into potatoes using RNA interference. This powerful technique allows for the development of new traits without introducing foreign proteins. Introduction of an inverted repeat expressing double-stranded RNA (dsRNA) containing the sequence of a native potato gene allows for sequence-specific targeting of transcripts for destruction. The reduction in expression of potato genes is directed by small interfering RNA (siRNA) that are by products of processing the introduced dsRNA by cellular RNAi enzymes. This technology has been used to produce new potato varieties with lower polyphenol oxidase activity, lower free asparagine, and lower reducing sugars in tubers, leading to lower acrylamide potential, less black-spot bruise, and improved cold storage. These traits are achieved solely through the introduction of RNA, which is a paradigm shift from traditional protein-expressing biotech crops and thus requires a shift in risk assessment methodology. Safety considerations for evaluating potatoes with traits based upon RNAi will be discussed, with special consideration to the ubiquitous and labile nature of RNA, biological and stoichiometric barriers, toxicological studies, and bioinformatics assessment.

## PS VII -2

### Assessing the impact of transgenic RNAi plants on non-target organisms: Current knowledge and future directions

Xuguo Zhou - University of Kentucky (UKY)

Co-author: Blair D Siegfried

The recent discovery of RNA interference (RNAi) and associated silencing pathways has revolutionized our understanding of gene regulation. Today, this paradigm-shifting technology has reshaped the agricultural industries by its specificity, effectiveness, and a brand new mode of action against arthropod pests. Here, we will review the current knowledge regarding the impact of transgenic RNAi plants on non-target organisms. Specifically, we are focusing on an incidental pollen feeder, honeybee, *Apis mellifera* (Vélez et al., 2015), an eco-indicator, monarch butterfly, *Danaus plexippus* (Pan et al., 2017), biological control agents, convergent lady beetle, *Hippodamia convergens*, multicolored Asian lady beetle, *Harmonia axyridis*, pink spotted lady beetle, *Coleomegilla maculata*, and seven-spotted lady beetle, *Coccinella septempunctata*, and soil decomposers *Sinella curviseta* (Pan et al., 2016) and *Folsomia candida*. Results from our dietary RNAi toxicity assays and the subsequent validation studies suggest that ingested dsRNAs have negligible biological impacts on honeybee, monarch butterfly, and soil decomposers. Predatory lady beetles, however, exhibit apparent differential responses to the ingested dsRNAs, derived from either themselves or the target insect pest, Western corn rootworm, *Diabrotica virgifera virgifera*. In addition, 21mer matches at the mRNA level (e.g., vATPase dsRNAs) between the target pest and nontarget organisms are not necessarily informative of the potential non-target impacts. Finally, we will discuss the challenges facing the current non-target testing framework as well as the organisms that might have been overlooked for the evaluation of potential non-target effects (USEPA, 2014; 2016).

## PS VII -3

### Environmental fate of an insecticidal, double-stranded RNA in two Brazilian soils

Daniella PV Braga - *Monsanto*

Co-authors: Marcela ES Joaquim, Marcia OMA José, Joshua R Fischer, Fatima Zapata, Changjian Jiang, Gustavo G Belchior, Geraldo U Berger

Larvae of the corn rootworm (CRW) complex (*Diabrotica* spp.) can cause severe root damage in corn, leading to water and nutrient intake deficiency. In Brazil, *D. speciosa* is an important pest found in production regions that reduces corn productivity. DvSnf7 is a double-stranded RNA (dsRNA) expressed in a genetically modified (GM) corn that triggers a potent RNA interference (RNAi) pathway restricted to *Galerucinae*, the subfamily to which CRW belongs. Despite the increased interest in the environmental risk assessment (ERA) of dsRNA-based agricultural products, few studies have been carried out towards evaluating the fate of genetically modified organisms (GMO)-derived dsRNA in soil. We sought to investigate DvSnf7 persistence in two different Brazilian soils, aiming at providing additional information for the ERA of this RNAi inducing molecule in a tropical environment. Two distinct soil types, sandy (RQ) and sandy-clay (LVd), were physico-chemically characterized, and amended with transgenic maize tissue (forage) expressing DvSnf7 dsRNA and fortified with in vitro-transcribed DvSnf7 dsRNA to simulate a post-harvest field environmental condition. Soil-extracted dsRNA was quantified using QuantiGene molecular analysis. Statistical analysis provided the time periods required for 50% (DT50) and 90% (DT90) dsRNA decay. Soil characterization indicated RQ is more alkaline and has higher sand proportion than LVd, but is lower in organic matter, clay, and silt content. Both soils presented a similar DvSnf7 degradation pattern, with a rapid total decay in the first 36 hours and no detection after a period of 3 days. The DT50 values were of approximately 21 and 16 hours for RQ and LVd soil types, respectively, whereas DT90 values reached 50 and 39 hours. DvSnf7 decay presents a similar pattern between both soil types, leading to the conclusion that the degradation of this dsRNA is not significantly influenced by these physico-chemically distinct soils.

## PS VII -4

### Research on modifying plants to produce interfering RNA: iPlanta a new EU scientific network

Jeremy Sweet - JTEC Ltd

Co-Author: Bruno Mezzetti

Methods to exploit plant defence mechanisms or changing plant metabolism by RNA silencing show great potential. Interfering RNA can be used to improve plant composition by enhancing levels of beneficial nutrients, and to improve plant productivity by suppressing undesirable traits and switching resources to more beneficial quality and yield traits. Gene expression in pathogens and pests can be targeted and plants modified to produce dsRNAs which trigger silencing and affect essential physiological functions in pest or disease-causing organisms. This presentation will discuss current research activities and some of the remaining scientific challenges. For example many of the modes of activity of the micro- and small interfering RNAs (miRNAs, siRNAs) that mediate the silencing effect are not yet fully understood and knowledge of systemic propagation, turnover and specificity of these molecules is limited.

Recently a new scientific action, iPlanta, was established in the EU. This is COST Action which will define and coordinate studies of the most important research tasks for the development of these novel transgenic strategies across 31 European and nearby countries, with inputs from cooperating researchers in Associated countries in N and S America, Australasia etc. It runs from 2016 to 2020.

The main activities include:

1. Evaluation of the efficacy of the RNA molecules for the induction of disease and pest resistance and metabolic changes.
2. Examination of the specificity of the selected miRNAs and siRNAs and their impacts on both target and non-target/off-target systems.
3. Developing specific risk assessment and risk management guidelines which relate specific effects of the miRNAs and siRNAs on food, feed and the environment.
4. Understanding the modes of transmission, uptake, systemic spread and degradation of dsRNAs, mi- and siRNAs.
5. Determining the environmental and socio-economic impacts of plant RNAi technology and products.
6. Communication through workshops, conferences and various media.

## PS VII -5

### The recent tendency in the ERA of GM crops in Japan

Ryo Ohsawa - *University of Tsukuba*

Japan ratified the Cartagena Protocol on Biosafety in 2003. To implement the Protocol, Japan adopted the “Cartagena Law” in 2004. Under the Cartagena Law, Ministry of Agriculture, Forestry and Fisheries (MAFF) and Ministry of Environment (MOE) grant joint approvals either for cultivation or for the use of GM crops as food and feed. A joint MAFF and MOE expert panel carries out an environmental risk assessment (ERA) to determine the potential for adverse effects on biodiversity, focusing on “competitive superiority,” “potential production of harmful substance,” and “crossability” of GM crops. During the past 13 years, more than 100 GM crops have been approved through the scientific review by the expert panel. As with other regulatory systems around the world, Japan’s ERA review system could benefit from leveraging cumulative data and experiences. Recently a part of the review system has been simplified concerning the GM stacked events and necessity of a confined field test for GM corn based on the experiences accumulated in Japan.

1) ERA of GM Stacked Events: When the interaction between modified characters is determined not to occur by examining mode of action of parental lines, it’s possible to review ERA of the stacked events using the results of parental lines without any stack data. But if it can be presumed that there is an interaction, every stacked event should be reviewed. Reviews of the stacked event, which keeps increasing every year, became fairly efficient by the simplification.

2) Confined field test for GM corn: Data transportability from cultivation country was accepted for GM corn with familiar traits which has already been assessed in the past and has clear a mode of action to exempt a confined field trial. In the presentation, I will explain the process of the simplifications and also discuss possible future simplifications that include soybean.



## PS VII -6

### Data transportability of non-target arthropod field data for GM traits across crops and geographies

Peter Asimwe - *Monsanto*

Co-authors: Aqeel Ahmad, Adam Schapaugh, Changjian Jiang

The New World screwworm is a green blow fly that is a devastating pest of livestock in South America and some Caribbean islands. Female screwworm flies lay their eggs on an open wound, and after hatching, the larvae eat the animal. The common name derives from the habit of the larvae to burrow into the animal. Over a 50-year period, this pest was eradicated from North and Central America through area-wide releases of radiation sterilized flies, a control program known as the Sterile Insect Technique or SIT. Currently the USDA-COPEG biosecurity facility in Panama mass rears and releases millions of sterilized insects in the barrier zone between Panama and Colombia, preventing the reintroduction of the pest from southern countries. As SIT is significantly more efficient if only males are released, we have developed transgenic male-only strains of this insect that carry a tetracycline repressible female-lethal genetic system. The transgenic lines have been tested for fitness parameters that are relevant for mass rearing and performance in the field, appearing similar to the wild-type strain currently used in the program. One transgenic line is currently being tested under mass rearing conditions at the COPEG plant, and an application has been submitted to the Panamanian government to perform field trials with sterilized transgenic males. We are also interested in developing and evaluating gene-drive systems for control of this pest. The drive would target a gene essential in females but not males and would carry an off-switch for rearing. This system could be more efficient and thus more economical than male-only SIT. However, given the likelihood of resistance developing to a gene drive, we suggest that it could be advantageous to use a gene drive to first reduce the pest population and then follow with a male-only SIT for local pest eradication.

## PS VII -7

### Data transportability of confined field trials from cultivation country to import country

Shuichi Nakai - *Monsanto*

Co-author: Seiichiro Yamane

Requirement of in-country confined field trials for genetically modified (GM) crops prior to unrestricted release is well established among countries with domestic regulations for the cultivation approval of GM crops. However, the requirement of in-country confined field trials is not common in countries where the scope of the application does not include cultivation. Nonetheless, Japan and China request in-country confined field trials for GM crops which are intended only for use as food, feed and processing (FFP). This paper considers the transportability of confined field trial data from cultivation countries (e.g., United States, Canada, and South American countries) to import countries like Japan for the environmental risk assessment (ERA) of GM crops by reviewing: 1) The purpose of confined field trial assessment, 2) Weediness potential, defined as “an ability to establish and persist in an unmanaged area that is frequently disturbed by human activity,” of host crops, and 3) Reliability of the confined field trial data obtained from cultivation countries. To review the reliability of the confined field data obtained in the U.S., this paper describes actual examples of three confined field trials of approved GM corn events conducted both in the U.S. and Japan. Based on the above considerations, this paper concludes that confined field data of GM corn and cotton is transportable from cultivation countries to importing countries (e.g., from the U.S. to Japan), regardless of the characteristics of the inserted gene.

## PS VII -8

### **Evaluating the transportability of ecological risk assessment on transgenic crops to associated breeding stacks**

**Justin McDonald** - *Syngenta*

To inform ecological risk assessment (ERA) of a genetically modified crop with more than one insecticidal trait combined by conventional breeding, a comparative field study is conducted to compare transgenic protein concentrations in plants of a breeding stack to those of corresponding component single events. This study tests the hypothesis that transgenic protein expression will not significantly increase due to stacking, such that existing margins of exposure are eroded to unacceptable levels. Corroboration of that hypothesis justifies using existing ecotoxicology results with test concentrations based on Estimated Environmental Concentrations (EECs) determined for a component single event to inform ERA of a breeding stack.

The results from over 20 of these studies on insecticidal proteins produced by commercial transgenic events in various combinations of conventionally bred stacks were examined to assess the utility of the comparative field study for testing the stated hypothesis and justifying the use of predetermined EECs for ERA on a stack. The mean protein concentrations in stack samples from each study were also evaluated in relation to corresponding EECs. This review reveals a large number of tests that corroborate the hypothesis of no significant increase in transgenic protein expression due to combining by conventional breeding, and much of the variation in protein expression is due to genetic and environmental factors. Therefore, future tests of the stated hypothesis may not be critically informative for ERA on breeding stacks.

This work demonstrates that the expression data generated to support ERA on a single event transgenic crop may be applied to ERAs of breeding stacks. Rather than comparative field studies, expression data could be generated on the stack and compared to existing single event data while also considering the conservative margin between exposure and the no-observed effect concentration determined from existing ecotoxicology tests.

## Parallel Session VIII - Abstracts

### ERA Studies/Tools

Session Organisers: **Adinda De Schrijver** - *Scientific Institute of Public Health* & **Michael Meissle** - *Agroscope*

## PS VIII -1

### ***Bt*-rice in China – Focusing the non-target risk assessment**

**Yunhe Li** - *Chinese Academy of Agricultural Sciences (CAAS)*

Co-authors: Michael Meissle, Jörg Romeis

*Bt* rice can control yield losses caused by lepidopteran pests, but may also harm non-target species and reduce important ecosystem services. We have compiled a comprehensive dataset on the arthropod fauna and food-web interactions in Chinese rice fields to support the assessment of risks that these plants would pose to valued non-target organisms and the ecosystem services they provide. Analyses of the Cry protein content in arthropods collected from *Bt* rice indicates which species are most exposed to the insecticidal trait and should be in the focus of regulatory risk assessment studies. Based on these data, several arthropod species were recommended as indicator species for initial, early-tier non-target risk assessment of *Bt* rice. Furthermore, a set of laboratory testing approaches was established that have been used in risk assessment of *Bt* rice lines. The results suggest that the *Bt* rice lines expressing cry1C or cry2A genes pose a negligible risk to the non-target arthropod species.

## PS VIII -2

### Resistance risk assessment of target pests to *Bt*-rice in China

Lanzhi Han - *Chinese Academy of Agricultural Sciences (CAAS)*

Co-author: Yufa Peng

Many lines of insect-resistant genetically modified (IRGM) rice containing *Bacillus thuringiensis* (*Bt*) insecticidal genes have been developed and undergone different environmental biosafety assessments stages in China, showing robust application prospects. The potential risk of targeted pests developing resistance is a key consideration influencing IRGM rice regulation and sustainable use after widespread adoption. Therefore, predicting the likelihood of resistance development and implementing precautionary insect-resistance management (IRM) strategies for the sustainable use of IRGM rice are critical. Based on these, we surveyed the baseline susceptibilities and conducted lab selection experiments of resistant populations of three main target pests, *Chilo suppressalis*, *Sesamia inferens* and *Cnaphalocrocis medinalis*, to Cry1Ab, Cry1Ac and Cry1C proteins. The results showed *S. inferens* exhibited a significantly lower susceptibility and more rapidly evolved resistance to Cry1A, compared to *C. suppressalis* and *C. medinalis*. Presumably, *S. inferens* is more likely to evolve increased resistance, which threatens the sustainability of cry1A rice. Further, the lower susceptibility of *S. inferens* to Cry1A proteins was confirmed to be associated with reduced Cry1A-binding as a result of decreased binding site concentration. Interestingly, transgenic cry1C rice line provided high efficacy against *S. inferens* throughout the whole growth season. Moreover, a Cry1A-selected strain of *C. suppressalis* did not exhibit cross-resistance to Cry1C. Therefore, the pyramiding of cry1C and cry1A genes in IRGM rice is an optimal resistance management strategy for control of rice pests complex due to increasing the control of *S. inferens* and reducing the risk of resistance evolution. Additionally, we also identified the Cry1A toxin-binding proteins, aminopeptidase-N (APN) and cadherin, from the midgut of *C. suppressalis* as Cry1A toxin receptor by biochemical and molecular biology method. This research will be helpful for proactively designing, implementing an IRM strategy, and delaying the resistance evolution of rice pests to *Bt* rice.

## PS VIII -3

### Biosafety aspects in the pre-commercialisation phase of developing GM sugarcane in South Africa

**Sandy Snyman** - South African Sugarcane Research Institute (SASRI)

Co-authors: M Gouse, L Potgieter, S Siebert, Johnnie Van Den Berg

The South African Sugarcane Research Institute (SASRI) has conducted research on genetic modification (GM) of sugarcane for traits such as insect resistance, herbicide tolerance, and improved nitrogen use efficiency. The sugar industry recently made a strategic decision to invest in the development of an enabling environment to commercialise a GM sugarcane variety. It subsequently commissioned a business case study for insect resistant GM sugarcane (identified as the most appropriate GM trait in an industry workshop held in 2013), which identified several commercialisation scenarios and highlighted gaps in biosafety-sustainability research and data as one of the hurdles to commercialisation. Several collaborations are underway to undertake research in the following fields: (1) efficacy studies using diet feeding bioassays to determine base-line susceptibility of South African (SA) Lepidopteran stalk borers that are pests of sugarcane and maize, e.g., *Chilo partellus* (a surrogate for *C. sacchariphagus*), *Eldana saccharina* and *Sesamia calamistis* using selected *Bacillus thuringiensis* (*Bt*) Cry proteins in order to determine high dosage and possible "gene stack" combinations necessary for insect-resistance management; (2) a spatial assessment of wild relatives of the *Saccharum* species complex viz. *Miscanthus junceus*, *M. ecklonii* and *Imperata cylindrica*, and a preliminary phylogenetic analysis to assess the likelihood of outcrossing; (3) an *ex ante* socioeconomic analysis to support adoption of *Bt* GM sugarcane in all grower sectors and consideration of local and international market/trade implications for sugar derived from GM cane; and (4) determination of optimal size and distribution of refugia using simulation models to minimise the development of resistance in target insects. In addition to generating biosafety data necessary to support regulatory dossiers, it is anticipated that the development of human capacity skills will enable a wholly SA-developed GM crop in the near future.

## PS VIII -4

### Non-pesticidal R-proteins: A case study of late blight protected potato

Cathy Zhong - JR Simplot Company

Co-author: Jeff Habig

As a risk assessment principle, a weight of evidence approach is employed to assess the safety of introduced proteins in biotech crops. Late blight, caused by the fungus-like oomycete pathogen, *Phytophthora infestans*, is the most devastating disease of potato worldwide, responsible for the Irish Potato Famine. R-genes from cultivated and wild *Solanum* species, providing natural protection to late blight, exist in potato germplasm. Potatoes, being tetraploid and highly heterozygous, are notoriously difficult to breed. Genetic engineering provides a more efficient way of introducing R-genes into potato varieties to provide late blight protection. R-proteins have been well-studied, and their mechanism of action documented in many edible plants, including potato, indicating a long history of safe consumption. R-proteins share high sequence homology with each other and are expressed at exceedingly low levels. The detection and quantification of introduced R-proteins (e.g., VNT1 protein from Rpi-vnt1 gene) in late-blight protected potatoes presents significant challenges. Heterologous expression and purification of biologically active R-proteins in quantities sufficient for traditional safety studies is impractical, making it problematic to provide the standard protein biosafety data packages expected for novel proteins. A weight of evidence approach is employed to assess the safety of non-pesticidal R-proteins in late-blight protected potatoes. With minimal hazard and negligible exposure, the risk of consuming introduced R-proteins from cultivated and wild potatoes is close to zero. Introduced R-proteins in late-blight protected potatoes are safe for human and animal consumption.



## PS VIII -5

### Can systematic reviews inform GMO risk assessment and risk management?

Ralf Wilhelm - *Julius Kühn-Institute (JKI)*

Co-authors: Joachim Schiemann, Christian Kohl, GRACE team

Systematic reviews represent powerful tools to identify, collect, synthesize, and evaluate primary research data on specific research questions in a highly standardized and reproducible manner. They enable the defensible synthesis of outcomes by increasing precision and minimizing bias whilst ensuring transparency of the methods used. This makes them especially valuable to inform evidence-based risk analysis and decision making in various topics and research disciplines. Although seen as a “gold standard” for synthesizing primary research data, systematic reviews are not without limitations as they are often cost-, labor- and time-intensive, and the utility of synthesis outcomes depends upon the availability of sufficient and robust primary research data. We (1) consider how systematic reviews may provide an added value when synthesizing primary research data on genetically modified organisms and (2) critically assess the adequacy and feasibility of systematic reviews for collating and analyzing data on potential impacts of GMOs in order to inform specific steps within GMO risk assessment and risk management. Furthermore, we provide a brief introduction of the online tool CADIMA that eases performing an efficient evidence synthesis process and facilitates reporting of all activities.

## PS VIII -6

### Use of species sensitivity distributions to characterise hazard for insect control traits

**Chad Boeckman** - *DuPont Pioneer*

Genetically modified (GM) crops expressing genes that provide control of agricultural insect pests have historically relied heavily upon Cry proteins from *Bacillus thuringiensis* (*Bt*). Cry proteins have an established long history of safe use with a well characterized spectrum of activity. Technology developers are on the cusp of bringing to market a new generation of products, some of which express genes from non-*Bt* source organisms. These new insect control traits will undergo an extensive environmental risk assessment (ERA) to characterize the spectrum of activity and relative safety to non-target organisms, among other key pieces of information. Species sensitivity distributions (SSDs) have been used extensively in traditional chemical risk assessments and may inform decisions regarding potential risk of GM crops to non-target organisms, including threatened and endangered species. This presentation will provide an overview of SSDs, discuss benefits and limitations, and position how SSDs fit into the current environmental risk assessment (ERA) framework for GM crops that express new insect-control traits.

## PS VIII -7

### Interactions between stacked *Bt*-maize and herbivorous aphids and spider mites

Yinghua Shu - South China Agricultural University

Co-authors: Jianwu Wang, Jörg Romeis, Michael Meissle

Genetically-modified *Bacillus thuringiensis* (*Bt*) crops can successfully control certain Lepidoptera and Coleoptera pests. The widespread use of *Bt*-crops secures yield and reduces problematic pesticide usage. Many studies have shown that herbivores outside the targeted taxonomic orders are not directly affected by the *Bt*-crops. In recent years, stacking multiple *Bt* proteins with different modes of action into one plant has become an efficient way of increasing the target spectrum and reducing the likelihood of resistance evolution in the target pest(s). However, concerns have been raised that the different *Bt* proteins may interact and cause unpredictable effects on non-target species that are not susceptible to the individual Cry proteins. Furthermore, herbivore infestation may alter expression patterns of *Bt* proteins. In the current study, the interactions between *Bt* maize (SmartStax expressing Cry1A.105, Cry1F, Cry3Bb1, Cry2Ab, Cry34Ab, and Cry35Ab1) and two non-target herbivorous pests, aphids (*Rhopalosiphum padi*) and spider mites (*Tetranychus urticae*) were investigated. One aim was to assess potential effects of the stacked *Bt* maize on herbivore performance. The second aim was to investigate whether herbivore infestation influences the concentrations of the different Cry proteins in *Bt* maize. Results will be presented and discussed.

## PS VIII -8

### Characterisation of the differences between natural *Bt*-toxins and commercialised GMO *Bt*-toxins

Jonathan Latham, *Bioscience Resource Project*

Co-authors: Angelika Hilbeck, Madeleine Love

Almost all commercial insect-resistant GMO crops contain Cry insecticidal proteins obtained from the bacterium *Bacillus thuringiensis*. This bacterial species infects and kills its host because its Cry proteins (called Cry because they are crystalline) make holes in gut cellular membranes. These holes allow entry into the insect body cavity. Cry proteins are generally considered highly insect species-specific in their activity. In 1988, however, Toll noted that *Bt*-crops "bypass a chemical containment mechanism that limits exposure to a narrow range of species" (BioScience 38: 588), because plant-produced Cry toxins are not crystals and the crystalline nature of wild-type Cry proteins restricts their toxicity to those species that can dissolve it. Extending this logic much further, we decided to determine all the alterations made to natural Cry proteins, either introduced into or resulting from, the commercialisation of GMO Cry toxins, up to and including the characterisation of Cry toxins in the GMO crop itself. This information was gathered primarily from publicly available commercial applications. Second, we asked whether the alterations observed would be likely to bypass other natural containment mechanisms. We show that between all GMO and natural Cry toxins, differences exist with respect to DNA sequence, toxin size, toxin solubility, toxin structure, and usually protein sequence as well. The nature and abundance of these differences have implications for effective risk assessment. First, they make the questionable the usefulness of surrogate Cry proteins, which are widely used in risk assessment, questionable. Second, the changes also appear to invalidate the use in risk assessment of historical data for wild-type Cry proteins. Lastly, some researchers and some risk assessments have found Cry proteins purified from insect-resistant GMOs (and even insect-resistant GMOs themselves) to be unexpectedly harmful to non-target species. Our research for the first time provides a mechanistic explanation of these putative differences.

## Parallel Session IX - Abstracts

### Regulatory Issues & Data Requirements

Session Organisers: **Christine Tibelius** - *Canadian Food Inspection Agency (CFIA)* & **Karen Hokanson** - *University of Minnesota (UM)*

## PS IX -1

### Suppression gene drives for non-insect pests and conservation biology

Allison Snow - *Ohio State University (OSU)*

Gene drives represent a radical new approach for managing short-lived, sexually reproducing wild species, by forcing them to inherit genetically modified traits that spread quickly throughout interconnected populations. Theoretically, CRISPR/Cas9 gene drives could be used to eradicate unwanted species (for example, by conferring female sterility), rescue endangered species, or alter disease vectors so they no longer can serve as hosts for target pathogens. Kevin Esvelt et al. (2014) argued that gene drives could lead to a promising new era of “ecological engineering”. However, a 2016 report by the US National Academy of Sciences warned that many ethical, social, regulatory, and ecological/evolutionary questions need to be addressed very carefully before this new technology is deployed. Another challenge is technical advances needed for more effective gene-drive systems beyond current proof-of-concept examples from laboratory studies. In this presentation I will examine potential gene drive applications for suppressing populations of rodents, fish, and weeds in terms of

1. the perceived need for developing gene drives,
2. challenges for developing them to work as intended,
3. ecological and evolutionary questions related to risk assessment, and
4. challenges for mitigating any unwanted consequences after a gene drive has been released.

As with other types of GMOs, each application should be considered on a case-by-case basis, keeping in mind that newly engineered safeguards may become available in the future. Unlike previous GMOs, however, some gene drives will be designed to spread widely and persist until the affected wild populations become altered or extinguished. These characteristics and the global availability of CRISPR/Cas9 techniques add a new level of complexity to anticipating possible risks and benefits of gene drives. Expertise from ecologists and population geneticists will be needed to evaluate questions related to gene drives for wild populations.

## PS IX -2

### Draft ERA of a hypothetical gene drive *Aedes aegypti* for population suppression

Paulo Paes De Andrade - *Universidade Federal de Campina Grande*

Co-authors: Amaro de Lira Castro Neto, Marília Andreza da Silva Ferreira

*Aedes aegypti* control uses a combination of approaches, with limited success. Transgenic mosquitoes, expressing a conditional lethal gene, recently proved successful in controlling urban wild mosquito populations (1,2). Another approach would be the use of a gene drive. Here we briefly describe the ERA of a hypothetical gene drive *Ae. aegypti* producing a 95% male-only offspring to be used for vector control in Brazil, as a proactive approach towards its future adoption, as described elsewhere for *Anopheles gambiae*. (3) The strain harbors a single copy of the construct per haploid genome, in the same chromosomal position. Its genotypic and phenotypic stability is near 100% and no other changes were observed, except for the dependence on a selective substance in the lab and the offspring sex bias. Taking into account the premises of a regular Problem Formulation (4) it is possible to establish the context in which such mosquitoes would be used and regulated. A broad set of perceived hazards was derived from a diffuse set of stakeholders, most of them reviewed elsewhere for the GM *Ae. aegypti* adopted in Brazil (2). Although essentially very improbable, the eradication of *Ae. aegypti* from the country has no impact in its biodiversity. The successful spread of the gene drive mosquito beyond the country's border, however, is a new hazard and should be closely assessed, especially by Parties to the Cartagena Protocol. Indeed, due to its biological features, *Ae. aegypti* may spread to neighboring areas and even to other countries. The transboundary movement of *Ae. aegypti*, however, is an environment concern only in the centers of origin of this species. In most countries, the same ERA considerations would possibly apply, with very limited risks of losses in biological diversity or health related concerns.

## PS IX -3

### Regulating gene drives: Are African regulators up to the task?

**Olalekan Akinbo** - *NEPAD African Biosafety Network of Expertise (ABNE)*

Co-author: Diran Makinde

Modern biotechnology, especially genetic modification (GM) technology, brought a hope not a panacea for resolving several agricultural constraints associated with the increase potentials of crops. This partly explains the ever-rising adoption of transgenic crops worldwide during the past 20 years; initially from 1.7 million hectares in 1996 to over 180 million hectares in 2015. In a bid to exploit the potential benefits of modern biotechnology, some countries like South Africa, Sudan and Burkina Faso have commercialized some GM products, while countries like Ethiopia, Kenya, Ghana, Malawi, and Nigeria have approved the event in readiness for commercialization.

The new emerging technology gene drive is currently the flagship tool in the area of biotechnology across many sectors, including agriculture, health, and climate-smart mitigation. The gene-editing mechanism through the use of the Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR-Cas9) technique has recently brought in a new revolutionary tool in the field of biotechnology which offers incredible possibilities to increase performance in various sectors. Gene editing has a biased inheritance of particular gene to alter entire population has been proposed for changing wild populations of harmful organisms such as mosquitoes. It has been suggested that this technique could be used to reduce mosquito populations. This is of immediate interest to Sub-Saharan Africa where malaria still represents the most harmful threat to public health.

NEPAD Agency, as the technical arm of the AU, has strong political base and is developing effective regional harmonized biotechnology regulatory systems to reinforce the confidence in the African regulators and in the decision-making research community to harness both existing and emerging technologies like gene editing. Through its two specialized entities: African Medicines Regulatory Harmonization (AMRH) and the African Biosafety Network of Expertise (ABNE), NEPAD Agency is well positioned to assist in building functional biosafety regulatory systems in Africa with the integrity and experience from lessons learned on the ground in the past years.

NEPAD Agency has demonstrated a solid experience in facilitating regulatory capacity building and regional harmonization for medicines and for agricultural biotechnology. NEPAD Agency will combine both approaches from regulating GMO crops and medicines to build the regional regulatory capacity for gene editing applied to control malaria vector mosquito populations. Mosquito is a moving insect and therefore its regulation should be without boundary, hence the use of a regional regulatory approach will offer the best cost-efficient approach in Africa for the benefit of the member state.



## PS IX -4

### ERA: Does science matters?

**Marlene Keese** - *Therapeutic Goods Administration (TGA)*

Co-author: Paul Keese

The world is awash in guidance and capacity building on GMO risk assessment. The assumption is that scientifically sound risk assessments should, as a direct consequence, result in sound regulatory decisions. We wish to challenge this assumption. Instead, we believe that risk assessment is but a small part of regulatory decision-making and science but a small part of risk assessment. Regulation of GMOs is typically bound by mandatory legislative requirements that require decisions to consider many matters in addition to a risk assessment, which may or may not be required. Judicial review of regulatory decision by the courts would not put any weight on the science; it would be based on the decision-maker complying with the requirements of the law, and in particular, the statutory requirement in relation to decision-making. This is not limited to national law, and similar reviews can be made internationally. Thus, although robust risk assessment may be carried out that is scientifically sound, this would not be enough to make a decision defensible. Furthermore, risk assessment is not a scientific method, but a human artifice intended to provide a structured, rational approach to address societal values and concerns and relies on judgment of the quality of the evidence. That evidence may involve scientific or technical information or rest on expert opinion. Therefore, we suggest the ERA methodology should: be more closely aligned with national legislation and policy requirements; provide more justified linkages between assessment endpoints and societal values; provide clear risk criteria during the preparation phase; and provide greater transparency for the judgment of quality of information.

## PS IX -5

### Refining data requirements for risk assessments of GM plants

**Heidi Mitchell** - *Office of the Gene Technology Regulator (OGTR)*

Co-authors: Brian Weir, Andrea Robold, Peter Thygesen

In Australia, the Gene Technology Regulator (GTR) is responsible for authorising the release of GMOs into the Australian environment. The Regulator's decisions on whether to authorise the release of a GM plant under the Gene Technology Act 2000 (GT Act) must be based on an assessment of whether any risks to people or the environment can be managed, i.e., an environmental risk assessment (ERA). Sound science underpins the Regulator's risk analyses. The approach of the Office of the Gene Technology Regulator (OGTR) for regulation and ERA of GM plants has evolved over the 15-year span of operation of the GT Act, informed by practical experience. Consideration of ERAs conducted for plants in other contexts has also informed this approach. In particular, this has included incorporating the knowledge and experience used for risk assessment of potential weeds into the OGTR's ERA to identify potential risks from GM plants.

As part of the development of a more focussed ERA for GM plants, the OGTR has recently reviewed the quality, amount and type of data needed. Consideration of the different information requirements for field trials and commercial scale releases has resulted in development of separate, specific application forms; this has allowed us to tailor science-related questions to the specific information required for risk analysis. The new application forms focus on information that will address key risk assessment questions, and plausible pathways to harm. The aim has been to use the questions to guide the applicant to provide information that addresses the important ERA considerations in the way most appropriate to their crop or trait.

## PS IX -6

### **Transgenic *Agrostis stolonifera*: Gene flow, establishment and abandonment**

**Carol Mallory-Smith** - Oregon State University

Co-author: Maria Zapiola

Transgenic glyphosate-resistant *Agrostis stolonifera* was developed by Scott's Company and Monsanto. In 2002, 160 ha in Jefferson County, Oregon, the transgenic grass was planted for seed production. A wind storm in 2003 spread panicles with seed across a wide area and the company was required to remove the crop from the area. Surveys of the area showed gene flow through both pollen and seed was widespread (Zapiola et al. 2008). In 2010, transgenic *Agrostis stolonifera* plants were identified and found to be widespread in Malheur County, Oregon, where there were no authorized plantings of the transgenic grass. In 2016, hybrids between *Agrostis stolonifera* and compatible species were identified in situ in Jefferson County and in Malheur County. Scott's Co. entered an agreement with USDA-APHIS that in essence said that Scott's Co. would not commercialize glyphosate-resistant *Agrostis stolonifera* if USDA-APHIS would approve their request for deregulation. In 2017, USDA-APHIS (2017) granted The Scotts and Co. and Monsanto's request for nonregulated status for transgenic glyphosate-resistant *Agrostis stolonifera*, even though the companies failed to contain the gene or to mitigate problems that the release of this gene caused. The deregulation of transgenic *Agrostis stolonifera* removes the obligation from the company to survey and remove the plants. The agency and the companies transferred the responsibility for the control of this species to individuals and entities that had nothing to do with the release of the gene into the environment. This decision has implications for other cases where companies could decide against commercialization of a genetically modified crop that had been field-tested in order to avoid responsibility for agricultural or environmental problems that resulted from the release.

## PS IX -7

### **The limited value of agronomic and phenotypic characterisation for the risk assessment of GM crops intended for import in the EU**

Lieselot Bertho - *Monsanto*

Co-authors: EuropaBio ERA Working Group

Genetically modified (GM) crops have been cultivated, imported, processed, and consumed on a global scale for more than 20 years. During this period, humans, animals and the environment have been exposed to different GM crops/traits and products derived therefrom. To date, no unintended adverse effects have been shown to result from exposure to GM crops and their derived products as they have an excellent safety record. In contradiction, data requirements for the risk assessment of GM crops continue to increase in the EU, resulting in the discontinuation of submissions for approval of GM crop cultivation by agricultural companies, leaving the region behind with the sole option to import these crops rather than to cultivate them. Obtaining authorization of GM crop import applications has become more burdensome due to the continued increasing data requirements that are not proportionate to the scope of the applications, and lack of consideration of the experience and knowledge gained globally over the past years for GM crops/traits. A telling example is the increase in data requirements as recommended in the guidance for the agronomic and phenotypic characterisation of genetically modified plants, published by EFSA in June 2015. It has been demonstrated that, considering the environmental exposure under import scenario is minimal, the agronomic and phenotypic characterization of crops with a safety record, such as maize or soybean, provides no added value for the risk assessment of import applications and consequently should no longer be required. Based on the safety record, documented benefits and lack of any documented adverse effects of GM crops/traits, a further increase of regulatory data requirements is unjustified and unduly adds to the burden of proof without contributing to the safety assessment. To enable needed innovation in sustainable agricultural methods, to benefit from modern biotechnology, and to give a chance to public sector and smaller companies to develop commercial GM crops, regulatory systems should evolve towards appropriate and proportional data requirements that take into account the two decades of scientific evidence and safety record.

## PS IX -8

### **Future introductions of GM microbial biocontrol agents in the EU – Is current legislation and risk assessment fit for purpose?**

**Boet Glandorf** - *National Institute of Public Health and the Environment (RIVM)*

Co-authors: Jacqueline Scheepmaker, Petra Hogervorst

Given the rapid biotechnological developments in disease control of agricultural crops and the urge to intensify integrated pest management, applications for the use of genetically modified (GM) microbial biocontrol agents may be expected in the EU in the near future. In order to be prepared for future applications, it was studied whether the current EU GM legislation and risk assessment sufficiently addresses the potential risks for human health, the environment and food and feed derived from plants treated with these biocontrol agents.

This inventory demonstrated that applicable EU legislation covers environmental protection, occupational health and safety, the safety of local residents in agricultural areas, and the main safety aspects of food and feed treated with GM microbial biocontrol agents. However, it was not clear if all aspects concerning the safety of edible food and feed parts derived from crops treated with GM microbial biocontrol agents were covered by relevant legislation and the respective risk assessment, given the fact that the GM food feed Regulation (EC) 1829/2003 is not applicable to these microorganisms.

It was concluded that only in case the GM microbial biocontrol agent or its novel metabolites are capable of changing the composition of the food/feed product there seems to be a potential gap in the risk assessment. This may be the case when these agents or their newly expressed metabolites interfere with or induce specific pathways in the plant that result in the formation of toxic or allergenic compounds. Micro-organisms are known to interfere with plants and their pathways, such as those involved in systemic induced resistance or in the formation of antimicrobial metabolites in plants. It is suggested to include this aspect in the risk assessment of GM microbial biocontrol agents on a case-by-case basis.

## Parallel Session X - Abstracts

### Gene Drive and GM Insects for Pest Control

The use of GM insects for pest control has long been under consideration, but is now moving to practical applications. The development of new molecular technologies, including gene drive systems, have led to an increase in interest and engagement around GM insects for public health, agriculture and conservation biology. This session will examine some of the recent and on-going investigations into the use of GM insects, including gene drive systems, and their potentially novel biosafety considerations, as well as providing an overview of potential applications of gene drive and more traditional GM technologies for use in pest control.

Session Organisers: **Anthony Shelton** - *Cornell University* & **Andrew Roberts** - *International Life Sciences Institute (ILSI) Research Foundation*

## PS X -1

### Trialing gene drives to control invasive species: The what, where and how?

Tim Harvey-Samuel - *Pirbright Institute*

Co-author: Luke Alphey

Invasive species represent one of the greatest threats to global biodiversity. Their control would be enhanced through the development of novel, more effective and sustainable management methods. One control option yet to be trialed in the field is to deploy "Gene Drives": transgenic technologies which force the inheritance of a synthetic genetic construct through the gene pool of a wild population. Within the context of pest control, a released gene drive could work to eradicate an invasive population by spreading a genetic load or replacing it with a less harmful form, for example one which is unable to transmit a certain disease. Development of previous Genetic Pest Management (GPM) technologies has followed the Phased-Testing-Pathway with candidate transgenic lines being taken through iterative assessment from laboratory to contained-field and then open-field trials. Applying these technologies to invasive species control differs from these initial demonstrations in two fundamental ways. Firstly, the emphasis is on utilising self-sustaining gene drives rather than self-limiting lethal transgenes. Unique characteristics of these self-sustaining systems are that they are expected to persist in and potentially spread within/between populations once released and the ecological consequences of their deployment are potentially irreversible. Secondly, the taxonomic scope for their application is far wider than for these initial trials which focused, in large part, on a few mosquito species of human-health importance. Here the ramifications of these differences on gene-drive development and testing are discussed through the lens of three important questions:

- What types of invasive species should we use to trial gene drives?
- Where should we be trialing them?
- How should these trials be conducted?

Due to the enormous potential and transformative nature of gene-drive technology, these questions are addressed with the aim of trialing these systems as efficiently, safely, and rapidly as possible.

## PS X -2

### Biosafety for gene drive research

**Paul De Barro** - *Commonwealth Science and Industrial Research Organisation (CSIRO)*

Novel genetic technologies such as gene drive represent a very different approach to the development and use of genetically modified organisms (GMOs). Unlike "traditional" GMOs, most notably genetically modified agricultural crops, gene drives are genetic elements that are favoured for inheritance, and which can therefore spread through populations at a greater rate than genes with standard Mendelian inheritance, even after releases have ceased. This latter element represents a substantial departure from the usual GMO approach with agricultural crops, which is centred on ensuring spread is minimal or does not occur at all. As with all technologies, gene drives represent a suite of approaches, but here the focus is on low-threshold drive systems, where rapid spread and persistence are desired outcomes. Three aspects of biosafety are the focus. Risk assessment, the methodological approach used to define and characterize hazards, estimates the likelihood of each hazard occurring and the potential adverse impact. Biocontainment of laboratory studies, a comparative assessment of existing containment regulations for GMOs, biological control agents and animal and human pathogens and 3) post biocontainment physically confined or ecologically confined field trials. We view these through the lens of genetically modified mosquitoes and the WHO Guidance Framework and in particular which elements of the guidance framework may bear further revision.



## PS X -3

### **Policy and regulatory issues for use of gene drives to control insect-borne human disease and insect agricultural pests**

**Robert Friedman** - *J. Craig Venter Institute (JCVI)*

Recently, two groups—one in California, a second in the United Kingdom—developed methods to use a new gene-editing technology (CRISPR/Cas9) to quickly “drive” a desired genetic trait throughout a population of mosquitoes. The hope is that the method could be used to engineer insects in the wild, with the goal of reducing insect-borne diseases such as malaria, or controlling insect agricultural pests. Although use of gene drives to modify insects has been explored for at least four decades, the effectiveness and ease of use of CRISPR/Cas9 has led to the recognition that neither the research nor regulatory community is prepared for what might turn out to be rapid technological advance. The benefits are obvious if the research is successful. However, the risks of unintended consequences are not clear, nor are the pathways for regulatory oversight.

In January 2016, JCVI and UC San Diego co-hosted a 2-day workshop that brought together scientists working to apply gene-drive technologies to insects with US Federal regulators, ecologists, ethicists, and environmental policy analysts. The goal of the workshop was to identify the key challenges and hurdles that both scientists and regulators will face as scientists work to develop gene-drive technologies intended for eventual release into the environment.

We separately considered each step of the phased testing pathway proposed by WHO for testing genetically modified mosquitoes, starting with laboratory containment, then moving to physically contained and ecologically confined field trials, and finally to stages of release. At each step, we explored the experience to date with prior GM technologies and analog technologies, the regulatory and risk assessment needs, and gaps in our knowledge or regulatory structures that would need to be filled before a new gene-drive insect could be deployed safely.

## PS X -4

### **Problem formulation for the use of gene drive in *Anopheles gambiae* to control malaria transmission**

**Andrew Roberts** - *International Life Sciences Institute (ILSI) Research Foundation*

Malaria is a disease which continues to take an enormous toll on human health and productivity, particularly in sub-Saharan Africa. Recent advances in molecular biology and genetics have made the practical applications of gene drives to control the malaria vector *Anopheles gambiae*, a potential new tool to ease this burden. However, before this technology can be used to reduce malaria incidence, the potential for harm to the environment that might result must be assessed.

This talk will describe a workshop, convening experts on mosquito biology, public health programs, gene-drive research, and risk assessment for genetically modified organisms to engage in problem formulation for environmental risk assessment (ERA) as a prerequisite for the use of gene drive in *Anopheles gambiae*. In addition, the presentation will discuss the publication of this work as well as subsequent efforts to convene similar expert workshops in sub-Saharan Africa for consultation with African risk assessors and regulators.

## PS X -5

### ERA of GMOs with engineered gene drives – Lessons from non-GM ERAs?

**Peter Thygesen** - *Office of the Gene Technology Regulator (OGTR)*

There has been significant debate about the potential issues raised by the creation of genetically modified organisms (GMOs) with engineered gene drives. Debate has focussed on the novel potential for “driving” a trait into a sexually reproducing population, and the uncertainty regarding potential adverse outcomes and whether current tools for environmental risk assessment (ERA) will be adequate (National Academies, 2016).

Many of the proposed applications of gene drive technology are directed at addressing biological problems that are not new. These include: controlling populations of the vectors of human, animal or plant diseases; control of pest animals or plants; and species conservation (Johnson et al 2016).

It is obvious that the ERA of GMOs with engineered gene drives will raise specific issues that need to be considered. However, current conceptual approaches and risk assessment frameworks should be adequate to undertake such ERAs. It may be argued that specific issues raised in connection with engineered gene drives, e.g. super-Mendelian inheritance of the gene drive, are different in degree rather than type with other GMOs. Current ERA frameworks for GMOs already direct the risk assessor to focus on the reproductive biology of the organism (OECD Pts to consider). Different types of data might be required but the ERA questions to be addressed remain qualitatively the same.

This presentation will explore what lessons may be learned from the ERA for the deployment and/or control of non-GM organisms (e.g. van Lenteren et al 2006, Chai et al 2016) in similar contexts as those proposed for engineered gene drives.

## PS X -6

### Challenges for the regulation of gene drive technology

**Detlef Bartsch** - *Federal Office of Consumer Protection and Food Safety (BVL)*

Co-authors: Werner Schenkel, Tom J de Jong, Michael Bonsall

Before any GMO can be released into the environment it is subject to an Environmental Risk Assessment (ERA). The ERA develops hypotheses of what can happen under different scenarios. These hypotheses will guide the type of data that need to be collected before the release. Constructing hypotheses of what might happen, requires input from several fields.

Gene Drive (GD) is the transmission of a specific allele with a frequency greater than 50% to the next generation. The genetic mechanism is active in the germline or when the embryo is formed. Gene drives can spread to all populations of a species or might be restricted to local areas or populations. Not all gene drives increase in frequency when being introduced in natural populations and the conditions for spread were analyzed by modeling. Most attention is now focused on CRISPR Cas9 technology but there are many other GD's including Homing Endonuclease Genes (HEG), *Wolbachia*, chromosome translocations and Maternal Effect Dominant Embryonic Arrest (MEDEA).

GD can offer great benefits to society when it comes to disease and pest control, but there are also risks associated with this technology since wild species or ecosystems might be harmed by its application. GD could therefore raise new challenges for technology regulation. To discuss how regulators can best anticipate these challenges, we organized a workshop at the Lorentz-Center in Leiden, the Netherlands on 20-24 March 2017, and bringing together scientists from various disciplines. In total, 53 participants contributed to the workshop, representing a wide range of Technology Developers (Small & Medium Enterprises, Industry), Technology Users (from Europe, South America, and Africa), Regulators (including Risk Assessors and Risk Managers), Scientific Community (from disciplines of Ecology, Mathematical Modeling, Population Genetics, Molecular Biology) and Governance (representing Ethics, Politics, and Socio-Economy). The talk will present in more detail the lectures and main outcomes of the discussions.

## PS X -7

### “Friendly™ *Aedes*” and the challenges for the regulation of GM insects in Brazil

Fabiano dos Santos Ferreira - Oxitec

Over one million people die from mosquito-borne diseases every year, and hundreds of millions suffer from life threatening arboviruses transmitted by *Aedes* mosquitoes, including dengue, Zika and chikungunya. According to the World Health Organization (WHO, 2016) an important way to combat these viruses is to control the primary vector, usually through environmental management, insecticides and biological methods. Oxitec developed its self-limiting OX513A *Aedes aegypti* mosquito in 2007. The Oxitec biologically based approach to mosquito control involves the release of OX513A males to mate with wild females, and the offspring die as larvae, therefore reducing the wild *Aedes aegypti* populations. The Brazilian National Technical Commission of Biosafety (CTNBio), granted a “commercial release” approval for OX513A in 2014, and in April 2016 the National Health Surveillance agency of Brazil (ANVISA) classified the mosquito as a household product and required its registration. The Agency, however, is seeking an appropriate regulatory framework for genetically modified (GM) insects and has been working to establish the guidelines for experimental use and commercial registration of OX513A. In April 2015, Oxitec and the City of Piracicaba began the “Friendly™ *Aedes*” project, a large-scale field test, and OX513A mosquitoes were released in the CECAP/Eldorado neighborhood covering an area of 5,000 residents. Results showed a reduction in wild *Aedes aegypti* larvae by 82%, and the project was expanded to cover an area of 60,000 residents in 2016. Oxitec’s self-limiting, genetically modified mosquitoes are a promising solution to reduce the population of human disease vectors in a manner that is highly effective and more sustainable and environment-friendly than existing chemical-based approaches.

## Parallel Session XI - Abstracts

### Biosafety and ERA of GM Algae

There is a lot of research both at the academic level as well as by the industry on the use of unicellular eukaryotic algae and cyanobacteria for alternative biofuels and for food, feed and nutritional supplements. These organisms provide a source of renewable energy and can harness the sunlight by the use of one of the most common metabolic processes, i.e., photosynthesis. Research is aimed at use of GM algae and cyanobacteria for trait development and therefore, poses a challenge for ERA and biosafety. The objective of this session is to get the stakeholders to brainstorm towards formulating a regulatory framework and the guidelines for large scale cultivation of GM algae and cyanobacteria. Ideas on assessing the environmental risks involved both in open raceway ponds, as well as in contained photobioreactors will be discussed. The session aims at discussing ERA considerations for the deliberate and accidental releases of GM algae into the environment, whether current ERA approaches are applicable and where fine-tuning may be required. This session will serve as a platform for bringing together the key people from algal research as well as the biosafety experts. It will assist in the long term goal of setting the path forward for commercial exploitation of the outcome of such research

Session Organiser: **Tomal Dattaroy** - *Reliance Industries Ltd*

## PS XI -1

### **Algal biology – Technological advancements to harness potential benefits and regulatory implications**

**Tomal Dattaroy** - *Reliance Industries Limited*

Co-authors: Santanu Dasgupta, Ajit Sapre

Cyanobacteria and green algae are among the earliest precursors of life forms in the evolutionary time scale. Focus on these organisms has renewed for exploring potential benefits for feed, fuel and food industries. Harnessing sunlight for photosynthesis places them among the best options for renewable sources for these industries with depleting fossil fuel and agricultural land resources, as well as a burgeoning population. Synthetic biology and gene-editing processes, such as CrispR-Cas9 and TALENs, open up exciting prospects for deriving these benefits optimally. However, absence of a defined regulatory framework worldwide for genetically modified algae makes it even more pertinent today to brainstorm for developing the tools required for the same.

## PS XI -2

### Overview of guidance and data needs for ERA of GM algae

**Carolina Peñalva-Arana** - *US Environmental Protection Agency (US EPA)*

The use of genetically modified (GM) unicellular eukaryotic algae and cyanobacteria has shown great promise and resilience for the production of biofuels and other industrial products. Under the Toxic Substances Control Act, the U.S. EPA Office of Pollution Prevention and Toxics (OPPT) is required to make an affirmative finding that addresses whether or not a new substance (including a new microorganism) may present an unreasonable risk of injury to health or the environment, including the risk to a potentially exposed or susceptible subpopulation under the conditions of use of the microorganism. This requires that OPPT develop a risk evaluation that characterizes the microorganism, the human health and ecological hazards, and potential exposures. As the cultivation of these new GM organisms is expected to be performed primarily outdoors, there exists a potential for deliberate or accidental releases into the environment, thus presenting new challenges for ecological risk assessment (ERA). Although many genetically modified algae have undergone extensive laboratory research, little to no field experience is available for either the native or genetically modified forms. Therefore, there is a need for risk assessors to provide guidance and for developers to provide the most relevant and latest data thus ensuring that ERAs are based on the best science available while allowing for innovation and advancement of the field. This talk will discuss OPPT's data needs and guidance to generate fit-for-purpose ERAs for GM algae. This will enable developers to understand and consider OPPT's data needs and submit pertinent data and information when applying to commence either experimental releases or commercial production of GM algae.



**PS XI -3****Evaluation of phenotype stability and ecological risk of a GM alga in open pond production****Stephen Mayfield** - *University of California San Diego (UCSD)*

Co-authors: Shawn J Szyjka, Shovon Mandal, Nathan G Schoepp, Briana M Tyler, Christopher B Yohn, Yan S Poon, Steven Villareal, Michael D Burkart, Jonathan B Shurin

Genetically modified (GM) algae offer the promise of producing food, fuel, and other valuable products with reduced requirements for land and fresh water. While the gains in productivity measured in GM terrestrial crops are predicted to be mirrored in GM algae, the stability of phenotypes and ecological risks posed by GM algae in large-scale outdoor cultivation remains unknown. Here, we describe the first US-EPA approved experiment aimed at understanding how GM algae perform in outdoor cultivation. *Acutodesmus dimorphus* was genetically modified by the addition of two genes, one for enhanced fatty acid biosynthesis and one for recombinant green fluorescence protein (GFP) expression. Both the genes and their associated phenotypes were maintained during fifty days of outdoor cultivation. We also observed that while the GM algae dispersed from the cultivation ponds, colonization of the trap ponds by the GM strain declined rapidly with increasing distance from the source cultivation ponds, and GM algae were not identified in several traps 50 meters from the cultivation ponds, even after 50 days of growth. In contrast, many species of indigenous algae were found in every trap pond within a few days of starting the experiment. When inoculated in water from five local lakes, the GM algae's effect on biodiversity, species composition, and biomass of native algae was indiscernible from those of the wild-type (wt) progenitor algae, and neither the GM nor wt algae were able to out compete native strains. We conclude that GM algae can be successfully cultivated outdoors while maintaining GM traits, and that for the specific GM algal strain tested here, they did not outcompete or adversely impact native algae populations when grown in local lake waters. This study provides an initial evaluation of GM algae in outdoor cultivation, and a framework to evaluate GM algae risks associated with outdoor production.

## PS XI -4

### Environmental and biotechnological risk assessment of GM algae

Jeremy Sweet - *JT Environmental Consultants*

Co-authors: Tracey Beacham, Mike Allen

New biotechnology and genetic techniques allow algae to have the potential to revolutionise food, feed, fuel and pharmaceutical production. Both marine and fresh water microalgae and cyanobacteria have the potential to be developed by exploiting genetic combination and selection of key physiological characteristics together with modified metabolic activities. However, commercialisation of GM microalgae will require culturing them at larger scales, increasing the likelihood of environmental exposure. This paper reviews the key issues to identify, characterise and assess the factors that will need to be considered in an ERA in order to progress GM microalgae scale up in both closed and open systems. We discuss an ERA guidance document being developed to assist researchers and developers to identify potential hazards, assess exposure and determine the data requirements for conducting environmental and biotech risk assessments. Since the ecological roles and interactions of some algae have received little attention, we also discuss approaches to post-release monitoring in order to cover knowledge gaps.

## PS XI -5

### Using algae biotechnology to develop high-value colostrum proteins as formula ingredients

**Xun Wang** - *Triton Algae Innovations*

Co-author: Miller Tran

Triton Algae Innovations is a small life sciences start-up that is pioneering a unique technological pathway for the efficient commercial-scale production of nutritious wild-type green algae, and the expression from this algae platform of high-value colostrum (milk) proteins. Triton utilizes a closed fermentation process in stainless steel tanks for this production, and is in the final stages of navigating the regulatory pathway for its first commercial product. In this presentation, Triton will provide an overview of its production process, its current commercial pathway and the subsequent regulatory operating environment, and the longer-term market potential of its IP-protected technology on the algae and other industries.

**PS XI -6****Biosafety assessment for environmental release of GM algae: An Indian perspective**

**Abhijit Poddar** - *Biosafety Support Unit*

Co-authors: Sangeeta Agarwal, Vanga Siva Reddy, S Raghavendra Rao

As resources of fossil fuels are constantly receding and their large-scale consumption is also not considered as environmentally friendly, there is an increasing demand to develop alternate sources of clean energy. In this scenario, GM algae are emerging as an alternate and a major source of clean energy. Also, GM algae are considered as a useful bioreactor for manufacturing high-value proteins/molecules used in pharmaceutical and other industries. Scale of GM algae production in either contained or open ponds may have different sets of risks depending on the exposure to potential hazard posed by nature of genetic modification, levels of cultivation, production of harmful toxins, environmental persistence and disposal of waste. Considering the thrust given on commercialization of biofuel in India under “National Policy on Biofuel” and flourishing research and development in GM algae, Indian biotechnology regulatory agencies are anticipating applications for approval of GM algae for resource development in the near future. In view of these developments, to protect environment and human health, specific guidance documents and standard operating procedures are under preparation by competent agencies under the purview of “Rules 1989” of “Environment (Protection) Act (1986)”. For regulators and stakeholder, the document will serve as a roadmap to systematically present the risks associated with release of GM algae and the basket of data requirements for the regulatory safety assessment in step of research, cultivation, extraction and use of product (biofuel) and related co-products. It will be presented in the meeting for discussion.

**PS XI -7****Risk assessment of GM algae**

**Richard Sayre** - *New Mexico Consortium (NMC)*

Recently, there has been substantial interest in ecological risk assessment for GM algae being developed for commercial mass cultivation. We will discuss the potential ecological, economic and health impacts of GM algae that potentially persist in and alter natural ecosystems. Horizontal gene transfer with native organisms is of particular concern for certain traits. In general, however, we predict that most target GM algal traits are unlikely to confer a selective advantage in nature, and thus would rapidly diminish, resulting in low but nonzero ecological risk. Genetic and mechanical containment, plus conditional matching of GM algal traits to unnatural cultivation conditions, would further reduce risk. Recent evidence suggests, however, that some commercial strains of algae are actively undergoing meiosis and sexual reproduction. Thus, the possibility exists for unlinking multiple introduced GM traits, including those designed to restrict escape of GM organisms. Overall, predictions of invasiveness or traits that could confer some risk to the environment must be verified through rigorous ongoing monitoring and mesocosm experiments to minimize risk and foster public and regulatory acceptance.

## Parallel Session XII - Abstracts

### Capacities for the Risk Assessment of GMOs: Challenges to build Sustainable Systems

Risk assessment is a dynamic, scientific exercise that requires significant technical capacity. In most countries, this is not a formal specialisation option. Therefore, only practice and experience make professional risk assessors and this is long term process that may take between three and five years. The need for skilled, functional risk assessment bodies demands a continued effort and commitment from regulatory agencies, if sustainability of the regulatory systems is to be achieved. The lack of formal procedures to train and update risk assessors on the criteria to be applied, the high rotation in some cases, or the lack of experienced professionals in others, can be challenging. Capacity building initiatives with different approaches have been implemented in many countries over the years, supported by diverse governmental and nongovernmental organisations. Some of these programs were aimed to build in-country capacities, also encouraging active participation of country experts in international fora. Inclusive discussions are critical to develop consensus on scientific criteria, conceptual tools and common standards that enable evidence-based risk assessment and regulations, ultimately facilitating greater harmonisation among countries and regions. The purpose of this session is to present several experiences regarding strengthening and follow-up of risk assessment capacities in regulatory systems around the world, in order to learn from past experiences and exchange ideas for the development of self-sustainable systems in the future.

Session Organiser: **Carmen Enriqueta Vicién** - *Universidad de Buenos Aires*

## PS XII -1

### CONABIA as FAO Centre of reference for biosafety of GMOs

**Martín Lema** - *Ministry of Agro-industry & Quilmes National University*

Co-author: Agustina Whelan

Argentina was one of the first countries in Latin America to implement an organized system to evaluate the biosafety of genetically modified organisms (GMOs) for agricultural use through the creation of a regulatory framework for carrying out activities with GMOs. That is why it is considered one of the oldest regulatory systems and recognized worldwide by both regulatory agencies and scientific institutions in developing countries. National Advisory Committee on Agricultural Biotechnology (CONABIA) was created in 1991 based on the need to evaluate biosafety aspects in the release of GM crops for experimental and/or commercial purposes. CONABIA has the responsibility of evaluating the environmental biosafety of GM crops that will be planted in field trials and produced on a large scale. It also establishes the conditions of control, safety, and monitoring that will be carried out during experimentation with GM plants, animals and microorganisms. Since the beginning, CONABIA has carried out capacity-building activities in Asian, African, and Latin American countries, bilaterally or through initiatives of third parties such as ICGB, ILSI, United Nations University, IICA, among others. Among the issues addressed are the risk analysis for field trials of plants, animals, microorganisms and commercial release of GM crops. Due to its long history and as a leading country in issues related to regulation of GMOs, the Food and Agriculture Organization of the United Nations (FAO) has recently recognized CONABIA as Reference Center for Biosafety of GMOs. In this presentation we will discuss our experience, difficulties, and perspectives regarding capacity building in biosafety of product derived from modern biotechnology.

## PS XII -2

### Capacity building support program for Paraguay

**Danilo Fernández Ríos** - *Universidad Nacional de Asunción*

Co-author: Nidia Benítez Candia

In Paraguay, a country whose economy relies mainly upon agriculture, the adoption of agrobiotechnology has been growing rapidly. Thus, the regulatory framework for this technology must be constantly updated and the specialists in the field must receive continuous training. Several activities were carried out with the purpose of enhancing the technical expertise of the regulatory and scientific communities to implement a robust regulatory system based on scientific evidence.

Towards the end of 2013, the members of the National Agricultural and Forest Biosafety Commission evaluated Paraguay's regulatory system and concluded that it was necessary to update it so that it would keep up with the evolution of scientific knowledge. The work focused on updating the framework for Biosafety Risk Assessment, which includes the application forms, taking into account a science-based problem formulation approach, which represents a major shift from the prior system applied by the Commission for risk assessments that resembled the decision-tree approach.

The framework shift required extensive training based on cycles comprised of the presentation of problems, the identification of sources of relevant information, and the discernment of the additional information required. Both the training and the framework were designed to assist regulators in constructing a flexible and extensive knowledge base, focused on the development of effective abilities for problem formulation, and to provide them with an orientation on the risk assessment of agrobiotechnological products' unifying concepts, and to consider the regulatory framework in place in Paraguay, both in confined field trials and in the applications for commercial release. This may facilitate pursuing the questions that need to be answered and to improve communication between applicants and regulators. The training of all professionals involved in risk assessment is an ongoing process as new knowledge on agrobiotechnological products emerge and more efficient tools for biosafety assessment are developed.



**PS XII -3****Managing agricultural biotechnology research for food security in Africa: Capacity building efforts for research, innovation and application**

**Ruth Mbabazi** - *Michigan State University (MSU)*

Co-authors: Marc Heijde, Karim Mareida

The continent of Africa is an emerging global economy with the majority of its one billion population engaged in the agricultural sector. Institutional and human capacity-building efforts implemented in the region to address agricultural challenges and to transform agriculture into a vibrant sector are creating a strong impact on African countries. The national governments and regional economic communities (RECs) are taking positive steps in building their capacities for adoption of new technologies, such as modern biotechnology, to enhance agricultural productivity, food and nutritional security and economic growth. At national level, current trends reveal changing and improving capacities in agricultural research, innovation and technology transfer in key national research institutions across Africa. This has also triggered strategic and effective public and private partnerships for transforming research to practice. New plant varieties and hybrids of key staple crops have been developed or are in the pipeline for testing and possible deployment in coming years. These crops have great potential to address some of the key challenges Africa is facing today, such as reducing hunger, malnutrition and poverty. These include crops with enhanced micronutrient content, insect and disease resistance, herbicide tolerance, and crops resilient to changes in environmental conditions. The integration of modern biotechnology tools in agricultural research and development programs has concurrently progressed with biosafety capacity building in Africa. The biotechnology research initiatives present the opportunity for dealing with environmental biosafety policies and regulations in an organized way. This paper highlights the biotechnology regulatory capacity- building experiences in Africa, presenting the respective roles and impacts of key continent-wide and international institutions and examines key issues related to technology transfer policies, practices, and regulation of biotech products and their uptake in Africa.

## PS XII -4

### **e-Learning courses: Providing a sustainable and interactive resource**

**John Teem** - *International Life Sciences Institute (ILSI) Research Foundation*

Co-author: Libby Williams

Biosafety risk assessment is a dynamic, scientific exercise that requires significant technical capacity. In-person workshops and meetings are an ideal way to provide education and training. However, there are several challenges that can make this traditional style of capacity building unsustainable, including limited resources and travel constraints. e-Learning courses provide an alternative to stand-alone in-person training. By being cost effective, interactive and accessible, e-Learning courses can be used to complement face-to-face training to achieve optimal learning outcomes. This presentation will highlight a capacity-building case study with the National Biosafety Authority (NBA) of Kenya that utilized e-Learning courses developed by the ILSI Research Foundation to share biosafety information in a resource-efficient format. The ILSI Research Foundation worked to provide Kenya's regulatory staff with training in a science-based risk assessment process and the use of problem formulation to identify the risk hypotheses they would need to address and the specific data needed to test those hypotheses. Through this program, Kenya's regulatory staff received training in problem formulation, risk characterization and assessment, and risk communication through both face-to-face and eLearning training. This presentation will also focus on the current open access courses available through the ILSI Research Foundation.

## PS XII -5

### **A curriculum-based approach to teaching biosafety through e-learning**

**Dennis O Ndolo** - *International Centre for Genetic Engineering and Biotechnology (ICGEB)*

Co-authors: Michael Wach, Patrick Rüdelsheim, Wendy Craig

As anyone working in biosafety capacity enhancement will know, incorporating approaches into activities such that their impact becomes sustainable once funding has been depleted can be a truly Sisyphean task. Many training efforts face the limitation of one-off events: they only reach those people present at the time, it becomes incumbent upon the trainee to pass on the training to colleagues as best they can, while the demand for the training never appears to diminish. However, beyond the initial effort to establish the basic content, repeating capacity enhancement events in different locations is usually not economically feasible. Also the lack of infrastructure and other resources needed to support a robust training programme hinder operationalising a “train-the-trainer” approach to biosafety training. One way to address these challenges is through the use of eLearning courses that can be delivered online, globally, continuously, at low cost, and on an as-needed basis to multiple audiences. After the courses are developed and peerreviewed, they can be maintained on a remote server and made available to various audiences through a password-protected portal that delivers the course content, administers preliminary and final exams, and provides the administrative infrastructure to register students and track their progress through the courses. Crucial to the implementation of such an eLearning programme is an approach in which the courses are intentionally developed together as a cohesive curriculum. Once developed, such a curriculum can be released as a stand-alone programme for the training of governmental risk assessors or used as accredited components in graduate degree programmes in biosafety, at minimal cost to the government or university. Examples from the ICGEB portfolio of biosafety eLearning courses are presented to demonstrate these key features.

## PS XII -6

### **Brazilian capacity building experiences in biosafety: Impacts in governance and supporting decision-making**

**Deise Maria Fontana Capalbo** - *Brazilian Agriculture Research Corporation (EMBRAPA) – Environment*

Co-author: Carmen Enriqueta Vicién

GMOs are widely spread around the world, and Brazil is now the second producer behind the USA (1). Initially a defined policy in biosafety was put in place by 1995 which was revised in 2005 (2) with the participation of politicians, decision makers, scientific organization representatives, and groups from organized civil society. The main decision body in place since then is CTNBio, comprised of 27 PhD members and their respective alternates who hold a two-year term, renewable for up to two consecutive periods. So, a significant technical capacity had to be gathered and a critical mass had to be prepared. As expertise is gained with practice and experience, it was recognized that capacity-building initiatives were urgent for different levels of audiences. This presentation will show some experiences on how individuals, groups, institutions, and governmental authorities acted to provide training and technical assistance for the decision bodies. There were, and still are, many types of capacity-building activities in place. Different approaches incorporated a variety of forms and disciplines, and many factors were taken into account (e.g., target beneficiaries, effective content for the level of decision-maker's audience, specific needs, and integration and collaboration among the various disciplines and capacity builders). Among such actions, active participation of country experts in international fora was also encouraged. The need for skilled risk assessors demands a continued effort from governmental and non-governmental organizations; so capacity-building has to be a continuous action. Inclusive discussions, robust scientific criteria and methods are some of the key factors that are needed to support evidence-based risk assessment, and they should be part of the content addressed by any reliable capacity building initiatives.

**PS XII -7****Institutional capacity strengthening to overcome systems challenges towards building functional biosafety systems in Africa**

**Samuel Edudzi Timpo**, *NEPAD African Biosafety Network of Expertise (ABNE)*

Co-authors: Hashini Galhena Dissanayake, Joseph F Guenther, Godwin N Lemgo, Karim M Maredia

Crops derived through modern agricultural biotechnology can provide significant productivity gains that could in turn change the food insecurity and poverty landscape of the African continent. However, potential health and environmental concerns over this technology motivated the need to have biosafety systems in place for food safety and environmental risk assessment (ERA). While functional biosafety systems are critical to the safe adoption of genetically modified (GM) crops in Africa, the development of these systems are constrained by a number of factors. Key among these challenges is the lack of institutional and human capacity to design and implement suitable biotechnology regulatory framework that has the capability to make science-based decisions on risks and benefits of various GM events, as well as to provide mechanisms for inspection and monitoring. One hundred seventy countries are parties to the Cartagena Protocol on Biosafety, an international agreement intended to ensure safe handling, use, and safe transboundary movement of living modified organisms. The national governments and international stakeholders also recognize the need to build a strong scientific base through the strengthening of institutional and human capacity for the successful implementation of the protocol and to overcome any systems challenges that may result from lack of such capacity that could debilitate the functionality of national biosafety systems. In view of these ongoing efforts, this paper attempts to identify knowledge and skill gaps through a multi-stakeholder field research carried out in six countries in Africa and to discuss strategies to enhance biosafety capacity in Africa. The findings emphasize the importance of continuing capacity-building programs and coordinating efforts and investments, as well as broadening training modules and extending to groups beyond regulators, policy makers, and scientists. Such efforts will help minimize prevalent concerns about food and environmental risk, and empower stakeholders with accurate information to counter misconceptions.

## Poster Session I - Abstracts

### PO I -1

#### Establishing biodiversity damage resulting from GMOs

**Claudia Colmenarez Ortiz** - *Ghent University*

**Purpose:** This paper examines the definition of biodiversity damage in the Nagoya-Kuala-Lumpur Supplementary Protocol on Liability and Redress for damage to biodiversity from GMOs (Supplementary Protocol). This paper focusses on:

1. The current status of the Supplementary Protocol and challenges of implementation.
2. The concept of biodiversity damage and the damage-related definitions in the Supplementary Protocol, the Convention on Biological Diversity (CBD), and the Cartagena Protocol on Biosafety.

**Description:** The Supplementary Protocol is the first treaty dealing with liability in the event of damage to biodiversity. In essence, the Supplementary Protocol refers to damage to conservation and sustainable use of biodiversity and applies to damage resulting from GMOs that find its origin in a transboundary movement. Currently, neither the CBD nor any other treaty includes a definition for damage to biodiversity. However, the existing definition of biodiversity damage is quite complex and requires careful interpretation. To date the Supplementary Protocol needs only four more ratifications to enter into force and it is likely that this will happen before the next COP-MOP-9 in 2018. After coming into force, Parties to the Supplementary Protocol will have to implement its international rules and procedures.

**Evaluation:**

- Identification of elements for liability and redress.
- Evaluation of the reports of the CBD inter-regional and regional workshops on capacity needs for the implementation of the Supplementary Protocol.
- Analysis of the outcomes of the meetings of the Technical Group of Experts on Liability and Redress in the context of the Cartagena Protocol.

**Outcomes:**

- Draft of a guidance tool to clarify concepts as reference for the Parties.
- Acknowledgement from all the actors involved in biosafety research of the importance to harmonise core definitions prior to addressing the operational liability provisions as part of the GM technology regulations.

**\*Pecha Kucha participant**

## PO I -2

### **Inspired eyes: The current biotechnology legislation in the international landscape from a student's perspective**

**Eliel Ignacio Villegas Félix** - *Instituto Tecnológico y de Estudios Superiores de Monterrey*

Co-authors: Daniel Gómez Domínguez, Luis Francisco García

William Butler Yeats wrote, "What man does not understand, he fears; and what he fears, he tends to destroy." Public misunderstanding of biotechnology is widespread. This extends to genetic engineering tools of modern biotechnology and to the rapidly emerging technologies of "synthetic biology" that include gene editing tools such as gene drives and CRISPR. The expanded international debate on biosafety and regulation of these new technologies mirrors the history of agricultural GMO regulation. The inevitable "paralysis by analysis" is slowing down technology development and adoption.

Despite well-intentioned efforts to establish better regulations to benefit all segments of society, strong opposition, driven by ideology and politics, is preventing the development of coherent, science-based risk assessment approaches to properly assess the costs, benefits, and potential unintended consequences of these technologies.

Application of the precautionary principle to adopting biotechnologies for food, agriculture, medical and pharmaceutical products must be reevaluated on the basis of credible scientific understanding. A variety of factors, including activist group opposition, misinformation, and public misunderstanding of the risks and benefits of these technologies, have impeded coherent policy development. Unnecessary obstacles to technological development and adoption deprive society of the economic, social and environmental benefits new technologies offer. Such obstacles especially hinder technological development and deployment of products from the academic and small industry sector (start-up companies), strongly represented by young scientists who are expanding biotechnology applications by merging them creatively with tools from other fields.

Our work explores the current regulatory landscape from the perspective of young Mexican scientists who attended the 13th Conference of the Parties, 8th Meeting of the Parties of the Cartagena Protocol, and the 2nd Meeting of the Parties of the Nagoya Protocol (COP13-MOP8-MOP2) in Cancun, Mexico, in 2016, as part of a group of international biotechnology students. As future biotechnologists that will drive tomorrow's industry, we offer our perspective and present recommendations for developing public policy.

**\*Pecha Kucha participant**

## PO I -3

### **New biotechnologies and innovation: A challenge for the Mexican regulatory system**

**Diana Priscilla Bonilla Ruelas** - *Instituto Tecnológico y de Estudios Superiores Monterrey*

Co-author: Luis Antonio Ventura Martínez

Over the last twenty years, agricultural biotechnology use has expanded exponentially in many parts of the world. Yet many countries have not adopted GM crops and other related technologies because their regulatory systems are infused with anti-science ideologies that make rational decision-making onerous, complex, and unable to match the speed of innovation.

As a signatory to the Convention of Biological Diversity and the Cartagena Protocol on Biosafety, Mexico must have a GMO Biosafety Law. The Mexican law was developed to harmonize and consolidate Mexican biotechnology policies. The coordinating agency CIBIOGEM, has wide regulatory authority over modern biotechnology, representing the interests and policy positions of seven agencies. This law emphasizes scientific evidence as the basis for obtaining approvals to use GMOs. However, internal judicial procedures have restrained GM crop adoption in some border states, which could lead to international conflict under World Trade Organization policies. Complying with the Mexican regulatory structure is unnecessarily onerous and costly considering the worldwide safety record of GM crops. Furthermore, its current complexity presents important challenges that may unnecessarily retard the adoption of new imported and locally developed biotechnologies by creating a threatening perception of these new agricultural technologies. Mexico has a double challenge: first, as a large and diverse country it needs to protect its biodiversity; second, it needs to utilize its natural resources to promote economic growth. To attain these goals, research and development need to be supported, coupled with the necessary political will to adopt science-based decision-making.

This paper, written from the student perspective of future Mexican biotechnologists, offers a candid opinion of how current processes in policy development in Mexico present important challenges to the new generation of scientists.

**\*Pecha Kucha participant**



**PO I -4****Problem formulation approach to assess the risk of GM maize use in Mexico: A preliminary exercise using the proposed Official Mexican Standard (NOM)**

**Sol Guerrero-Ortiz** - *Cornell Alliance for Science*

Co-author: Sol Ortiz García

The first GM maize experimental releases in Mexico took place between 1995 and 1998 under an Official Mexican Standard (NOM) that dealt with field trials for genetically modified crops. In 1998, the Secretary of Agriculture established a de facto moratorium for the release to the environment of GM maize. After ten years of the moratorium, between 2009 and September 2013, more than 300 applications for the release of GM maize have been submitted (211 in experimental, 79 in pilot, and 19 in commercial phases, 63% of which have been accepted, most as experimental and none as commercial). Since September 2013, all applications for environmental release of GM maize in Mexico have been suspended due to a “diffuse collective action to protect rights” (lawsuit). Precautionary measures have been imposed by the judiciary power precluding any procedure for the environmental release of GM maize in Mexico. Recently a new NOM has been published for public comments. This new standard includes problem formulation in its approach for contextualizing risk assessment. We used the NOM’s guidelines and formats to perform an environmental risk assessment (ERA) for the cultivation of GM maize, as an exercise to test its applicability and to assess the risk for the cultivation of this crop with a case-by-case approach. Although the NOM seems quite prescriptive, it allows for structuring risk assessment in a practical and scientific way. A key element deals with the identification of assessment endpoints and how to focus the assessment in the context of the use of the technology. After the precautionary measures are lifted, the real test for this NOM will come to light. Our exercise could inform decision-makers in a context where Mexico’s imports of maize are reaching historical maximums of over 12 million tons per year.

## PO I -5

### **Regulated field trials in Mexico. Planning and implementation through interdisciplinary approach**

**Carlos Patiño-Echeverri** - *Monsanto*

Co-authors: S Escoto-Hernández, A Tellez L Castillo G Medina-Palacios

Field trials are an essential step in the development of GM crop knowledge and further enjoyment of the benefits of higher yield, improvement in the life quality of growers, risk assessment and environmental protection. They are useful to obtain the necessary data to assess product performance, as well as data relevant to environmental risk assessment (ERA). Field tests and outdoor developments that occur within authorized sites must comply with comprehensive structural and operational requirements because the appropriate measures and controls are required to conduct field trials safely.

Before planting any regulated field trial, a careful evaluation of the conditions of the approval must be done to ensure the compliance with legal, regulatory, and administrative obligations, and to satisfy the strict internal policies and procedures established for these activities.

Our Regulated Field Trial Implementation Program, to be managed at full compliance, requires excellent team coordination and multifactor combination regarding pillars and areas involved in the planning and implementation of the trials, such as trainings (field personnel, cooperators and third parties), institutional memory (effective and documented control processes, work instruction, standard operation procedures), protocol alignment, trial data quality control measures, inspection and verification procedures, audit regulatory records and reports, Geographic Information Systems (GIS) data analysis, traceability, and stewardship, among others.

The ability to satisfactorily implement an appropriate compliance-management program for a successful compliance management of the field trials is also a significant factor that will influence the granting of future permits and approvals.

## PO I -6

### ERA studies for biotechnology-derived products in Brazil

Daniella PV Braga - *Monsanto*

Co-authors: Gustavo G Belchior, Marcia OMA José, Daniel J Soares, Hallison V Vertuan, Geraldo U Berger

The Brazilian National Technical Biosafety Commission (CTNBio) is the regulatory agency for technical and advisory matters pertaining to genetically modified organisms (GMO) in Brazil. Normative Resolution #5 under Law #11,105 sets the provisions for food, feed and environmental safety. Applicants seeking to commercialize biotechnology-derived crops should provide CTNBio with molecular characterization, product biosafety data to human and animal health, and environment data from a risk assessment perspective. Data from risk assessment based on regulatory studies conducted in Brazil include agronomic/phenotypic characteristics, transgene product expression, environmental fate, proximate composition, soil microorganisms and physicochemical attributes, biomass degradation, NTO abundance and pollen morphology/ viability. Throughout the years, the diversity and absolute number of studies has consistently increased, enabling CTNBio to reach sound technical decisions based on information pertaining to the interactions of the GMOs with environments representative of agricultural regions where corn, soybean, and cotton are grown in the country. Moreover, the large amount of generated data has systematically led to the conclusion that these GM crops, many of which share the same transgenes and expressed proteins, are as safe as their conventional counterpart, and do not pose an increased risk to the tropical environment. Such an outcome is coherent with decisions made by the several regulatory agencies around World that have been approving GM crop commercialization for two decades. This scenario creates an opportunity to evaluate the stringency level of study requirements for low risk GMOs, and/or those possessing similar genetic constructs, without jeopardizing the safety assessment of such products, considering that these GMOs are delivering significant environmental benefits towards a more sustainable tropical agriculture, reaching near 80-90% area penetration.

## PO I -7

### **The joint evolution of institutional organisation and GMO risk analysis in Argentina**

**Agustina Whelan** - *Ministry of Agro-industry*

Co-author: Martín Lema

Argentina is one of the leading countries in the development, use and export of products derived from biotechnology, and in particular of genetically modified crops (GMOs). In 1996, the first soybean tolerant to the herbicide glyphosate was introduced to trade, and it has continued uninterruptedly with almost unprecedented worldwide acceptance dynamics. The objective of this work is to review the history of the regulatory authority for GMOs in the Argentine Republic and to assess the impacts of its organizational changes on risk analysis and innovation pertaining to GMOs. Certain changes in the administration led to changes in organizational structures, particularly in the regulatory area currently denominated Directorate of Biotechnology and the associated National Advisory Committee on Agricultural Biotechnology (CONABIA). These changes in turn had visible impacts on several indicators of regulatory activity.

## PO I -8

### **Government support for deregulation of public sector GMOs in Argentina**

**Agustina Whelan** - *Ministry of Agro-industry*

Co-author: Martín Lema

Biotech products for use in agriculture and animal health are subject to costly regulations that limit market accessibility for developers such as public sector institutes and SMEs. Many products potentially useful to society are created but not commercialized just because of this. To cope with this situation, in Argentina the Regulatory Fund for Biotechnological Products (FONREBIO) was created as a joint initiative of the Ministry of Science, Technology and Productive Innovation and the Ministry of Agroindustry. FONREBIO provides financial support in order to allow for GMOs developed in Argentina to comply with regulatory requirements. It is an innovative program in regards to its objectives, possibly the first of its kind. This work analyzes the genesis of this program, its technical and political objectives, its current state of implementation and its insertion in the pre-existing menu of financial instruments for applied research and innovation.

**PO I -9****Uruguayan biosafety framework for developing and/or handling GM vegetables under confined conditions**

**Alejandra Ferenczi** - *Ministry of Livestock, Agriculture and Fisheries*

Co-author: Mariela Mauro

Under Decree 353/008 of July 21, 2008, the National Biosafety Cabinet (GNBio for its acronym in Spanish) established the Resolution N° 65 on September 1, 2014, which gives the legal framework for handling in a laboratory or greenhouse genetically modified vegetables not yet deregulated in Uruguay. Under this Resolution, the biosafety system defined a procedure for public or private organizations to enter a Registry. The Registry is at the national level and includes organizations that meet certain requirements for developing and/or handling genetically modified vegetables under confined conditions. One of the requirements to enter the Registry is the creation of an Internal Biosafety Commission (CIB for its acronym in Spanish). In addition, each organization's laboratory and/or greenhouse must comply with the biosafety protocol defined for confined scale. A responsible researcher for each laboratory or greenhouse informs the regulatory system by submitting to the CIB of his institution a form for each project that involves the development and/or handling of genetically modified vegetables. After the organization has been registered, in order to determine compliance with the biosafety protocol in each laboratory and greenhouse, and to assess whether it has been implemented and maintained effectively, the competent authority conducts annual audits. Seven organizations were identified that develop and/or manipulate genetically modified vegetables, with a total of ten laboratories and two greenhouses. To date, seven laboratories and two greenhouses have been authorized to enter the registry. One laboratory was not authorized and two others are in the process. A total of fourteen research project forms and five project forms at the academic level, including undergraduate teaching and postgraduate theses, were presented. This regulation provides the necessary biosafety framework for public or private organizations with the potential to work with genetically modified vegetables in line with current regulations.

## PO I -11

### 20 years of biosafety in Bolivia. Lessons learned

**Cecilia González Paredes** - *Instituto Boliviano de Comercio Exterior*

Bolivia's experience with GMO Biosafety can become a learning lesson of how regulation should be developed in accordance with capacity-building and defining the administrative structure to put all into action. Bolivia approved a general norm for biosafety in 1997. This allowed the approval of one soy resistant to glyphosate in 2005. Now, Bolivia still ranks among the top 15 countries that produce GMO soy.

In 2009, Bolivia changed its Political Constitution and name. The change of government and political view, as well as the introduction of new laws, created a gap in terms of procedure and administration. Meanwhile, the National Biosafety Committee (NBC) tried to elaborate its rulebook.

From 2010 to 2011, 3 new laws were approved. The first one is the Law Of Mother Earth Rights, then came the Productive Agrarian Community Revolution Law, and finally, the General Law of Mother Earth and Integral Development. All of them restrict or ban the use of GMO and contradict the Political Constitution. This confusion interrupted the work that the NBC was doing. In 2011, the last meeting of this NBC was held, after some false accusations.

This situation also has an impact in research, where academia does not request permission for laboratory trials since regulation is not clear. On the other hand, some producers have already introduced illegal events for corn, soy, and cotton. In 2017, Guanella presented a study about how much the country could gain if it allowed 3 more GMO events. As of today Bolivia has a new GMO product-labelling norm, no biotechnology or biosafety policy, no risk assessment analysts, and no research in this area. All this has become an obstacle for crop production and achieving food sovereignty as it's proposed with the current government goals.

**PO I -12****Biotechnology and biosafety in Africa: Building functional regulatory systems for safe deployment of GM crops in Africa**

**Olaekan Akinbo** - *NEPAD African Biosafety Network of Expertise (ABNE)*

Co-author: Diran Makinde

Solutions to the problem of future food needs are challenging tasks, although the successes of the "Green Revolution" demonstrate the importance of technology in generating more food output as shown in Asia. Despite these successes, conventional crop breeding, as well as emerging technologies based on molecular biology, genetic engineering, and natural resource management, will continue to improve productivity in the coming decades. Modern biotechnology is considered to be a technology and a powerful tool that has the potential to contribute towards enhancing agricultural productivity and to help mitigate food security and climate change challenges that the African continent faces. Based on this premise, the African Union-NEPAD Planning and Coordinating Agency (NPCA) places a high priority on the safe use and management of biotechnology. As a specialized centre of the AU-NPCA, African Biosafety Network of Expertise (ABNE) is mandated to support African countries in building functional biosafety regulatory systems that will ensure the responsible and safe development, adoption, and utilization of agricultural biotechnology crops and products. A functional biosafety system of a country on the continent at minimum should entail policy provisions regarding biotechnology and its safe deployment, a legislative framework, administrative establishment, infrastructure in place, capacity to review biosafety applications and make decisions, and the capacity to monitor and evaluate. As policy is the key in setting out clearly the intentions and values of the government, the policy positions for enforceability will have to be reduced into legislations, regulations, ordinances and guidelines. A Biosafety administrative establishment is a key to successful handling of applications and making regulatory decisions that are science-based. A good administration must entail personnel and equipment for keeping institutional memory. The system must not only put in place a capable and well resourced evaluation and monitoring system, but it also should put in place mechanisms of ensuring public and stakeholders participation.



## PO I-15

### Technical specifications and procedural scope of the new Mexican official standard (NOM) for the ERA of GMOs

Jaime E Padilla-Acero - *AgroBIO Mexico*

Co-authors: G Medina-Palacios, D Lugo-Barrera, A Navarro-Gómez, D Gutiérrez-Galeano, M Palomera-Cárdenas, N Torres Arredondo, JM de la Fuente-Martínez

Mexico as a megadiverse country, and center of origin and diversification of worldwide important crops as cotton and maize, has been developing its regulatory framework for cultivation of genetically modified (GM) crops since its commercial introduction to international markets. The Mexican GMO Biosafety Law (LBOGM, 2005) requires a stepwise process that starts with an Experimental Phase followed by a Pilot Phase prior to Commercial permits. The implementation of LBOGM required an Official Standard (NOM) to specifically conduct the Environmental Risk Assessment (ERA) studies for GMOs to be released experimentally in the environment.

Formal committees integrated by regulators and normative staff of government, along with academics and developers of GMOs, finished in 2016 the technical procedure started in 2012 for issuing this NOM for ERA. In 2017 this standard is at the end of its Federal Regulatory Improvement and Administrative Process before coming into force and being implemented by developers.

The current standard project articulates legal and former requirements for field trials of GM crops following the most adequate methodological approach. However, workshops have been carried on to test its generality (applicable to any GMO), its functionality (compliance of all steps) and a practical integration of the risk study into the permit application (organization of the dossier to be submitted). The process for risk assessment runs through five stages: the first one is focused in the identification of possible risks by 'problem formulation', the second stage consists in the evaluation of the occurrence of possible risks; the third stage is to evaluate the consequences of possible risks; in the fourth stage, risk levels are estimated and finally the fifth stage is to develop recommendations for risk management.

This national standard will allow a more systematic analysis of the information to guide decision making, based on the risks assessed.

## PO I -16

### **Rethinking regulatory policy and practice for effective GMO oversight in Uganda: A perceptive treatise**

**Gumisiriza Gilbert** - *Uganda Biosciences Information Center (UBIC)*

Co-author: Karim Maredia

The institutional context for regulatory oversight of Genetically Modified Organisms (GMOs) in Uganda was largely shaped by commitments to international instruments for environmental policy and governance. Particularly, the national biosafety agenda was framed out of the imperative to domesticate provisions of the International Biosafety Protocol.

In 1997, Uganda was among only 18 countries globally that participated in the “Pilot Biosafety Enabling Activity Project” under the joint auspices of the Global Environment Facility and the United Nations Environment Programme (UNEPGEF). The project’s goal was to develop and test National Biosafety Frameworks (NBFs) for effective oversight regarding the transboundary movement and use of GMOs. It was on the basis of experiences gleaned from the pilot project that (in November 2002) the GEF Council adopted the “Initial Strategy on Biosafety” as an operational compass to guide its capacity-building efforts aimed at assisting state parties to put in place workable biosafety systems in anticipation of the Protocol’s commencement.

For Uganda, these initiatives presented the first real opportunity for dealing with Biosafety in a more systematic way and also helped to create diffuse institutional capacities for biosafety management. However, they also helped to entrench a parochial approach to the determination and management of risks associated with GMOs. In today’s radically different contextual realities, this regulatory bent appears anachronistic and continues to restrict national autonomy in priority-setting regarding the potential role of transgenic technologies towards realising Uganda’s development aspirations.

This paper recapitulates the evolution of the biosafety landscape in Uganda – accounting for the respective roles and influences of key international institutions and events – and examines the key issues that need to be resolved towards more effective and responsive regulation of GMO use in Uganda.

**PO I -17****Complementarity or contradiction: Application of ERA and SECs for GM crops deregulation in Africa**

**Francis Nang'ayo** - *African Agricultural Technology Foundation (AATF)*

Co-author: Sylvester Oikeh

Transgenic crops were first approved for commercial cultivation in 1995-96 when the total area planted stood at 1.7 million hectares spread over half a dozen countries. During the last 20 years, we have witnessed over 100-fold increase in adoption of biotech crops, currently grown on about 180 million hectares in 28 countries around the world. However, the potential revolution in farming made possible by genetically modified (GM) crops has been met with regulatory bottlenecks resulting in a great deal of ambivalence regarding the central practical approach to regulatory decision-making on GM crops. Whereas the use of environmental risk assessment (ERA) is regarded as the gold standard for reaching regulatory decisions on GM crops, some countries generally digress to look beyond ERA, and often choose to incorporate an array of socioeconomic parameters in the decision-making process. This broad-based, precautionary approach towards GM technology regulation has, at best, only served to increase layers of complexity, resulting in bureaucratic inertia on important regulatory decisions in some African countries. Not surprising, therefore, only a paltry three countries, South Africa, Burkina Faso and Sudan, have approved commercial cultivation of transgenic crops in Africa. This paper draws attention to the apparent dilemma around the use of ERA, taking also into account social economic consideration (SECs) in reaching regulatory decisions regarding testing and deregulation of GM crops. The paper discusses the apparent "conflict" between a scientific-based approach, i.e., ERA vis-a-vis socioeconomic policy choices made by governments in Africa towards GM technology. Since many African countries are parties to the Cartagena Protocol on Biosafety, an attempt will be made to link our discussion with the risk assessment framework and SEC contained in the Protocol.

**PO I -18****GMO regulation in New Zealand: Unique features, first GMO release and recent changes in the “not GMO” regulations**

**Tim Strabala** - *Environmental Protection Authority (NZ EPA)*

Co-author: Stephen Cobb

In New Zealand, live genetically modified organisms (GMOs) require approval under the Hazardous Substances and New Organisms Act 1996 (the HSNO Act), regardless of use. As such, all medicines containing live GMOs must be risk-assessed for their potential effects on the environment separately from the assessment of their potential effects on the patient. To streamline the assessment process for medicines, the Environmental Protection Authority (EPA) may approve medicines that contain a live GMO under a rapid assessment pathway. Until recently, there has never been a GMO released in New Zealand.

In 2015, the EPA approved the conditional release of a genetically modified oncolytic vaccinia virus, Pexa-Vec, for use in a Phase 3 clinical trial for patients with hepatocellular carcinoma, subject to seven controls. In this approval process, the EPA did not assess the efficacy and safety of the GMO medicine on the treated individual.

The HSNO Act has a legal definition of a GMO that is deliberately broad in scope, relying on separate regulations to define what is not a GMO (the Not GMO Regulations), and thereby exempted from this definition. In 2014, a ruling by the High Court in relation to the status of gene-editing techniques within the Not GMO Regulations prompted their review.

In 2016, the EPA and the Ministry for the Environment carried out a public consultation intended to correct the flaws in the Not GMO regulations that were identified by the High Court. The consultation resulted in changes in the regulations that meant that any organism that had undergone gene editing, in addition to any other techniques developed after 1998, were not exempted from the definition of a GMO in the HSNO Act. The near-term implications of these developments will be discussed.

## PO I -19

### **Regulatory science versus research science: Decision making for environmental release of GM plants**

**Peter Thygesen** - *Office of the Gene Technology Regulator (OGTR)*

Co-author: Alison Wardrop

Risk assessment is the cornerstone of decision-making under the Gene Technology Act (2000). Although scientific and technical evidence is used for risk assessment, it is important to distinguish between the purposes of “regulatory science” vs. “research science.”

Research science applies scientific methods to understanding a physical or biological system, often directed to furthering knowledge. Timeframes may be open-ended, and uncertainty may be addressed through generation of additional data to increase understanding. In regulatory science, the scientific method is used for the purpose of making a decision about whether to allow something to be used, or activities to be undertaken, within defined legislative framework and timeframes. Decisions are based on analysis and interpretation of scientific knowledge and, where necessary, assumptions to address data gaps or uncertainty.

This difference in perspective can lead to confusion between regulators and research scientists or applicants around the type of data required for risk assessment. The OGTR has recently reviewed the quality, amount and type of data needed to perform an effective risk assessment for environmental release of GM plants. This has resulted in a focussed revision of the application forms for intentional release of GM plants into the environment. This poster will summarise aspects of the distinction between regulatory and research science, with particular reference to data requirements for risk assessment of GM plants.

## PO I -22

### ERA of RNAi-based crops in Argentina

**Germán Ceizel Borella** - *Ministry of Agro-industry*

Co-authors: Agustina Whelan, Martín Lema

Eukaryotic RNA-based gene regulation, or RNA interference (RNAi), is a mechanism discovered more than two decades ago in plants. Since then, different classes of regulatory RNA molecules have been reported. Examples include RNA hair pin (RNAhp) [1], small interference RNAs (siRNA) [2] and micro RNA (miRNA) [3], among others. This mechanism is widely distributed in nature (i.e., plants [4], fungi [5] and animals [6]) and proved to be a useful tool in early GM crop development, giving the first genetically engineered food to be granted a license for human consumption, the FlavrSavr<sup>®</sup> Tomato [7]. During the last years, three RNAi-based crops were evaluated and approved in Argentina by the National Advisory Commission on Agricultural Biotechnology (CONABIA), Insect resistance soybean, high-oleic-acid soybean and Potato Virus Y resistant potato, the first RNAi-based crop locally developed. Interestingly, in RNAi there is no new protein expression and gene silencing depends on the homology between the regulatory RNA and its RNA target. This technology allows silencing either endogenous (i.e., FlavrSavr<sup>®</sup> or high oleic soybean) or exogenous genes (i.e., Virus or insect resistance). Thus, non-target and off-target gene silencing are central in the ERA of this technology. In this respect the continuous growth of sequence data bases allows the use of bioinformatics to assess non-target /off-target analysis, helping to increase the stringency of target selectivity in RNAi. Thereby, the lack of homologous non-target/off-target sequences, compared with existing databases, could be enough evidence to exclude further analyses (i.e. laboratory based, early tier testing). However, this is decided on a case by case basis. Here we present the criteria used by CONABIA in conducting the ERA of the aforementioned RNAi-based crops in Argentina

**PO I -23****Biosafety strategies for tropical tree (*Cedrela odorata*) transformation**

Yuri Jorge Peña-Ramirez - *El Colegio de la Frontera Sur*

Co-authors: Luisa López-Ochoa, Max Mizraim ApolinarHernández

Spanish cedar (*Cedrela odorata* L.) is a tropical timber well known for its high-quality wood. As occurs in other Meliaceae family species, it is attacked by the borer (*Hypsipyla grandella*) during the tree's early years of development, resulting in branched boles and rendering them useless for First Class milling. The production of varieties expressing entomotoxic proteins may be an alternative to overcome this problem. From the biosafety point of view, the use of plastid transformation may reduce the risk of transgene dissemination by pollen. Chloroplast transformation vectors need an expression cassette flanked by homologous plastid sequences to drive plastome recombination. To construct a *de novo* expression vector for *C. odorata*, the *rrn16-rrn23* plastome region was cloned, and sequenced. Using this region, the pCBL5 vector was constructed using pUC19 as a backbone, by inserting the plastome sequences from *C. odorata* and adding 2 independent expression cassettes into the *trnI-trnA* intergenic region, conferring spectinomycin resistance, the ability to express the *gfp* reporter gene, and a site that can be used to express any other gene of interest. As a result, the biolistic conditions for transformation, regeneration and selection of transformed embryogenic calluses from *C. odorata* were established. Currently, we are working on selection of homotransplastomic plants by successive regeneration rounds.

**PO I -24****Relevance of environmental safety assessments of individual biotechnology-derived traits for products combining multiple traits through conventional breeding**

**Ernest L Clawson** - *Monsanto*

Co-authors: Lulu Cheng, Jamis Perrett, Aqeel Ahmad, Yan Wei, Oscar Heredia, Muhammad Asim, Hallison Vertuan, Murtaza Quddusi, Daniel Soares, Peter Asiimwe

Crops with multiple biotechnology-derived traits (stacks) offer advantages over individual-trait products (singles) and are increasingly important in the agricultural biotechnology industry. Currently, global regulatory requirements are not harmonized on the types of environmental data needed to allow cultivation or import of stacks. The demonstration of environmental safety of the singles leads to a predictably similar outcome in breeding stacks, requiring much reduced or no breeding stack environmental data submission requirements in the U.S. and Canada. In contrast, many world areas continue to require substantial environmental safety assessments on breeding stacks (e.g., the European Union and Korea). To date, across the many commercial breeding stack products, no meaningful observations of increased environmental risk compared to conventional counterparts have been documented. For this reason, it is proposed that environmental safety data for breeding stacks is not necessary if each single has prior regulatory approval and there is no plausible hypothesis for an interaction between the single traits that would create an environmental risk. Empirical evidence is provided in support of this approach using a maize breeding stack of insect-protected MON 89034 (YieldGard® VT PRO®) and glyphosate-tolerant NK603 (Roundup Ready® 2) for which environmental safety would be predicted based on the criteria above. Data from agronomic and phenotypic environmental safety studies are presented from multiple world areas for MON 89034, NK603, and the breeding stack MON 89034 × NK603. Environmental safety conclusions for each product are compared, showing that environmental safety of MON 89034 × NK603 was adequately demonstrated by environmental safety assessments of its component singles MON 89034 and NK603. This approach, if adopted in world areas where environmental safety assessments of breeding stacks are required, would provide a means of breeding stack approval that is common across regions, reduces unnecessary regulatory burdens, and maintains adequate safety information for regulators.



**PO I -25****Regulatory assessment of breeding stacks of approved parental events: Case study in Argentina and Paraguay****Magdalena López Olaciregui** - *Dow AgroSciences*

Co-authors: Cecilia Roca, Nicholas P Storer, Greg Bradfisch

Stacking proteins with differences in their modes of action constitutes a powerful Insect-Resistance Management tool. The first insecticidal events available at the commercial level expressed one protein. Driven by confirmed cases of resistance to *Bt* proteins, the industry has mostly shifted to products that express two or more proteins that target the same species. The stacking of commercial events constitutes an effective component of strategies to protect the efficacy of currently available proteins and to extend the durability of *Bt* products. In Argentina, the approach for evaluation of breeding stacks of approved parental events is not different from the one for single events. Dow AgroSciences Argentina submitted MON-89Ø34-3xDAS-Ø15Ø7-1xMON-ØØ6Ø3-6xSYN-IR162-4, a breeding stack of approved parental lines MON-89Ø34-3xDAS-Ø15Ø7-1xMON-ØØ6Ø3-6 and SYN-IR162-4, with a risk assessment based on the interaction of the newly expressed proteins of the previously assessed parental events. This product expresses four proteins providing protection from lepidopteran pests. The studies confirmed that there is no interaction between the insecticidal traits of the parental events. The food and feed risk assessment was based on the risk hypothesis of no unexpected effects arising from a conventional cross based on lack of interaction between the traits and was accepted by the authorities. The same approach is applicable to the environmental evaluation of breeding stacks with approved parental events. This simplified risk assessment approach enabled the accelerated approval for commercialization of MON-89Ø34-3xDAS-Ø15Ø7-1xMON-ØØ6Ø3-6xSYN-IR162-4. In Paraguay, event MON-89Ø34-3xDAS-Ø15Ø7-1xMON-ØØ6Ø3-6xSYN-IR162-4 was submitted under a new regulatory framework (Resolution 27/2015) that accepts the interaction approach for breeding stacks with approved parental events. The stack is currently under evaluation by the authorities. Regulatory frameworks that focus on the possibility of interaction can streamline risk assessment of breeding stacks. Agile regulatory frameworks for breeding stacks accelerate effective IRM strategies, improve sustainability of available technologies, and maintain the increased productivity of *Bt*-crops.

**PO I -27****Risk assessment of GM potato with the erf gene for bacterial wilt resistance in Uruguay****Federico Boschi** - *National Seed Institute*

Co-authors: Francisco Vilaró, Sara Murchio, Claudia Schwartzman, Cyril Zipfel, Marco Dalla Rizza

Bacterial wilt is caused by *Ralstonia solanacearum* is the main bacterial disease in potato crops (*Solanum tuberosum*) and worldwide there is no a variety resistant to this pathogen. The potato-breeding program at National Institute for Agricultural Research (INIA) is evaluating the EFR gene obtained from *Arabidopsis thaliana* for the development of bacterial wilt-resistant genotypes. INIA's Iporá cultivar, and the breeding clone 09509.6, which has quantitative resistance against bacterial wilt introgressed from the wild species *S. commersonii*, was genetically modified with this gene at The Sainsbury Laboratory. The EFR cell surface immune receptor is unique to the *Brassicaceae* family; it has the ability to recognize the presence of most bacteria and activate the defense mechanism of the plant. The Problem Formulation methodology was applied to identify environmental relevant risk scenarios that should be evaluated. In Uruguay, two native wild species related to cultivated potatoes: *S. chacoense* and *S. commersonii*, are commonly present. Both of them have severe crossing incompatibility with *S. tuberosum*, thus the occurrence of natural hybridization would be very rare. Besides, although natural crossbreeding with other cultivated potato varieties would happen, volunteer plants generally do not survive outside of cultivation settings. In the end, they would be sharing a gene that is shortly distant in evolutionary terms; that would confer a bacterial defense attribute through a mechanism without releasing any toxins into the environment. In conclusion, the potential risk to the environment and human health derived from the use of this GMO would be reasonably similar to the risk entailed by other breeding systems already used in potato cultivation.

**\*Pecha Kucha participant**

## PO I -29

### Data transportability for field trial research

**John Teem** - *International Life Sciences Institute (ILSI) Research Foundation*

Co-authors: Larissa Jarvis, Mònica García-Alonso, Paul Hendley, Marc L Metzger, Navin Ramankutty

The development of a genetically modified (GM) crop plant follows a progression from experimentation in laboratory and other contained facilities, to field studies, and eventually to cultivation following pre-market environmental risk and food/feed safety assessments have been conducted by the appropriate regulatory authorities. It is commonly held that field studies used to evaluate the potential environmental risks associated with a GM plant that is being considered for cultivation approval should be conducted in each country where cultivation is intended, and some countries explicitly require in-country CFTs for any GM event that will be submitted for cultivation approval (e.g CTNBio 2008; MoE 2004). This means that multi-site CFTs are often repeated on a country-by-country basis, irrespective of any similarities between growing environments. It seems reasonable that data from CFTs conducted in one country could potentially be accepted as relevant, and even sufficient, for the purposes of ERA by regulators in another, i.e., that CFT data relevant to ERA should be transportable between countries. ILSI Research Foundation's work on data transportability focuses on the generation of methodology and, ultimately, is a useful tool for identifying similar agricultural environments such that data generated in one environment during the conduct of comparative field trials can be used to inform a risk assessment conducted in another environment.

## PO I -30

### **How to detect synergism among *Bacillus thuringiensis* insecticidal proteins without *a priori* assumptions regarding the mode of action**

**Jianhong Wu** - Syngenta Crop Protection

Co-authors: Frederick S Walters, Gerson Graser

Transgenic insect-resistant crops created by combining two or more insect control traits through conventional breeding are increasingly common in commercial cultivation. These crops produce multiple insecticidal proteins, providing a broader pest control spectrum and reducing the risk of resistance development. An assessment of whether the combined insect control proteins interact synergistically has been part of environmental risk assessments regarding cultivation of these transgenic crops.

Various methods are available to examine potential interactions between insecticidal proteins, and the mode of action (MoA) should be considered when selecting a testing approach. Similar action models are useful for evaluating insecticidal proteins with a similar MoA, while an independent joint action model is useful for proteins with a differing MoA. Recently, Syngenta scientists used an alternative empirical approach, originally described by Tabashnik (1992) as the “simplest approach”, which tests a lethal dose of one component of a mixture in the absence or presence of a sub-lethal dose of a second component. The strength of this approach is that it can be used in cases where the MoAs of the proteins being combined are unknown, similar, independent, or a combination of different types.

This poster describes the approach using experimental data and highlights its strengths when assessing synergy among proteins and protein mixtures in support of meaningful environmental risk assessments.

## PO I -32

### **CADIMA: An online tool supporting the reporting and conduct of the evidence synthesis process**

**Ralf Wilhelm** - *Julius Kühn-Institute (JKI)*

Co-authors: Christian Kohl, Stefan Unger, Steffen Kecke, Joachim Schiemann

Systematic reviews and systematic maps represent powerful tools to identify, collect, evaluate, and summarise primary research pertinent to a specific research question or topic in a highly transparent and reproducible manner. Even though seen as the “gold standard” when synthesising primary research, systematic reviews and maps are typically resource-intensive and complex activities. Thus, managing the conduct and reporting of such reviews can become a complex and challenging task. Decision-making frequently demands more rapid processing of information through transparency and rigour. Here we introduce the open web tool CADIMA, implemented to promote the use of thorough evidence synthesis as it increases the efficiency of the process and facilitates reporting of all activities in a flexible manner while maximising the methodological rigour. The display explains how CADIMA supports review teams during the synthesis process by: 1) providing step-by-step guidance for review authors through the evidence synthesis process; 2) facilitating remote, digital cooperation between team members; 3) reducing the overall workload and increasing efficiency during conduct; and 4) facilitating and standardising documentation of the synthesis process.

**PO I -33****Research with GM plants in a government-funded protected field site in Switzerland**

Jörg Romeis - *Agroscope*

Co-authors: Susanne Brunner, Michael Meissle, Andrea Patocchi, Michael Winzeler

The spectrum of traits and plant species modified by genetic engineering is rapidly broadening and the area worldwide cropped with genetically modified plants (GM) is steadily increasing. In basic and applied research, field trials with these plants are essential to study their performance under natural environmental conditions and their interactions with biotic and abiotic environmental factors. However, vandalism of GM field trials is a major factor restricting the ability of researchers in many European countries to perform these studies. In Switzerland, field trials with GM wheat were conducted between 2008 and 2010 by a large research consortium in the frame of a national research programme. Vandals performed a major attack at one of the two field sites and two minor attacks at the other. In order to continue the trials, extensive protection had to be established, entailing costs equal to those for research. With a look to the future, the Swiss Federal Council recognized the need for protected field sites to enable researchers to evaluate the advantages and disadvantages of GM crops undisturbed of vandalism. They decided to finance the establishment of a protected site on about 3 hectares of land at the Swiss centre of excellence for agricultural research Agroscope at Zurich, Reckenholz, starting in 2014. Currently, four field trials are running on the protected site. They include GM spring wheat carrying alleles of the powdery mildew-resistance gene Pm3 (run by the University of Zürich since 2014); cisgenic potatoes from Wageningen University carrying single or multiple Rpi genes against late blight (Agroscope, since 2015); cisgenic apple trees developed at ETH Zurich with increased resistance to fire blight (Agroscope, since 2016); and GM winter wheat with an increased yield potential (Agroscope in collaboration with the Leibniz-Institute of Plant Genetics and Crop Plant Research IPK, since 2016).

**PO I -34****Effects of Cry1Ab *Bt*-rice straw return on the earthworm *Eisenia fetida***Yinghua Shu - *South China Agricultural University (SCAU)*

Co-author: Jianwu Wang

*Bacillus thuringiensis* (*Bt*) protein can enter the soil through *Bt*-crops straw return to the field, which has the potential effects on soil-dwelling invertebrates, such as earthworms. Here, 5% *Bt* rice (b2B138) and conventional rice (Anfeng A) straw were returned in soil to evaluate the impact of *Bt* rice on *Eisenia fetida*. The survival rate, relative growth rate, reproduction, enzymes activity of earthworm, the Cry1Ab concentrations in soil-straw mixture and earthworm, soil nutrients were detected after 7, 15, 30, 45, 60, 75, 90 d. The results showed that *Bt* rice straw return had no adverse effect on growth and reproduction, enzymes activity (superoxide dismutase, glutathione peroxidase, catalase) of *E. fetida*. Enzyme-linked immunosorbent assay (ELISA) results indicated that immunoreactive Cry1Ab was detectable in soil-straw mixture and *E. fetida* from *Bt* rice treatments, and a strong decline was observed in soil-straw mixture with the increase of treated time. *Bt* rice return increased the soil organic carbon and available nitrogen, while the content of total nitrogen, phosphorus and potassium and available phosphorus and available potassium was not affected by *Bt* rice straw return. Therefore, Cry1Ab and nutrients released from *Bt* rice straw return had no adverse effects on the growth and reproduction of *E. fetida*.

**PO I -35****Testing insecticidal proteins and GM plant material on a surrogate dipteran species****Michael Meissle** - *Agroscope*

Co-authors: Simone Haller, Jörg Romeis

Ecosystem functioning might be affected by GM plants through effects on non-target organisms fulfilling important ecosystem services, which are addressed in the ecological risk assessments. Despite the fact that Diptera play important roles in the agricultural ecosystem as predators, parasitoids, pollinators and decomposers, only few studies investigated potential adverse effects. We propose *Drosophila melanogaster* (Drosophilidae) as a surrogate species for premarket risk assessment and developed two study systems. The toxicity of insecticidal proteins and GM plant tissues is assessed by recording mortality, development time, and body mass. Cryolite, avidin, E-64, GNA, and SBTI were used to validate the test system. The effects of several purified *Bt* toxins as well as pulverized leaves from *Bt* cotton and *Bt* maize were also tested. The fate of the *Bt* proteins was analyzed by ELISA and the bioactivity by a sensitive species assay using *Heliothis virescens* (Noctuidae). While cryolite and avidin clearly showed negative effects on *D. melanogaster*, our results did not indicate any effects of purified Cry1Ab, Cry1Ac, Cry1B, Cry1C, Cry1F, and Cry2Aa, or of transgenic plant material.



**PO I -36****The risk assessment of Cry1Ie protein on *Chrysoperla sinica* larvae****Kanglai He** - Chinese Academy of Agricultural Sciences (CAAS)

Co-author: Xinxin Gao

Cry1Ie maize has been developed by the Institute of Crop Science, CAAS, which will target the Asian corn borer, *Ostrinia furnacalis*, and the most important insect pests on maize in China. In this study, the Cry1Ie protein expressed by transgenic maize of China was studied for the risk assessment on the growth and development of the larvae of green lacewing *Chrysoperla sinica*. Bioassays were done with a Cry1Ie mixed artificial diet used in rearing larvae of *C. sinica*, of which the protein content of the treated artificial diet was 10 times higher than that expressed in the transgenic maize tissues. Artificial diet containing the insecticidal potassium arsenate (PA) was included as positive control. Using the established dietary assay, we subsequently studied the growth, digestive enzymes, and nutrient status of *C. sinica* larvae. The results showed that the biological parameters, including pupation rate, eclosion rate, larval development time, pupation development time, and adult fresh weight of *C. sinica*, were not affected when larvae were fed on the artificial diet contained Cry1Ie protein. Compared with the normal diet, the larvae of *C. sinica* larvae were significantly prolonged and the survival rate was significantly decreased when the diet contained PA, i.e., *C. sinica* larvae were adversely affected by PA. The activity of general protease, trehalase and lipase of *C. sinica* larvae, were not affected in treatments of the artificial-diet-contained Cry1Ie protein. Compared with the normal diet, the total protein, glycogen, trehalose and fat content of the larvae fed with Cry1Ie protein were not significantly different. The experiments demonstrate that the Cry1Ie protein expressed by transgenic maize have no adverse effects to *C. sinica* larvae.

**\*Pecha Kucha participant**

**PO I -37****Levels of Cry1Ac protein in herbivorous and predatory arthropods in Bt-soybean**

**Young-Joong Kim** - *Seoul National University*

The potential impacts of insect-resistant transgenic *Bt*-crops on non-target organisms are a major concern. For assessing the non-target effects of these crops, it is essential to identify the species that are most exposed to the plant-produced *Bt* protein. To investigate the level of exposure and the routes of Cry1Ac protein flow through the arthropod food chain, we collected *Bt* soybean leaves and arthropods that occurred in the field between June and August 2016. Enzyme-linked immunosorbent assays (ELISA) were used to measure Cry1Ac levels in the plant and arthropod samples. Cry1Ac levels in the transgenic soybean leaves were highest at the R1 stage (197.7 to 291.1  $\mu\text{g g}^{-1}$ ), intermediate at the V3 stage (181.8 to 250.6  $\mu\text{g g}^{-1}$ ), and lowest at the R3 stage (71.8 to 151.1  $\mu\text{g g}^{-1}$ ). Among the 41 arthropod taxa collected in the field, measurable amounts of Cry1Ac were detected in a total of 22 taxa belonging to both herbivores and predators. In the case of herbivores, the Cry1Ac concentrations were relatively high in *Nezara antennata* (Hemiptera) and *Monolepta auadriguttata* (Coleoptera). On the other hand, one abundant soybean herbivore, *Metcalfa pruinosa* (Hemiptera) did not contain measurable amounts of Cry1Ac. In the case of predators, *Thomisidae* sp. (Araneae) and *Orius* sp. (Hemiptera) contained higher Cry1Ac than the other predators. The Cry1Ac concentrations varied among arthropod samples collected at different soybean growth stages. However, we could not find any correlation between Cry1Ac protein levels in soybean leaves and in arthropods. Cry1Ac protein levels in arthropods likely depend on the food resources, quantity consumed, and the excretion rate. Our results will help to identify the arthropod species that are directly or indirectly exposed to *Bt* toxin within the food web and the degree to which they are exposed during the cultivation of Bt soybean.

**\*Pecha Kucha participant**

**PO I -38****Impacts of sugarcane expressing Cry1Ab protein on non-target arthropods in Brazilian field conditions**

**Adriana Cheavegatti Gianotto** - *Centro de Tecnologia Canavieira*

Co-authors: Danielle Angeloni Oldemburgo, Silvio Christofolletti Junior, Mariana Abdal, Tarciso Morescalchi Bortolin, Wladecir Salles Oliveira

Sugarcane is a major crop which, unlike other important Brazilian crops such as corn, soybean and cotton, currently does not present any commercially available genetically modified cultivar. In the past few years, several research efforts have been made to develop genetically modified sugarcane cultivars that could potentially leverage sugar and ethanol Brazilian production. Here we evaluate the impacts of a sugarcane cultivar expressing Cry1Ab protein (Event CTC175-A), which confers resistance to the sugarcane borer (*Diatraea saccharalis*), on non-targets arthropods naturally occurring in Brazilian sugarcane cultivation fields. Besides Cry1Ab, the CTC175-A event also expresses NPTII protein, used as a selection marker during the transformation process. Four field experiments were planted in 4 different Brazilian locations: Piracicaba and Conchal (SP), Montividiu (GO), and Uberlândia (MG). Experiments were conducted in a random block design, with 4 repeats of 4 treatments: event CTC175-A; a null control (sugarcane genotype cultivated in tissue culture conditions like those of CTC175-A cultivation); and one wild type sugarcane control with and without insecticide treatment. Each experimental plot presented 8 lines of 15m of planted sugarcane spaced 1.5m from each other (180m<sup>2</sup>). The incidence of aerial and terrestrial naturally occurring arthropods was evaluated, during a whole year of sugarcane cultivation cycle, by placement of stick, pitfall and ant traps into experimental plots. Statistical analysis of ecological parameters as Shanon diversity index ( $H'$ ), species richness (S), and evenness (J), revealed seasonal differences on naturally occurring arthropod population but revealed no consistent statistical difference among treatments. These results suggest that the cultivation of sugarcane event CTC175-A presents no detrimental effect over naturally occurring Brazilian non-target arthropods.

**PO I -39****Change of *Bt*-protein in the process of eight-times continuous *Bt*-corn planting and straw returning to soil and its effects on soil nutrient content**

**Jianwu Wang** - South China Agricultural University (SCAU)

Co-author: Yuanjiao Feng

*Bt* (*Bacillus thuringiensis*) corn is one of the most rapidly commercialized insect-resistant transgenic crops in the world. *Bt* protein released by corn root and pollen in the process of continuous planting and straw returning may affect the soil environment. We observed the change of *Bt* protein in rhizosphere soil, root surface soil and bulk soil (0-20 cm, 20-40 cm and 40-60 cm) of two *Bt* corns (5422Bt1 and 5422CBCL), as well as its effects on soil nutrient contents in the process of eight-times continuous planting and straw returning through the greenhouses cement pool simulation. The results indicated that *Bt* protein content was obviously higher in *Bt* corns than conventional corn 5422 for the rhizosphere soil and root surface soil during the eight-times continuous planting, but there was no apparent difference for the bulk soil. *Bt* protein could degrade rapidly after corn straw returning to soil, and no significant difference in *Bt* protein was observed in *Bt* corns and corn 5422. Difference was only observed in few nutrient content parameters and soil layers for the root surface soil and bulk soil of conventional and *Bt* corns. In the termination of trial, there was no significant difference in the contents of organic matter, alkaline hydrolysis N, available P, available K, total N, total P, or total K for the conventional and *Bt* corns. The results suggest that *Bt* protein released from corn root or straw will not accumulate in soil, and hence it has no effect on soil nutrient contents.

**PO I -40****Effect of Cry1Ab *Bt*-maize straw return on greenhouse gases emission and nitrogen cycle in soil**

**Jianwu Wang** - South China Agricultural University (SCAU)

Co-author: Yinghua Shu

The use of transgenic plants expressing insecticidal Cry proteins derived from *Bacillus thuringiensis* (*Bt*) is increasing worldwide. However, a major concern with the cultivation and return of *Bt* maize is potential effects on soil ecosystems due to the presence of insecticidal proteins (direct effects) and the changes in plant components (non-expected effects). Here, effects of two hybrids of *Bt* maize [5422Bt1 (event *Bt*11) and 5422CBCL (MON810)] straw return on soil greenhouse gases emission, nutrient content, and the amount of genes related to N cycle were investigated, compared to near-isogenic non-*Bt* maize (5422). Enzyme-linked immunosorbent assay (ELISA) revealed that Cry1Ab protein concentrations in the *Bt* corn straws significantly decreased over time. N<sub>2</sub>O emission flux from 5422CBCL treatment was significantly higher than that of 5422 and 5422Bt1 over the whole experiment period, and CO<sub>2</sub> emission flux from 5422CBCL treatment was significantly higher than that of 5422 and 5422Bt1 treatment at the earlier experiment period. The cumulative N<sub>2</sub>O of 5422CBCL treatment was significantly higher than that of 5422Bt1 treatment, while *Bt* maize return had no significant effect on CO<sub>2</sub> emission. Real time PCR demonstrated that *Bt* maize return had significant effect on the number of *amoA* and *nirS* but not *nirK* gene. No significant difference among three maize varieties treatments was found in the content of total nitrogen (N), total phosphorus (P), total potassium (K) and alkali hydrolyzable N, ammonium N, nitrate N, available P, while available K from 5422Bt1 treated soil was significantly higher than that of 5422 and 5422CBCL. Therefore, *Bt* maize straw return presented significant effects on the cumulative N<sub>2</sub>O emission, the content of organic matter and available K, and the copy numbers of *amoA* and *nirS* genes in soil, which was caused by non-expected effects of *Bt* maize straw.

**PO I -41****Transgenic overexpression of EPSPS in *Arabidopsis thaliana* can enhance fecundity in the absence of glyphosate**

Zachery T Beres - *Ohio State University (OSU)*

Co-authors:, Xiao Yang, Lin Jin, Jason T Parrish, Wanying Zhao, David M Mackey, Allison A Snow

Widespread use of glyphosate, the active ingredient in RoundUp®, has led to the evolution of glyphosate-resistant weed biotypes, some of which persist by overproducing the herbicide's target enzyme, 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS). Likewise, The Scotts Company has developed a glyphosate-resistant turfgrass, *Poa pratensis*, with over-expression of an EPSPS gene from *Arabidopsis thaliana* driven by an ubiquitin promoter from rice, *Oryza sativa*<sup>1,2</sup>. Therefore, insights from transgenic *Arabidopsis* lines that overproduce EPSPS may be relevant to both cultivated and weedy taxa that overproduce this unique enzyme. EPSPS is a key enzyme in the shikimic acid pathway for biosynthesis of aromatic amino acids, lignin, and defensive compounds, but little is known about how overproducing EPSPS affects downstream metabolites, growth, or lifetime fitness in the absence of glyphosate. We engineered a binary vector expressing a native EPSPS gene from *Arabidopsis* under control of the CaMV35S promoter (denoted as OX, for overexpression) and an empty vector (denoted EV). We produced six OX and seven EV independent, homozygous T3 lines for each construct. OX lines were more resistant to glyphosate and had ED50 values that were ~7- to 23-times greater than those for EV lines. In the absence of glyphosate the OX lines exhibited ~24- to 66-fold greater EPSPS expression, and two of the OX lines produced significantly more seeds per plant than the non-transgenic wild-type, while the other OX lines were not significantly different. Fecundity of the EV lines was similar to or less than that of wild-type lines, suggesting a fitness cost that may be mitigated by over-production of EPSPS. Our results are consistent with the hypothesis that overproduction of EPSPS in *Arabidopsis* does not have a fitness cost and may have a fitness benefit.

**PO I -42****Crop wild relatives of cultivated eggplant (*Solanum melongena* L.) in the Philippines – Does *Bt*-eggplant pose a real threat?**

Desiree M Hautea - University of the Philippines Los Baños

Co-authors: Nestor C Altoveros, Visitacion C Huelgas, Maria Lea H Villavicencio

Genetically modified eggplant (*S. melongena* L.) producing an insecticidal protein from *Bacillus thuringiensis* (*Bt*) has been developed to reduce serious damage caused by its most important insect pest, the eggplant fruit and shoot borer, *Leucinodes orbonalis* Guenee. Based on information obtained from herbarium specimens, it has been reported that crop wild relatives (CWR) of *S. melongena* exist in the country. Thus, there is a need to assess the potential for gene flow from *Bt* eggplant to CWR when the former is commercialized. In 2011-2012, survey and collection trips were undertaken in 10 major eggplant-growing provinces in Philippines where interspecific hybridization between *S. melongena* and the CRW were carried out. Hand-pollination, morphological, cytogenetics, and molecular techniques were employed. The CRW species encountered were: *S. aethiopicum*, *S. torvum*, *S. verbascifolium*, *S. americanum* (= *S. nigrum*), *S. linnaeanum* (= *S. sodomaeum*), *S. lasiocarpum* (= *S. ferox*) and *S. mammosum* and *S. macrocarpon*. Of the CRW species encountered, three were found exclusively cultivated as ornamental plants in gardens (*S. aethiopicum*, *S. macrocarpon*, *S. mammosum*); three species were exclusively found in disturbed habitats and non-agricultural areas ; and two species were found in both habitats (*S. lasiocarpum* and *S. linnaeanum*). A total of 6248 interspecific reciprocal crosses were performed, which yielded 308 putative hybrids in some crosses. Viable F1 seeds were obtained only from the *S. aethiopicum* x *S. melongena* cross, with the former as female parent. Successful crosses were verified by SSR analysis. Pollen fertility of the true hybrids obtained from crosses of *S. aethiopicum* x *S. melongena* was low, ranging from 8.67% to 12.34%. The F2 generation formed seedless fruits with morphological characters that were very similar to the female parent. These results suggest the potential risk of gene flow from *Bt* eggplant to CWR is very low.

**PO I -43****Assessment of impact of gene flow on biodiversity: Experience with GM mustard**

**Pranjali Vishwakarma** - Biosafety Support Unit

Co-authors: Sangeeta Agarwal, Vanga Siva Reddy, S Raghavendra Rao

The impact of transgene flow from genetically modified (GM) crops to related and/or wild species is one of the major environmental concerns due to potential loss or contamination of biodiversity that regulators assess as part of risk assessment prior to environmental approval. The environmental risk due to gene flow depends immensely upon the biology of the crop, geographical location, and nature of the trait introduced. Intra-species gene flow can be expected in virtually every crop species that is grown to the reproductive stage, even if the cross pollination percentage is very low. However, inter-species gene flow depends upon sexual compatibility, differences in ploidy level, proximity to other species among several other factors. Recently in India, safety assessment of GM mustard (*Brassica juncea*) containing barnase-barstar meant for pollination control was performed. This combination of male-sterile (barnase) and restorer (barstar) lines in *B. juncea* constitutes a functional male-sterility/restorer system that can be used to produce hybrid seeds utilizing a wide range of germplasm. *B. juncea* is a cultivated crop in India; however, it is considered as a wild species in certain other geographical locations outside India. The incidence of wild relatives growing in and around the mustard fields is low in India, which are found mainly in the foothills of Himalayas and show differences in ploidy levels as compared to GM mustard. The risk assessment data generated to assess the impact of gene flow due to the presence of barnasebarstar will be presented in the meeting.



**PO I -44****Agronomic, ecological and genetic-segregation assessment of GM traited landraces: Evidence for the safe coexistence of maize landraces with modern GM maize hybrids****Bill Duncan - Monsanto**

Co-authors: Baltazar Baltazar, Todd Werk, Silverio García, Duška Stojšin, Juan Manuel de la Fuente Martínez, Aniruddha Raychaudhuri

Genetically modified (GM) maize has been extensively grown by farmers since 1996 and rigorous scientific testing suggests the equivalence between GM and conventional maize hybrids for all characteristics except for the GM trait. The Mexican landrace project was conducted to confirm that no unexpected changes to a landrace's plant pest/weed potential and agronomic characteristics would result in the unlikely event of a transgene becoming introgressed into a landrace. In 2013, a backcross breeding program was begun that introgressed VT3Pro traits (MON-89034 × MON-88017) that confer insect resistance and herbicide tolerance into two different Mexican landrace accessions: Tuxpeño (PI 479072) and Tabloncillo (PI 515340). Several agronomic and ecological characteristics were evaluated during two-year (2015 and 2016) field trials in the USA, located within ecoregions in which these landraces are grown in Mexico. A randomized complete block design (RCBD) with four replications was utilized at all four environments to compare Tabloncillo and Tuxpeño landraces with and without the GM traits. In addition, materials from four different generations (segregating for GM traits) were used for Mendelian segregation analysis. Experimental results revealed that the evaluated GM traits segregated across multiple generations following expected Mendelian segregation ratios like any non-transgenic allele. Furthermore, when comparing entries with and without the GM traits, no biologically meaningful differences were observed that indicated increased pest/weediness potential or the loss of desired agronomic characteristics. These results provide strong evidence supporting the safe coexistence of GM maize hybrids and landraces in Mexico.

**PO I -45****Assessing the risk of GM sugarcane outcrossing with a related wild species using phylogenetic and pollen viability studies**

**Khanyi Hlobisile** - *North-West University*

Co-authors: DM Komape, SJ Snyman, SJ Siebert, S Barnard

Gene flow between crops and their cross-compatible wild relatives is undesirable in commercial production systems. When cultivating GM plants, the concern is that the transfer of transgenes to their relatives may enhance their capacity for invasiveness. Therefore, biosafety risk assessment studies are a legal requirement to evaluate the potential impact of GM crops on the environment before commercial release. The aim of the study was to assess the gene flow potential from sugarcane to its indigenous relatives in KwaZulu-Natal, South Africa. Three approaches were used:

1. Peer-reviewed publications on sugarcane hybridization with wild relatives were used to identify *Andropogonae* individuals that have crossbred with sugarcane;
2. Chloroplastic (*matK* and *rbcl*) and nucleic (ITS) DNA barcodes were sequenced from wild relatives, and a phylogenetic tree was constructed to show relatedness amongst the tribe;
3. Pollen viability of commercial sugarcane varieties was assessed using the stains Iodine Potassium Iodide (IKI) and Triphenyl Tetrazolium Chloride (TTC).

Literature indicated that thirteen related wild species have been crossed with sugarcane under experimental conditions. Of these, eight belong to the *Saccharine* and four to the *Sorghinae* subtribe. While modern sugarcane cultivars might have been derived from *Saccharum officinarum*, the genus *Miscanthus* seems to be the most closely related to these modern cane cultivars. The eleven different commercial sugarcane varieties tested for pollen viability showed decreasing viability (from 64 %) from the north to the south eastern regions of the country.

**PO I -46****Conservation and biosafety alternatives for productive coexistence of conventional and GM maize in its center of origin and genetic diversity**

**Jaime E Padilla-Acero** - *AgroBIO Mexico*

Co-authors: L Córdova-Téllez, S García-Lara, E Molina-Macías, G Medina-Palacios, S Escoto-Hernández, D Lugo-Barrera, JM de la Fuente-Martínez

Mexican GMO Biosafety Law has a special protection regime for maize. Its implementation requires geographical areas determined as its Center of Origin and Genetic Diversity (CO&GD), where activities with GM maize are prohibited. First maize CO&GDs maps were issued by governmental ministries, including considerations not only for the distribution of maize landraces and its wild *Zea* ssp. & spp. relatives (Teosintes) but also for *Tripsacum* spp. The acting rules to define CO&GDs in northern states overestimate its extension excluding the potential use of GM varieties in important agricultural regions where maize production is largely based on hybrid seeds and threatens productive chains.

A better understanding and operation of this protection goal, useful to update and effectively manage maize CO&GD, results from:

1. Conservation, characterization and sustainable use of native maize. Programs by several R&D institutions include ex situ conservation of landraces and its geno/ phenotypic characterization to bring its agrodiversity available to breeders and farmers.
2. Diversity, gene flow and introgression studies. Around 60 maize landraces are distributed in the country but, (a) high genetic diversity and/or uniqueness are concentrated along with ethnic groups; (b) if samples with transgene presence are found, frequencies are very low, highly diluted and not found in subsequent years; (c) GM traits on landraces segregate by Mendelian rates with no phenotypic modifications\*; (d) Safe distances avoiding crossings and no interbreeding between GM maize and *Tripsacum*\*\* have been confirmed.
3. Protection of communal and intellectual property. Biosafety together with Property Rights legislations (UPOV, WIPO), ensure that native/-public maize germplasm will continue as a source of food/ feed, research, innovation and cultural heritage.

The evolution and coexistence of production systems and seed markets requires an operative policy which attends the challenges (and rights) for different agricultural/ rural communities along the country.

## PO I -47

### **Evaluating the risks of possible adverse effects of glyphosate on human and environmental health**

**Robert McDowell** - *Consult MRS*

The 20+ year continuing debate on the safety of glyphosate remains a largely manufactured controversy where the debate has been long on emotion and politics and short on facts. At pivotal points, a few studies, now debunked or discounted, significantly affected public perception and the ensuing policy decisions regarding glyphosate.

This presentation traces the history of glyphosate use, glyphosate chemistry, and the various hazard assessments and risk assessments of glyphosate. In particular, this presentation discusses the Séralini 2012 paper and the Intl. Agency for Cancer Research (IARC) finding in 2015 that glyphosate was a probable carcinogen. These are discussed in the larger context of comparative risk assessment and the numerous glyphosate risk assessments undertaken around the world, and the response of the various international scientific communities to the Séralini study and the IARC findings. In addition, the hypothesis that glyphosate is carcinogenic is evaluated in light of human cancer data for the USA.

A variety of possible adverse environmental effects (superweeds, loss of biodiversity, impacts on pollinators, introgression into other crops and wild plants, and increased rates of herbicide applications) are evaluated and the empirical evidence is discussed.

**PO I -48****Genetic engineering for environmental restoration? Transgenic American chestnut shows heritable resistance to chestnut blight with minimal non-target impacts**

**Andrew Newhouse** - *State University of New York College of Environmental Science & Forestry (SUNY-ESF)*

Co-author: William A Powell

American chestnuts (*Castanea dentata*) were unique, valuable, and ecologically important trees in eastern North American forests until chestnut blight (caused by the invasive fungus *Cryphonectria parasitica*) decimated nearly all mature trees. We aim to address the chestnut blight by introducing a gene for a detoxifying enzyme (oxalate oxidase) into American chestnuts, which protects the tree without killing the fungus. This enzyme was isolated from wheat, but it is also naturally found in many other food crops and wild plants. Transgenic American chestnuts have shown very high levels of blight resistance, while retaining their original American chestnut form and growth patterns. Non-target effects observed to date are generally smaller than those produced through traditional breeding, and further ecological comparisons are in progress. However, unlike traditional breeding, trees produced through genetic engineering must be approved by federal regulators prior to distribution. While genetic engineering has been widely applied to US commercial agriculture, it has not yet been applied to environmental restoration. Any technology involves potential risks, and public acceptance is a potential concern, but promising results to date with chestnuts and the potential of this technology for addressing many similar threats suggests it should be carefully considered for other restoration projects.

## PO I-49

### GM cotton impact after 20 years of cultivation in Mexico

**Martha Graciela Rocha Munive** - *Universidad Nacional Autónoma de México*

Co-author: Valeria Souza, Luis Eguiarte, Alejandra Bravo, Mario Soberón, Saúl Castañeda, Esteban Niaves, Enrique Scheinvar, Urbano Nava-Canberos, Enrique Rosales Robles, Jose Luis Martinez Carrillo, Carlos Blanco, David Mota Sanchez, Antonio Palemon Teran, Concepcion Rodriguez-Maciel, Sotero Aguilar-Medel, José Falck-Zepeda, Greg Traxler

Cotton is the genetically modified crop most widely sown in Mexico in the last 20 years. Its cultivation has fulfilled all the regulatory requirements and has gone through all the regulatory stages. Plenty of scientific and technical information has been generated either by research institutions or the biotech companies. In the present work, several scientific experts contributed to collect and analyze data in order to conclude on the possible effects of the use of GM cotton in the country. The introduction of *Bt* cotton in 1996 made it possible to reactivate the planting of this crop, which during the previous years had greatly reduced its area due to pest problems. *Bt* cotton has been very efficient for the control of lepidopteran pests and is a widely accepted tool for cotton producers.

The economic benefits of its use are variable and depend on international prices and the costs associated with inputs. So far the mechanisms used to prevent resistance in insects have been efficient and there is no report of resistance to *Bt* in Mexico. On the other hand, the technology of resistance to herbicides has also been efficient and unlike other countries, there are no reports of resistant weeds in Mexico and no effects have been observed on non-target organisms. An environmental benefit has been achieved with a considerable reduction in insecticide applications, but other technologies should be explored for areas where *Bt* cotton-controlled pests are no longer important. We concluded that it is necessary to support national research so that biotechnology can be a useful tool in the development of varieties adapted to the conditions of our country and to fight pests of national importance.

## Poster Session II – Abstracts

### PO II -1

#### **Southern-by-Sequencing (SbS) for molecular characterisation of GMOs and gene edited varieties**

**Kent Brink** - *DuPont Pioneer*

Co-author: Maria Fedorova

Safety assessments of genetically modified (GM) crops require comprehensive molecular characterization of the inserted sequence and adjacent genome in transgenic plants. Typically, Southern blot analysis is used for molecular characterization, including copy number and intactness of the inserted DNA, absence of unintended plasmid sequences and analysis of stability across breeding generations. However, Southern blot analysis can be time-consuming due to numerous manual steps. Blot interpretation often requires considerable experience, and variability at multiple steps can lead to subjective interpretations.

Southern-by-Sequencing (SbS) is an efficient, high-throughput, sequence-based application which utilizes targeted sequence capture coupled with next-generation sequencing (NGS) and bioinformatics tools for molecular characterization. It is conducted by hybridizing a genomic DNA library to biotinylated probes designed to match sequences of interest, such as inserted DNA or plasmids used in the trait development process. Hybridization enriches the DNA fragments containing these sequences prior to NGS analysis. Following sequencing, bioinformatics tools compare the NGS reads to plasmid sequences and a control plant genome to identify any novel junctions within the GM plant genome. These junctions indicate the presence of any intended or unintended DNA insertions, and provide adjacent sequences that can be used to locate insertions within the plant genome or define potential rearrangements of inserted DNA. Comparison of SbS results to traditional Southern blots show that the two techniques yield comparable results for analysis of complex DNA insertions as well as detection of unintended plasmid sequences and small DNA fragments. Similarly, SbS is an efficient tool for molecular characterization of gene-edited varieties, where an integral part of development is selection of plants without unintended plasmid DNA.

Thus, SbS can deliver similar endpoints as Southern blot analysis to address key molecular characterization aspects of GMOs and gene-edited varieties, providing important information to guide regulatory decisions.

## PO II -2

### **Molecular characterisation of transgenic events for safety assessment using Next Generation Sequencing approaches**

**Satish Guttikonda** - *Dow AgroSciences*

Co-author: Pradeep Marri

In light of successfully feeding the growing population, demands for the use of commercial genetically modified (GM) crops have been increasing. Commercial GM crops undergo a rigorous safety assessment. One of the regulatory requirements for safety assessment is molecular characterisation of the GM crop at the DNA level. This molecular assessment determines the copy number, integration site, sequence integrity, and stability of the inserted transgene/s and confirms the absence of any backbone plasmid DNA. Historically, the above-mentioned characterization has been done using Southern analysis, which is a robust but time- and resource-consuming approach. With the advent of next generation sequencing (NGS), molecular characterization can be done in a cost-effective and high-throughput fashion compared with traditional Southern analysis. We present the application of both whole genome and targeted DNA capture sequencing approaches for the molecular characterization of both single and stacked GM events. The results and inferences are compared with traditional methods with respect to key criteria required for regulatory submissions. Our results show that NGS offers fast, robust, and reliable molecular characterization of transgenic events and, with further chemistry improvement, has the potential to replace Southern blot analysis.



## PO II -3

### Next-Generation Sequencing tools for molecular characterisation of new traits

**Kent Brink** - *DuPont Pioneer*

Co-author: Maria Fedorova

Molecular characterization of a genetically modified (GM) crop helps inform event selection, supports the safety assessment, and is required as part of the regulatory approval process. Typically, the copy number, intactness, and stability of inserted DNA are determined by a combination of Southern blot analysis, polymerase chain reaction (PCR) assays, and Sanger-based sequencing. Southern blots are also used to analyze for the presence of any plasmid backbone DNA that may be inadvertently incorporated into the plant genome during the creation of an event. The same techniques can be used to characterize plant varieties obtained by targeted editing of endogenous plant genes in order to confirm the absence of unintended plasmid DNA. Advanced sequencing technologies, commonly called Next Generation Sequencing (NGS), provide a more efficient approach for molecular characterization. One application of NGS is whole genome sequencing, which analyzes the entire genome and uses bioinformatics analysis to provide a wide view of the genome at relatively few sequencing reads for a given location. An alternate application of NGS is targeted sequencing, which utilizes hybridization enrichment of sequences derived from transformation plasmids to reduce the amount of DNA to be sequenced and the computing needs, while providing a higher sequence depth at the targeted location. Both applications of NGS analysis have advantages in the time and number of manual steps required when compared to Southern blots. In addition, NGS output comprises DNA sequence that then can be used to determine location of an insertion in the plant genome or design an assay to detect the insertion, whereas Southern blot images require interpretation and yield a high-level overview of the same insertion. NGS tools will be compared to Southern analysis to show that all methods result in the same characterization endpoints important for understanding the molecular makeup of new traits.

## PO II -4

### Meta-analysis of data on the expression of Cry proteins and field performance of Bt-cotton hybrids approved in India

Govind Kumar Rai - Biosafety Support Unit

Co-authors: Rajalakshmi Muralidharan, Sunil Nayak, Sangeeta Agarwal, Vanga Siva Reddy, S Raghavendra Rao

Cotton is a major cash crop in India that plays an important role in the national economy and impacts the lives of an estimated 60 million people. Insect-resistant *Bt* Cotton is the sole genetically modified crop approved, first in the year 2002, for commercial cultivation in India. Currently, *Bt* cotton is cultivated in ~11.6 million hectares, which accounts for 94% of the cultivated cotton area, suggesting a high adoption of biotech crop by the Indian farmers. A total of six events of *Bt* cotton expressing different cry gene: cry1Ac (MON531, Event 1, and BNLA-601), cry1C gene (MLS 9124), and stacked events of cry1Ac with cry2Ab2 (MON15985) or cry1Ab gene (GFM) have been approved so far in India. In India, the manufacture, import, use, research, and release of GM organisms, as well as products made thereof by the use of such organisms, are governed by Rules 1989, of the Environment (Protection) Act 1986 (EPA). In the last 15 years, Indian regulatory agencies have approved several hundred *Bt* Cotton hybrids for commercial cultivation to ensure the availability of more suitable hybrids in each of the three major agro-climate zones where cotton is cultivated. The evaluation and approval process has taken into account several key parameters, such as *Bt* protein expression levels in different tissues, bio-efficacy, boll damage, agronomic performance, etc. For the first time, we have undertaken a metaanalysis of four years of data (2013-2016) generated at many trial sites across >17 locations by more than 30 *Bt* cotton hybrid seed developers to assess *Bt* protein expression levels, target pest mortality, impact on non-target pests, agronomic performance, etc. In addition, disease and pest reaction of hybrids, and effect of irrigation on *Bt* protein expression were evaluated. The results of such a meta-analysis will be presented and discussed.

**PO II -5****Salt/drought tolerant and higher yielding aromatically prized Kalijeera rice by downregulating the Drought and Salt Tolerant Transcription factor, DST**

**Ar-Rafi Md Faisal** - *University of Dhaka*

Co-author: Zeba Islam Seraj

Abiotic stresses like salinity and drought directly affect plant growth and water availability, resulting in lower yield in rice. Salinity and drought tolerant mechanisms are very complex, and usually are regulated by multiple genes. Moreover, along with tolerance against these stresses, enhanced grain yield is also a major focus of rice breeding. It was reported earlier that reduced or loss in function of the Drought Salt Tolerant (DST) gene resulted in increase in grain production through down-regulating *Gn1a/OsCKX2* expression as well as enhanced drought and salt tolerance in rice by an inexplicit mechanism (Huang et al. 2009) (Li et al. 2013). We therefore proceeded to test these reports by downregulating DST by artificial microRNA technology using the highly-prized but low-yielding, small-grained, aromatic Kalijeera, which has traditional plant architecture. Genetic transformation was obtained using *in planta* technology for Kalijeera. Leaf disc assay at 150 mM NaCl of flag leaves of T0 transformants compared to WT indicated the transfer of salt tolerance. T1 seeds from panicles whose flag leaves performed extremely well in leaf disc senescence assay have been collected and are being subjected to another salt screen at 60 mM for advancing to T2. The T1 plants will also be subjected to drought- and salt-stress screens at seedling and reproductive developmental stages and will be assessed for yields under stress conditions. We have also performed similar experiments with high yielding BRRI dhan 28 rice variety as well.

## PO II -6

### Jasmonic acid induced defence responses in conventional and transgenic corn seedlings expressing *Bt*-insecticidal proteins

Yuanjiao Feng - South China Agricultural University (SCAU)

Co-author: Jianwu Wang

*Bt* (*Bacillus thuringiensis*) corn is one of the most rapidly commercialized anti-insect transgenic crops. In this study, the first leaf of *Bt* corn varieties 5422Bt1 and 5422CBCL, as well as their conventional corn 5422, were treated with jasmonic acid (JA), and the changes in contents of defense chemicals and expression of defense-related genes in the treated part (first leaf) and non-treated part (second leaf and root) were examined. The results showed that JA exposure had no effects on *Bt* protein content of two *Bt* corns. Direct JA-induced effects on the first leaf were not distinctly different; however, the systematically induced effects on the second leaf and root clearly differed among the three corn varieties. JA application to 5422 systemically enhanced the total phenolics content and expression of Bx6 and TPS genes in the second leaf. JA application to 5422Bt1 induced expression of MPI, PR-2a and TPS genes in the second leaf, as well as Bx6 and PAL genes in the root. After 5422CBCL was treated with JA, the expression of Bx6, PAL, MPI, PR-2a and TPS genes in the second leaf was systemically induced; total phenolics content was increased and the expression of Bx1, Bx6, Bx9, PAL, MPI, PR-2a and FPS genes in the root was also systemically induced. Our results suggest that systemically induced effects on *Bt* corn obviously are more significant than on the conventional corn. It can be concluded that *Bt* gene introduction can not influence the directly induced defense response, but enhance the systemically induced defense responses of corns during the JA induced defense processes.

## PO II -7

### Reduced caterpillar damage benefits *Lygus hesperus* on *Bt*-cotton

Jörg Romeis - *Agroscope*

Co-authors: Michael Eisenring, Steven Naranjo, Joe Hull, Michael Meissle, Sven Bacher

The wide-scale adoption of genetically modified cotton producing insecticidal Cry proteins from *Bacillus thuringiensis* (*Bt*), has led to area-wide suppression of major lepidopteran pests and a reduction of insecticide application. However, non-target pests not susceptible to the produced Cry proteins, such as the plant bug *Lygus hesperus*, have increased in *Bt* cotton fields in some parts of the world. In addition to the reduced application of insecticides, *L. hesperus* might also benefit from reduced caterpillar damage on *Bt* cotton. The latter was found to reduce the induction of insecticidal terpenoids enhancing the crops' susceptibility to other herbivores. The effects of plant induction on *L. hesperus* development was studied by caging nymphs on *Bt* and non-*Bt* cotton plants growing in a greenhouse. Plants were either nondamaged, previously damaged by *Bt*-tolerant caterpillars (*Spodoptera exigua*), or treated with jasmonic acid (JA), a plant hormone known to induce cotton defense. Caterpillar induction, and to a lesser extent, JA induction of plant defenses, negatively affected *L. hesperus* survival compared to nondamaged plants. This result was consistent for *Bt* and non-*Bt* plants. Induced plants showed increased levels of several terpenoids (incl. gossypol) compared to non-induced plants. Artificial-diet-feeding assays using purified terpenoids and molecular analyses of potential *L. hesperus* stress gene upregulation are being conducted to better understand mechanisms behind the greenhouse results. This study underpins the importance of plant-mediated, indirect interactions between herbivores for explaining agro-ecological processes and indicates how insect-resistance plant traits can indirectly impact herbivore communities.

**PO II -8****Brazilian industrial processing of GM sugarcane produces sugar and ethanol indistinguishable from products derived from conventional sugarcane**

**Adriana Cheavegatti Gianotto** - *Centro de Tecnologia Canavieira*

Co-authors: Danielle Angeloni Oldemburgo, Graciela de Amaral Merheb, Maria Lorena Sereno, Agustina Gentile, Ron Lirette, Wladecir Salles Oliveira

Most of the Brazilian sugarcane harvest is devoted to sugar and ethanol production. There are two types of industrial processes applied by Brazilian mills (tandem roller mill or diffuser mill), both very efficient in producing highly purified sugar and ethanol. Existing literature presents unambiguous evidence of lack of DNA/protein in these products, regardless of the nature of sugarcane used as raw material. Therefore, sugar and ethanol produced from genetically modified sugarcane should be classified as “pure substances, chemically defined,” by Brazilian Biosafety Law N° 11.105. In order for this classification to be adopted, these substances cannot be considered as “GMO derivatives,” and are therefore out of the scope of Law N° 11.105. In order to investigate this possibility, we evaluate several fractions derived from industrial processing of the genetically modified event CTC175-A, which expresses Cry1Ab and NptII, for the presence of these heterologous proteins, as well as for the presence of traces of recombinant DNA. We also evaluate the presence of the most abundant plant protein RuBisCo in the fractions of the industrial processing of existing conventional Brazilian sugarcane cultivars. Several assays employing ELISA, PCR and real-time PCR were performed and produced results which were concordant with confirmed existing literature. Rubisco, total protein, heterologous DNA and cry1Ab are not detected in the clarified juice and downstream processed fractions, including ethanol and raw sugar, indicating that the protein and DNA is removed or degraded during processing. These results allowed us to conclude that any protein and DNA present in sugarcane juice are degraded and eliminated as precipitate known as “filter cake.” Neither heterologous nor native DNA and protein were detected in ethanol or raw sugar, even when using very sensitive detections techniques. Results and implications are discussed.

**PO II -9****Compositional assessment of GM traited landraces: Evidence for the safe co-existence of landraces and modern maize hybrids**

Elisa Leyva-Guerrero - *Monsanto*

Co-author: Mariana Zavala Lopez

The composition of genetically modified maize and its comparison to a conventional control have been documented extensively, and there is significant evidence to support the equivalence between genetically modified (GM) and conventional maize hybrids. In Mexico, there have been concerns regarding the coexistence of modern maize hybrids (GM or conventional) with traditional landraces, including potential effects to the grain composition. The aim of this project was to address these concerns through the evaluation of the composition of a GM-traited landrace and its equivalence to a conventional counterpart. In 2013, a backcross breeding program was begun that introgressed GM traits that confer insect resistance and herbicide tolerance (MON89034 × MON88017) into two different Mexican landrace accessions: Tuxpeño (PI 479072) and Tabloncillo (PI 515340). The two GM traited landraces, their conventional counterparts, and references consisting of other diverse landraces were grown at four locations in the southwest USA, mirroring Mexico eco-regions where landraces are grown. Our composition analysis included proximates, soluble carbohydrates and phenolics in maize grain. The proximate analysis covers the major components of the grain, the soluble carbohydrates give an overview of primary plant metabolism, and the phenolics represent secondary metabolites found in maize. The results were statistically analyzed and the equivalence of the traited landraces to their conventional counterpart evaluated and discussed.

**PO II -10****Comparative assessment on key component compositions between imported GM soybeans and local non-GM soybeans from Taiwan**

**Huan-Yu Lin** - *Food Industry Research and Development Institute (FIRDI)*

Co-authors: Jen-Tao Chen, Mei-Li Chao, Bo-Chou Chen, Jo-Chi Wang, Hsuen-Chun Liao, Hsin-Tang Lin, Wen-Shen Chu

Soybean is an important protein source for consumers in Taiwan. Soybean production in Taiwan is not self-sufficient. Taiwan imports 2.5 million tons of soybeans annually to satisfy its need. More than 90% of the imported soybeans are genetically modified. The genetically modified (GM) soybean needs to be registered before import and sale. However, some consumers are still in doubt about the objectivity of the safety assessment information provided by the development industries of GM soybean. In order to provide an objective assessment on the safety of GM soybean and for postmarket monitoring, we conducted a comparative assessment on key component compositions between imported genetically modified (GM) soybeans and local non-GM soybeans from Taiwan. The imported GM soybeans that we purchased were herbicide-tolerant soybeans. The content of the proximate, the amino acid composition, the fatty acid composition, vitamins, minerals, antinutritional factors, and isoflavones of GM and non-GM soybean samples from local market at Taiwan were analyzed. Most contents of the key components of the GM soybean samples had no significant difference with those of the non-GM soybeans. However, of the 61 measured component contents, 8 were significantly different between GM and non-GM soybeans. But all the differences were within the range of reference value. Pesticide and herbicide residues of both samples were also analyzed. The residues were not detected in the non-GM soybean samples. The glyphosate residue was detected in most GM soybean samples. But the residue level was well below the threshold prescribed by the government. In summary, GM and non-GM soybeans are substantially equivalent in key component compositions.



**PO II -12****LC-MS/MS based methods for *in vitro* digestibility and quantification of transgenic membrane proteins**

**Xue-Rong Zhou** - Commonwealth Science and Industrial Research Organisation (CSIRO)

Co-author: Susan MacIntosh

Metabolic engineering of the omega-3 long-chain ( $\geq C_{20}$ ) polyunsaturated fatty acids ( $\omega 3$ LCPUFA), like eicosapentaenoic acid (EPA, 20:5 $\omega 3$ ) and docosahexaenoic acid (DHA, 22:6 $\omega 3$ ), in oil crops are involved in the transgenic expression of several fatty acid desaturases and elongases in  $\omega 3$ LCPUFA biosynthesis pathway. Food/feed and environmental risk assessment (ERA) requires evaluation of each transgenic protein, including protein stability and plant expression levels. Current antibodies, however, have not proved useful in the characterization of the  $\omega 3$ LCPUFA enzymes because of tight membrane association and nonspecific cross-reactions. Therefore, we developed LCMS/MS based methods to evaluate these transgenic membrane proteins. The proteins were digested with pepsin under SGF conditions for 0 to 60 min, followed by complete trypsin digestion. The decline of tryptic peptides was used as a proxy for intact protein, and the appearance of peptic peptides indicated the *in vitro* digestibility of the transgenic membrane proteins. We applied a similar principle to quantify each target protein in different plant tissues by LCMS/MS. The level of tryptic peptide markers, in a known quantity of total protein, was quantified using a spiked internal standard. The results from an example study demonstrated that >80% or >93% of the full-length protein was digested within 10 or 60 min of incubation, respectively. Applying the LC-MS/MS based method in transgenic plants, we demonstrate that seed-specific promoters correctly regulated expression of transgenes only in developing and mature seed, and that the enzymatic proteins were present at low levels (ng per mg total protein). By examining specific peptides (unique to each transgenic protein), this approach provides highly selective and sensitive measurement of membrane proteins. The LC MS/MS based methods described here are widely applicable to food/feed and environmental safety assessment.

## PO II -13

### Safety evaluation and approval status of GM foods in Korea

**Yun-Sook Kang** - *Ministry of Food and Drug Safety*

Co-author: Woo-Young Lee, Myung-Sang Yoo, Ji-Eun Shin, Mi-Ran Jang, Su-Eun Lee, Ji-Yeon Kwak, Ji-sun Park, Jin-Hwan Hong

Since 20 August 1999, Ministry of Food and Drug Safety (MFDS) in Korea has been responsible for safety evaluation of genetically modified foods (GM) foods including genetically modified crops, animals, fisheries and microorganisms. MFDS may order business operators who import, develop or manufacture GM foods to undergo safety evaluation of the relevant foods by the safety evaluation of GM foods in cases where GM foods is imported for the first time or for which ten years have elapsed since the approval. Safety of GM foods is evaluated according to Food Sanitation Act and Regulation on safety evaluation for GM foods (MFDS Notice No. 2016-117) based on the concept of substantial equivalence suggested by CODEX and OECD. For environmental risk assessment (ERA), Since 1 January 2008, Korea has implemented the Act on Transboundary Movement of Living Modified Organisms (LMO Act), the law implementing the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. Conducting the safety evaluation of GM foods, MFDS consults with Rural Development Administration (crop cultivation environment), National Institute of Ecology (natural ecosystem) and National Institute of Fisheries Science (fisheries environment and marine ecosystem) on LMOs which are released or are likely to be released into the environment.

As of February 2017, a total of 173 events have been approved by MFDS and they are 150 events of GM crops including soybean(26), maize(75), cotton(28), canola(14), sugar beet(1), potato(4), alfalfa(2), 4 events of GM microorganism and 19 events of GM food additives originated from genetically modified microorganisms. The reevaluation of 29 events also has been completed. So far, no GM crops have been grown in Korea and, therefore, approval of GM foods has only been applied to imported products.

## PO II -14

### The International Life Sciences Institute Crop Composition Database (ILSI-CCDB)

**Laurie Bennett** - *International Life Sciences Institute (ILSI) Research Foundation*

Co-authors: Véronique J Barthet, Alison Edwards, Brandon Fast, Nancy Gillikin, Jeffrey D Klucinec, Justin McDonald, Jane Sabbatini, Jannavi R Srinivasan, Theresa Sult, Gregory B Tilton, Andrew Roberts

The International Life Sciences Institute Crop Composition Database (ILSI-CCDB) is an open-access source of comprehensive nutritional composition data for eight conventionally bred crops (canola, cotton, field corn, potato, rice, sorghum, soybean, and sweet corn). The ILSI-CCDB is managed by a working group representing academia, government agencies, and the agricultural and food industries. In 2016, there were over 75,900 unique visits to the database website from users in 129 countries. End-uses of the database include methodology comparisons, assessment of natural variation, nutritional studies, and crop breeder identification of nutritional components that are of particular interest.

Version 6 of the ILSI-CCDB (972,340 data points) released in October 2016 contains a 15% increase in the amount of data as compared to Version 5 (842,500 data points), as well as two new crops (potato and sorghum). All data were derived from 20 years of field trials (1995-2015) spanning 19 countries. Data quality checks were conducted on all data to identify and correct any errors that may have occurred during upload and subsequent handling in the database.

The ILSI-CCDB has historically been viewed as an excellent source of crop composition data from conventionally bred crops due to the large quantity of data contained within the database for a comprehensive set of analytes. The result of the Version 6 updates is a database with increased utility and ease of use that provides a high-quality representation of variability in crop nutritional composition.

**PO II -16****Analysis of two varieties of transgenic soybean and a conventional variety by the Micronucleus Test, in mice**

**Edith Alba Segovia Corrales** - *Universidad Nacional de Asunción*

Co-authors: Romina Arrúa, Nathalia Barrozo, Guillermo Kurita, Carlos Mussi, Gisel Piris, Rosa Oviedo, Lider Ayala

Currently, Paraguay is among the top 10 soybean producers in the world (<https://www.produccionmundialsoja.com/>), and the production has been increasing, reaching a level of approximately 7.500.000 tons in 2011 (INBIO / UGP, 2011) and 9.200.000 tons in the 2015/2016 harvest, with more than 3 million hectares planted (CAPECO, 2017), of conventional and transgenic soybeans. The possible side effects of transgenic soybeans are still under discussion (Malatesta 2003; Malatesta et al., 2005; Malatesta et al., 2008). Azevedo et al. (2010) observed that the diet with 20% of the same exerted a protective effect against a known mutagen. The aim of this work was to study the mutagenic effect of the ingestion of two varieties of transgenic soybean in bone marrow cells of mice fed with a balanced preparation (commercial pig growth<sup>®</sup>) mixed with the two varieties of soybean. Method: the animals were fed for 15 days with the mix of both, the BR5 245 and Nueva Andrea 66 RR varieties; also the mice were treated with the conventional variety BR5 282 to verify possible differences in the treatments. The animals were sacrificed and the bone marrow cells were analysed by the Micronucleus test (Schmid, 1975). Results: Micronucleus frequencies found in bone marrow cells of the treated animals did not present significant difference when they were compared with the frequencies of the negative controls; we concluded that the soybean, transgenic or conventional, analysed in this study, did not present mutagenic effects in this experimental conditions.

**PO II -17****Comparison of nutritional composition between the transgenic rice varieties and conventional comparators using univariate and multivariate analysis**

**Soo-Yun Park** - *National Institute of Agricultural Science*

Co-authors: Seon-Woo Oh, Seong-Kon Lee, Yunsoo Yeo, Hyn Suk Cho

Composition analysis of genetically modified crops is an important consideration in the assessment of food safety. Content of key nutrients of three transgenic rice varieties developed in Korea was compared with those of nontransgenic counterparts and commercial cultivars grown together. The insect-resistant Agb0101 and Btt12R (*Oryza sativa* L.) contain a synthetic truncated cry1Ac gene and a cryIIIA gene isolated from *Bacillus thuringiensis* (*Bt*) respectively, which displayed high resistance to rice leaf folder under field conditions. The disease-resistant OsCK1 was developed by inserting a choline kinase (CK1) gene into the rice genome. Grains of Agb0101, Btt12R, OsCK1, and their parent cultivar (cv. Nakdongbyeo) and commercial rice plants grown in the adjoining fields under the same environmental conditions and field management were used for this study. In addition, to determine the impact of environmental influences on rice nutritional quality, the samples planted at two different growing locations were analyzed. The amounts of proximates, amino acids, fatty acids, minerals, and vitamins in brown rice from Agb0101, Btt12R, and OsCK1 were comparable to those of their nontransgenic counterparts, respectively. Statistical comparisons to test for equivalence showed that all the analyzed components in the insect- and disease-resistant rice plants were substantially equivalent to those of their nontransgenic counterparts. Furthermore, most of the measured values from the three transgenic rice varieties were within the range of values reported for other commercial rice varieties. The results of principal component analysis performed using quantification data from nutritional components revealed differences among the rice samples according to their growing locations rather than by their genotypes. These results confirm that the nutritional quality of rice grains was not affected by the insertion of the CK1 and cry genes, and suggest that the quality is more affected by environmental factors, such as growing conditions, than by genetic factors.

**PO II -18****Nutritional safety assessment of GM rice (insect resistance) using the database of commercial rice varieties**

**Seon-Woo Oh** - *National Institute of Agricultural Science*

Co-authors: Soo-Yun Park, Seong-Gon Lee, So Young Lee, Hyun-Suk Cho

Compositional analysis of GM rice (*Bt 9*, *Bt T*), non-GM comparator, and reference rice as commercial rice were conducted for the safety assessment. The tolerance intervals of commercial rice were also set to illustrate compositional variability. GM rice, non-GM rice, and reference rice were compared by principal component analysis (PCA) and variances (R<sup>2</sup>) to assess the impact of genetic modification versus environmental influence on the rice component. 14 components in 49 analyzed components were significantly different between *Bt 9* GM rice and non-GM rice. Otherwise, 30 components in 49 analyzed components were significantly different between *Bt T* GM rice and non-GM rice. But the mean ranges of components with significant differences were all within of tolerance intervals of the reference rices. These results demonstrated that the nutrition components of GM rice were biologically equivalent to non-GM rice. In addition, multivariate analysis by PCA and variance values revealed that environmental factors, such as growing locations, could affect the natural variations of nutritional values. It was concluded that both of the two *Bt* resistance GM rice (*Bt 9*, *Bt T*) were compositionally equivalent to non-GM rice in the safety assessment.

**PO II -19*****Diatraea saccharalis* resistance to Herculex® maize in an isolate area in San Luis in Argentina: Detection, characterisation and management**

Ana Maria Signorini - Dow AgroSciences

Co-authors: Magdalena Lopez Olaciregui, Gustavo Abratti, Analiza P Alvez, Desmi Chandrasena, Clint Pilcher, Nicholas P Storer

In 2005, Herculex I® maize, expressing Cry1F Bt protein, was launched in Argentina to provide control of certain lepidopteran pests, including *Diatraea saccharalis*. As part of the product stewardship plan for this trait, the baseline susceptibility to Cry1F was determined for *D. saccharalis*, and a resistance-diagnostic concentration was established. Biennially, 10 to 15 populations, randomly collected throughout the maize production regions in Argentina, have been tested against the diagnostic concentration as part of the resistance monitoring programme. In 2012, unexpected damage caused by *D. saccharalis* was detected in commercial fields in a geographically isolated area in northeast of San Luis province. Laboratory studies were conducted with insects collected from this area to confirm taxonomic identification, to bioassay against the diagnostic concentration, and to understand heritability of resistance. These studies confirmed the presence of Cry1F-resistant *D. saccharalis* in the affected area, that the resistance allele frequency was high, and that this resistance is autosomal and completely recessive at field-relevant concentrations of Cry1F. Laboratory and field monitoring continues in the area, in the adjacent zones, and in the rest of the country, confirming that the resistant population remains contained in the affected area. In order to protect Cry1F efficacy against *Diatraea saccharalis* in Argentina, several actions are taking place: the protein has been stacked with other effective proteins with differences in mode of action against this species; communication has been increased with end users to promote refuge compliance and best management practices; and the technology developers are coordinating with public agencies, the seed industry, and growers to limit the possibility of dispersal of this resistant population to other areas. Despite the development of resistance, the joint efforts of growers, public agencies and industry allowed the continuity of grain production and the containment of the Cry1F resistant population of *D. saccharalis* in the north east area of San Luis in Argentina.

**PO II -20****Differential gene expression among Philippine populations of Asian corn borer (*Ostrinia furnacalis* Guen.) (Lepidoptera: Crambidae)**

**John Carlo Medrano Marasigan** - *University of the Philippines Los Baños*

Co-authors: Desiree M Hautea, Ma Anita M Bautista

Maize (*Zea mays* L.), is an economically important crop in the Philippines with food, feed and industry applications. The Asian corn borer (ACB), *Ostrinia furnacalis*, its most threatening insect pest, can cause up to 80% yield losses. Next Generation Sequencing of the ACB transcriptome can reveal insights on its biology and influence its pest management. This study aims to collect total RNA from ACB populations in major corn-producing provinces; outsource the sequence, assembly, and annotation of ACB transcriptome, and compare differentially expressed genes between populations using the transcriptome dataset. Total RNA were successfully collected from larvae and adult populations from Isabela, Cebu, and South Cotabato. From the transcriptomes obtained from each population and developmental stages, a total of 69, 484 unigenes were successfully assembled, from which 39, 041 genes were annotated to the NCBI-Nr database and 3,463 to the gene ontology database. A total of 3, 913 genes were differentially expressed among and between populations.



**PO II -21****Development and characterisation of the Asian corn borer resistance to Bt-toxin Cry1Ie**

**Kanglai He** - *Chinese Academy of Agricultural Sciences (CAAS)*

Co-author: Yueqin Wang

One of two critical assumptions of the high-dose/refuge strategy proposed for effectively managing and/or delaying the resistance development in target insects for transgenic crops expressing *Bacillus thuringiensis* (*Bt*) toxins is that inheritance of resistance is recessive or incompletely recessive. A population of Asian corn borer, *Ostrinia furnacalis* (Guenée), selected with Cry1Ie in the lab for 49 generations, had evolved more than 800-fold resistance to Cry1Ie. The inheritance of resistance to Cry1Ie in the resistant strain was determined through bioassay by exposing neonates of reciprocal crosses and backcross offspring to agar-free semi-artificial diet incorporated with *Bt* proteins. The response of progenies of mass reciprocal crosses between resistant strain and susceptible strain were alike, indicating that the resistance was autosomal. The effective dominance decreased as the concentration increased. Bioassay of the backcross of the F1 generation with the selected strain suggested that the resistance to Cry1Ie was controlled by more than one locus. In addition, the resistant strain had no cross-resistance to Cry1Ab, Cry1Ac, Cry1F and Cry1Ah. The plant tissue bioassays indicated that transgenic maize was resistant to Asian corn borer. The result not only offers the guide for managing the resistance development, but also suggests that Cry1Ie can be proposed as an appropriate candidate for expression with Cry1Ac or Cry1Ab for the development of *Bt* maize in China.

## PO II -23

### **Seed industry management of field-evolved resistance to *Bt*-corn in a population of *Diatraea saccharalis* in Argentina**

**María Fabiana Malacarne** - *Asociación Semilleros Argentinos*

Co-authors: Gustavo Abratti, Damián Grimi, Marcos Machado, Florencia Figueroa Bunge, Betiana Parody, Laura Ramos, Ana Signorini

During the 2012-13 season, the first reports of unexpected damage by *Diatraea saccharalis* on some *Bt* corn lines occurred in the northeast of San Luis province in Argentina. This region is not part of the major corn-producing area; it is an isolated region, and the agricultural development was recent due to irrigation on aprox. 10000 hectares as it has a hot semi-arid climate. Particularly, the *Bt* technologies showing unexpected damage were Herculex I® (TC1507) and VT3PRO® (MON89034 x MON 88017). The event TC1507 expresses the *Bt* protein Cry1F and the event MON89034 expresses Cry1A.105 and Cry2Ab2, all with lepidoptericidal activity against *D. saccharalis* and *Spodoptera frugiperda*. These technologies were rapidly adopted by farmers with no implementation of recommended management practices (refuge, monitoring, crop rotation, etc.). The case was analyzed by the industry together with Argentine Seed Association (ASA) and promptly communicated to regulatory agencies, academia, and corn chain associations with whom we worked. The resistance to both technologies was genetically characterized, showing recessive inheritance and possible cross-resistance between Cry1F and Cry1A.105, given their level of homology (Grimi et al., 2015). Concomitantly, a Mitigation Plan was applied to the region, delimiting areas according to actions to be implemented (ASA, 2013). In the Red Zone, in-depth measures were applied: exhaustive monitoring and chemical sprays if needed, no planting of affected technologies, and use of effective technologies (expressing different MoA). Additionally, the area was not used for corn seed production (Governmental Resolution). In the Yellow Zone, monitoring and communication with farmers were the main actions. As a result of these actions, we observed significant reduction of damage on the affected technologies and a relevant increase in refuge adoption >85% in two seasons. These results show that despite resistance evolution, with appropriate management practices, corn can still be produced sustainably in an affected area.

**PO II -24*****Spodoptera frugiperda* resistance to Cry1F *Bt*-protein in maize in Argentina: Detection, characterisation, and management**

Ana M Signorini - *Dow AgroSciences*

Co-authors: Magdalena Lopez Olaciregui, Gustavo Abratti, Analiza P Alvez, Desmi Chandrasena, Clint Pilcher, Nicholas P Storer

In 2005, Herculex I<sup>®</sup> maize, expressing *Bt* Cry1F protein, was launched in Argentina to provide control of certain lepidopteran pests, including *Spodoptera frugiperda*. As part of the product stewardship plan defined for this trait, the susceptibility baseline of *S. frugiperda* to Cry1F was determined, a resistance diagnostic concentration was established, and an annual resistance-monitoring program was implemented. This program consisted of field efficacy monitoring and laboratory bioassays of randomly sampled populations to detect susceptibility variations of this species to Cry1F protein. *S. frugiperda* populations (20 to 28 per year) were randomly sampled from throughout the maize production regions in Argentina and progeny exposed in the laboratory to the diagnostic concentration of Cry1F in artificial diet. Until 2012, no unexpected survival was detected. Bioassay results of the 2013-2014 collections indicated a reduction in the susceptibility of several tested populations. These results were aligned with field observations that showed unexpected damage in several regions. The genetic basis of this reduction was confirmed through a heritability study, which confirmed the presence of Cry1F resistance that it is autosomal and recessive. Since then, field and laboratory monitoring results show that the resistance allele frequency in *S. frugiperda* populations is now high throughout the Argentinian corn production area. This experience confirms the importance of insect-resistance management strategies: using stacked proteins that target a certain species with differences in their modes of action, refuge adoption, and best management practices for *S. frugiperda* and *Bt* maize. Commitment to these strategies from all stakeholders, including producers, public agencies and industry, is key to extending the durability of the *Bt* technology and the productivity of maize cultivation in Argentina.

## PO II -25

### **Alternate hosts of eggplant fruit and shoot borer, *Leucinodes orbonalis* Guenee in the Philippines: Implications for resistance management with *Bt*-eggplant**

**Lourdes D Taylo** - *University of the Philippines Los Baños*

Co-author: Desiree M Hautea

In the Philippines, commercial eggplant (*Solanum melongena*) growers adopt hybrids, while open-pollinated varieties are grown for smaller markets. Wild related species are also present in undisturbed areas near eggplant farms. The destructive eggplant fruit and shoot borer (EFSB) is present in production areas even despite long fallow periods. Field, greenhouse and laboratory evaluations were conducted to assess the potential of different genotypes and related wild *Solanum* species to be alternate hosts of EFSB. Percentages of shoot and fruit damage were assessed under field conditions among accessions, Acc. 1518, 5302, 3305; farmer's variety, "Concepcion"; wild relatives, *Solanum nigrum*, *S. aethiopicum*, *S. aculeatissima*, *S. mammosum*, and *S. surratense*, with "Mara" as the check variety. Highest percentage EFSB shoot damage was observed in "Concepcion" and lowest in *S. mammosum*. Although highest in "Concepcion," the damage was not significantly different from accessions 5302, 1518, *S. aculeatissima* and "Mara." Percentage EFSB fruit damage was highest among accessions of *S. melongena* and *S. aculeatissima*, and lowest in *S. nigrum*.

In the greenhouse, potted eggplants were enclosed in nylon net cages and a free-choice ovipositional preference test was done. EFSB eggs were mostly laid on the underside of the lower leaf lamina while few eggs were deposited on the midrib, veinlets, axil and stem. Highest egg counts were observed in Acc.532. and lowest in *S. surratense*. In the laboratory, neonates of EFSB were force-fed using a detached fruit assay to compare total developmental times. EFSB was able to complete its development (larva to adult) on accessions of *S. melongena* and wild species, except *S. mammosum*.

Results showed that these ubiquitous wild *Solanum* and OPVs may serve as food and ovipositional hosts when eggplant is unavailable. Thus, they can provide unstructured refuges for susceptible EFSB when *Bt* eggplant is deployed in the field.

**\*Pecha Kucha participant**

## PO II -26

### Postmarket monitoring of biotechnology-derived crops in Brazil

Daniella PV Braga - *Monsanto*

Co-authors: Pedro PP Morais, Gustavo G Belchior, Augusto C Crivellari, Luis RG Favoretto, Geraldo Ubirajara Berger

After commercial use in Brazil, genetically modified organisms (GMOs) are required to undergo a monitoring period with the purpose of understanding if any adverse effects to the environment and human and animal health may arise from its intended application. Under its original format, the postmarketing monitoring (PMM) of GM crops was case specific (CS), a decision based upon public opinion and complying with Article 16 of the Cartagena Protocol. Accordingly, monitoring was carried out for five years, and approved products were submitted to studies in which several environmental interaction variables were assessed on a case-by-case basis. Given that GM crops have been consistently considered as safe as their conventional counterpart, and that their associated risk has been rendered negligible, PMM requirements were reevaluated by the Brazilian National Technical Biosafety Commission (CTNBio), resulting in a general surveillance (GS) model that is the current core process for GMO monitoring. Through determinations of Normative Resolution #9 under Law #11,105, a new approach to PMM has proposed a set of procedures aimed at detecting and identifying unanticipated adverse effects in the risk assessment of GMOs. This allowed for the opportunity for applicants to submit a well-grounded request for exemption of the monitoring plan. Monsanto do Brasil Ltda. has conducted a large number of precommercial field trial studies that consistently provided substantiated information on the GM crops it has developed, allowing for CTNBio to reach clear technical decisions and grant commercial approval for a total of 20 GM soybean, corn, and cotton events. The many PMM evaluations carried out so far have led to the conclusion that no new adverse effects have arisen regardless of a commercial scale of millions of hectares, corroborating the biosafety of two decades of GM crop use.

**PO II -29****Developing and implementing a national post-market environmental monitoring framework for GMOs in South Africa**

**Tlou Masehela** - *South African National Biodiversity Institute (SANBI)*

The adoption of biotech crops in various countries is subjected to processes that assess and evaluate their risks associated with the environment and human health. Countries develop and implement biosafety frameworks, legislations, and policies that drive this process. Environmental (ecological) Risk Assessments serve as an input for decision-making regarding biotech crops and other Living Modified Organisms (LMOs), taking into account any potential effects that may arise in their use – particularly when released into the environment. South Africa has over 15 years of experience in applying such regulatory frameworks, equivalent to those of international standards for various biotech crop events applications. Linked to this process is a requirement to manage and monitor potential environmental effects that may arise due to the presence of the LMO in the environment. To date, monitoring has only been carried out through permit compliance monitoring, which is done by the competent body awarded a permit for environmental release. However, the South African National Biodiversity Institute (SANBI), a body mandated to monitor and report on environmental impacts associated with genetically modified organisms (GMOs) in South Africa has embarked on a process to develop and implement a national postmarket monitoring framework for GMO impacts on biodiversity and/or the environment. The monitoring approach is impact-based, and makes provision for different monitoring methods and approaches. Different monitoring parameters and indicators are selected to suit the desired protection goals and assessment endpoints. In time, the monitoring system also should be appropriate to detect environmental effects of GMOs, support the implementation of adequate management and mitigation measures, and generate good quality data to support further assessments and decision-making processes for GMO applications.

## PO II -30

### **Technology transfer and capacity-building in biotechnology and biosafety for a sustainable and intensified agriculture in Africa**

**Marc Heijde** - *International Plant Biotechnology Outreach (IPBO)*

Co-authors: Sylvie de Buck, Silvia Travella, Vanessa de Bauw, Godelieve Gheysen, Marc Van Montagu

The IPBO (International Plant Biotechnology Outreach) promotes access to scientific and technological innovations as ways of enhancing food security and promoting a sustainable intensification of agriculture. Innovations in biotechnology hold massive opportunities for developing a more sustainable agriculture. However, converting these opportunities into practice in emerging economies requires a concerted effort in training in--and access to--the latest technological developments and the design of effective biosafety and regulatory mechanisms. IPBO is an active cell within the VIB, Belgium (Flemish Institute for Biotechnology) created by Prof. Marc van Montagu in 2000. Its mission is fourfold:

1. Improve understanding and create awareness about the importance of green biotechnology applications for sustainable development (communication),
2. Empower plant biotechnologists and plant breeders from developing countries and emerging economies through training and capacity-building in plant biotechnology and biosafety (training),
3. Act as a focal platform for green biotechnology in Europe and leverage outreach to developing countries and emerging economies.

For instance, with support of the Flanders Government, IPBO has joined forces with the UN Industrial Development Organization (UNIDO, Austria) to set up the International Industrial Biotechnology Network (IIBN, [www.iibn.eu](http://www.iibn.eu)). Under IIBN, agricultural constraints that are potential targets for biotechnology interventions are being mapped in different parts of the world, especially in Sub Saharan Africa. Also, a member-based cooperation network is being developed. Together, these efforts will create an effective platform for identifying new opportunities for cooperation.

**PO II -31****Risk communication – The understated game changer in biosafety policy development and implementation in Africa**

**Samuel Edudzi Timpo** - *NEPAD Agency African Biosafety Network of Expertise (ABNE)*

Co-authors: Joseph Guenther, Karim Maredia

Africa's agricultural development challenges are well documented. The African Union (AU) considers Science, Technology and Innovation (STI) as vital for the continent's agricultural transformation, leading to enhanced agricultural productivity on-farm and along the agri-food value chain, market access, market competitiveness and improved livelihoods. Modern biotechnology has been identified by the AU as a developmental tool that must be harnessed safely. Technology uptake has, however, been beset with controversies with ideological, political, and market considerations often overriding scientific evidence on safety of GMOs. The paper draws on findings from research conducted by the AU-NEPAD Agency African Biosafety Network of Expertise in 7 countries in West, East, and Southern Africa that sought to understand the issues that affect the functionality of biosafety systems and which benefitted from multi-stakeholder surveys and focus group discussions. To safely access the technology, efforts have been directed at capacity strengthening of biosafety systems in risk analysis, a bedrock of a functional regulatory process. Of the three pillars that constitute risk analysis, namely risk assessment, risk management and risk communication, the latter has been the least prioritised. This paper posits that a biosafety system comprises a complex set of interrelationships that must be carefully considered to achieve change through communication. Effective communication strategies are vital agents of change within biosafety systems and STI would only benefit communities if prioritized and strategically communicated. The paper examines the role of tacit knowledge in impacting perceptions and shaping policy development. Considering communication processes are nonlinear, the interplay between tacit knowledge and peculiarities relating to factors such as choice of channels of communication, messaging and timing, prudence in budget utilization, and cost-effective use of time and resources are examined. Also discussed is the role of risk communication in ensuring policy and implementation coherence towards national and regional socioeconomic development agenda.



## PO II -32

### The dismal failure of risk communication for GMOs

**Robert McDowell** - *Consult MRS*

Polls of scientists and the US general public about GM foods reveal a striking divergence. Scientist polls show 90% think GMO crops are safe. In a 2016 poll of US adults, only 33% thought GM foods were safe, 50% thought they were unsafe, 13% were undecided. Women hold stronger views: 62% think GM food is unsafe. A large majority, 75%, says they feel very strongly about GM food issues, and 2/3 say they don't trust scientists. Public opinions on this subject are even more extreme in Europe.

Why is public opinion so contrary to the preponderance of evidence? Scientific illiteracy is partly to blame; less than 20% read a newspaper and most (62%) get their news from social media. But poor communication by risk scientists is also to blame.

The reporting, and public reaction to GMO issues is exemplified by the recent IRAC proclamation that glyphosate is "probably carcinogenic" to humans. This was widely reported in the press, as was the 2012 Seralini et al paper, which was later withdrawn from publication. Information contrary to the IRAC finding--eight previous national-level risk studies on glyphosate found glyphosate not to be a carcinogen--was never reported. The popular press, like scientific journals, rarely publish "negative results" articles.

The glyphosate and GMO reporting is analyzed from the standpoint of hazard analysis, risk analysis, comparative risk assessment, the controversies surrounding the Seralini study and the IRAC carcinogenicity finding, focusing on the unpublished and unreported aspects that would further inform public opinion had they been made public. In addition, the failure to critically evaluate various claims or hypotheses about glyphosate by examining their consistency with epidemiological data is addressed. I conclude with specific recommendations to help scientists better communicate their work to the public.

**PO II -33****Stakeholders' attitudes towards implementing risk assessment and risk management for GMOs in Uganda**

**Barbara Mugwanya Zawedde** - *National Agricultural Research Organisation (NARO)*

Co-authors: Nassib Mugwanya, Yona Baguma

Uganda has been conducting agricultural biotechnology research since the late 1990's using an interim National Biosafety Framework, which was established using existing laws. Under this framework, the portfolio of transgenic crops' research has rapidly grown, resulting in Uganda being the African country that has conducted the largest number of confined field trials. Various traits have been tested for different crops, including banana, cassava, maize/corn, rice, sweet potato, potato, and cotton. However, the government of Uganda made a decision to enact a new legislation to provide for systems that support application and regulation of regulated modern biotechnologies including GMOs. A key stage in the approval process for the new legislation is public consultations. This paper analyzes the knowledge, attitudes and perceptions (KAPs) of stakeholders on genetically modified organisms (GMOs) over a three-year public engagement period. It compares the changes in attitudes towards GMOs for different stakeholders' groups using multivariate statistical analyses. It studies the implications of their KAPs on the confidence in capacity for risk assessment and risk management for GMOs in Uganda. The study also explored the associations between attitudes of different stakeholders' groups towards regulation of GMOs and various variables including associated benefits and risks to society, willingness to pay for GMOs, and trust in government regulatory agencies. These findings contribute to understanding the variability in patterns of attitudes toward GMOs in the different demographic categories. This will guide future public engagements. The paper also demonstrates how public engagement by different biotechnology outreach players has influenced public awareness, and will influence decision-making towards establishment of risk assessment and risk management systems in Uganda.

**PO II -34****Communication and public perception of GM crops: The experiences of South-South LA projects shaping a communication strategy**

**Deise Maria Fontana Capalbo** - *Brazilian Agriculture Research Corporation (EMBRAPA) – Environment*

Co-authors: Margaret G Karembu, Faith N Nguthi

Communicating agricultural biotechnology and biosafety issues encompasses a spectrum of issues from the factual dissemination of scientific research to societal values and beliefs. This affirms the need for deliberate strategies for biotechnology and biosafety communication to ensure consistency in messaging for the varied stakeholders. Despite remarkable progress in commercialization of GM crops in an increasing number of countries, their adoption in Africa and some Latin-American (LAC) countries remains extremely low. In Brazil, illegal introduction of GM soybeans in 2000 was an experience that has shown the importance of a solid and workable legal framework as well as a robust communication strategy. Nowadays Brazil is the second largest grower of GM crops in the world. A study developed between 2010-2012 in south-south (S-S) LAC partnership on environmental risk assessment (ERA), public perception and communication (1), demonstrated the importance of developing a communication strategic plan that would promote public awareness and stimulate a well-informed public debate on biosafety (2). Based on these achievements a similar S-S project was developed between Brazil, Kenya and Uganda (2014-2016) to share Brazil's experiences in using the communication strategic plan and science-based information to safely advance with GM crops. This was expected to enable the two African countries to make decisions on GM crops in accordance with their own values and needs without repeating Brazil's mistakes (3). Much advancement was achieved with this initiative. One of the key lessons learned is the fact that interest groups are similar in all the countries but the power structure differs among the groups. It is therefore important to define a clear communication strategy to ensure delivery of messages that inform the decision-making process on GM crops.

## PO II -35

### Readiness of the Nigerian public for the introduction of GM crops into the food market

**Oluwakemi Hannah Oladipo** - *National Biotechnology Development Agency*

Co-author: Harry A Kuiper

Genetically modified crops (GMCs) are crops whose DNA has been modified via genetic engineering techniques for the introduction of new trait(s). Some introduced traits are targeted at improving the nutritional value, preventing pest infestation, providing resistance to pesticides, and increasing adaptability to weather or growth conditions. GMCs have gained wide popularity over the years as many crops have been modified and grown for commercial purposes and their usage is accompanied by biosafety regulations. These crops are required to be evaluated for their safety both to the consumers, the farmers, and the environment. Biosafety, in this context, is defined as the precautions taken to control the cultivation and distribution of genetically modified crops and products. Nigeria signed its "National Biosafety Act" into law in 2015, and the presence of these laws and establishment of an officiating biosafety agency provides a legal support for the regulation and safety assessment of biologically entities including GMCs. Some genetically modified crops are under field trial in Nigeria and soon may be introduced for commercial production if they scale through the expected biosafety regulation procedures.

The purpose of this research is to study the preparedness and level of potential acceptance of consumers for genetically modified crops in Nigeria. A survey having the public and consumers of food crops in as respondents was carried out and the social media was used as the means of dissemination. Knowledge about GMO/GMCs, Safety issues associated with GMOs, the Nigerian biosafety law, labelling recommendations were considered in the study. The results of the survey will be discussed at the conference.

**\*Pecha Kucha participant**

## PO II -36

### Public awareness and the Asian BCH roadmap: The Philippines experience

**Julieta Fe L Estacio** - *National Committee on Biosafety of the Philippines*

Co-author: Katherine Soriano

Public awareness and acceptance is the key for any technology for it to be regarded as “acceptable” and the products thereof “safe for consumption.” The process of genetic engineering has been one of the most controversial, its products the most assessed, and has the most number of issues and concerns not only to the environment but to human and animal health. In the Philippines, research on modern biotechnology started in the mid-1970s; regulation was established in 1987 with no less than the scientists themselves spearheading this initiative.

As the field of modern biotechnology progressed, the country’s biosafety framework continued to evolve, enhancing its public awareness and education on the government’s efforts to ensure the integrity of the decision-making process.

The country’s establishment of the Biosafety Clearing House or the “BCH Pilipinas” in 2008 enhanced the existing mechanisms for public information and dissemination efforts and paved the way in reaching out to greater number of stakeholders in conveying the message regarding the government’s seriousness in its mandate on transparency and accountability. The BCH serves as a one-stop-shop for relevant laws, guidelines, policies, risk assessment, and decisions made by the country on GMOs. While the country continue addressing the challenges in registering national records, serious efforts are being made to improve and strengthen coordination with other agencies engaged in the regulatory process.

This paper will show the regulatory challenges in the regulation of GMOs, efforts made and coordination mechanisms with relevant entities in bringing accurate and timely information regarding biosafety regulatory system to the public, the initiatives that created the Asia BCH Family with the Philippines as Regional Coordinator to implement the Asia BCH Roadmap (2016-2020) public awareness initiatives on the issues attendant to modern biotechnology, and the risk assessment and decision-making process by governments.

**\*Pecha Kucha participant**

## PO II –37

### The interplay of gene editing regulation and social impacts

**Agustina Whelan** - *Ministry of Agro-industry*

Co-author: Martín Lema

Gene -editing technologies are a group of recent innovations in plant breeding using molecular biology sharing the capability of introducing a site-directed mutation or deletion in the genome. The first cases of crops improved with these technologies are approaching the market, and this has raised an international debate regarding how they should be regulated.

This dilemma for policymakers not only entails issues pertaining to safety information and legal/regulatory definitions. It also demands performing “on the making” social studies of science and technology as an additional basis for sound decision-making.

GECs having genome mutations/deletions, as a technological artifact, have just begun to be “constructed” by society at the national and global level. “On the making” studies on such social construction and the more probable technological trajectories for GECs are much needed, particularly by policymakers and developers to complement hard information pertaining to safety and performance.

Many lessons are to be applied from the recent, quite established, and very close experience with the technological trajectory of the “GM crops” artifact. The results of the case comparisons between GM crops and GECs may be informative mostly in regards to the real possibilities of diversifying the availability of crop species and traits improved by biotechnology.

Also, for countries where GM crops have encountered more resistance and consequently research and development has been virtually halted, these studies may be enlightening about how realistic are the possibilities of reopening opportunity for innovation in the seed sector from public research institutions to SMEs seed companies to the farmer.

**\*Pecha Kucha participant**

## PO II -38

### Impact assessment of genome editing in plants

**Dominik Modrzejewski** - *Julius Kühn-Institute (JKI)*

Co-authors: Joachim Schiemann, Ralf Wilhelm, Frank Hartung, Thorben Sprink, Dörthe Krause <ABSTC selection>

Genome-editing techniques using, e.g., TALENs (Transcription Activator Like Effectors Nucleases) or CRISPR/Cas9 (Clustered Regularly Interspaced Short Palindromic Repeats) are promising tools to facilitate crop breeding. However, in many countries the regulatory status of genome editing is an issue of ongoing controversy if - at all - the products or the techniques themselves require specific regulations. In order to address ethical, legal and socioeconomical aspects of genome editing in agriculture, the German ELSA-GEA project was established to analyze, compare and discuss the status of risk assessments and upcoming regulations on genome editing in the EU and worldwide. Systematic reviews and maps will be applied to explore and summarize the available evidence on potential impacts caused by the application of genome editing. A systematic review represents a powerful tool to identify, collect, synthesize, and evaluate primary research data in a transparent and reproducible manner. Pushed by the rapid increase of publications in this area, the identification of reports and the initial selection process, determining the eligibility of a study for being included in the review is considerably time and labor intensive. To enhance its efficiency, a machine learning tool for text-mining will be implemented in order to reduce the workload of the review team.

**\*Pecha Kucha participant**

**PO II -39****Biosafety regulators' challenge: Measuring and monitoring the socioeconomic impacts of GMOs in The Philippines**

**Leonardo A Gonzales** - *Philippine Department of Science and Technology Biosafety Committee (DOST-BC)*

The Philippine GM Corn technology is now fourteen years old. During this period, despite the nonmandatory nature of Article 26 of the Cartagena Protocol on Biosafety on Socio-economic Considerations (SECs), Biosafety Regulators were still faced with the challenges of measuring and monitoring both the *ex-ante* (pre-commercialization) and *ex-post* (post-commercialization) socioeconomic impacts of the GM Corn technology, because SECs are central to their policy decision-making process in commercializing GMOs. Some of the challenges in assessing the socioeconomic impacts of GMOs include, but are not limited to, the following: (a) The choice of the socioeconomic impact indicators (quantifiable, congruent with socioeconomic theory and technical change, and biosafety regulatory friendly); (b) The methods to be used in the estimation process (in line with accepted standard, congruence with specificity, and timing of the GM event, *ex ante* and *ex-post* methodologies, and counterfactual [with and without] analysis); and (c) Validation of research results through a sustained monitoring system. The paper analysed the comparative socioeconomic performance of 3,500 GMO and non-GMO corn producers from 2002-2012. The study analysed six performance indicators: productivity, cost efficiency, profitability, subsistence level carrying capacity (food security), returns on investment, and global cost competitiveness. The socioeconomic impact assessment of GM corn relative to ordinary hybrid (non-GM) corn, both *ex-ante* and *ex post*, showed robust results in terms of the six indicators. Given the time horizon of more than a decade in monitoring the socioeconomic impacts of GM corn, coupled with the large number of sample corn farmers randomly drawn across major corn-producing areas of the country as factors in the assessment, the paper concludes with confidence that the GM corn technology in The Philippines has succeeded in ensuring socioeconomic sustainability, assuming all other things constant, relative to the ordinary hybrid (non-GM) corn.



**PO II -40*****Ex-ante* assessment of the potential impact of transgenic banana resistant to BXW disease in East Africa**

**Leena Tripathi** - *International Institute of Tropical Agriculture (IITA)*

Co-author: Victor Manyong

Banana *Xanthomonas* wilt (BXW), caused by the bacterium *Xanthomonas campestris* pv. *musacearum*, is one of the most important diseases and is considered as the biggest threat to banana production in east Africa. Currently, there are no commercial chemicals, biocontrol agents, or resistant cultivars available to control the pathogen. In the absence of known natural host plant resistance among banana cultivars, transgenic bananas expressing the Hypersensitive Response Assisting Protein (Hrap) or Plant Ferredoxin Like Protein (Pflp) genes were developed. These transgenic bananas had shown 100% resistance against *Xanthomonas campestris* pv. *musacearum* under confined field trials and retained the resistance even in the ratoon crop, which confirmed that this technology can provide solution to farmers for controlling BXW. Aside from full resistance to BXW, the transformed lines also showed yields comparable to nontransgenic control. To gain a better understanding of future adoption and consumption of transgenic banana in East Africa, potential economic impacts of transgenic banana cultivars resistant to banana *Xanthomonas* wilt disease was evaluated. The *ex-ante* findings showed that the development of this banana is viable and has large economic impacts. The main beneficiaries of this technology development are consumers and farmers. The magnitudes of economic impacts vary substantially across the target countries, being highest in countries where disease incidence and production losses are high. The presentation will highlight the potential adoption and consumption and prospects for successful dissemination of transgenic banana in the target countries in East Africa.

## PO II -41

### Quantification of GM soybean pollen in Mexican honey using digital PCR

Amanda Galvez - *Universidad Nacional Autonoma de Mexico*

Co-authors: Maricarmen Quirasco, Eric Vides, Cindy Estrada, Irma Hernández, Remy Vandame, Michelle Chauvet, Francisca Acevedo, Elleli Huerta

Honey, the 5th agricultural export product of Mexico, is highly appreciated in organic markets worldwide. The objective of this work was the detection and quantification of GM pollen sequences from honey. Samples were collected in Mayan communities in Campeche, Mexico, in 2013 – 2014, by ECOSUR, where GM soybean has been authorized. Pollen DNA was extracted using the methodology published by the German government, modified in our lab. PCR primers and probes used for qPCR (ABI7500) and droplet digital PCR (ddPCR) (BioRad QX200) were published by JRC. The endogenous universal target plant gene used was Actin. Duplex reactions were set for 35S promoter/nos terminator, as well as for soy/maize species detection. GM positives samples were quantitatively analyzed for GM soybean events MON4032/MON89788, also in duplex reactions. Even though samples from the rainy month of September showed the presence of MON4032 pollen in 16/69 samples, the next season sampled (February 2014), were free from GM pollen. ddPCR allowed detection and quantification of an analyte found in a very low proportion with respect to the DNA of pollen from other plant species, present in a complex mixture such as multifloral honey from a highly diverse region. Such methods allowed the analysis of quantities as low as 0.1% (GM DNA/plant DNA). The presence of GM sequences, not accepted by international organic certification companies, compromises the premium price expected by 14000 Mayan families who produce organic honey. Considering the widespread presence of honeybees in the area, the fate of herbicide residues should be included in the ERA, in order to evaluate the undesired effects of herbicides on the ample ecosystem services the herbaceous plants, as well as the pollinators that strive on them, provide in Yucatan. And according to the Cartagena Protocol on Biosafety, also socioeconomic impacts on indigenous communities should be evaluated.

**PO II -42**

**The advantages of glyphosate-resistant corn production in China**

**Xiangju Li** - *Chinese Academy of Agricultural Sciences (CAAS)*

Co-authors: Hailan Cui, Huilin Yu

Corn is the major crops in China. Farmers hope to use broad-spectrum herbicides to maintain higher yield of corn. GR crop system provides corn growers a new way to use it. Chinese farmers showed a strong enthusiasm in GR corn. In this paper, the advantages of GR corn in China were discussed based on China's actual conditions of corn production and herbicide use.

**PO II -43****Evaluation of weed control efficacy and safety of glyphosate in herbicide tolerant transgenic maize**

Huilin Yu - *Chinese Academy of Agricultural Sciences (CAAS)*

Co-authors: ZongHua Quan, Xiangju Li

Herbicide-tolerant (Ht) maize has been planted widely and provided an effective tool for weed control. However, so far no Ht maize varieties have been commercially planted in China. Prior to the commercialization of any Ht crop, weed control efficacy and the safety of herbicide on Ht crops are two important aspects to assess. Transgenic G10evo-EPSPS maize expressing EPSPS protein conferring a herbicide-tolerance trait, was used in our study. The efficacy of weed control and the impact on transgenic maize growth were investigated under field conditions after application of glyphosate 41% aqueous solution. When maize plants were at 40 days after sowing (DAS), glyphosate was applied at the dosage of 615, 1230 (recommended dose), 2460 and 4920 g ai/hm<sup>2</sup>. These treatments were compared with hand-weeding on 40 DAS and unweeded control. Weed control efficacy was calculated as the following formula<sup>1</sup>. Weed control efficacy = (Fresh weight of weeds in unweeded control plot - Fresh weight of weeds in treated plots) / (Fresh weight of weeds in unweeded control plots) × 100. Our results showed that weed flora of experimental field plots predominantly consisted of four species of grasses and fourteen species of broadleaved weeds. Considerable reduction in the density of grasses and broadleaved weeds was observed under glyphosate at 1230, 2460 and 4920 g ai/hm<sup>2</sup> at 28 days after treatment (DAT), compared with hand-weeding. Glyphosate at 1230, 2460 and 4920 g ai/hm<sup>2</sup> at 28 DAT provided > 85% and > 90% control for grass and broadleaved weeds compared with hand-weeding treatment that separately provided 50.10% and 40.90% control. Lower dosage of glyphosate at 615 g ai/hm<sup>2</sup> did not prove effective in controlling grass weeds. No differences of the leaf number and plant height in maize among different treatments at any time of investigation indicated that no impact of glyphosate applied on maize growth.

## Award Winners

### Agricultural Biotechnology Stewardship Technical Committee (ABSTC) Winners

Biosafety regulatory systems overseeing the use of GMOs in the Latin America and the Caribbean region  
**Ayrton André Rosado Huaynasi**, *International Centre for Genetic Engineering and Biotechnology (ICGEB)*  
Co-author: Wendy Craig

Levels of Cry1Ac protein in herbivorous and predatory arthropods in *Bt*-soybean  
**Young-Joong Kim**, *Seoul National University*

Impact assessment of genome editing in plants  
**Dominik Modrzejewski**, *Julius Kühn-Institute (JKI)*  
Co-authors: Joachim Schiemann, Ralf Wilhelm, Frank Hartung, Thorben Sprink, Dörthe Krause

Establishing biodiversity damage resulting from GMOs  
**Claudia Colmenarez Ortiz**, *Ghent University*

Readiness of the Nigerian public for the introduction of GM crops into the food market  
**Oluwakemi Hannah Oladipo**, *National Biotechnology Development Agency*  
Co-author: Harry A Kuiper

Establishing biodiversity damage resulting from GMOs  
**Claudia Colmenarez Ortiz**, *Ghent University*

### South Asia Biosafety Conference (SABC) Winner

Alternate hosts of eggplant fruit and shoot borer, *Leucinodes orbonalis* Guenee in the Philippines: Implications for resistance management with *Bt*-eggplant  
**Lourdes D Taylo**, *University of the Philippines Los Baños*  
Co-author: Desiree M Hautea

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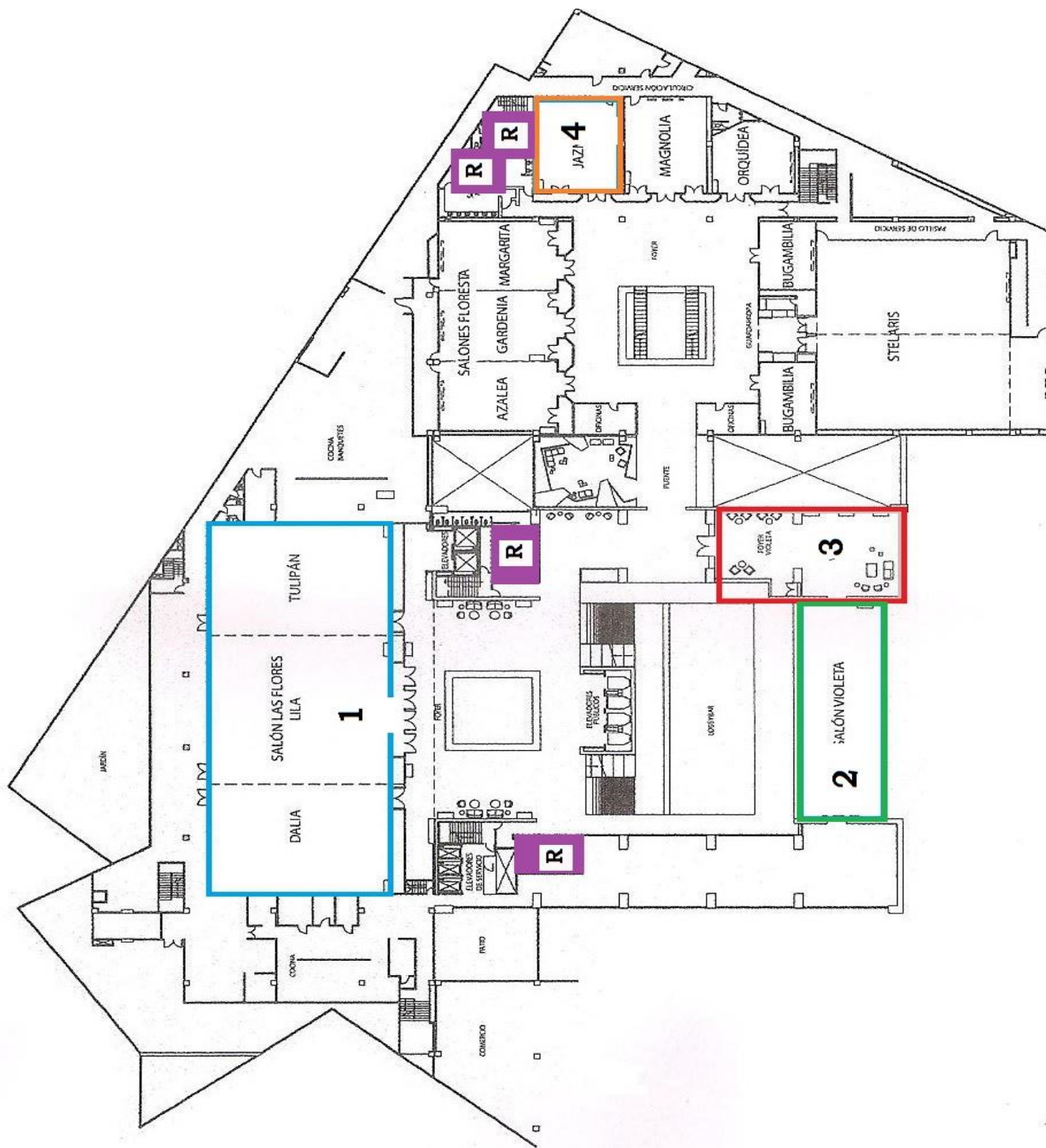


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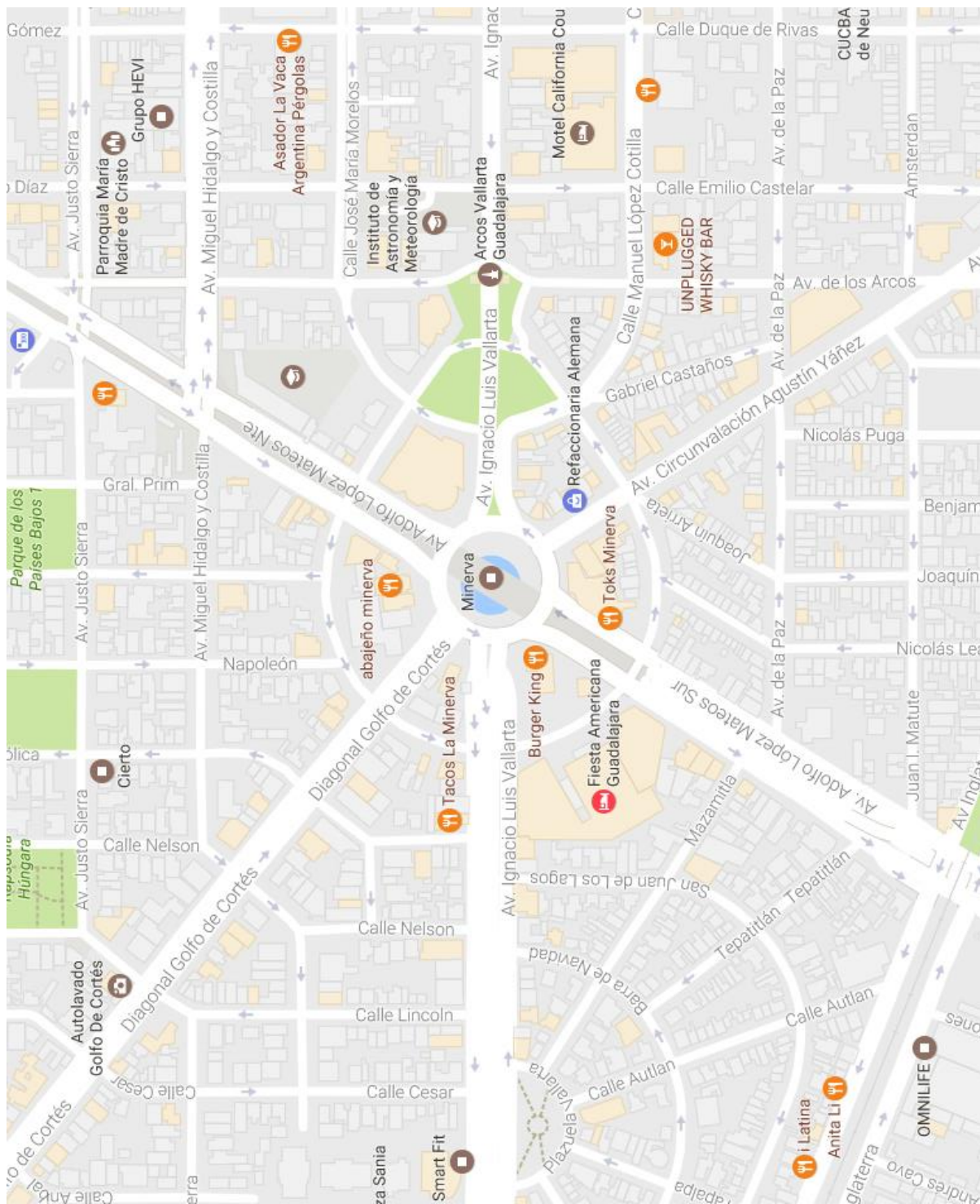
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Zhou	Xue-Rong	Commonwealth Science and Industrial Research Organisation	PO II-12
Zhou	Xuguo	University of Kentucky	PS VII-2

### Map of the hotel



### Map of the area





## Notes



