Dear colleagues

It is a pleasure to welcome you all to the 15th ISBR Symposium. Our program committee has worked tirelessly to put together an interesting and exciting scientific programme. Many volunteers have helped us to organise an array of parallel sessions and workshops that cover many of the scientific topics currently under intense discussion in our scientific community. We are also very honoured to have with us an outstanding group of keynote and plenary speakers. We hope that with such a program you will all find plenty of opportunities to hear about the latest scientific developments in this field, to learn new things and to interact with other scientists, widening your network and fostering new collaborations.

We have chosen the beautiful city of Tarragona to host this Symposium for many reasons. With the stunning Mediterranean Sea as the backdrop, the many historical Roman sites and its laid back nature, Tarragona provides a wonderful venue to engage in the Symposium at the Palau Firal and then relax and enjoy its many offerings when the sessions are over.

We warmly welcome you and sincerely hope that you enjoy this Symposium and have a pleasant stay in Tarragona.

Dr. Ariel Alvarez
ISBR President

Dr. Monica Garcia-Alonso
Symposium coordinator and local organiser
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SYMPOSIUM COORDINATOR / LOCAL ORGANISER

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> Estel Consult Ltd / ISBR

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PLENARY SESSIONS
PL I: COMMUNICATIONS AND ENGAGEMENT WITH POLICY AND PUBLIC AUDIENCES

Session Organizers:
Hennie Groenewald, Biosafety South Africa, South Africa and Jennifer Anderson, Corteva Agriscience, USA

PL I - 1

Can agriculture save the planet before it destroys it?

Jack Bobo
Intrexon Corporation, Germantown, USA

Abstract

With the global population expected to reach more than nine and a half billion in a little over 30 years, the sustainable production of agriculture will be increasingly on the minds of governments, industry, farmers and even many consumers. Not only do we have to increase the amount of food available, we have to find ways to minimize its footprint on the planet. There is no activity that humankind engages in that has a bigger impact than agriculture, but there is also nothing more important. Therefore one of the great challenges that confronts us in the next 30 years is to figure out how to maximize the production of food while minimizing the negative consequences of agriculture -- from polluted waterways to disappearing rainforests. Science and technology may hold the key to addressing many of the world’s biggest problems but only if scientific breakthroughs make it to the fields. In a hot, crowded and hyper-connected world public perception of risk, not science, may ultimately determine if agriculture saves the planet by 2050 or destroys it. This presentation will examine global trends in food and agriculture, the interplay between science and public perception of risk and how scientists build trust to navigate these trends.

References

How do you want agbiotech science and scientists to be perceived?

John C. Besley
Michigan State University, East Lansing, MI USA

Abstract

A substantial body of literature tells us that trying to increase knowledge about scientific topics such as agricultural biotechnology is unlikely to have much impact. This presentation seeks to suggest a range of communication objectives we could pursue beyond filling knowledge deficits. It will specifically describe a way of thinking about science communication strategy that focuses on the importance of deciding on audience specific behavioral goals and then working backwards to identify evidence-based communication objectives that might help achieve those goals. Strategic communicators should then begin to identify tactics that provide the potential of ethically achieving prioritized objectives. The presentation will particularly focus on agbiotech-focused research that suggests that science communicators might benefit from paying greater attention to communication activities and objectives associated with showing that scientists care about, respect, and listen to their audiences. This research is partly based on the premise that too many science communicators—including those involved in topics such genetic engineering—opt for aggressive communication or communication that unnecessarily frames key issues in terms of conflict. It further highlights the importance of thinking beyond our audiences’ cognitive biases and putting the emphasis on the choices that communicators make that have the potential to promote polarization. The talk will ultimately emphasize how the science community could improve if it wants to increase the probability of long-term support for science-based policy and individual behavior.
Agribiotech proponents: guilty till proven innocent. How do we get a fair chance?

Mahaletchumy Arujanan
Malaysian Biotechnology Information Centre, Kuala Lumpur, Malaysia.

Abstract

Modern agribiotechnology and its branch GM technology is the biggest victim of scaremongering and a field that is the most polarised. The proponents of GM technology and crops are demonised by critics of this technology. It is an uphill task to communicate science-based information in this field as it involves rebutting absurd claims, fictional risks and unscientific demands. Some examples of these are food safety tests spanning for a few generations, zero-risk guarantee, patent-free innovation, labelling of GMOs, adoption of precautionary principles, and the list goes on. On the other hand, the public falls prey to any unscientific claims made by the critics and scientists are expected to prove the claims wrong. Where do we start in order to prove ourselves innocent when we are convicted even before given a fair trial? Research in science communication is also evolving, from deficit to public engagement model. A lot of research has shown that by providing more scientific facts we will not be able to influence, shape and shift public opinion. But a recent study says science education improves attitude towards GMO foods. This is where the understanding of our target audience, cognitive bias, cognitive dissonance, knowledge illusion, and psychology of extremism is important for scientists to effectively engage in a polarised situation and with a heterogenous audience. Anti-scientific attitudes cannot be countered just with education. We need to first make our audience understand the gaps in their knowledge, work with their value and belief systems instead of antagonising with them. The presentation will attempt to provide some insight into risk communication to address public concerns on agribiotechnology.
The critical role of C&E in a developing world, biotech policy context

Ben Durham
Bio-innovation Chief directorate, National Department of Science and Technology, South Africa

Abstract

A provocative look into why trust is scarce, is difficult to build, and may need to be side-stepped to give new technologies the rein in the Developing World. Leadership, communication and engagement remain critical as building blocks, but need to be culturally adapted to the local setting.
PL II: ENVIRONMENTAL RISK ASSESSMENT AND REGULATION OF GENE EDITED PRODUCTS

Session Organizers:
Heidi Mitchell, Office of the Gene Technology Regulator, Australia and Joerg Romeis, Agroscope, Switzerland

PL II - 1

Current environmental risk assessment for genetically modified organisms and implications for gene edited products

Jeffrey Wolt
Iowa State University, Ames, USA

Abstract

Over thirty years of effort has been devoted to developing harmonized principles for the risk and safety assessment of genetically modified organisms. This effort has clear implications for how scientists, regulators and broader society views environmental risk assessment for products of genome editing. Experts recognize that genetically modified products do not reflect new classes of risks different from those of products derived from traditional plant breeding methods. Regardless, regulators have implemented procedures to evaluate the incremental harms that may be ascribed to genetic modification and these have resulted in the development of increasingly complex study packages for regulatory authorizations. In many regulatory domains this approach to regulation has neither enabled sound decision-making nor mollified public questioning of the technology. This outcome contrasts with the intent of harmonization with its adherence to risk-based principles using strong problem formulation to determine the nature of/need for the environmental risk assessment of a given product of genetic modification. Genome editing represents a continuum of processes along a path from natural mutation to transgenesis and enables the generation of phenotypes representing a potential flood of useful products. In many cases the outcomes of genome editing are indistinguishable from those possible through spontaneous or induced mutation. The a priori application of existing approaches of environmental risk assessment to gene edited products, simply on the basis of the process used, leads down the pathway of risk/safety assessment for genetically modified crops which has not satisfactorily addressed societal needs. The case-by-case paradigm at the core of harmonized principles for environmental risk assessment should dictate whether risk/safety assessment, or regulation itself, may be warranted for those gene edited products that are in principle no different than products derived from conventional plant breeding methods.
Abstract

Gene editing based on site-directed nucleases is recognized as a breeding method best suited to introduce animal health, well-being, and climate adaptive alleles into naïve populations of food animals. These methods provide new opportunities in the marketplace with great potential to address growing societal concerns regarding animal health and welfare, and facilitating efforts to meet global food security challenges. Importantly, “precision breeding” allows for accelerating breeding efforts to address these needs without sacrificing genetic diversity or negatively impacting elite production traits. To date, there has been relatively few privately funded initiatives attempting to bring edited animals to market; suggesting commercial providers of elite genetics are still reticent to apply this technology as a method for animal improvement. The pre-commercial deployment of animal welfare traits for genetic improvement in food animals and potential economic value to producers must be discussed in the context of perceived biosafety risks associated with this technology. An understanding of these factors are important for future acceptance and widespread adoption of gene editing technology as a primary tool of animal breeding. Acceligen (agricultural division of Recombinetics) is actively pursuing the pre-commercial deployment of polled and SLICK variants in beef cattle breeds based on their economic potential to producers to create emerging markets, and as a complement to their traditional breeding programs.
Normative criteria and their inclusion in a regulatory framework for new plant varieties derived from genome editing

David J. S. Hamburger
University of Passau, Faculty of Law, Germany

Abstract

Any legal regulation has to take into account fundamental interests and concerns, whether of private or public nature. This applies in particular to the politically and socially sensitive question of regulating plant biotechnology. With the advent of new breeding techniques, such as genome editing, new challenges are arising for legislators around the world. However, in coping with them not only the technical particularities of the new breeding techniques must be taken into account but also the diverse and sometimes conflicting interests of the various stakeholders. These normative criteria, which can have an impact on regulatory decisions regarding genome edited plants and products derived from them, include inter alia industry interests, farmer interests, public opinion, consumer rights and interests, human health and food safety, food security, environmental protection, consistency and coherence of the regulatory framework, and ethical or religious convictions. Since those interests differ from country to country depending on the respective political, economic, and social circumstances, the respective legislator has the task of identifying these normative criteria and must find a suitable balance between them. As a result, the individual country-specific regulatory outcomes regarding genome edited plants are likely to be as manifold as the interests and regulatory measures at hand.

References

Problem formulation and phenotypic characterisation for the development of gene-edited crops

Alan Raybould
Syngenta Crop Protection AG, Basel, Switzerland

Abstract

Phenotypic characterisation provides important information about novel crops that helps their developers to make technical and commercial decisions. Phenotypic characterisation comprises two activities. Product characterisation checks that the novel crop has the qualities of a viable product – the intended traits have been introduced and work as expected, and no unintended changes have been made that will adversely affect the performance of the final product. Risk assessment evaluates whether the intended and unintended changes are likely to harm human health or the environment. Product characterisation follows the principles of problem formulation, namely that the characteristics required in the final product are defined and criteria to decide whether the novel crop will have these properties are set. The hypothesis that the novel crop meets the criteria are tested during product development. If the hypothesis is corroborated, development continues, and if the hypothesis is falsified, the product is redesigned or its development is halted. Risk assessment should follow the same principles: criteria that indicate the crop poses unacceptable risk should be set, and the hypothesis that the crop does not possess those properties should be tested. However, risk assessment, particularly when considering unintended changes introduced by new plant breeding methods such as gene editing, often ignores these principles. Instead, phenotypic characterisation seeks to catalogue all unintended changes by profiling methods and then attempts to work out whether any of the changes are important. This paper argues that profiling is an inefficient and ineffective method of phenotypic characterisation for risk assessment. It discusses reasons why profiling is favoured and corrects some misconceptions about problem formulation.
Argentine practical experience in the regulation of gene-edited products for agroindustry

Martin Lema
Biotechnology Directorate, Ministry of Production, Argentina

Abstract

The Argentine republic issued in 2015 a regulation aimed at clarifying the status of products obtained with the so-called “New breeding techniques” -including gene-editing- in regards to the regulatory framework applied to Genetically Modified Organisms, where determinations are made case by case. After three years of experience applying this regulation, several and very diverse cases have been submitted and analyzed by the National Commission on Agricultural Biotechnology (CONABIA).

This presentation will explain the underlying criteria for this regulation, and then will present the overall practical experience gained from applying such criteria. In this respect, the whole caseload of cases representing different new breeding techniques will be discussed. For further clarity, focus will be made in three gene-edited products: one animal, one plant and one microorganism.

Finally, the presentation will discuss practical implications on how to handle the environmental risk assessment to be applied when considering different kinds of products.
PL III: FOOD SAFETY ASSESSMENT OF NOVEL MOLECULES – WHAT DOES THE FUTURE HOLD?

Session Organizers:
Vibha Ahuja, Biotech Consortium India Limited, India and Joe Smith, ISBR President Elect, Australia

PL III - 1

Innovation, equity and rates of change

Robert Horsch
Retired, formerly Deputy Director, Agricultural R&D, Bill & Melinda Gates Foundation, Seattle, USA

Abstract

The power of innovation to improve the quality and sustainability of life on earth can be readily seen in nature and in human social and economic development. To quote Jonathan Swift: “that whoever could make two ears of corn, or two blades of grass, to grow upon a spot of ground where only one grew before, would deserve better of mankind…” What is less self-evident is the power of equity as a driver of progress and sustainable development. We usually think of equity as a goal or a value, rather than as a lever for change. But the history of development reveals it is on a par with innovation to improve the lives of all, not just the lives of the poor.

An even less self-evident driver is the rate of progress. I will discuss all three factors and examine the transformative nature of agriculture and how agricultural investment can best translate into poverty reduction, particularly in lower income countries with the potential for catch-up growth. Economic multipliers and momentum from an initial burst of agricultural development enables economic growth well beyond the farmers themselves and becomes a key ingredient for diversification into higher margin exports both in agricultural products and outside of agriculture entirely.

The key elements of agricultural modernization and progress include the central role of government institutions and initial, large public investments in agriculture, as well as that of small commercial farmers who have sufficient potential to earn enough farm income to lift themselves out of poverty. Agricultural modernization is driven by innovative science and technology, and, once staple foods are well attended to, by increased emphasis on diversifying research and extension into a broad range of livestock, horticultural and export commodities. Then private sector is equally important, particularly related to fertilizer supply, seed production, and innovation in other commercial products where the government’s task is to incentivize and facilitate companies engagement through improved policies.
Dispatches from the frontier of fact and fiction: the past, present and future of dietary RNA studies

Kenneth Witwer
The Johns Hopkins University School of Medicine, Baltimore, United States

Abstract

A rich variety of native regulatory RNA-mediated traits of food plants are known, and mammals including humans have safely consumed plant products with regulatory RNA-related traits. Against this “generally regarded as safe” (GRAS) background, newly introduced regulatory RNAs, including double-stranded RNAs and derived small interfering (si) or micro (mi) RNAs, have led to new safety evaluations with varying levels of grounding in reproducible science. In this presentation, I will highlight safety considerations for both exogenous and endogenous RNAs that may be consumed in food products. I will begin with a review of the literature on canonical post-transcriptional gene regulation and non-canonical processes mediated by endogenous and exogenous RNAs. Next, we will judge the strength of the evidence for functional uptake of exogenous dietary RNA by mammals and address the question of whether delivery methods affect our conclusions. For example, are specific types of extracellular vesicles (EVs or “exosomes”) a magic bullet for distribution of RNA? Furthermore, might dietary RNA exert effects short of systemic distribution and function? I will conclude with perspectives on outstanding questions that may prompt further research and development.
PL III - 3

Plant and animal genome editing using CRISPR/Cas9

Okjae Koo
ToolGen Inc, Seoul, Republic of South Korea

Abstract

Innovative genome engineering technology utilizing programmable nucleases enables fast and efficient editing of genetic information in various cells and organisms. CRISPR/Cas9 nucleases, recently developed from a prokaryotic adaptive immune system, provide a robust, programmable nuclease platform with high reliability and specificity. Though this technology became available just a few years ago, it has already become a standard molecular tool for studying genetics, modeling disease and generating animal models in basic research. In biomedical fields, CRISPR/Cas9 nucleases are expected to enable therapeutic genome editing for many rare hereditary diseases. It can also be used to establish and improve the efficacy and safety of cell therapies for various diseases. On the other hand, this technology can be used as an innovative molecular breeding tool for various plants and animals. It can be used as an alternative approach to traditional breeding or genetic engineering (transgenic) to develop new breeds of plants and animals very rapidly and efficiently. This presentation will review CRISPR/Cas9 technology and examine current trends and contemporary applications in the practical use of the technology. In doing so, the presentation will seek to explore some of the implications of genome edited crops and livestock for food safety assessment and regulation.
PL III - 4

▶ Development and deregulation of DHA-canola - a novel and sustainable source of essential omega-3 fatty acids

Allan Green
CSIRO Sydney, Australia

Abstract

Omega-3 long-chain (≥C20) polyunsaturated fatty acids (ω3 LC-PUFA) such as DHA and EPA have critical roles in human health and development with numerous studies indicating that deficiencies in these fatty acids can increase the risk or severity of cardiovascular and inflammatory diseases in particular. They are currently obtained primarily from fish and other marine sources, which have significant limitations in terms of their sustainable harvest scale. In order to meet the increasing demand for these oils there is an urgent need for alternative, safe and sustainable sources. This need is now being addressed through the engineering of plant oils to contain equivalent levels of EPA and DHA to those in fish oils. At the forefront of this effort is DHA-containing canola oil, for which commercial production is imminent. This new crop has recently received regulatory approvals from the Australian OGTR and FSANZ authorities and is currently undergoing equivalent regulatory assessments in the USA and Canada. The development of a DHA-rich canola crop is a triumph in plant metabolic engineering, both in the complexity of the biosynthetic pathways that have been transferred to higher plants, and in the number of genes that have been introduced to encode these pathways. The unavailability of antibodies for membrane-bound proteins necessitated the development and authorisation of new LC-MS based techniques to characterise the multiple enzymes involved in the introduced pathway, establish their seed-specific localisation in the transgenic plants, and confirm their breakdown during simulated human digestion processes. DHA-canola is a significant advance in the use of gene technology to develop improved food products that will have significant consumer benefits, and is expected to be a forerunner for further GM-based product enhancements. The regulatory assessment processes established for this crop may well have implications for such future GM crops involving engineering of metabolic pathways.
Paradigms for the interaction of nanoscale objects with living organisms

Kenneth Dawson
University College Dublin, Dublin, Ireland

Abstract

Man-made nanostructures are of the size and nature that they gain access to new biological (intracellular and other) compartments, and there are potentially endogenous energy dependent mechanisms to lead them there. We summarise the foundations and progress to date in this arena. In particular we clarify the range of nanoscale (surface, shape etc) control parameters that may determine the biological outcomes. These considerations suggest an enduring potential to target substances to specific locations, for benefit of therapeutics, and the progress to date is summarized.

In the (typical) absence of exquisite control of the nanoscale structures (and thereby processes) in vivo, nanoscale materials are (guided by biomolecular coronas derived from the biological environment) incorporated and ultimately processed within endogenous intra-, trans- and cellular trafficking and processing pathways. There they may persist for extended periods of weeks, months (or longer) potentially either leading to persistent dis-regulation of signaling and other biological processes, or slow degradative production of secondary (and other downstream) metabolites not commonly observed in other situations. The absence of much in depth understanding of the long term effects represents the most obvious risk in the arena.

It is clear that new future dimensions are opening up at the nanoscale, involving convergent outcomes between the nanoscale structures, gene editing, and other forms of biological intervention. These areas are in their infancy, but one can already see many of the key issues for the future.

As a community, and a society, our management of these arenas was dedicated, and sincere and quite effective, but we confronted new questions and issues, without the tools early on to deal with them. What we learned from responsible management of ‘risk’ issues (in the larger sense) may be useful for future generations of risk managers in other arenas.
PL IV: CHALLENGES IN THE DEVELOPMENT AND ADOPTION OF NOVEL BIOTECHNOLOGIES

Session organizers:
Carmen Vicién, University of Buenos Aires, Argentina and Camilla Beech, Cambea Consulting Ltd, United Kingdom

PL IV - 1

▶ Enabling innovation in agricultural breeding programs: promises and prospects

Alison Van Eenennaam
Department of Animal Science, University of California, Davis, California, USA

Abstract

The information provided by the sequencing of entire agricultural genomes has enabled the development of powerful new breeding methods such as genomic selection. Advances in assisted reproductive technologies, such as ovum pickup and in vitro maturation, have provided further tools for breeders to maximize the genetic contributions of highly productive individuals. Genetic engineering and genome editing go a step further, allowing breeders to introduce useful genetic variation, further improving the rate of genetic gain. Such variation may include the repair of genetic defects, the inactivation of undesired genes, and the introgression of useful alleles and haplotypes between breeds in the absence of linkage drag. Editing could also be used to accelerate the rate of genetic gain by altering other components of the breeder’s equation. This could involve increasing the intensity of selection by replacing the germ cell lineage of commercial breeding animals with cells derived from elite genetic lines, or decreasing the generation interval by enabling in vitro derivation of gametes. Public engagement efforts undertaken at UC Davis suggest public support for using gene editing to address animal welfare issues (e.g., dehorning). For editing to be incorporated into agricultural breeding schemes, it will need to seamlessly integrate with genetic improvement program design. This will ultimately require introducing edits into multiple elite lines to avoid genetic bottlenecks. This requirement is at odds with the process-based trigger and event-based regulatory approach that has been proposed for the products of gene editing by several economies. In the absence of regulatory harmony, researchers in some economies will have the ability use genome editing in food animals, while others will not, resulting in disparate access to these tools, and ultimately the potential for trade disruptions. The early applications that successfully navigate regulatory hurdles will likely influence the public discussion and impact the trajectory of future applications.
Establishing a community of practice around public sector product development

Donald J. MacKenzie
Donald Danforth Plant Science Center, St. Louis, Missouri, USA

Abstract

Development of new agricultural biotechnology crops in countries with new or emerging regulatory systems has been supported for many years by organizations like USAID and the Bill & Melinda Gates Foundation, often through public-private partnerships with academic institutions, national and international agricultural research organizations, and life-science and seed companies. Current projects are taking place in Asia and Africa, and include important food security crops (e.g., cowpea, cassava, banana etc.) and a range of traits intended to address biotic or abiotic stresses, or micronutrient deficiencies. Some products are now entering the pre-market regulatory review stage, and in some countries will be the first genetically engineered plants to undergo regulatory assessment. However, many of these countries are characterized by a lack of well-developed product regulatory pathways, the absence of clear guidance on the regulatory studies required to demonstrate environmental and food safety, and weaknesses in existing risk assessment, inspection, and enforcement capability. Individually, the projects face their own internal challenges, including access to product development expertise and the specialized organizational structure (e.g., regulatory affairs, regulatory science, quality control and quality assurance) and institutional capacity needed to retain and build upon lessons learned each time a product moves through the pipeline. This presentation will illustrate some of the challenges using case examples and will also describe efforts to build a community of practice to share individual project strategies, technical, regulatory, and stewardship approaches, and lessons learned. This will promote a cycle of continual learning and improvement that contributes to regulatory and product deployment success over the long term.
Local developments: why they have not reached the market yet?

Dalia Marcela Lewi
Instituto Nacional de Tecnología Agropecuaria, Buenos Aires, Argentina

Abstract
The history of the development of biotechnology in Argentina begins at the end of the 80s. This trajectory led to the development of numerous research groups in public institutions- and a decade later some private initiatives too-in order to obtain transgenic events with different purposes. The numerous scientific and technological capacities existing in the country allowed the early constitution of a solid regulatory system in 1991 with the formation of the CONABIA (National Advisory Commission on Agricultural Biotechnology) that was declared as a reference center by FAO in 2014. Commercial approvals began in 1996 and to date 52 events have obtained commercial approval, of which only 2 were developed locally from public-private consortiums. There are, however, numerous transgenic events with different objectives in different crops in public institutions (universities, research institutes): potatoes, alfalfa, wheat, corn, sunflower, sugar cane, soybeans, lettuce, fescue, cotton. However, once obtained in laboratories, these events find it difficult to move towards possible commercial approval. The reasons why local developments have not been able to cross the regulatory system are related to the lack of strategic vision in the institutions to focus resources on projects that develop biotechnological products. Thus, there are no grants with specific funds for regulatory tests, neither programs nor projects organizing scientific capacities to address them. Although progress has been made in generating some regulatory rules adapted for research institutes (such as the regulations for biosafety greenhouses), researchers still do not conceive of regulatory science as a discipline, in which a scientific career can develop, and generally prefer not to be involved in the design of trials or regulatory issues related to the evaluation of events. Consider forming a regulatory affairs department for the public scientific system could help.
Abiotic stress (drought) tolerant transgenic wheat

Patricia V. Miranda
Instituto de Agrobiotecnologia Rosario (INDEAR), Rosario, Argentina

Abstract

Water availability is nowadays one of the major parameters restricting crop production. Under the perspective of a limiting availability of arable land, effect of climate change on crop yields, shortage of conventional breeding on yield improvement and limitation of gene editing to address complex physiological processes, transgenesis remains a unique and valid approach.

The HB4® technology is based on the sunflower HaHB4 (Helianthus Annuus HomeoBox 4) gene, involved in the natural response to abiotic stress. Its mechanism of action is reflected in a reduced sensitivity to ethylene. This effect is mediated by the action of its expression product: the transcription factor HAHB4. The HB4® technology presents singular advantages: the HAHB4 protein has a history of safe use and, being a transcription factor, it is expressed at extremely low levels and exerts its action using the natural pathways of plant response to environmental stress.

The selected HB4 wheat event (IND-ØØ412-7) has been tested in the field since 2009. The HB4® technology allows the plant to keep active its biological processes when water availability become scarce while the non-transgenic counterparts trigger senescence. As a result, yields are higher in HB4-plants when compared to non-transgenic ones. No penalty has been observed in case of absence of abiotic stress episodes. On the other hand, the yield increased is proportional to the stress, reaching values around 20% under moderate stress conditions.

An extensive characterization, which included a wide range of studies, support the agronomic, compositional, nutritional and functional equivalence of the IND-ØØ412-7 event with conventional wheat, which confirmed its environmental and food/feed safety.
What dialogue is needed? The example of engagement for innovative genetic approaches to malaria elimination

Delphine Thizy
Target Malaria, Imperial College London, United Kingdom

Abstract

Recent history has demonstrated that evidence-based information about a particular technology's efficacy and safety is no longer sufficient to create trust and adoption (Hussain et al., 2018). If a well-established technology like vaccines to prevent measles is facing some growing adoption challenges, it is easy to imagine that novel biotechnologies, even in the field of public health like gene drive mosquitoes against malaria, will face challenges for their development and adoption.

Gene drive mosquitoes are an innovative genetic technology under development that could contribute to malaria elimination. While this technology is still under development, there are promising developments in the laboratories (Hammond et al., 2016; Kyrou et al., 2018). Based on these promises, the first opposition movements have emerged calling for moratorium on the research process or technology evaluation steps.

Scientific arguments and evidences are part of the response to such calls for moratorium and should guide evidence-based policy-making. However, in a period when bias in the production of evidence is questioned (Krimsky, 2013), a broader dialogue is needed to build trust with stakeholders and more broadly the public for the development and adoption of novel technologies.

This presentation will draw some lessons from the experience of Target Malaria in building trust and establishing a constructive dialogue leading to the co-development and potentially future adoption of a novel genetic technology for malaria control and elimination. This will look at the experience from African partners on the continent as well as broader experience at the global level engaging with civil society groups and policy makers.

References

PARALLEL SESSIONS
PS1: Scientific assessment of the food and feed safety of genetically engineered crops

Organizer:
Jay S. Petrick, Bayer CropScience, USA

PS I - 1

Framework for food safety assessment of GM crops: Codex and historical learnings

Lisa Kelly
Food Standards Australia New Zealand, Canberra, Australia

Abstract

The Codex guideline for the Conduct of Food Safety Assessment of Foods derived from Recombinant-DNA Plants (CAC/GL 45-2003) was adopted in 2003. According to the Codex guideline, the purpose of the GM food safety assessment is to identify new or altered hazards relative to the conventional counterpart, which is the benchmark for what is regarded as safe. The comparison is used to identify any differences, which are then further characterised to determine if they raise any safety concerns. Ultimately, the goal of the assessment is to determine whether the GM food is safe rather than how different/similar it is to the chosen comparator(s). The main elements of the food safety assessment are: molecular characterisation of the genetic modification; safety assessment of expressed substances; compositional analysis. The guideline specifies the types of studies necessary to address these three elements, and also provides guidance on their conduct.

While this assessment approach has been embraced by many governments around the world, over the years differences have developed in how the approach is being applied at a national level, including the type of studies that are required. This has generated debate about the extent to which the Codex guideline remains fit for purpose, given regulatory experience over the last 15 years and new scientific knowledge that has emerged since its adoption. The presentation will reflect on what has been learned from applying the Codex approach to GM food safety assessment, and will consider whether additional or different types of studies are necessary or likely to add value to the current assessment approach.
Compositional assessment and safety assessment in the light of natural variability

Rod Herman
Corteva Agriscience™ Agriculture Division of DowDuPont™, Indianapolis, IN., USA

Abstract

Precautionary regulation for genetically engineered (GE) crops was instituted >25 years ago due, in part, to potential unexpected effects on crop composition. Since that time, >100 studies have demonstrated that GE techniques cause fewer and less dramatic compositional effects compared with traditional breeding, and none have adversely affected health or safety. Furthermore, advancements in molecular biology confirm that the genetic effects of transgenesis are as expected. Similar to chemical- and radiation-induced mutations accompanying various traditional breeding methods, insertional mutagenesis is possible in GE crops, but changes are generally less widespread and more predictable. Thus, current evidence suggests more hypothesis based studies are now warranted compared with the comprehensive analyses required today. However, regulatory requirements have become increasingly cumbersome over time raising the cost of studies >10-fold, often justified on the basis of gaining public trust. In contrast, such requirements may actually have the opposite effect by giving credibility to unwarranted fears through official sanctioning of risks as worthy of investigation. Such regulation also impedes innovation and prevents all but the largest companies from developing GE crops, potentially further eroding trust.
Food and feed safety assessment of proteins expressed in genetically engineered (GE) crops

Jay S. Petrick
Bayer Crop Science, Chesterfield, MO, USA

Abstract

Enhancement of agricultural productivity can be achieved through expression of exogenous proteins in GE crops to confer tolerance to biotic and abiotic stresses, reduce use of agricultural inputs (e.g. insecticides), enable more sustainable production (e.g. no-till farming), and improve nutritional quality. These traits can result in yield protection and labor reductions, through effective management of insect and weed pressures. The proteins utilized to confer traits in GE crops undergo an extensive safety evaluation through application of an internationally accepted weight of the evidence approach first described by the Codex Alimentarius commission. This protein safety assessment consists of a two-tiered evaluation. The first-tier evaluation includes assessment of: (a) the source organism from which the proteins are derived, (b) their function and history of safe use, (c) a structural comparison to known toxins and allergens, and (d) their digestibility and heat lability. Further assurances of safety can be provided by considering familiarity and/or specificity of protein functional domains. When scientifically necessary, a second-tier mammalian toxicity study can be performed to build on the above weight of scientific evidence. This widely used and accepted protein safety assessment framework is scientifically robust, comprehensive, and broadly applicable to proteins expressed in GE crops, including classes of proteins not previously consumed in foods nor used in agricultural production.
PS2: New breeding technologies: regulatory hurdles for existing frameworks

Organizers:
Thorben Sprink, Julius Kühn-Institut, Germany and Detlef Bartsch, Federal Office of Consumer Protection and Food Safety, Germany

PS II - 1

► New breeding technologies: regulatory hurdles for existing frameworks

Detlef Bartsch¹, Thorben Sprink²
¹Institute for Biosafety in Plant Biotechnology, Federal Research Centre for Cultivated Plants, Julius Kühn-Institut (JKI), Berlin, Germany;
²Genetic Engineering Department, Federal Office of Consumer Protection and Food Safety (BVL)

Abstract

Genome editing technologies have been boosting plant and livestock breeding since only a few years, but already first promising products are pushing to the market. In contrast to this, in many countries the current Directives regulating genetically modified plants and animals have been established more than 20 years ago, based on clear differentiations between transgenic and conventional breeding. To date these directives aren’t suitable to face the new challenge of genetic engineering. This session will discuss the use of Genome Editing in plant and livestock breeding and will discuss how these techniques will change breeding in the future. The speakers of this session will give an insight in the current legislative frameworks of their countries and will discuss and evaluate the existing frameworks for regulation of genetically modified plants in a worldwide comparison. Furthermore, the speakers will discuss if there is a need for an updated legislation, regulating the use of organisms produced by novel genome editing techniques and by genetic engineering and how such legislation could be composed matching the scientific progress made in their corresponding position.
The CJEU ruling on new techniques of mutagenesis - a broad hint to EU law makers?

Georg Leggewie, Jens Kahrmann, Ulrich Ehlers, Detlef Bartsch
Federal Office of Consumer Protection and Food Safety (BVL), Berlin, Germany

Abstract

On July 25th, 2018, the Court of Justice of the European Union (CJEU) issued a decision of outstanding importance to Europe’s regulation of genetic engineering. The ruling said basically that all organisms obtained by means of techniques/methods of mutagenesis have to be considered as genetically modified organisms (GMO). It concluded further, that organisms created by new techniques of mutagenesis, e.g. genome editing (GE), do not fall under the exemption clause foreseen for organisms created by mutagenesis techniques that, according to the judges, must have been conventionally used in a number of applications and must have a long safety record. It follows that even single point mutations created by GE are to be regulated by Directive 2001/18/EC. In doing so, the ruling deep-freezes the usage of the exemption clause by excluding any scientific development after the year 2001. The process-based interpretation of the GMO-definition in Directive 2001/18/EC and the non-dynamic interpretation of recital 17 has been widely critizised by many scientists and, at least in Germany, by a huge part of mainstream media. It also started a discussion on to whether this disappointingly brief CJEU ruling should be understood as a hint to European lawmakers to think about a reformation of the in essence almost 30 year old legal framework. The discussion on how such an amendment of the Directive may be achieved was initiated in November 2018 by SAM, the Scientific Advisory Mechanism, a scientific advisory body to the European Commission. In a report, SAM recommended to the commission to revise the existing GMO directive to reflect current scientific knowledge and to strengthen a product based risk assessment. In theory, there are a number of different options to solve the problem created by the judges in Luxembourg: The modification of the GMO definition in Article 2(2) of the Directive in order to establish a more product oriented approach; an expansion of the exemptions laid down in Annex I B alongside a provision in the main text that allows for an amendment of the Annex via comitology procedure or a separate regulation with a science-based set of rules for genome edited organisms. This talk will summarize the present problems caused by the CJEU ruling and try to initiate a discussion on various possible regulatory amendments. However, there isn’t just one way of achieving a modern GMO regulation that will be fit for the future.

References

Current situation of NPBTs regulation in Latin America

Agustina Whelan
Biotechnology Directorate, State Secretariat of Foodstuff and Bioeconomy, Buenos Aires, Argentina

Abstract

From the moment that NBTs started to develop globally, Argentina decided to work in a special regulatory regime to determine if a product obtained using NBTs could be contemplated or not by the GMO resolution. After two years of debate a resolution becomes official, followed by Chile in 2017 and recently Brazil and Colombia. Due to the need to establish agile and synchronized regulatory criteria, representatives from more than 12 Latin American countries participated in “Genome Editing for Biotechnology Regulators in the Americas”, in Colombia. In this seminar, the countries that participated began to show great interest in being able to work on a regulation for these innovative products supporting the criteria used by Argentina, Chile, Brazil and Colombia who have similar resolutions. On the other hand, at the XXXVI Regular Meeting of the Council that took place in September 2018 in Buenos Aires, Argentina, Ministers of Agriculture of the CAS countries (Argentina, Brazil, Chile, Paraguay and Uruguay), signed a declaration supporting the importance of the use of these technologies for agriculture. In this presentation we will review the status of the regulation applicable to gene editing in various Latin American countries.
PARALLEL SESSIONS

The recent regulatory framework of genome editing organisms and foods in Japan

Yutaka Tabei
Institute of Agrobiological Sciences, National Agriculture and Food Research Organization (NARO), Tsukuba, Japan

Abstract:

The Japanese government has considered the handling of living organisms and foods prepared using genome editing techniques. In Japan, organisms with foreign genes are regulated as genetically modified organisms (GMOs). GMOs are evaluated their influence on biodiversity under the Cartagena domestic law, and genetically modified foods are also confirmed their safety under the Food Sanitary Law prior to commercialization.

Regulatory framework has been examined by relevant agencies based on different genome editing type (SDN-1, SDN-2 and SDN-3). The Ministry of Environment prepared a draft framework of genome editing organisms, which described the modified organisms produced by SDN-2 and SDN-3 are regulated as GMO, however, those by SDN-1, if those were null segregant, are not regulated under Cartagena domestic law. The basic regulatory policy for environmental safety of genome editing organisms was established.

In regulatory framework of genome editing foods, although being null segregant is major premise, it has been discussed whether the genome editing foods should be regulated by the Food Sanitary Law or new regulation is necessary. According to the draft prepared by the Ministry of Health, Labor and Welfare (MHLW), the products developed by SDN-3 will be regulated as genetically modified foods. On the other hand, regarding SDN-1 and SDN-2, it is appropriate to evaluate by modified DNA sequence as a result, rather than by the difference of genome editing types. As a product-based evaluation, this draft stated that genome editing foods will not be regulated as genetically modified foods if modified DNA sequences were indistinguishable from natural or artificial mutations. Meanwhile, MHLW requests developers to provide information for genome editing foods prior to commercialization on voluntary basis. While considering confidentiality, MHLW propose a mechanism to disclose a part of the information to the public. This policy is planned to be confirmed by the end of March 2019.
PS3: Familiarity in the context of risk assessment of transgenic crops in the Americas

Organizers:
Deise Capalbo, EMBRAPA Environment, Brazil and Carmen Vicién, University of Buenos Aires, Argentina

PS III - 2

Familiarity in the context of problem formulation

Clara Rubinstein
Bayer Crop Science Argentina, Buenos Aires, Argentina

Abstract

Risk Assessment criteria for transgenic organisms have been set decades ago, built on four fundamental pillars: case by case, comparative assessment, tiered approach, and consideration of the weight of evidence. While these pillars are still current and have been repeatedly validated along these years, both for environmental and food and feed safety assessment purposes, the use of the Problem Formulation (PF) methodology as the first step to formulate risk hypotheses, is of more recent application as a routine exercise, at least in formal reviews in different agencies. The concepts of Familiarity and History of Safe Use (HOSU) are part of PF, as the availability of existing information on the case under review, is a critical element that adds to the weight of evidence. These concepts do not replace the case by case approach and are not taken as safety standards, but are valuable components of the risk assessment process. In this way, HOSU and Familiarity help in the generation of risk hypotheses that are plausible and testable. Familiarity builds on existing knowledge (evidence/data) and experience in the use of technologies and products, in particular, those that have undergone a risk assessment process or for which substantial data is available. HOSU, on the other hand, would be preferably left for traditional uses, for which formal scientific knowledge is not available or may be limited.

As different countries apply these concepts in different ways, the terms “Familiarity” and “HOSU” still need to be clearly defined, formally included in guidelines and ideally, harmonized. Experience with the practice of risk assessment is in itself, a substantial component of familiarity too, which along with scientific advances, supports the evolution of evidence based risk assessment criteria.
The use of familiarity and a history of safe use in the decisions of the Brazilian National Biosafety Technical Commission

Patricia Machado Bueno Fernandes
Brazilian National Biosafety Technical Commission (CTNBio) and Federal University of Espírito Santo (UFES), Vitoria, Brazil

Abstract

The current GMO legislation in Brazil centers around Law nº 11.105/2005 (also known as Biosafety Law) and Norms and Technical opinions issued by CTNBio (the Brazilian National Biosafety Technical Commission). Even though neither the Biosafety Law nor CTNBio’s Normative Resolutions mention the terms “familiarity” and “history of safe use” in the context of Risk Assessment of Genetic Modified Organism (GMO) and their by-products, these concepts are implicit in the analyzes made by CTNBio members. Since, as stated by the Biosafety Law, all member of CTNBio must hold a doctorate degree and shall have acknowledged technical competence and notable participation and scientific learning, and have been professionally active in the biosafety, biotechnology, biology, human and animal health areas and the environment, the scientific method has to be present in their analysis. Moreover, the Law states on the Article 10, Sole paragraph: “CTNBio shall monitor the development and technical-scientific progress attained by the biosafety, biotechnology, bioethics and related areas, with aims at increasing their capacity of protecting human, animal and plant health and the environment”. Therefore, it is observed that the law itself stipulates in an intrinsic way that CTNBio’s decisions must be based on publications on the subject worldwide. Therefore, CTNBio’s decisions should reflect the degree of maturity of science and society.
The regulation of agricultural biotechnology and science. A Canadian perspective on the conceptual tools for problem formulation

Philip Macdonald
Canadian Food Inspection Agency, Ottawa, Canada

Abstract

The OECD was among the first to articulate some of the core principles of familiarity for GMO environmental risk assessment in the Blue Book in 1986. 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. Canada has actively sought to incorporate science in improving risk assessment methodologies for products that do not fit easily into conventional approaches, such as the use of plants as platforms for the production of industrial or immunotherapeutic products or the use of genome editing. Science remains the foundation for addressing not only new GM products but also the mass of information generated through the advances in genomics. Regulatory policy will help guide the problem formulation of the environmental risk assessment of a GM crop and familiarity is a tool that will shape the risk hypotheses. Examples of how these principles are operationalized in Canada will be discussed.
Case study: Transportability of virus resistant transgenic common bean- field studies from Brazil to Argentina

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2National Agri Food Health and Quality Service, Ciudad Autónoma de Buenos Aires, Argentina;
3Corteva Agriscience™ Agriculture Division of DowDuPont™, Ciudad Autónoma de Buenos Aires, Argentina;
4Bayer Argentina/Monsanto Argentina, Ciudad Autónoma de Buenos Aires, Argentina

Abstract

The conceptual framework for Data Transportability, builds on the premise that results from well-designed studies conducted for the environmental and food/feed risk assessment of transgenic crops may be relevant and therefore, transportable to other geographies. Looking to generate case study materials on data transportability, ILSI Argentina’s (International Life Sciences Institute) Biotechnology Working Group, convened a sub team to discuss the application of the framework to the case of a transgenic virus resistant common bean.

Bean crop (Phaseolus vulgaris) production took relevance in Argentina in the 70’s as an alternative for rotation with other crops. One of the main diseases causing important yield losses is golden mosaic, caused by the Bean Golden mosaic virus (BGMV). In 2011, Brazil approved a transgenic bean-resistant to BGMV for cultivation and consumption, that was developed by EMBRAPA (Brazilian Agricultural Research Company), through an RNA interference mechanism. The objective of this work is to analyze the set of studies developed by EMBRAPA to deregulate the event in Brazil, and discuss if they are transportable and sufficient for the purpose of an Environmental and Food and Feed risk assessment, according to the evaluation criteria for transgenic crops currently applied in Argentina.

Using the problem formulation methodology, the relevant questions were defined and the available information was identified. Throughout the exercise, risk hypotheses were identified and the assessment endpoints and data that would respond to these questions were defined. This discussion considered that data generated in field trials is transportable provided that trials were properly designed and conducted in diverse agroclimatic environments, allowing the expression of any biologically relevant phenotypic differences. Under these considerations, it should be analyzed if the evidence produced and the conclusions of these studies would be enough to respond to the risk hypotheses identified, without the need to generate additional in country data.
PS4: Open Session 1 - Building technical capacity in biosafety

Chair:
Wendy Craig, International Center for Genetic Engineering and Biotechnology, Italy

Measuring effectiveness of training

Hector Quemada¹, Wendy Craig⁴, Brinda Dass³, Adam DeHoek⁴, David O’Brochta³, Scott Shore⁵, Willy Tonui⁶
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Abstract

There has been much investment in strengthening the capacity of regulators to operate functional regulatory agencies and conduct science-based risk assessments, through workshops and other training methods. However, the paucity evidence-based measurement makes proof of training effectiveness difficult to document. Western Michigan University (WMU) and the Foundation for the National Institutes of Health (FNIH) are developing a series of workshops that are designed to develop an understanding of gene drive organisms and their applications; establish a basis for conducting or evaluating risk assessments, and making risk management decisions regarding gene drives; and build a framework and relationships for coordinated review of gene drive permit applications and collaborative policy development within countries and regionally.

To enhance the quality of training, WMU and FNIH are incorporating contemporary learning theory into the development of workshop content. Assessment tools, including pre and post measures of workshop-related content, are being developed to better measure the effectiveness of the training and to document short-term retention of knowledge.

In another approach, the International Centre for Genetic Engineering and Biotechnology (ICGEB) and the University of West Indies submitted to countries in CARICOM a mock dossier based on a genetically modified sterile mosquito with a record of previous regulatory approvals in other countries. Regulatory offices were assisted during the processing of the dossier, with problems identified and potential solutions offered. The results were helpful in assessing the preparedness of emerging regulatory systems in the Caribbean Region, and thus to measure the longer-term effectiveness of the technical assistance previously provided to those countries. ICGEB will share experiences and results from this exercise.

By presenting these two approaches, we aim to stimulate discussion on methods and approaches to obtain data that can be used to objectively and rigorously assess effectiveness of regulatory capacity building programs.
The ICGEB eLearning portfolio: Key outcomes and lessons learned

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International Centre for Genetic Engineering and Biotechnology (ICGEB), Trieste, Italy

Abstract

Most international cooperation agencies face the challenge of implementing capacity enhancement activities with in-built sustainability mechanisms in order to maintain their impact beyond funding depletion. With respect to targeted training, the demand is constantly increasing in the face of acknowledged limitations: it usually comprises a one-off event, it only reaches the limited number of stakeholders present, and repeating such events in different locations is usually not economically feasible. To address this issue, the use of eLearning platforms has arisen as an alternative, as a means of providing global, continuous and low-cost training to multiple audiences. With this in mind, under the framework of our biosafety capacity enhancement project for sub-Saharan Africa (SSA), the International Centre for Genetic Engineering and Biotechnology has recently launched a portfolio of online biosafety-related eLearning modules available for adoption worldwide. Incorporating new teaching methods and approaches to technology-assisted education, our online platform encompasses curriculum-based and peer-reviewed modules on legal, technical and regulatory matters associated with the biosafety of genetically modified organisms (GMOs; https://showcase-icgeb.elearning.it/). Currently, the portfolio is available to users in regulatory authorities of six SSA project countries, whilst efforts are underway to extend access to a greater number of African regulatory authorities, African product developers and international development agencies. This review presents the main features of our eLearning portfolio and key outcomes and lessons learned from our first group of associates located in SSA when administering and taking ownership of the portfolio. Adopting this eLearning approach can assist countries when building and enhancing their capacities in key aspects of biosafety, to result in transparent, effective and reliable GMO decision-making.
PARALLEL SESSIONS

PS IV - 3

Post-release monitoring: pathway to technology sustainability in Africa

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²Michigan State University, Michigan, USA

Abstract

Africa is in a period of transition, which demands exploring and harnessing advances made in modern biotechnology. Agriculture plays an important role in economic growth, enhancing food security, livelihoods, and rural development. Hence the need to explore and harness modern biotechnology as a key tool to achieve sustainable agriculture and economic growth. However, technology adoption in developing countries is dependent on various factors, some of which fall under a broad category related to characteristics and relative performance of the technology. The identification of direct, indirect, immediate, delayed, or unforeseeable effects that products of modern biotechnology and their application might cause on environment and human health throughout their lifecycle is essential. Effective monitoring will help in early detection of any potential and/or unintended effect, provision of evidence-based scientific facts on such effects to environment and human health, and assessment of performance. Moreover, the need for effective Post-Release Monitoring (PRM) system cannot be overemphasized considering some African countries have granted approvals for commercial release of genetically engineered crops while some others are moving towards commercial release. This paper highlights how PRM ensures the assessment of identified risks, identification of unanticipated effects and evaluation of performance of technology throughout the product’s lifecycle. In the absence of timely, accurate and evidence-based information due to inadequate PRM system, public confidence may be undermined thereby impacting technology adoption and sustainability. In addressing this, the Cartagena Protocol on Biosafety made provisions for monitoring of Living Modified Organisms in the receiving environment where there is uncertainty regarding the level of risk. However, the PRM element in most Biosafety regulatory frameworks in Africa needs to be strengthened considering the new horizons in biotechnology. This paper therefore, reiterates the rationale, plan, roles and responsibilities, as well as discusses challenges and opportunities for PRM vis-à-vis technology sustainability in Africa.
Strengthening biosafety compliance in public sector research institutions in India

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¹Biotech Consortium India Limited, New Delhi, India;
²Indian Council of Agriculture Research, New Delhi, India

Abstract

A “Program on Biosafety Awareness and Compliance Readiness”, was initiated at a pilot scale with an objective to strengthen the biosafety capacity within 10 ICAR institutions. The programme is being implemented jointly by Indian Council of Agricultural Research (ICAR), ILSI Research Foundation and Biotech Consortium India Limited (BCIL) under the South Asia Biosafety Program (SABP). This program consists of a series of capacity building activities to train 20 officers from 10 ICAR institutions nominated as Institutional Biosafety Officers (IBOs). Seven training programmes have been conducted so far on various aspects viz. biosafety regulations, roles and responsibilities of competent authorities, compliance monitoring at laboratory, greenhouse and confined field trials and audits. An ICAR Biosafety Portal has also been set up to provide relevant information for biosafety compliance. The programme is an attempt to ensure that performance standards vis-à-vis compliance with regulatory requirements are established in public sector research institutions engaged in development of genetically engineered plants. This presentation will share experiences and challenges in implementing the programme.
PS5: Science-based allergenicity risk assessment for food derived from genetically engineered crops

Organizer:
Ping Song, Corteva Agriscience, USA

PS V - 1

Evaluating potential risks of food allergy and celiac disease from intended and unintended changes in a genetically engineered food crops

Richard E. Goodman
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Abstract

Genetically engineered (GE) food crops were first approved in the United States in 1995 following guidelines published by the Food and Drug Administration. There have been suggested improvements by the CODEX Alimentarius Guideline and others, though the primary human health risk remains potential allergenicity or potential celiac disease compared to non-engineered genetically similar crops. Food allergy is specific to the individual consumer. Major allergenic sources are known globally and the number and characteristics of allergenic proteins has grown markedly since 1996.

Evaluate potential risks of food allergy and celiac disease of the gene donor organism and the recipient using keyword searches with the protein name using PubMed before transformation. Perform bioinformatics sequence comparisons to a validated, allergen database www.allergenonline.org current version using overall FASTA3 to identify long, high identity matches. Use the 80-mer FASTA for identities of >35% over 80AA. Review raw data and decide whether there are potential risks for some consumers using references and basic information from the database for allergenic proteins. If significant matches are found identify scientists and clinicians who are skilled in subject selection for serum tests and test methods that show specificity of binding. Perform a similar test with the NCBI Protein database using keyword limits allergen and allergy with BLASTP to identify matches of > 35% ID over 100 amino acid and collect references for matched proteins. Compare the protein sequence to the Celiac Database on AllergenOnline.org using Exact Ppeptide Match and then an overall FASTA alignment following criteria listed on the website. If questionable matches are identified, have a celiac expert test for T cell clonal activity or toxicity with celiac samples. Then potential junctional fusion proteins are evaluated and if needed by a country evaluate potential open reading frames of 30AA or greater throughout the insert and into the plant sequence.
In vitro gastro-intestinal digestion protocols for allergenicity assessment: are more physiological conditions helpful in separating allergens from non-allergens?

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Abstract

Background
Susceptibility to pepsin digestion of candidate transgene products is regarded an important parameter in the weight-of-evidence approach for allergenicity risk assessment of genetically modified (GM) crops. It has been argued that protocols used for this assessment should better reflect physiological conditions encountered in representative food consumption scenarios.

Aim
To evaluate whether inclusion of more physiological conditions, such as sub-optimal and lower pepsin concentrations, in combination with pancreatin digestion, improved the performance of digestibility protocols used in characterization of protein stability.

Methods
Four pairs of established allergens and their related non/weakly-allergenic counterparts (seed albumins, muscle tropomyosins, plant lipid transfer proteins [LTP] and collagens) plus fish parvalbumin, were subjected to nine combinations of pH (1.2 – 2.5 – 4.0) and pepsin-to-protein ratio (PPR: 10 – 1 – 0.1 U/µg) for pepsin digestion, followed by pancreatin digestion in the presence of bile salts. Digestion was monitored by SDS-PAGE in conjunction with Coomassie staining and immunoblotting using rabbit antisera and human IgE.

Results
At pH 4.0 and at PPR 0.1 most proteins, both allergen and non-allergen, were highly resistant to pepsin. Under conditions known to favor pepsin proteolysis, the established major allergens Ara h 2, Pru p 3 and Pen a 1 were highly resistant to proteolysis, while the allergen Cyp c 1 was not. However, this resistance to pepsin digestion only made Ara h 2 and to a lesser extent Pen a 1 and Pru p 3 stand out compared to their non-allergic counterparts. Largely irrespective of preceding pepsin digestion conditions, pancreatin digestion was very effective for all tested proteins, allergens and non-allergens, except for Cyp c 1 and bovine collagen.

Conclusion
Sub-optimal pH, low pepsin-to-protein ratio, and sequential pepsin and pancreatin digestion protocols do not improve the predictive value in distinguish allergens from non-allergens. Digestion conditions facilitating such distinction differ per protein pair.
Bioinformatic evaluation of newly introduced proteins in GM crops

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Abstract

Prior to government regulator approval of a GM crop for cultivation or importation, the GM crop undergoes an extensive, multifaceted safety evaluation. This evaluation includes an assessment of the potential allergenicity of the newly introduced transgenic protein(s) using bioinformatic methods. The goal of the bioinformatic assessment is to determine whether the transgenic protein shares sufficient sequence similarity with known allergens that it may itself be either an allergen or a cross-reactive allergen. The bioinformatic analysis used to draw such a conclusion is performed by comparing the transgenic protein sequence to a collection known allergen sequences such as those found in the COMPARE database using either the BLAST or FASTA sequence aligning program. The resultant alignment data are then reviewed in the context of the transgenic protein source organism, function and structural family. Since nearly all known allergens are related to one another by source organism and/or a structure/function relationship, the bioinformatic assessment provides a highly effective means of identifying potential allergenicity. Furthermore, because the bioinformatic assessment is repeated regularly during product development in coordination with allergen database updates, the results of the bioinformatic assessment can be used to discontinue product development if sequence similarity is identified between a transgenic protein and a newly identified allergen. A description of the databases, algorithms, alignment thresholds and considerations that are made when interpreting bioinformatic alignment data will be presented.
Celiac risk assessment of newly expressed proteins in GM crops using bioinformatics, its implications, potential issues, and proposed solutions

Ping Song, Rod A. Herman, Shravan Sukumar
Corteva Agriscience™, Agriculture Division of DowDuPont™, Indianapolis, USA

Abstract

EFSA (European Food Safety Authority) recently published an additional guideline on the celiac-disease risk assessment of GM crops. To evaluate the specificity of the recommended sequence identity searches in the context of risk assessment, protein sequences from celiac-disease-causing crops as well as from various food crops and animals not associated with celiac disease were compared with known HLA-DQ restricted epitopes and searched for the presence of motifs followed by peptide analysis. While the false-positive rate for a 9mer exact match with HLA-DQ2 peptides was found acceptable, searches for the presence of the Q/E-X1-P-X2-motif indicated very poor selectivity with an extremely high false-positive rate. Following current guidelines, more than 50% of the proteins in a given species must be subject to modeling to determine whether a hit of a 9mer containing the Q/E-X1-P-X2 motif could bind to known HLA-DQ2 or HLA-DQ8 receptors. Considering that current scientific evidence limits celiac disease incidence to the intake of grains from wheat, barley, rye, oat, and their closely related species such as the wheat subfamily (Pooideae), we propose that evaluation of newly expressed proteins in GM food crops for potential risk to elicit celiac disease should focus on genes derived from these four known celiac-causing food sources. In the case that bioinformatics analysis is indicated based on being sourced from these crops, identification of a 9mer exact match between a newly expressed protein and the known celiac disease peptides along with a supplementary sequence comparison (www.allergenonline.org/celiachome.shtml) is considered better suited to more specifically capture the potential risk of a newly expressed protein for celiac-disease risk. Furthermore, evaluation of several pareptide docking algorithms shows that the use of peptide modeling to determine the potential binding of a 9mer with the Q/E-X1-P-X2 motif or 3 mismatches to known HLA-DQ2 or DQ8 receptors should be approached in a case-by-case manner.
PARALLEL SESSIONS

PS6: Regulation & sustainability: enabling an innovative and sustainable bio-economy through a harmonized global biosafety framework for industrial biotechnology

Organizer:
Thiago Falda Leite, Brazilian Industrial Biotechnology Association

PS VI – 1

The new regulatory framework of genetically modified microorganism in Brazil: impact to industrial biotechnology development and its consequences to environment

Maria Sueli Soares Felipe
CTNBio - Comissão Técnica Nacional de Biossegurança, Brasília, Brazil

Abstract

Genetically Modified Organisms (GMOs) in Brazil are regulated by Law 11.105/2005 which provides for research and commercial use of GMOs and its derivatives. According to this legislation, previously to be commercialized it is mandatory to perform risk assessment to the environment and human and animal health, and to submit it to analysis of the Brazilian National Biosafety Technical Commission (CTNBio). It is well known that industrial biotechnology provides very powerful tools to contribute to sustainable development allowing, among others, reduction of energy use, production of biobased raw materials and sequestration of large volumes of carbon. In accordance with the brazilian legislation that provides that CTNBio must follow the development and scientific progress and considering the current and promised development of industrial biotechnology sector, CTNBio published the Normative Resolution No 21 (NR 21) that establishes specific norms to Genetically Modified Microorganisms (GMM) commercialization. Among the rules established in NR21 emphasis is placed on: i) specific procedures of risk assessment for GMMs with defined characteristics as those who the genetic modification have previously been approved by CTNBio, self-cloning GMM and those which the genetic modification is limited to a gene silencing; ii) specific procedures of risk assessment for GMM derivatives; iii) possibility, in specific situations, to submit more than one product in the same process and iv) Rules addressed commercial use of GMM which will be maintained exclusively under contention conditions. NR 21 was published in June 2018 and the first decisions about products submitted under these rules represented an important advance in timing for approval and also in the regulatory costs. In this context, this presentation aims to detail the main points of NR 21, focusing the impacts of these new rules to sectorial development, enabling the competitiveness of this important sector in the construction of a more sustainable future.
Advances in science and biosafety to build a green economy

Patrick Rüdelsheim, Greet Smets
Perseus BVBA, Sint-Martens-Latem, Belgium

Abstract

Integrating innovative lifescience tools with industrial processes enables game changing improvements of "old" technology, leading to superior production processes and products. While most countries promote the circular bioeconomy, the legal framework may require finetuning to create a conducive environment. As an example, we present the results of an analysis performed as part of an FP7 project, Nano3Bio (www.nano3bio.eu), of the EU regulatory framework applicable for the entire chain from research to development and production of chitosans. Conventionally, chitosans are derived from shrimp and other crustacean shells. Biotechnology offers an alternative route to produce chitosans and more importantly, specific chitosan structures tailored to the needs of a diversity of industries.

Our regulatory analysis focused on legislations that are applicable to operations, to specific product types and to the placing on the market of chitosan products. Important factors in determining the level of regulatory complexity are the derivation from animals, the use of genetically modified organisms (GMOs) in the production process, and additional requirements when considered nanomaterials. Analysing regulatory gaps and hurdles the following recommendations were formulated:

• Creating fast-track and reduced data requirements for biotechnology products replacing conventional products and harnessing the full potential of designed products.
• Applying the nanomaterial definition in a pragmatic way, ensuring that products are not stigmatised and subject to more requirements just because of a matter of definition.
• Further harmonisation of legislation and its implementation, in particular for aspects related to market introduction.
• Bridging the knowledge gap of hazards related to nanomaterials and establishing realistic regulatory study designs that deliver information adapted to competent authorities’ needs.
Combining advances in science and biosafety - impacts on the market

Fred Wondergem
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Abstract

The world economic and population growth have been increasing the demand for natural resources, energy, land, among others. Therefore, drastic changes in the environment, highlighting the growth of greenhouse gas emissions at levels that have never seen before, have been resulting in a global climate disruption. Several interconnected consequences resulting from such disruption, such as extreme weather events, biodiversity loss, water crises, and the associated side effects, can potentially lead to a collapse of the global economy. In this context, industrial biotechnology emerges as powerful tool providing solutions to mitigate these impacts and improve the quality of life. In this context, this presentation aims to discuss the advances of industrial biotechnology focusing on sustainable development, the safety of products and the interplay with regulations impacting the market.
PS7: Open Session 2 - Risk assessment and new technologies

Chair:
Andrew Roberts, ILSI Research Foundation, Washington DC, USA

PS VII - 1

Assessment of risks for human health and the environment of new developments in modern biotechnology

Petra Hogervorst, Eric Van Den Akker, Debora Glandorf, Pim Klaassen, Cécile Van Der Vlugt, Jaco Westra
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Abstract

Due to rapid developments in modern biotechnology, many new applications are expected in the next ten years. To be prepared, RIVM has developed a framework to assess whether the current risk assessment method for human health and the environment is still adequate. This framework was applied to a selection of nearly thirty new applications. The current risk assessment method appears to be adequate for about half of these. For the other half, the risk assessment method may no longer be adequate, or insufficient knowledge or information is available to effectively assess risks.

In the present study the risk assessment method for genetically modified organisms was reviewed. This method is used for living organisms whose genetic material has been modified, as has been the case for most current biotechnology applications. However, some new applications do not consist of living organisms. In the near future, for example, this will be the case for RNA sprays, which are used to suppress pests on crops. For such applications, the current risk assessment method may not be the best choice. For some applications that are still at an early stage of development, it remains unclear whether the current assessment method is usable. This applies, for example, to ‘orthogonal systems’, which use biochemical building blocks or DNA coding systems that are not found in nature.

It is concluded that in order to deal with the expected bottlenecks in the current risk assessment, there is a need to draw lessons from other risk assessment methods, to gather existing information and knowledge and to fill knowledge gaps.
Hazard characterization and risk assessment considerations for dsRNA agricultural products

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Abstract

The discovery and development of double-stranded RNA (dsRNA) products that confer protection from arthropod pests presents an additional mode of action with the potential to provide significant value in agriculture. The sequence specific nature of dsRNA-based products allows for targeting pest species with a high level of specificity, while mitigating risks to non-target organisms. Additionally, agricultural uses of nucleic acids have been shown to pose negligible risk to humans, other vertebrates, and non-responsive non-target organisms (NTOs) following dietary exposure, even those with high sequence similarity. Like other biologically based pest management technologies, registration and commercialization of these products requires science-based risk assessments to ensure these products are safe for humans and the environment. As is the case with traditional crop protection products, risk from a dsRNA arthropod control product is a function of potential hazard and environmental exposure.

This presentation will discuss the development of human and ecological risk assessments for a topically applied dsRNA developed to control Varroa mites in managed honey bee hives. As previously established with dsRNAs expressed in planta, the mode of action, activity spectrum and bioinformatics analysis can provide guidance for appropriate NTO testing and can be used to inform the human health risk assessment. Unique to this product is direct application to bee hives, a use pattern that will greatly limit environmental exposure. The problem formulation, hazard and exposure assessments, and impact on the risk assessment approach will be discussed. Finally, the risk assessments for this product will be discussed in context of a previously registered plant-expressed dsRNA for corn rootworm control and empirical toxicity data, highlighting that core tenants of assessing the potential for hazards and risks from dsRNAs are consistent regardless of dsRNA sequence, target gene, and product use pattern (i.e. topical vs. in planta).
EFSA's updated explanatory note on literature searching – Learning from experience

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³ York Health Economics Consortium (YHEC), University of York, United Kingdom

Abstract

In 2017, the European Food Safety Authority (EFSA) published an explanatory note on literature searching conducted in the context of GMO applications for (renewed) market authorisation and annual post-market environmental monitoring (PMEM) reports on GMOs authorised in the EU market (https://www.efsa.europa.eu/en/supporting/pub/en-1207). This explanatory note to the guidance: (1) clarifies the scope and methodology for literature searching; and (2) provides detailed recommendations on how to conduct and report systematic/extensive literature searches, and present the results of any scoping reviews, thereby complementing previous guidance of EFSA and its GMO Panel. Specific recommendations are given for: (1) formulating review questions and clarifying their purpose; (2) searching for/identifying relevant publications; (3) selecting publications; (4) extracting high level data from the relevant publications, where appropriate; and (5) summarising and reporting the data, and considering the implications of the findings. The explanatory note aims to: (1) assist applicants to perform consistent and sensitive literature searches; (2) ensure that as many relevant publications as possible are retrieved to minimise biases such as publication bias; and (3) ensure that sufficient detail about the search process and its results are provided to promote transparency, facilitate appraisal and enable reproducibility. In view of the experience gained in the application of the explanatory note, EFSA has updated its note to provide further guidance on some issues (e.g., search strategies through case studies, eligibility/inclusion criteria to establish relevance, approaches to identify search terms and subject indexing terms, reference publications, reviewers, reporting, search updates), or to relax former requirements (e.g., eligibility/inclusion criteria to establish relevance, searches of internet pages of key organisations), where appropriate. The revisions will be presented.
Sublethal endpoint assessment for NTOs - results from a workshop on non-Bt GE Plants

John Teem¹, Chad Boeckman², Jörg Romeis³, Marina Muhl⁴, Richard Hellmich¹, Fernando Valicente⁵, Andrew Roberts¹
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²Corteva Agriscience, Johnston, IA, USA;
³Agroscope, Zurich, Switzerland;
⁴Secretaría de Agroindustria, Buenos Aires, Argentina;
⁵Iowa State University, Ames, IA, USA;
⁶Embrapa Milho e Sorgo, Sete Lagoas, MG, Brazil;

Abstract

Historically, genetically engineered (GE) plants with pest protective traits have been based on insecticidal proteins (primarily derived from Bacillus thuringiensis – Bt proteins). As a result, most regulatory systems have developed standard test methods and data requirements for these GE plants that are well suited to addressing potential effects on non-target organisms (NTO). However, recent developments in multiple technologies have led to the production of GE plants that incorporate pest protection without pesticidal proteins (e.g., using RNAi) or use of proteins that are not functionally related to Bt proteins. Although the overall assessment paradigm for GE plants is robust, and can still be used to produce NTO assessments, there are ongoing discussions about the appropriate NTO tests, and measurement endpoints for these new technologies. When is it appropriate to conduct sublethal endpoint assessment testing and what types of assays should be employed? To answer such questions, results will be presented from an ILSI Research Foundation workshop involving academic, government and industry participants who considered possible sublethal effects of non-Bt GE plants in order to produce consensus points for guiding risk assessments of these products.
Managing adaptation of the potato late blight pathogen to disease resistance genes

Phillip Wharton¹, Sandesh Dangi¹, Nicholas Champouret¹, Hui Duan², David Douches³, Karen Hokanson⁴

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Abstract

Development of late blight resistant potato cultivars by classical breeding is continuously under threat due to rapid evolution of the late blight pathogen Phytophthora infestans. Though the U.S. P. infestans population is predominantly clonally propagating, we have still seen emergence of new strains over the past 10 years. In Indonesia P. infestans is sexually reproducing, yielding higher genetic diversity. To address this challenge, the USAID FtFBPP is working to transform potato cv. Granola, a popular Indonesian variety, with multiple P. infestans resistance Rpi-genes. To evaluate the potential durability of the three-gene stack in Indonesia, it is important to understand the genetic diversity of P. infestans strains in Indonesia. Isolates of P. infestans were collected from cultivars Atlantic and Granola growing in Pangalengan, Indonesia. Twenty-two isolates were extracted and analyzed using microsatellite markers. A comparison of allele sizes in Indonesian isolates compared to US and European standards, showed that they clustered into 3 groups which were different to those in US and European isolates. Isolates were also tested for the presence of P. infestans avirulence effectors Avr-blb1, Avr-vnt1, Avr-blb2, Avr2 and Avr3a. Potato resistance genes RB, Rpi-vnt1, Rpi-blb2, Rpi-mcq1 and R3a recognize these effectors. For resistance to be expressed in the plant, effectors need to be present in the P. infestans strain and the resistance genes need to be present in the plant. Results showed that one strain of P. infestans was missing the Avr-blb1 effector. Therefore, any new Indonesian cultivars containing the RB gene alone would be susceptible to this strain. This data will serve as a baseline to inform future deployment of genetically engineered potato and it will lead to integrated strategies to extend the efficacy and durability of these disease resistance genes through use of fungicides and deployment of specific potato lines.
PARALLEL SESSIONS

PS8: Targeted crop improvement: genome editing in the plant breeder’s tool box

Organizers:
John McMurdy, CropLife International, USA and Alessandra Salamini, Bayer Crop Science, USA

Abstract

Over the last few decades, the technologies of DNA sequencing, genomics, cellular transformation and gene editing have come together to underpin efficient molecular breeding and reverse genetics for crop and animal breeding. The main gene editing tools used both in basic and applied research and in commercial applications are: clustered regularly interspaced short palindromic repeats (CRISPR) coupled with a CRISPR-associated protein (Cas), zinc-finger nuclease (ZFN) and transcription activator-like effector nuclease (TALEN). Although differing in some details, these tools possess the common features of DNA sequence recognition and (usually) linked endonuclease activity. CRISPR utilises a single-guide RNA (sgRNA) to direct a Cas endonuclease (or a variant thereof) to a pre-determined genomic target whereas ZFNs and TALENs incorporate a Fok1 endonuclease linked to a sequence recognition domain of repeated amino acids. In all these examples, the binding of an exonuclease to a short, pre-determined target region in the DNA sequence of the host nuclear genome is normally designed to generate a double-strand break (DSB) at that site. Also in all these examples, there is a chance that DSBs also occur in genomic regions that are not the primary target. The majority of DSBs are repaired using the error-prone, non-homologous end joining (NHEJ) pathway which is native to the cell and which can introduce small insertions and deletions (indels) at or around the cut site. This function is analogous to the processes of DNA repair that every cell constantly (and naturally) performs to maintain the integrity of its genome. This has been described as ‘type 1’ gene editing by some authors. The NHEJ pathway can also be used to insert larger sequence into the DSB site by introducing an additional DNA fragment during the repair process. Depending on the host cell type, the alternative minor repair pathway, known as homology directed repair (HDR), can be also exploited to insert a DNA fragment into the DSB site. The use of in-vitro prepared DNA templates that are introduced alongside the gene editing machinery have been described as ‘type-2’ or ‘type-3’ editing depending on the length of the inserted sequence but without always defining the cut-off. An extreme example of this would be the insertion of one or more complete functional genes which may or may not be from a sexually-compatible organism and may or may not be targeted to their native allelic position in the host genome. The distinctions between these gene editing types have limited biological relevance but are important because they are being used by various global jurisdictions to define how regulate the products of such technologies.
Reflections on the UK’s first field trial of gene-edited plants and the impact of the ECJ ruling on European plant sciences

Johnathan Napier
Rothamsted Research, Harpenden, United Kingdom

Abstract

In 2018, the first field trial of a CRISPR-Cas-9 gene-edited crop was carried out at Rothamsted Research in the UK. DEFRA, the UK’s competent authority for regulatory oversight, concluded that the CRISPR-Cas9 gene-edited (GE) Camelina plants were not genetically modified organisms (GMO) and could therefore be sown without formal Consent from the Secretary of State. However, during this growing season, the European Court of Justice ruled that techniques such as gene-editing fall within the European Union’s 2001 GMO directive, meaning that the field-released GE Camelina was now reclassified as genetically modified (GM). I will describe our experience of running this trial and the legal transformation of our plants. I will consider the future of European plant research using gene-editing techniques, which now fall under the burden of GM regulation, and how this will likely impede translation and innovation of publicly-funded basic research. I will also highlight the continued importance of active communication and dialogue on all aspects of plant genetic modification, and the role researchers should play in obtaining societal consent. Despite all of these factors, it is clear that gene-editing has the potential to transform plant sciences and agriculture. Therefore, we should work collaboratively to identify useful targets to demonstrate the value of this new plant breeding tool.
Bringing consumer-focused products to market

Chloe Pavely
Calyxt, Inc., Roseville, MN, USA

Abstract

Calyxt, Inc. is a consumer-centric, food- and agriculture-focused company. Calyxt is pioneering a paradigm shift to deliver healthier food ingredients, such as healthier oils and high fiber wheat, for consumers and crop traits that benefit the environment and reduce pesticide applications, e.g. disease tolerance, for farmers. Calyxt develops non-transgenic crops leveraging processes that occur in nature by combining its leading gene-editing technology and technical expertise with its innovative commercial strategy. Calyxt is about to launch its first product, High Oleic Soybean Oil. I will discuss product value, the regulatory path and business model. I will also present our other upcoming product, High Fiber Wheat.
**The need for consistent genome editing policies globally to foster innovation in agriculture**

**Detlef Bartsch¹, Nicola Consmüller¹, Georg Leggewie¹, Thorben Sprink²**  
¹Genetic Engineering Department, Federal Office of Consumer Protection and Food Safety (BVL), Berlin, Germany;  
²Institute for Biosafety in Plant Biotechnology, Federal Research Centre for Cultivated Plants, Julius Kühn-Institut (JKI), Quedlinburg, Germany

**Abstract**

Innovation is only possible when four basic requirements are fulfilled: 1. Feasibility of the technology, 2. Desirability for society including consumers and technology users, 3. Viability for business and 4. Encouragement by policies and regulations. For the last point, globally harmonized regulatory policies are a prerequisite for realizing the benefits of technological innovation while decreasing unnecessary burden for international trade. Thus innovations in plant breeding like genome editing are dependent on appropriate regulatory frameworks, balancing environmental & health protection with room for fair economic development. Policymakers and the publics’ response to products developed using genome editing tools will ultimately determine their utility to plant breeders. The talk will give a brief overview and comparison of the current legislative frameworks for genetically modified plants in key countries and will discuss and evaluate these frameworks in the context of genome editing, topic covered in more depth in the parallel session: “New breeding technologies: Regulatory hurdles for existing frameworks”.
PARALLEL SESSIONS

PS9: Risk assessment and management of gene drive research

Organizer:
Fabio Niespolo, Outreach Network for Gene Drive Research, Puerto Real, Spain

Chair:
Delphine Thizy, Target Malaria, Imperial College London, UK

PS IX - 1

Safeguarding gene drive research: measures to support responsible research using gene drives

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¹GBIRd/Island Conservation, Raleigh, United States;
²National Wildlife Research Center WS/APHIS/USDA, Fort Collins, USA;
³North Carolina State University, Raleigh, USA;
⁴Island Conservation, Puerto Ayora, Ecuador;
⁵Island Conservation, Kelowna, Canada.

Abstract

The loss of biodiversity is intensified from extinctions caused by invasive rodents on islands. The use of widespread anticoagulant rodenticide to remove this threat from islands is effective for some of these islands, yet poses risks to wildlife, domestic animals and humans due to its high toxicity and lack of specificity. The Genetic Biocontrol of Invasive Rodents (GBIRd) partnership is an international consortium exploring the use of gene drive solutions to bias the sex ratio of invasive mouse populations on future target islands, causing eradication via inviability. Creating exclusively male or female populations may be achieved by linking sex-determining elements to genome editing mechanisms including CRISPR-Cas9 or t-complex meiotic drive found in Mus musculus. GBIRd is assuring safety using layered spatially limited genetic mechanisms and policy. Genomic effects of divergent evolution between islands and source populations of mainland mice lead to “locally fixed alleles” in island populations. These may be utilized as genome editing sites to limit the efficacy of this gene drive to target islands. Using biosafety best practices, active engagement with stakeholders and regulatory agencies from multiple countries, and biosecure captive trials, we aim to facilitate a thorough understanding of the risks and benefits of this technology. GBIRD is multinational and includes conservation practitioners, academic experts, and government scientists. Structured involvement of a semi-autonomous ethics committee during the development and potential delivery of this technology serves as another safeguard of our program.
Building an evaluation pathway to assess gene drive technology for malaria control

Hector Quemada
Western Michigan University, Kalamazoo, Michigan, USA

Abstract

Recent developments in gene drive research have led to a wide variety of proposals concerning the potential applications of resulting technologies, particularly in the fields of conservation and public health. Many of these proposals suggest using gene drive to limit the spread of vector-borne diseases, particularly those spread by insect vectors, such as malaria, which affect several hundred million people per year. However, the characteristics of this technology have raised concerns that necessitate careful consideration of the product development pathway, to ensure that any eventual uses do not pose unacceptable risks to local stakeholders or environments. In light of this, in 2018 a multidisciplinary group of experts from a wide range of countries, developed a set of recommendations entitled “Pathway to Deployment of Gene Drive Mosquitoes as a Potential Biocontrol Tool for Elimination of Malaria in Sub-Saharan Africa: Recommendations of a Scientific Working Group.” This presentation will discuss the comprehensive guidance provided by these recommendations in the context of risk assessment and management of broader applications of gene drive.
Ethical considerations raised by synthetic gene drive research

Aaron Roberts, Claudia Emerson
Institute on Ethics and Policy for Innovation, McMaster University, Hamilton, Canada

Abstract

The advent of synthetic gene drive technology is attended by great hope for powerful and promising applications. It also creates an intricate landscape of ethical issues demanding study, careful reflection, and stepwise navigation. Despite the tendency to believe that novel technologies raise novel ethical issues, it is more accurate to say that the moral issues surrounding gene drive technology are ones we’ve encountered before. This means that we have experience, guidance and previously developed risk and ethics assessment frameworks to draw upon and adapt as we tackle the ethical challenges posed by the research, testing, and potential use of synthetic gene drives. Notwithstanding this body of knowledge, the novelty of the technology and the multifaceted and ever changing geopolitical and cultural contexts of our world require that our thinking and approaches be responsive to this complexity to properly carry out risk assessment, governance, and regulation of this first-in-class technology. Synthetic gene drives raise a variety of ethical issues, each of which fall under one of two major categories: the philosophical, and the practical. I will identify ethical considerations from both categories but will spend most of my discussion focused on defining practical ethical issues, and explaining why attending to them is imperative to responsible development of synthetic gene drive technology.
Perspectives from a regulator on biosafety assessment of products containing gene drives

Martin Lema
Biotechnology Directorate, Ministry of Production, Argentina
National University of Quilmes, Argentina

Abstract

Products containing the so-called (artificial) “gene drives” are still a scientific novelty. Nevertheless, potential applications of high societal, environmental and/or commercial relevance have been identified and being developed already. Moreover, there are significant probabilities of developers submitting requests of permits for environmental release, of one or more of these products, in different parts of the world and in the next few years.
Therefore the regulatory community has begun to discuss how to handle this technology at the national as well as the international level.
This presentation will ruminate on the conceptual and technical challenges that products derived from gene drives may pose to regulators when actually facing a concrete submission. This would be an anticipation exercise aimed at fostering discussions around of applicable regulations and criteria, and subsequently the need or not of regulatory updates. The objective is to have regulatory frameworks prepared to handle with efficiency these technologies in the near future.
In addition, some impressions gained during the latest technical debates about this topic in the Convention of Biological Diversity will be shared.
PS10: Fall armyworm IPM in Africa and Asia - The challenge of creating an enabling environment for knowledge, policy and tools

Organizers: Joe Huesing and Regina Eddy, United States Agency for International Development, Washington, USA

PS X - 1

The fall armyworm in Africa and Asia – Lessons on controlling an invasive pest in the developing world

Joseph Huesing and Regina Eddy
USAID - U.S. Agency for International Development/ Bureau for Food Security, Webster, USA

Abstract

Native to the Americas, the Fall Armyworm (Spodoptera frugiperda) was first reported as an invasive pest in West Africa in 2016. Since that time the pest has been confirmed in nearly every African country of Sub-Saharan Africa. Today the pest is rapidly spreading across Asia and is confirmed in Bangladesh, China, India and Myanmar. In response, the U.S. Government created a FAW Task Force under the lead of USAID to align with system actors to rapidly mitigate losses to the pest. The Task Force identified three thematic areas on which to focus: Knowledge, Tools and Policy. Knowledge addresses the need for farmer training in GAP/IPM. Tools addresses the key technologies used in the Americas to control FAW, namely GM crops and pesticides. Finally Policies are key to farmers having rapid access to the latest technologies as well as in creating the enabling environment for the private sector to service the needs of the small holder farmer.
PARALLEL SESSIONS

PS X - 2

► Risk considerations in technology selection for FAW and other invasive pests

Paul Jepson
College of Agricultural Sciences, Oregon State University, Corvallis, USA

Abstract

The initial response to fall army worm has been dominated by use of broad spectrum pesticides. This carries significant hazards and quantifiable risks. These will be reviewed in some detail to clarify the level of knowledge and understanding that currently exists, and to illustrate the magnitude of the problems of achieving progress in risk reduction through regulation, or through education. Technologies are available that can circumvent these challenges, and achieve risk reduction among small farmers, and sustain crop production. We will discuss the role and purpose of comparative risk assessment in facilitating conversations and processes that enable technology adoption.
Fall Armyworm *Spodoptera frugiperda* in Asia, an update from Thailand

Mao Chen  
Bayer Crop Science, Singapore

**Abstract**

Fall armyworm (FAW), *Spodoptera frugiperda*, used to be a major insect pest only in tropical and subtropical areas of the Americas, however since its first discovery in central and western Africa in early 2016, it has rapidly spread to almost all Sub-Saharan Africa, except in Djibouti and Lesotho. At the end of July 2018, FAW was detected in India and Yemen as the first occurrence in Asia. In December 2018, it was discovered in Thailand. FAW is now probably the most dangerous invasive insect pest in Asia and Africa countries because of absence of biological control by natural enemies and good management experiences and practices in Asia and Africa. FAW feeds on a wide range of host plants including corn and rice which are the two major staple crops in Asia Africa. In this talk, we’d like to provide a current view of FAW spreading in Thailand, its impact on corn, rice and other crops, options for effective control of FAW. Most importantly, we’d like to raise the awareness of this devastating insect pest to millions of small holder farmers in Asia countries.
PARALLEL SESSIONS

PS X - 4

Aligning policy and science for effective regulatory decision-making

Alan Raybould
Syngenta Crop Protection AG, Basel, Switzerland

Abstract

Rapid and predictable regulatory decision-making can contribute significantly to the successful development and deployment of products that help farmers to cope with immediate, critical problems, such as the spread of FAW. Good decision-making flows from having clear policy objectives and explicit criteria for determining that a particular course of action is more likely to achieve those objectives than are other options. Such an approach enables existing knowledge and data to be organised quickly and effectively to make decisions about a proposed product use; in effect, the data are used to test the hypothesis that use of the product meets certain acceptability criteria. The practical implementation and advantages of this approach to regulatory decision-making will be discussed.
Gene drives allow for a trait to be distributed throughout a population deviating from Mendelian inheritance. Active in sexually-reproducing species, they are powerful tools to “drive” a gene, i.e. increase its frequency, independent of external selection pressure. They have been proposed as offering solutions for challenges in public health, agriculture, conservation and others. They have inspired researchers to use gene drives to combat diseases transmitted by insects such as malaria, dengue and Zika. For decennia attempts have been made to use or modify naturally occurring gene drive mechanisms. In recent years advances in genetics have allowed for co-opting natural gene drive systems and the development of synthetic gene drive systems.

We report on a study commissioned by the Netherlands Commission on Genetic Modification (COGEM) to map experience with gene drive systems, both natural and synthetic, in order to inform the risk assessment. Key-findings include:

- Research on synthetic gene drives is so far limited to lab experiments and modelling;
- Field (cage) experiments and releases are almost exclusively with mosquitoes;
- The most advanced programme is the release of Wolbachia-infected Aedes aegypti in several parts of the world to fight mosquito-vectored human diseases;
- When evaluating the possible effect both the impact of the gene drive as well as of the “load” or gene of interest must be taken into account;
- “Success” depends on the biology of the host organism, population dynamics, the drive’s efficacy, its fitness cost to the host, resistance development by the host and fitness cost of the “load”;
- Depending on these factors, an increasing proportion of gene drive-bearing individuals will be required to result in a successful invasion;
- Gene drives are delicate constructs and safeguards can be built in when working with CRISPR/Cas systems to avoid that they are created by chance.
The first field release of a genetically engineered, self-limiting insect in North America and its potential for pest management

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Abstract

Biologically-based pest management approaches are sorely needed to ensure sustainable production of crops with minimal hazard to humans and the environment. A promising approach utilizes genetic engineering to create ‘self-limiting’ insects that carry a gene that, after mating with wild counterparts, prevents female offspring from surviving. Sustained releases of self-limiting males will lead to pest population declines. We have used a self-limiting strain of the diamondback moth (DBM), a global pest of crucifers, in a series of studies conducted in the laboratory, greenhouse and open-field to explore its potential for pest management. The strain is identified as OX4319L. Laboratory studies found no differences in mating competitiveness or population growth rates between the OX4319L and a wild-type strain. Few differences in longevity were found between strains. Studies in a wind tunnel indicated that OX4319L males responded to a synthetic DBM pheromone in a similar manner as individuals from three wild-type strains of DBM. Collectively, these laboratory studies indicated OX4319L males were similar to wild-type males, except for the formers’ self-limiting trait. In greenhouse experiments, introductions of OX4319L males into wild-type populations led to rapid pest population decline, and then elimination. In separate experiments on broccoli plants, relatively low-level releases of OX4319L males in combination with broccoli expressing Cry1Ac (Bt broccoli) suppressed population growth and delayed the spread of Bt resistance. In a series of mark-release-recapture field studies with OX4319L males and its wild-type counterpart, the dispersal, persistence and field survival of each strain were measured. In most cases, no differences were detected in these parameters. Using results from these studies, mathematical models were developed that indicate release of OX4319L males will offer efficacious pest management.
PS XI - 3

Advances in genetic modification techniques and challenges in detection of GMOs on a regulatory perspective

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Abstract

Cultivation of genetically modified (GM) crops got a great momentum after its commercialization in 1996. The data shows tremendous growth of about 112-fold increase in its cultivation globally for the past 21 years (ISAAA, 2017) made it as the fastest adopted crop technology in the history of modern agriculture. India, one of the biotech megacountry, grew about 11.4 million hectares of Bt Cotton is also actively involving in the research and development of GM plants through several public and private sector institutions. The commercialization of GMOs are strictly regulated, and in order to comply with these regulations, suitable and effective detection methods are required. To the recent past, GM events have been developed by introducing transgene into the plant genome. The detection method of choice by most of the laboratories were targeting those transgenes, marker genes and specific GM events. Further, the crop development utilizing genome editing technologies were evolved and such crops were not considered under the purview of GM crops by some countries which doesn't require to be regulated. Whereas, in case of other countries the gene-edited crops also should be subject to the same stringent regulations that govern conventional GM crops. In India, the definition of genetic engineering in the Rules, 1989 implies that, new genome engineering technologies including gene editing and gene drives, may be covered under the rules. This scenario will add to the complexity of detecting authorized and unauthorized GMOs. Presently, the internationally accepted and standard methods available are mainly based on GM crops developed by trans-genesis. Therefore, it is the need of hour for the enforcement & regulatory laboratories to be equipped with appropriate detection methods based on more advanced technologies such as whole-genome sequencing which could be applied without prior knowledge on the DNA sequences considering the latest advancements in crop technology.
Assessing the risk of resistance development of the target pest Sesamia nonagrioides to Bt maize in the EU

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²University of Minnesota, Saint Paul, MN, USA;
³Centro de Investigaciones Biológicas (CSIC), Madrid, Spain.

Abstract

In the EU, the cultivation of Bt maize expressing the insecticidal toxin Cry1Ab is subjected to regulations that guarantee its safety for the environment. Resistance monitoring is a key element of the Post-Market Environmental Monitoring (PMEM) of Bt maize. It aims at detecting shifts in the susceptibility of the target pests to the toxin Cry1Ab that could be indicative of resistance evolution, considered as the main threat for the long term sustainability of Bt maize. Insect resistance management in the EU is based in the strategy known as high-dose/refuge (HDR). For this strategy to be effective, resistance must be recessive and the frequency of resistance alleles low (<0.001). We have evaluated whether these requirements are being met in populations of Sesamia nonagrioides from the Ebro Valley, the only hotspot for resistance evolution in the EU. The results of an F₂ screen carried out in 2016 indicate that the frequency of resistance alleles in the Ebro Valley was not significantly different from the value estimated in 2004-2005, and that it is increasing as predicted by the existing S. nonagrioides resistance evolution model. These findings suggest that the HDR strategy is effectively delaying resistance evolution in this area. However, the frequency of resistance alleles in 2016 (0.0036) was more than triple the value recommended for the effective implementation of this strategy, indicating the importance of continuing with the careful and thorough monitoring in this area. Additionally, a resistance allele was detected in one of the lines screened in the F₂, making out the first resistance allele reported in the EU to Bt maize. Early results in the undergoing selection of this line for resistance to Bt maize shed light on the dominance of resistance and its effect on the susceptibility of S. nonagrioides to the protein Cry1Ab.
Regulation of genetically modified organisms and new breeding technologies: Brazilian experience

Edivaldo Domigues Velini¹, Alexandre Lima Nepomuceno², Rubens José Nascimento³, Maria Lucia Zaidan Dagli⁴, Maria Sueli Soares Felipe⁵

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²Embrapa Soja, Londrina, PR, Brazil;
³CTNBio Office of the Executive-Secretary, Brasília, DF, Brazil;
⁴Department of Pathology, College of Veterinary Medicine and Zootechny, University of São Paulo, São Paulo, SP, Brazil;
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Abstract

In Brazil, genetically modified organisms (GMOs) are regulated by law 11,105/05. This law put an end to the dispute surrounding GMOs in the Country, caused by a conflict between the previous biosafety law (nº 8,974/95) and the environmental law. As a result of this controversy, from 1995 to 2004, only three GMOs were approved in Brazil (one herbicide tolerant soybean and two vaccines). Although the National Technical Biosafety Committee (CTNBio) existed since 1995, only with Law 11,105/05 was established that it would become the authority, of a consultative and deliberative nature, on biosafety of GMOs and its derivatives. The passing of the Law granted CTNBio the legitimacy it needed to perform technical analysis and make available innovations that have benefited Brazilian agriculture, health care, energy and several other sectors. As a consequence, in the next decade, from 2005 to 2014, 62 GMOs were approved. These approvals were composed by 38 GM plants, 18 vaccines, five microorganisms and one insect. During the last two decades, CTNBio was able to develop, modernize and propose the best possible scientific criteria to perform its duties. The accumulated learning in 20 years (including the first GM bean and GM mosquito of the world) coupled with the capacity build from the exchange with mature international biosafety legislations, led to an even more efficient process. From 2015 on, with the approvals of new normatives the rhythm of analysis increased preserving a rigorous scientific approach. Between 2015 and 2018, in only four years, 82 GMOs were approved by the Committee (46 plants, 18 vaccines, 17 microorganisms and 1 medicine). Among these, it is worth mentioning the first GM eucalyptus (2015) and the first GM sugarcane (2017) of the world. Additionally, in 2018, CTNBio approved a new normative regarding gene editing. Biosafety system deal with evolving concepts and technologies and CTNBio have been working on the adjustment of its procedures and requirements to remain functional. The next challenge in this fast moving and ever-changing process is to explore modern science-based concepts that shall increase the effectiveness of Brazilian regulatory body and keep Brazil updated to innovations.
PARALLEL SESSIONS

PS12: Developing innovative genetic technologies for malaria control: risk assessment and stakeholder engagement for field testing

Organizer:
Delphine Thizy, Target Malaria, Imperial College London, United Kingdom

PS XII - 1

▶ Introduction to Target Malaria: co-development for success

Delphine Thizy
Target Malaria, Imperial College London, United Kingdom

Abstract

Gene drive mosquitoes are an innovative genetic technology under development that could contribute to malaria elimination. While this technology is still under development, there are promising developments in the laboratories (Hammond et al., 2016; Kyrou et al., 2018), calling for early thinking about the process to evaluate it. Several institutions and groups have started to analyse whether the current frameworks could be used to evaluate future gene drive technologies or what improvements or changes would be required (Australian Academy of Science, 2017; National Academies of Sciences Engineering and Medicine, 2016).

In the emerging literature as well as in the media coverage on this topic, the question of stakeholders’ participation in the development of this technologies is often discussed (National Academies of Sciences Engineering and Medicine, 2016; Resnik, 2017; Van Mil, Hopkins, & Kinsella, 2017). Target Malaria has been working for several years in this field and has been reflecting on how to engage and integrate stakeholders’ perspectives into its development. This is based on a strong commitment to the values of co-development, openness and accountability, which are part of the core values of the project. This is an example of how R&D projects can move away from a more traditional engagement process based on a knowledge deficit model (Marris, 2015) to engage in a real dialogue where stakeholders are contributing to a process.

This presentation will discuss practical examples of how Target Malaria is approaching stakeholder engagement in the perspective of co-development, including how this aspect related to risk assessment.

References

PARALLEL SESSIONS

PS XII - 2

The importance of preparedness – plans and steps for innovation in the field of genetic technologies for malaria control

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¹Institut de Recherche en Sciences de la Santé, Bobo Dioulasso, Burkina Faso;
²Target Malaria, Imperial College London, London, United Kingdom.

Abstract

Laboratory contained research with genetically modified arthropods is not new, genetic modification of the germline in a malaria vector was first demonstrated at Imperial College in the early 2000 (Catteruccia et al. 2000). Containment measures for genetically modified arthropods are well documented and accepted (Benedict, 2003). However for Burkina Faso and more generally for Africa until recently no contained research with a genetically modified mosquito had ever taken place. The Institut de Recherche en Sciences de la Santé was the first institution to receive a regulatory authorization in 2016 to import and carry contained use studies on genetically modified mosquitoes in Africa as part of the Target Malaria project.

This authorization was the result of important preparedness work in this institution. Based on existing guidance, and technical support from Target Malaria partners, important work was carried-out to lay biosafety grounds for future contained work. This went from the renovation of a laboratory to comply with arthropod containment level 2, to the documentation of Standard Operating Procedures for all activities to take place in the lab, to the training of the local scientists and technicians on biosafety and compliance to regulatory authorization.

Building from the experience of the partner laboratories of Imperial College London and University of Perugia, the IRSS team established processes and protocols to manage safely the contained studies. This whole process was reviewed as part of the national biosafety regulatory process and led to the authorization for contained studies with genetically modified sterile male mosquitoes, which were imported in November 2016 and have since then been in containment in Bobo Dioulasso, Burkina Faso.

This presentation will share the processes put in place to comply with biosafety, containment measures, outdoor monitoring, and other measures relevant. It will also discuss challenges and opportunities for technology and knowledge transfer to African scientists.

References


Pathway to deployment of gene drive mosquitoes as a potential biocontrol tool for elimination of malaria in sub-Saharan Africa

Brinda Dass
Foundation for the National Institutes of Health, North Bethesda, USA

Abstract

Despite best efforts using available control tools, the 2018 World Malaria Report indicated recent progress in reducing malaria mortality has leveled off, particularly in Africa. Additional affordable and sustainable tools are needed to achieve malaria elimination.

After decades of research on harnessing naturally occurring drive mechanisms to insert beneficial traits into vector mosquito populations to control disease transmission, mosquitoes modified with synthetic gene drive systems, such as those based on CRISPR/Cas, show promise in the laboratory. Modeling predicts that gene drive strategies for reducing or modifying vector mosquitoes have the potential to provide a transformative tool for conquering malaria. However, the characteristics of persistence and spread that make gene drive-modified mosquitoes attractive as a durable new control tool have raised concerns about possible ecosystem or health effects that necessitate careful consideration of the product development pathway by researchers, regulators, and funders before field-testing begins.

This presentation will review the recommendations of a multidisciplinary working group of international experts in mosquito research, containment/quarantine of arthropods, modeling, epidemiology, clinical trial design, statistics, ethics, regulatory science and policy, which considered the implications of low threshold gene drive mosquitoes for reduction of malaria transmission by *Anopheles gambiae* s.l. mosquitoes in Africa on the phased testing pathway and best practices for evaluating genetically modified mosquitoes as public health tools that were described in the World Health Organization Guidance Framework for testing genetically modified mosquitoes. Specifically, it will describe a testing plan that seeks to maximize safety by incrementally increasing human and environmental exposure to the product. Recommendations for addressing important challenges presented by field testing of gene drive mosquitoes will be discussed. While the recommendations directly relate to malaria transmission in Africa, it is expected that they would be relevant to development of gene drive approaches for other vectors and prevention of other vector-borne diseases.
Mapping inputs and evidence to support regulatory decision making for target malaria gene drive strategies

Geoff Turner
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Abstract

Existing guidance for the risk assessment of genetically modified organisms has principally evolved from crop based applications which are generally not intended to persist and spread by design. Persistence and spread is however an intended effect of synthetic gene-drive strategies envisaged by Target Malaria for vector control in Sub-Saharan Africa. As recommendations to inform biosafety decision making in the area of gene drives and synthetic biology are proposed by various international, regional and national bodies, and more generally in the literature, there is an emerging consensus that regulatory decision making should be informed by multidisciplinary inputs beyond those established in existing guidance. Target Malaria has been working to understand how emerging tools and risk assessment paradigms such as quantitative ecological risk assessment and socioeconomic impact assessment can better inform potential future regulatory applications for synthetic gene-drive Anopheles mosquitoes. Lessons learned will be built into comprehensive impact assessment models aligned with international obligations, and focused on protection goals common across the regulatory landscape.

This talk will share experiences towards advancing the development of project best practices to support regulatory decision making for potential Target Malaria synthetic gene drive strategies envisaged for Malaria vector control.
**PS13: Opportunities and challenges in public sector biotechnology crop improvement**

**Organizer:**
Donald MacKenzie, Institute for International Crop Improvement, Donald Danforth Plant Science Center, St. Louis, USA

**PS XIII - 1**

> Uncertain regulatory and policy environments. Lessons from the Virus Resistant Cassava for Africa Plus (VIRCA Plus) project in Kenya and Uganda

Andrew Kiggundu¹, Nigel Taylor¹, Barbara Mugwanya Zawedde², Catherine Taracha³, Donald MacKenzie¹

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**Abstract**

Cassava (*Manihot esculenta*) is a major staple food crop in Africa where it provides basic food subsistence and income to rural households. Two virus diseases; Cassava mosaic disease (CMD) and Cassava brown streak disease (CBSD), presently constrain sustainable cassava productivity. Whereas conventional breeding of varieties with resistance to CMD has made considerable success, no varieties with CBSD resistance are available to farmers. The Virus Resistant Cassava for Africa Plus (VIRCA Plus) project initiated a genetic engineering (GE) approach and developed RNA interference (RNAi)-mediated resistance against CBSD in elite cassava varieties that possess inherent resistant to CMD. In a second approach, a crossbreeding program with GE selections has generated several hundreds of lines showing combined field resistance to CMD and CBSD. The project is currently in the final stages of completing the molecular-genetic characterization, comparative phenotypic and compositional studies needed to support a regulatory application for general release. However, the regulatory pathways in Kenya and more so in Uganda have remained a considerable challenge. This paper reviews the status of the project and regulatory environments in Kenya and Uganda ahead of delivering a cassava product with dual virus disease resistance to farmers in the region.
Public sector efforts on agricultural biotechnology development – Case of PBR cowpea in Africa

Onyekachi Francis Nwankwo¹, Mohammad F Ishiyaku², Tjv Higgins³, Francis Nang’ayo¹, James Okeno¹, Donald J. Mackenzie⁴, Issoufou Kollo Abdourhamane¹, Oluseun Bolarinwa¹

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Abstract

The legume pod borer, Maruca vitrata, is one of the most devastating insect pests limiting cowpea (Vigna unguiculata Walp) production in Africa. In the absence of genetic resistance, the management of the pod borer relies on the use of chemical insecticides which are often ineffective. AATF in collaboration with public/private organizations is implementing the development and deployment of farmer-preferred and locally adapted pod borer resistant (PBR) cowpea varieties in Sub-Saharan Africa (SSA). PBR cowpea varieties were developed to produce the Cry1Ab insecticidal protein from Bacillus thuringiensis using Agrobacterium tumefaciens-mediated transformation of the cowpea variety IT86D-1010. The Bt-Cry1Ab expressing events were tested under severe artificial infestation and event 709A was selected as a parental line to introgress the Cry1Ab trait into farmer-preferred varieties. In confined experimental field trials and in confined farmer-managed field trials, PBR-cowpea consistently gave higher grain yields (20-80%) than the conventional cowpea variety and reduced the need for insecticidal sprays from 6-10 to 2 per season. The regulatory dossier for commercial release of the PBR cowpea in Nigeria has been submitted to the National Biosafety Management Agency for its review and decision. This paper highlights public sector efforts at PBR cowpea product development, with particular focus on effective product stewardship and biosafety regulation in Africa.
Recent advances on research and development of golden rice in Bangladesh

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Abstract

Vitamin A deficiency (VAD) is a widespread public health problem in the developing countries in South and South-east Asia where rice, which lacks beta-carotene, a precursor of vitamin A, makes up nearly two-thirds of caloric intake. As a complementary, sustainable, food-based approach to reducing VAD in high rice-consuming countries like Bangladesh, Golden Rice was developed using biotechnology to express the enzymes necessary to produce beta-carotene in the rice endosperm. Completion of the beta-carotene biosynthetic pathway was accomplished through endosperm-specific expression of the maize phytoene synthase enzyme and a phytoene desaturase enzyme from Pantoea ananatis. The Bangladesh Rice Research Institute (BRRI) is working on the development of locally adapted Golden Rice varieties in collaboration with International Rice Research Institute (IRRI). Evaluation of BRRI dhan29 containing the GR2E Golden Rice event has been ongoing in Bangladesh since 2015 under contained and then confined field conditions. Confined field trials (CFTs) were conducted from 2016 to 2018 in different locations in Bangladesh to generate agronomic and phenotypic data to complete the environmental risk assessment as required by the National Committee on Biosafety (NCB). Simultaneously, nutrient composition data and protein safety studies were completed with the assistance of IRRI. All these data have been submitted to the NCB for assessment and consideration for environmental and food safety clearance. During greenhouse evaluations and CFTs, GR2E introgression lines were carefully selected to have equivalent agronomic performance to the parental BRRI dhan29 variety and to express high concentrations of carotenoids in the grain. Across years and locations, grain yield of the best-performing GR2E line compared to the BRRI dhan29 parent was not significantly different (+2.9 percent advantage to GR2E) and mean total carotenoid concentration in the milled GR2E rice after two months storage at ambient temperature was approximately 12 ppm, with a retention rate of 85 percent after cooking. Considering the estimated average requirement (EAR) for vitamin A and the bioavailability and bioconversion efficiency of beta-carotene, it is predicted that about 75g of GR2E Golden Rice would be sufficient to meet 50 percent of the EAR for preschool-aged children. This presentation will discuss the most recent status of the biosafety review in Bangladesh and some of the challenges of delivering a biofortified rice as a public health intervention.
PS14: Biosafety considerations for the use of genetic variation in plant breeding

Organizer:
Maria Fedorova, Corteva Agriscience, USA

PS XIV - 1

Sources and uses of genetic variation in conventional plant breeding: Spontaneous mutations, untargeted induced mutagenesis, and tissue culture

Robert Stupar
University of Minnesota, Saint Paul, MN, USA

Abstract

Plant breeding requires selecting superior genes from a pool of genetic variants available in a crop’s germplasm. The variation available to plant breeders can be derived from various sources, including natural variation in seed banks, variation induced by traditional mutagenesis, and variation introduced by modern biotechnologies. In recent years, advances in genome resequencing and other molecular technologies have enabled a high-resolution view of DNA variation in plant genomes, providing insight into the sequence variants underlying phenotypic variation. This talk will address the types and relative rates of DNA sequence variation derived from different crop germplasm sources. It has been revealed that crop genomes naturally harbor high rates of DNA sequence variation, based on historical mutation and recombination. Furthermore, some sources and treatment levels of traditional mutagenesis, such as irradiation, can generate frequent and/or large sequence variants de novo. For both natural and induced variation, downstream plant breeding, based on crossing and selection of superior phenotypes, identifies and enriches the rare beneficial variants, while purging detrimental variants. This concept holds for variation from any germplasm source, including those based on natural, induced, and biotechnology-derived variation.
Comparison in mutation frequency among wild types, tissue cultured mutants, genome-edited mutants, and transgenic lines in rice

Mai Tsuda¹, Masao Oshima¹, Takeshi Itoh², Toshiyuki Sato³, Masaki Endo², Yutaka Tabei² and Ryo Ohsawa¹
¹University of Tsukuba, Tsukuba, Japan; ²National Agriculture and Food Research Organization, Tsukuba, Japan; ³Mizuho Information & Research Institute, Inc., Chiyoda-ku, Japan

Abstract

Mutation has long been used for plant breeding. Tissue culture is one methodology of mutagenesis inducible technology used for breeding, it can induce genetic variation by the occurrence of somaclonal mutations with high density during the culture process. Since the 20th century, mutagenesis techniques, which can randomly induce a number of mutations with high density on the whole genome, have been used to treat mutagen such as chemical mutagen, radiation, and heavy ion beams. As the process of transgenic technology and genome-editing technology in plants also include tissue culture technology, so many random mutations might occur in the products. It is common to remove unnecessary mutations with adverse effect by selfing or backcrossing using parental varieties, using only desired mutations by removing randomly induced undesirable mutations in plant. No comparisons have been studied on regarding mutation frequency on the whole genome level of products through each breeding technique. In this study, we compared the mutation (SNPs and Indels) frequency between wild types, tissue cultured mutants, genome-edited mutants, and transgenic lines in rice. The total number of mutations in mutants and transgenic lines were identified as significantly higher than wild types. Specifically, both frequencies of genome-edited and transgenic rice were within the frequency of tissue cultured rice. This result suggests that the mutation frequency through genome-editing technology would not beyond the range of common culture variability. These results are expected to be useful as knowledge to promote the understanding of the effect on mutation frequencies by breeding methods including tissue culture processes in the future.
Evaluation of *S. pyogenes* Cas9 specificity in maize genome editing and its relevance in crop improvement

Joshua Young¹, Gina Zastrow-Hayes¹, Stéphane Deschamps¹, Sergei Svitashev¹, Mindaugas Zaremba², Ananta Acharya¹, Sushmitha Paulraj¹, Brooke Peterson-Burch¹, Chris Schwartz¹, Vesna Djukanovic¹, Brian Lenderts¹, Lanie Feigenbutz¹, Lijuan Wang¹, Clara Alarcon¹, Virginijus Siksnys², Gregory May¹, Doane Chilcoat¹, Sandeep Kumar¹

¹Corteva Agrisciences, Johnston, USA; ²Vilnius University, Vilnius, Lithuania

Abstract

Genome editing with CRISPR-Cas9 has enormous potential for improving crop genetics and productivity, but the possibility of unintended off-target edits has raised some concerns. To interrogate Cas9 nuclease specificity, we paired computational prediction with genome-wide biochemical off-target detection, followed by validation in maize plants. This combined three-step approach revealed high frequency (~90%) on-target editing in plant cells with no detectable evidence of off-target cleavage activity when guide RNAs were bioinformatically predicted to be specific. Predictable off-target cutting was observed with a ‘promiscuous’ guide RNA, intentionally designed to validate our approach. Robust bioinformatics tools alleviate the potential for off-target cleavage by identifying targets that are a) unique within the genome, or b) differ minimally from similar sequences by at least three nucleotide mismatches and/or bulge combinations, where at least one of the three mismatches is located within the PAM proximal “seed” region. We also report that the presence of inherent genetic variation in the maize genotype used in this study far exceeded potential genetic changes generated by CRISPR-Cas9 genome editing using ‘promiscuous’ guide RNA. Taken together, our study indicates that with appropriately designed guide RNAs, genetic changes observed through CRISPR-Cas9 off-target editing are negligible and much less than the naturally occurring diversity in plants.
PARALLEL SESSIONS

PS15: Open Session 4 - Experiences with communication and stakeholder engagement

Chair:
Gabriela Levitus, ArgenBio, Argentina

PS XV - 2

The Alliance for Science: partnering for impact

Sarah Evanega¹, Joan Conrow², Md. Arif Hossain³, Joseph Opoku Gakpo⁴
¹Cornell, Ithaca, United States;
²Cornell Alliance for Science, Ithaca, United States;
³Farming Future Bangladesh, Dhaka, Bangladesh;
⁴Ghana Alliance for Science, Accra, Ghana

Abstract

The Cornell Alliance for Science is a global communications initiative aimed at improving access to biotechnology innovations that can support environmental sustainability and improve livelihoods. We are founded on the notion that investments in agricultural biotechnology have often failed to reach their intended beneficiaries due to insufficient parallel investments in community engagement, proactive communications, and a science-based policy framework. In this talk we will offer real world examples of how the Alliance for Science is partnering with technology developers to develop forward leaning communication and advocacy campaigns supported by multimedia deliverables. Specifically, we will share examples from our partnership with the Bt eggplant project in Bangladesh and Africa’s WEMA-TELA maize project that illustrate the power of personal stories, connecting on core values, developing proactive strategic advocacy campaigns, and amplifying local voices in support of the technology and its human and environmental benefits. These examples will demystify the process of creating and implementing a strategic outreach plan and clarify how technology developers, biosafety experts and communications professionals can collaborate. We will also share our strategies for scaling impact through our innovative global training, empowerment, and leadership programs, which focus on communication and advocacy skill-building in science and agriculture. By sharing science stories that are already helping to move ag biotechnologies into the hands of smallholder farmers, we hope to inspire more collaborations with the technology developers and biosafety experts in the ISBR15 audience. We also hope to increase their awareness of the critical need to proactively pair scientific innovation with effective communications and advocacy programs to achieve maximum impact. Working together, we can ensure that these powerful tools reach their intended beneficiaries in a timely fashion and biotechnology does not bypass the poor.
Challenges and achievements communicating the safety of GMOs

Maria Luz Zapiola, Valeria Durand, Gabriela Levitus
ArgenBio, CABA, Argentina

Abstract

Considerable effort goes into assessing GMOs safety but the public doesn’t know or perceive it. Misinformation is harmful. Because public perception influences the acceptance of GMOs, communicating about GMOs safety to policy and public audiences is crucial. ArgenBio celebrated 15 years communicating biotechnology and the main challenge we identified is that scientific information rarely reaches the public, while myths and fake news spread quickly, dominating the scenario, and are hard to debunk. The approach we take is to listen to audiences empathetically, identify their concerns and address them based on the breadth of knowledge, using appropriate language. It must also be considered that worries change in time, they evolved from Monarch butterflies and genes in our food to food safety and how food is produced. Concerns differ according to region and may be contagious, so a constant monitoring of issues is also important. To respond to these concerns, it helps to open different channels and engage in conversation with different audiences. Consumers should have access to educational materials about GMOs and food safety through sites, social networks, schools, rural/food fairs, museums and any other channel that helps make information viral. Consumers can also be reached through advocates. In that sense, “training trainers” is a successful strategy to build a net of partners who can be vocal. From teachers and parents to health professionals and policy makers, the goal is that they understand and replicate the message. We must go a step ahead and communicate proactively, if not others speak on our behalf and not always accurately. In conclusion, we learnt that audiences’ concerns cannot be underestimated, neither can the power of communication. We should fulfil our audiences’ expectations by telling them what they demand to know, not only telling them our story, to bridge the gap between science and society.
PS XV - 4

Safeguarding Africa’s interest in ongoing international negotiations on regulating emerging technologies

Samuel Timpo¹, Modupe Adeyemo¹, Jeremy Ouedraogo¹, Karim Maredia², Aggrey Ambali³
¹AUDA/NEPAD African Biosafety Network of Expertise, Dakar, Senegal;
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³AUDA/NEPAD, Midrand, South Africa

Abstract

Emerging technologies derived from the application of biosciences are on the horizon and hold great promise for various sectors of an economy with anticipated socio-economic benefits if safely deployed. The Convention on Biological Diversity and its Protocols, to which most African Union (AU) member states are Parties, has over the years addressed a broad range of emerging technologies and their potential impact on biodiversity, including living modified organisms, genetic use restriction technologies and geoengineering, and more recently, synthetic biology, engineered gene drives, genome editing and digital sequence information. The goal is to promote an international governance framework that ensures broad mandates that utilize a holistic approach to regulation. Noting that the development and regulation of these technological advancements may pose challenges to existing regulatory frameworks, and that their potential risks may not be understood until the technologies are further developed, the negotiations have often been polarized with divergent views regarding their potential impacts on biodiversity and sustainable development. This paper notes the rapid pace of technological developments and discusses decisions made by AU member states towards the development and regulation of emerging technologies on the continent. The opportunity for governance systems to develop concurrently with technologies, unlike the historical antecedent of regulations lagging behind, is also argued. The paper posits a more proactive approach to governance requires a transparent, participatory, flexible, adaptable, science-based regulatory framework that has adequate legal authority and clearly defined standards. Such a framework would ensure technological development is supported while protecting the public from unintended consequences. The paper, in discussing the challenges emerging technologies present to traditional regulatory frameworks, recommends principles to adhere to in regulation and concludes by outlining current efforts ongoing in Africa including governance structures being put in place to ensure that emerging technologies contribute to addressing the continent's challenges for socio-economic development.
PARALLEL SESSIONS

PS XV - 5

Food innovation dialogue: how gene editing could benefit from the GMO experience

Adriana Brondani, Frederico Bastos
CIB - Council for Information on Biotechnology, São Paulo, Brazil

Abstract

Adoption of gene editing depends on several factors, including public acceptance. This challenge entails making non-scientists create understanding and trustfulness about a complex subject. GMOs perception has been in this situation in late 1990’s, when first GM seeds attracted attention. Most of communications done by then, instead of promoting encouragement, resulted in public hostility. Because of that, in 2001 CIB was created as a think tank to make technical information about GMOs available, to elaborate messages and to demystify misconceptions. After more than 15 years of work and data collection, public opinion has shown a shift towards GMOs. For example, in 2001, only 14% of the sample surveyed said they would consume GMOs. More than a decade later, 60% revealed willingness to consume GMOs. The understanding about this technology also increased. In 2001, 31% of the respondents have declared they have heard about GMOs. Recent survey, however, showed that 80% of them knows what these products are. Media coverage also changed from negative tone to a more neutral and science-based one. Challenges, however, are not completely overcame. In this latter survey, only 17% of the respondents knew they consume DNA in their food. Thus, although we’ve seen better acceptance, it is clear that it is harder to regain public trust than to create it from scratch. Communicating GMOs is a work in progress, but gene editing could learn from this experience. Our data reveal that both GMOs and gene editing, when applied to food production, are sensitive issues. Besides, we have learned that in food innovation dialogue, it is crucial to avoid lab approach, unnatural readings and emphasis in the process rather than in the product. We propose a friendly, transparent and interactive conversation about gene editing. Since this technology could positively transform food production, it will need public support.
PECHA KUCHA SESSIONS
PK I - 1

 ► Comparative evaluation of bacterial diversity from GM and non-GM maize rhizosphere

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³King Fahd Center for Medical Research, King Abdulaziz University in Jeddah, Saudi Arabia

Abstract

The rhizosphere is a critical interface supporting the exchange of resources between plants and their associated soil environment. Rhizosphere microbial diversity is influenced by the physical and chemical properties of the rhizosphere, some of which are determined by the genetics of the host plant. However, within a plant species, the impact of genetic variation on the composition of the bacterial biota of GM and Non GM maize rhizosphere is poorly understood. Here, we studied the bacterial diversity and population dynamics in the rhizosphere of one GM and two Non GM maize cultivars using cultured and uncultured based analysis (16S rRNA gene-based molecular analysis). Using pyrosequencing of bacterial 16S rRNA genes, around 160,000 sequences were obtained (20,000 reads per sample) representing 21 phyla’s, 184 families, 469 genera and a small amount of unclassified bacteria. Based on cultured and uncultured approaches no significant variation was observed in the transgenic samples as compared to un-transgenic.
PK I - 2

**Mutual acceptance of food and feed safety assessments of transgenic crops: an attainable goal**

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²Universidad de Buenos Aires, Facultad de Agronomía. Buenos Aires, Argentina

**Abstract**

Authorization for the consumption of a transgenic crop requires a thorough assessment of the potential risks to human and animal health. International organizations (FAO, WHO, OECD) have worked on the development of assessment criteria for food and feed derived from transgenic crops. The Codex Alimentarius Commission has established guidelines with the assessment criteria to be considered, which most countries follow. This work analyzed the regulatory frameworks of different countries, and it found considerable similarities in the type of information required: expression of new substances, analysis of allergenic or toxic potential, compositional analysis, impacts on the nutritional profile, among others; however, there are still differences regarding required data and methodologies. This heterogeneity, which is not always science-based, contributes to the complexity of the risk assessment process, thus making it longer and increasing costs, which in turn may lead to asynchronous authorizations. Mutual acceptance of food safety assessments would allow regulatory systems to make better use of their human, financial, and institutional resources, and it would stimulate inter-agency cooperation. As a first step toward the mutual acceptance of food safety assessments, countries must have a clear understanding of the scientific grounds for these criteria. In the case of food safety these criteria are sufficiently harmonized, which would facilitate mutual acceptance. In addition, it is important to note that these processes will depend on the level of trust between the actors of the regulatory process, on the application of validated methodologies, and on the assurance of the quality and integrity of regulatory data.
PK I - 3

▶ Introgression of cry1Ab transgene into open-pollinated maize and its effect on Cry protein expression levels and target pest survival

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Abstract

Genetically modified Bt maize that express insecticidal Cry proteins has been cultivated for more than 20 years in South Africa for control of the stem borers. Bt crops are grown in large scale commercial systems while small holders generally grow local non-Bt open pollinating varieties (OPVs). Gene flow may result in introgression of the cry1Ab transgene into OPVs, with unknown patterns of Cry1Ab protein expression in plants during follow-up seasons when these seeds are planted. Little is known about the effects of transgene introgression into OPVs and the possible effects thereof on the survival of target pest species. The aim of this study was to determine the effects of introgression of the cry1Ab transgene into an OPV on the survival of Busseola fusca. For this study, Bt transgene introgression was done by crossing a transgenic donor cultivar containing the cry1Ab gene with a non-Bt OPV as well as with a non-Bt isogenic cultivar. Together with the parental hybrids, F1 and F2 crosses and back crosses were done, yielding 11 genotypes (treatments). Cry1Ab protein concentrations in leaf tissue of these crosses were determined by means of ELISAs. Survival of Cry1Ab-resistant and susceptible B. fusca larvae were evaluated in bioassays in which larvae were reared for 14 days on whorl leaf tissue of the different maize plant treatments. The concentrations of Cry1Ab protein differed significantly between and within the various maize plant crosses. Larvae of the susceptible population were effectively controlled by all Bt-containing maize plant treatments, albeit not fully. Resistant larvae survived equally well on all maize plant treatments, irrespective of the presence of the Bt transgene. Results suggest that Bt transgene introgression into OPVs produces plant progenies that express the Cry1Ab protein at sufficient concentrations to effectively control larvae of a susceptible B. fusca population.
PK I - 5

Cross compatible transferability of ground nut microsatellite primers (SSR) across with pearl millets and chickpea crops

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Abstract

Simple sequence repeats (SSRs) are useful DNA markers in plant genetic research. However, they are not fully exploited in Ground Nut because of the high cost and labor intensity involved in their development. SSR markers are highly polymorphic, abundant and easy to use, they have become the marker of choice for genetic mapping, hybrid testing, population studies etc. Many studies have showed that DNA markers could be transferable among related species due to the conserved regions in their genomes. The objective of this study was to investigate the transferability of ground nut SSR markers to pearl millets and chickpea crops. 12 SSR primer pairs (P92, P56, P34, P60, P76, P55, P70, P71, P94, P49, P32, P8) were used to amplify Pearl millets in (SAVA mm1, SAVA mm2, SAVA mm3, SAVA mm4) and Chickpea (JG 63, RVG-202, JGG-1, Dindori Chana) genomic DNAs extracted from four cultivated lines. The result showed that Ground nut SSR primer pairs tested in this study could amplify with pearl millets and chickpea genomic DNA. Among these transferable SSR markers, have detected polymorphism among these pearl millets and chickpea lines. These transferable markers will benefit pearl millet and chickpea genome research by not only providing additional DNA markers in pearl millets and gram, but also allowing comparative mapping to be possible between ground nut, pearl millet and chickpea. Transferability of single and multiple alleles were observed across the genera thus proved the enormous value in crop specific genomic studies like marker-trait association, QTL mapping and genetic diversity studies. and transferable molecular markers in pearl millets and chickpea can be useful for exploiting the genetic resources of this genus and detecting allelic variants in loci associated with other important crops.
PK I - 7

Exploring Porteresia coarctata (Roxb.) Tateoka, a promising salt-loving plant for developing highly salt tolerant rice

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Abstract

Climate change induced soil salinization is a worldwide problem. Porteresia coarctata, a salt-loving wild rice, can complete its life cycle in 200-400 mM NaCl and set some rice like grains. The halophyte can be used as a rich source of germplasm for developing highly salt tolerant rice varieties. We have explored P. coarctata in mainly three different ways. Firstly, Porteresia coarctata possesses soil desalinization ability. For example, it can exclude salt from the surrounding environment, allowing sensitive rice to grow adjacent to it. We have grown a high yielding but salt sensitive rice variety, BRRI Dhan28, in close proximity to P. coarctata in 100 mM salt stress. Surprisingly, the salt sensitive rice shows significantly higher yield than those grown without P. coarctata. Secondly, three key regulatory genes directly linked with salt resistance of P. coarctata, Abscisic Acid stress ripening Protein gene, H+ ATPase subunit c, and Metallothionein Type 3 have been cloned and individually transformed into two Bangladeshi high yielding but salt sensitive rice varieties. The transgenic rice show promising salt-tolerance in Leaf disk Senescence Assay in 150 mM salt. Lastly, one of our local rice varieties, Latishail has been forcibly hybridized with P. coarctata. As P. coarctata is genetically different and tetraploid (48 chromosomes) while rice is Diploid (24 chromosomes), we have used an induced tetraploid (4n) of Latishail as mother, previously produced by our lab. Two hybrids have been already reported by our laboratory. Advanced generations of the putative hybrids are being selected using salt-containing media. Cytological analysis and DNA Sequencing of the putative salt tolerant hybrids will be performed to find DNA introgressions from P. coarctata to enable these to be used as salt tolerance donors in breeding programs.
Biosafety of Helicoverpa resistant transgenic chickpea lines expressing either a Cry1Ac or Cry2Aa gene

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Abstract

Biosafety assessment is an important part during the process of release of any genetically modified crops in the field. The Bt chickpea lines harboring either cry1Ac or cry2Aa gene were generated and a comparative seed protein composition analysis was performed to compare with the non-transgenic version. Amino acid content, seed storage protein profile and the digestibility of chickpea protein which in turn affect the bioavailability of amino acids were determined. The amino acid profile and factors affecting protein digestibility like trypsin inhibitor, tannins and phytic acid content were assessed, which revealed no significant variations between transgenic chickpea and their non-transgenic counterparts. The seed storage proteins, fractionated and separated on SDS-PAGE followed by mass spectroscopy confirmed major peptides of 11S (legumin-type), 7S (vicilin-type) and 2S (albumin) and showed no variations between the chickpea samples. Both the quantitative and qualitative seed protein digestibility calculated using multi-enzyme (trypsin, chymotrypsin and peptidase) system and transient pepsin hydrolysis (mimics simulated gastric fluid) followed by trypsin (mimics simulated intestinal fluid), respectively, revealed similar digestibility pattern of Bt chickpea protein and their non-transgenic counterpart. Our findings suggest no potential unintended effects on chickpea seed protein quality due to accumulation of Bt protein, thereby indicating towards its safety.
PK I - 9

Effects of mCry51Aa2-producing cotton on the non-target spider mite Tetranychus urticae and the predatory bug Orius majusculus

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Abstract

Today’s genetically modified (GM) cotton is protected against lepidopteran pests, while other herbivores remain unaffected. Sucking pests, such as plant bugs or stink bugs, however, become increasingly important pests in cotton fields worldwide. A novel GM cotton that protects against certain sucking pests has been developed lately. Both herbivores, that consume insect protected GM crops, and their natural enemies can be exposed to plant-produced insecticidal proteins. In this study, we investigated tritrophic interactions to evaluate the potential impact that Bt cotton (Gossypium hirsutum) producing mCry51Aa2 protein might have on a non-target herbivore, the spider mite Tetranychus urticae, as well as on a generalist predator, the pirate bug Orius majusculus. Enzyme-Linked Immunosorbent Assays (ELISA) showed that levels of mCry51Aa2 protein in T. urticae were one order of magnitude, those in O. majusculus three orders of magnitude lower than in Bt cotton leaves. O. majusculus fed with spider mites collected from Bt cotton had lower survival, increased developmental time, and reduced fecundity compared to specimens fed with spider mites from non-Bt near-isogenic cotton. Because Bt cotton did not affect the survival and growth of the spider mites, we conclude that indirect prey-quality mediated effects of the Bt cotton on the predatory bugs are unlikely. Our laboratory study with spider mites as an exclusive prey, which represents worst-case exposure conditions, thus suggests a potential hazard of mCry51Aa2-producing cotton for O. majusculus. Follow-up studies including more realistic exposure conditions are currently conducted to further characterize the risk posed by mCry51Aa2-producing cotton to O. majusculus. Preliminary results indicate that the effects observed under worst-case conditions are likely to be mitigated when alternative, high-quality prey with low mCry51Aa2-levels is available.
PK II - 1

Public perceptions of Bt brinjal in Bangladesh

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Abstract

Bangladesh is the first country of South Asia where the genetically engineered Bt brinjal has been successfully introduced in 2014. Starting with 20 farmers in 2014, 27,012 farmers have cultivated Bt brinjal in the year 2018. Therefore, the number of farmers cultivating Bt brinjal has been increasing day by day. It results in the intrusion of Bt brinjal in the market alongside with non-genetically modified brinjal. However, there are lots of arguments about the introduction of Bt brinjal in Bangladesh. Also, careful investigation of their impact regarding cultivation and market placement is an urgent need. We conducted a survey by communicating with 700 people to assess the public perceptions toward Bt brinjal. This study included peoples of numerous educational and occupational background as well as different age group and geographical distribution. The questionnaire focused on knowledge about Bt brinjal, consumption of Bt brinjal, possibility of risk, future prospects, requirement of rules and regulations. Our study found both positive and negative perceptions on Bt brinjal. People with scientific knowledge are more positive to Bt brinjal while other’s possess mixed idea about it. People with no scientific knowledge have some misconception about the Bt brinjal as well as on GMOs. However, our study has found critical need of strict rules and regulations for the cultivation and marketing of Bt brinjal. Finally, it came to the conclusion that, they also need to be properly labelled in the market.
Prospective biosafety evaluation regarding genetic modified cultivars of sugarcane: gene flow assessment and nutritional composition

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Abstract

Normative Resolution 05/2008 (RN05) of the Brazilian National Technical Commission on Biosafety (CTNBio) establishes the need of a previous risk assessment of the release of GMOs for evaluating their potential impact on the environmental safety and human/animal health. Our project addresses questions included in those norms. (1) Is gene flow likely between sugarcane and wild species? (2) Are GMOs substantially equivalent to their original cultivars? As to (1), the subsidiary questions are as follows. (a) Which species? A cpDNA-based phylogenomic reconstruction of 12 close relatives of Saccharum×officinarum showed that the Brazilian native species S. angustifolium, S. asperum and S. villosum are the closest to sugarcane in Brazil, in support to our selecting them as the target of this study. (b) Are they sympatric with sugarcane? Extensive travelling and herbarium surveys mapped the native species, concluding that they are sympatric with sugarcane only from around 14°S southwards, which frees most northeastern sugarcane-producing states from the possibility of introgression. (c) Do they flower at the same time as sugarcane? We have found that the overlap between the flowering periods of sugarcane and the native species is very short. (d) Are the wild species outcrossing? Germination tests and histology have pointed to the same conclusion, that they are unable to outcross naturally, producing seeds inside the rolled flag leaves. The combined results of (1) indicate lack of interspecific gene flow among Saccharum species. As to (2), a two-year study on the nutritional composition of the 20 main sugarcane cultivars planted in six of the foremost Brazilian producing regions was performed. Considerable amounts of genetic variation and plasticity, and many instances of genotype-by-environment interaction were found. The results are to be included in the ILSI database, paving the way for future substantial equivalence comparisons with the respective transgenic cultivars.

Financial support: FAPESP and AgroBio-Brasil.
Inter-species sensitivity variation of non-target Lepidoptera affects risk assessment of Bt maize

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Abstract

European legislation requires ecotoxicology tests on non-target (NT) organisms, as part of the risk assessment of genetically modified (GM) crops. However, the lack of clear guidelines and standards regarding test protocols leads applicants to use different test protocols and focus on pest species, possibly overlooking risks to NT organisms. As risk is a function of exposure and hazard, it is vital to select non-target Lepidoptera species for the laboratory trials that are potentially exposed to the Bt toxins in the planned cultivation areas. Regarding the hazard, sensitivity to Bt toxins may vary considerably among species, which must be taken into account when selecting the most suitable species for the risk assessment studies. The aims of this study were to assess sensitivity of relevant non-target Lepidoptera species to Bt maize pollen in order to a) develop and assess a common testing methodology focusing of key aspects such as experiment duration, controls or endpoints assessed; and b) provide relevant input data, which is currently lacking, for the risk assessment (e.g. survival, sublethal effects; data to complement a species sensitivity distribution).

NT Lepidoptera species for the laboratory testing were selected according to an informed step-by-step selection process taking into account species’ potential exposure and suitability. The species selected were Ematurga atomaria (Geometridae), Pieris napi (Pieridae), Aglais io (Nymphalidae) and, as a known sensitive species for the positive control, Plutella xylostella (Plutellidae). Species’ sensitivity to pollen expressing the Cry1F toxin (event TC1507) was tested. The methodology was designed to be similar to the natural exposure pathway, which is the accidental ingestion of Bt maize pollen deposited on larval host plants. Pollen was applied to host plant leaf discs and larvae were exposed to treated leaves for 7 days. Mortality was assessed daily until emergence of adults. Sublethal effects were assessed on feeding activity, body size and development time, as they can affect fecundity due to reduced adult fitness or delays in adult emergence.

All species tested were susceptible to the Cry1F expressed in the pollen, LC50 values were estimated at 92, 127, 186 and 5,103 pollen grains /cm² for P. xylostella, E. atomaria, A. io and P. napi respectively. The duration of experiments had profound effects on the estimation of LC50 values, when assessed at exposure time end, mortality was strongly underestimated as compared to the end of larval development. Effects of Cry1F on body size and development time varied but, in general, at higher Cry1F pollen concentrations, the larval feeding activity was reduced and development time increased. The study demonstrated high variability of Bt susceptibility in NT Lepidoptera detecting a highly sensitive species (E. atomaria) and demonstrated the need for more ecologically relevant test conditions.
Variations in resistance to the diamondback moth of feral *Brassica napus* growing around the ports in Japan

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Abstract

Most of the oilseed rape (*Brassica napus*) used in Japan is imported. Approximately 90% of imported oilseed rape seeds are estimated to be genetically modified [GM] varieties. Recently, a Bt oilseed rape cultivar has been developed. Because large numbers of feral *B. napus* are distributed throughout Japan, it is necessary to evaluate whether there are environmental risks from GM oilseed rape before starting commercial use. In this research, we compared variations in resistance to the diamondback moth, as a representative oilseed rape-damaging insect, in oilseed rape cv. Westar (frequently used as donor of GM oilseed rape) and 12 feral lines. Insect resistance of plants was divided into two categories, repellency and lethality. As factors related to resistance, contents of defensive substances commonly found in Brassicaceae: glucosinolate [GSL] and allyl-isothiocyanate [AITC], were investigated for repellent and lethal assessments, respectively. In addition, repellent tests of adults in a greenhouse and survival rate of neonates and pupae after an in-vitro feeding test were investigated for lethality. There was no significant difference between the distribution of GSL content of feral *B. napus* and the cultivars. The AITC contents of all samples were below the detection limit of HPLC. In repellent tests at two weeks of larval feeding, leaf damage scores (0 [no] to 9 [maximum]) were 1.0-4.2 for feral *B. napus*, and 1.3 for Westar. In *in vitro* feeding tests, survival rates were 66%-96.7% in feral *B. napus*, and 100% in Westar. These results suggest the possibility of introgression from Bt oilseed rape to feral *B. napus* varies case by case because feral *B. napus* in Japan maintains diversity in insect resistance. Of course, it is necessary to investigate more feral *B. napus* and cultivars and actually observe the gene introgression ability of Bt oilseed rape.
PK II - 5

Characterization of cp4-epspS, Cry1Ac and Cry2Ab genes pyramided transformed in to tobacco plants

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Abstract

Genetic transformation with pyramided constructs results in the integration of multiple genes at a single locus, which is desirable in terms of expression efficiency of transgenes. The CP4-EPSPS gene was pyramided with insect resistant Cry1ac and Cry2ab genes and cloned in pSb187 vector was used to genetically transform tobacco using Agrobacterium mediated approach. Transgenic lines were confirmed through PCR using gene specific primers of respective genes. The mRNA transcript level of CP4-EPSPS gene detected through qRT-PCR using GAPDH gene as an internal control was found to be variable among different transgenic lines. Transgenic lines were tested for checking the translational efficiency of all three genes using immunoblot strips. Transgenic tobacco lines found expressing all three proteins were subjected to detached leaf insect bioassays to evaluate the effectiveness of Bt genes in putative transgenic tobacco against insect attack using first instar larvae from Spodoptera littura and Helicoverpa armigera. Transgenic tobacco found to be resistant against these insects showed that cry1Ac and cry2Ab genes were efficient enough in pyramided form. Transgenic tobacco lines tolerated the glyphosate applications at 5 leaf stage, however, when these transgenic tobacco lines were exposed to elevated levels of glyphosate (19% v/v) at 10 to 12 leaf stage, chlorotic symptoms were observed which hinted that herbicide tolerance potential of transgene declined with increasing age of the plants.
PK II - 6

► Socioeconomic considerations - a benefit or hindrance to advancing agricultural biotechnology

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Abstract

Modern agricultural biotechnology research and development efforts focus on delivering technologies that can potentially address the challenges facing food systems around the world ranging from pests, diseases, food quality and safety, as well as environmental stress. Concerns over safety and risks to human health and the environment have led to regulation of products derived from genetic engineering and 198 countries have agreed to comply with the standards set by the Cartagena Protocol on Biosafety, a legally binding international agreement negotiated, concluded and adopted within the framework of the Convention on Biological Diversity. Article 26 of the Protocol abstractly provides for socioeconomic considerations that may be relevant to agricultural biotechnology but Parties are at liberty to adopt domestic measures as deemed applicable. While efforts have been made to shed light on the issue by explicating a conceptual framework and defining possible areas for social and economic impact assessment, there remains much variability across countries and within their public and private domains on the interpretation, scope and specification of socioeconomic considerations as well as its applications in policy, regulatory, and public realms. Absence of conceptual clarity on socioeconomic considerations in biosafety decision-making, leaves room for multiple interpretations that are too broad and ambiguous as evidenced by stipulations within some national biosafety regulations that endeavor to define socioeconomic considerations rather generally but vaguely. Such ambiguity could result in a process that is subjective, irregular, costly and cumbersome. Starting with an initial analysis of literature that draws on the concept of socioeconomic considerations for agricultural biotechnology, this paper highlights existing constraints in harmonizing the scope of socioeconomic considerations. The paper concludes with current efforts underway to address this issue and policy interventions that could streamline efforts to help structure and coordinate the extent of the information needed to satisfactorily demonstrate socioeconomic impacts.
PK II - 7

- A critical review of the Namibian biosafety regulations and their implication on processed food importers

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Abstract

Namibia has recently passed the Biosafety regulations to the Biosafety Act 2006 (Act no.7, 2006) of Genetically Modified Organism (GMOs). The regulations allow for the labelling of GMO products placed in the Namibian market. Namibia is a net importer of food and feed product yet the impact Biosafety regulation on food and feed importers are not know. This study is aimed in reviewing the process involved in the approval of GMO food and feed to be placed on the Namibia market. The study will also look at the labelling laws around the world and determine if Namibia Biosafety regulations will result in barrier to trade. Further the study will look at the status of GMO in Namibia. The study will also suggest mechanisms to assist in the implementation of the Biosafety framework and guide policy makers in decision making.
PK II - 8

DPea p68, a DEAD-box helicase, enhances salt tolerance in marker-free transgenic soybean

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Abstract

Protein p68 is a prototype constituent of DEAD-box protein family, which is involved in RNA metabolism, induced during abiotic stress conditions. In order to address the salinity stress faced by economically important soybean crop, we have transformed soybean cv. PUSA 9712 via direct organogenesis with marker free construct of p68 gene by Agrobacterium-mediated genetic transformation. The putative transgenic plants were screened by Polymerase chain reaction (PCR), Dot-blot analysis and Southern blot hybridization. Reverse transcriptase-PCR (RT-PCR) and Quantitative real-time PCR (qRT-PCR) established that the p68 gene expressed in three out of five southern positive (T1) plants. The transformed (T1) soybean plants survived irrigation upto 200 mM of NaCl whereas the non-transformed (NT) plants could not survive even 150 mM NaCl. The transgenic soybean (T1) plants showed a higher accumulation of chlorophyll, proline, CAT, APX, SOD, RWC, DHAR and MDHAR than the NT plants under salinity stress conditions. The transformed (T1) soybean plants also retained a higher net photosynthetic rate, stomatal conductance and CO2 assimilation as compared to NT plants. Further analysis revealed that (T1) soybean plants accumulated higher K+ and lower Na+ levels than NT plants. The transformed (T1) soybean plants expressing the p68 gene were morphologically similar to non-transformed plants and produced 22-24 soybean pods/plant containing 8-9 g (dry weight) of seeds at 200 mM NaCl concentration. The present investigation evidenced the role of the p68 gene against salinity, by enhancing the tolerance towards salinity stress in soybean plants.
PK II - 9

**Effect of Busseola fusca damage on Cry1Ab protein expression levels in Bt maize plants and Bt maize crosses**

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**Abstract**

Genetically modified maize, expressing the Cry1Ab insecticidal protein has been commercialised in South Africa for the control of Busseola fusca for over 20 years. It is expected that transgenic crops with insect resistance traits express transgenes at a consistent rate throughout the plant’s life cycle. However, low dose expression of Cry toxins has been identified as one of the contributing factors to the evolution of resistance in B. fusca to Cry1Ab. Agricultural practices or environmental conditions that lead to reduced expression of insecticidal proteins in Bt crops may compromise insect resistant management. For example, gene flow under subsistence farming practices, where Bt maize and open pollinated varieties (OPVs) are planted in adjacent fields, will lead to the introgression of the cry1Ab gene with unknown patterns of insecticidal proteins. The possibility that pest-induced stress could also contribute to varying levels of Cry protein expression in Bt crops has not been investigated. To obtain Bt-introgressed crosses, a transgenic donor cultivar containing the cry1Ab gene was crossed with a non-Bt open pollinated variety. Together with the parental varieties, F1 and F2 crosses as well as back crosses were produced, yielding 6 genotypes (treatments). When plants reached the V6 growth stage, 10 neonate B. fusca larvae were inoculated into maize whorls of the respective treatments. Larvae were allowed to feed on whorl tissue for a period of one week after which plant tissue samples were taken for ELISAs and qPCRs to determine the Cry1Ab protein concentrations and the Bt transgene expression respectively. Leaf tissue from damaged plants of the F2 cross and back crosses had a significantly lower Cry1Ab protein concentration than undamaged plants, with no significant correlation between transgene expression and Bt protein concentration. Results indicate that Cry1Ab protein concentrations in undamaged Bt introgressed plants differed significantly between and within crosses.
P - 01

Effects of Bt genetic engineering on induced volatile organic compounds in maize and host selection behavior of Trichogramma ostriniae

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Abstract

In order to control lepidopteran and coleopteran insects, the genes expressing Bacillus thuringiensis (Bt) insecticidal proteins are transferred into crops. Ecological risk assessments of the transgenic plants include impacts on non-target entomophagous insects, such as parasitoid wasps. Herbivore-induced plant volatiles were considered to be important defensive traits of plants because these compounds were released to recruit natural enemies. Here, we evaluated the composition and quantity of induced volatile emissions of 8 Bt maize varieties and their isogenic non-Bt lines after mechanical damaged, herbivore damaged by Prodenia litura and induced by exterior jasmonic acid, aim to study the host selection behavioral effects of the differential compounds emitted by Bt maize and living Bt maize on Trichogramma ostriniae. Compared to the non-Bt isolate 5422 and the Bt maize 5422CBCL (event Mon810), the other Bt maize 5422Bt1 (event Bt11) released more (3E)-4,8-dimethyl-1,3,7-nonatriene (DMNT) when they were all treated by artificial wounds and caterpillar regurgitant; and released more linalool, DMNT and (E)-β-farnesene when applied with JA solution. Correspondingly, the total volatile emission of the 5422Bt1 was highest in general. However, the difference in volatile emission did not affect the attractiveness of the Bt maize plants to the egg parasitoid Trichogramma ostriniae compared to the non-Bt isolate. The variability of induced volatiles of maize cultivars derived from conventional breeding programs and transgenic methods, and the key volatile attractants to parasitoid wasps were discussed.
Reassessment of exclusion zones of GM cotton in Brazil: the case of Rondônia State

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Abstract

Cotton (Gossypium hirsutum) was the second crop to received commercial approval to planting GM cultivars in Brazil, in 2005. At that time, the main concern was the possibility of gene flow from GM cottons to affect in situ maintenance of others species sexually compatible – G. barbadense and G. mustelinum. To avoid this problem, the National Biosafety Technical Commision (CTNBio) conditioned the cultivation of GM cotton to the creation of GM Cotton Exclusion Zones, where just non-GM cultivars could be planted. Cotton cultivation is an important agricultural activity in Brazil and the producers are almost unanimous: fields of GM cultivars yield more, the management is less laborious and the protection against weeds and pests is higher. For these reasons, farmers in the Rondonia, a state included into the exclusion zones, requested CTNBio to remove Rondônia from the exclusion zones. To deliberate, CTNBio asked Embrapa for information. To properly answer, an expedition was performed in 20 of the state’s 52 municipalities, and only one species was found, Gossypium barbadense. Plants were present just in highly anthropized areas, mainly in dooryards of urban and rural houses, and they were maintained as medicinal plants. Plants of G. barbadense were found in 5% to 10% of the houses, protected from gene flow by walls, houses, and trees. There was no signal of interspecific crossing, even in municipalities where conventional Gossypium hirsutum were planted. The main risk to in situ mainatenance of G. barbadense is the loss of cultural habits resulting from the expansion of the public health care, which increases the use of chemical drugs over medicinal plants. In conclusion, gene flow is not a significant concern to the preservation of Gossypium barbadense in Rondônia, and there is no reason for the state to remain as an exclusion zones.
P - 03

Safety assessment of *Bacillus thuringiensis* insecticidal proteins Cry1C and Cry2A with a zebrafish embryotoxicity test

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Abstract

As a result of the large-scale planting of transgenic *Bacillus thuringiensis* (Bt) crops, fish would be exposed to freely soluble Bt insecticidal protein(s) that are released from Bt crop tissues into adjacent bodies of water or by way of direct feeding on deposited plant material. To assess the safety of two Bt proteins Cry1C and Cry2A to fish, we used zebrafish as a representative species and exposed their embryos to 0.1, 1, and 10 mg/L of the two Cry proteins until 132 h post-fertilization and then several developmental (survival rate, hatching rate, body length, malformation rate), biochemical (SOD and CAT activities, MDA level), and molecular parameters (*sod2, cat, cox1, gstp2*, and *bcl2* mRNA expression levels) were evaluated. Chlorpyrifos (CPF), a known toxicant to aquatic organisms, was used as a positive control. Although CPF exposure resulted in significant developmental, biochemical, and molecular changes in the zebrafish embryos, there were almost no significant differences after Cry1C or Cry2A exposure. Thus, we conclude that zebrafish embryos are not sensitive to Cry1C and Cry2A insecticidal proteins at test concentrations.
A genetic engineering approach to develop greening and canker resistant citrus cultivars

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Abstract

Citrus greening and Canker are the serious threats to the citrus-growing industry worldwide due to the complexity, destructiveness, and difficult to control strategy. Citrus is a nutrient-rich delicious fruit and one of the most popular fruit in the world. Citrus processed juice products play an integral role in human nutritional requirements, is one of the most important fruit crops grown worldwide. No effective commercial cultivars have shown resistance to HLB so far and conventional breeding has no success yet to combat those diseases in the commercial cultivars. The progress of the cloning of candidate genes and transfer to them into the targeted tissues has opened new avenues for augmenting disease resistance in citrus. Therefore, identification and cloning of suitable candidate genes and optimization of efficient transformation protocols are needed for citrus improvement programs for both rootstock and scion development. Our main research objective was to produce genetically modified citrus cultivars those are resistant to endemic HLB and canker. In this study identification and cloning of diseases combating genes and production of genetically modified citrus cultivars using genome engineering will be discussed.
Evolution of very strong resistance to glyphosate in horseweed (*Conyza canadensis*), a major weed of Roundup Ready soybean fields in the USA

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Abstract

Worldwide, >40 weed species have evolved resistance to glyphosate. To better understand evolutionary outcomes of continued and strong selection from glyphosate exposure, we characterized variation in resistance in highly self-pollinating *Conyza canadensis* (horseweed) in Ohio and Iowa, USA, where glyphosate resistance (GR) was first reported in 2002 and 2011, respectively. We chose to focus on horseweed because it is a major weed in no-till crops such as Roundup Ready soybean. We also tested for a point mutation that is associated with GR in Canadian horseweed populations, and we conducted common garden experiments to test for possible fitness costs of resistance in the absence of glyphosate. In 2015, we collected seeds from >70 maternal plants (biotypes) from no-till soybean fields and non-agricultural sites in each state, using one representative maternal plant per site. Resistant biotypes with at least 80% survival at each of four dosages were designated as R1 (1x = 840 g ae ha⁻¹), R2 (8x), R3 (20x), or R4 (40x). Nearly all Ohio agricultural biotypes were R4, as were 62% of biotypes from the non-agricultural sites. In Iowa, R4 biotypes were clustered in southeastern no-till soybean fields, and 45% of non-agricultural biotypes were classified as R1-R4. These results show that levels of resistance to glyphosate can be very high (surviving at least 40x) and non-agricultural sites likely serve as a refuge for GR biotypes. All of the R4 biotypes that were sequenced at EPSPS2 (N=21) had a point mutation converting proline to serine at p185. Common garden experiments carried out in 2016 and 2017 at two sites in Iowa did not detect any reduction in survival or early growth of R4 biotypes compared to susceptible controls in the absence of exposure to glyphosate. Thus, strong resistance to glyphosate may be able to persist indefinitely in horseweed populations.
Indirect, plant-mediated interactions between target and non-target pests in Bt rice

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Abstract

Introduction of insect-resistant genetically engineered plants into an agroecological system will undoubtedly influence the ecological interactions of insect species closely associated with the plants due to their insect-resistance trait. Using Bt rice, we studied the intra- and interspecific interactions of herbivorous insects including the target pest Chilo suppressalis and a non-target pest Nilaparvata lugens. Under confined conditions, we observed that C. suppressalis females had no oviposition preference to healthy Bt or non-Bt rice plants, but were repelled by rice plants (Bt or non-Bt) that had been damaged by conspecifics. Semi-field and field experiments showed that C. suppressalis egg masses were more numerous on Bt plants than on neighbouring non-Bt plants which was due to the significantly greater damage on the non-Bt plants. GC-MS analyses revealed that larval damage induced the release of volatiles that repelled mated C. suppressalis females. Similarly, the rice planthopper N. lugens had no feeding preference for undamaged Bt or non-Bt plants but in contrast to the target pest, it exhibited a strong preference for caterpillar-damaged plants whether Bt or non-Bt. Under field conditions, rice planthoppers were more abundant on caterpillar-damaged non-Bt rice than on neighbouring healthy Bt rice. GC-MS analyses revealed that caterpillar-damage induced the release of rice plant volatiles known to be attractive to planthoppers, and metabolome analyses revealed increased amino acid contents and reduced sterol contents known to benefit planthopper development. Field experiments indicted that this lead to a movement of N. lugens from Bt rice to non-Bt rice plots. With these findings, we conclude: i) Bt rice could act as a dead-end trap crop for C. suppressalis and thereby protect adjacent non-Bt rice plants; ii) Lepidoptera-resistant Bt rice is less attractive to planthoppers due to reduced caterpillar damage relative to non-Bt rice, suggesting Bt rice could provide ecological resistance to non-target planthoppers.

References:

P - 07

Evaluating potential risks of Bt rice straw as cultivation base for earthworm *Eisenia fetida*

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**Abstract**

Multiple lines of transgenic rice expressing insecticidal genes from the bacterium *Bacillus thuringiensis* (Bt) have been developed in China. An important part of environmental risk assessment is the possible accumulation and persistence of plant produced Bt proteins in soil. Rice straw is the largest agricultural crop residue constituting approximately 45% of the biomass in total rice production, which is also returned to the soil as manure, livestock feed, and as a cultivation base for mushrooms and earthworms in China. This indicates that organisms, e.g., earthworm, bred in a cultivation base with Bt rice straw are directly exposed to or even ingest Bt proteins. In the current study, the straws of 5 pairs of Bt rice and corresponding conventional rice varieties were returned in soil as cultivation base. We evaluate the potential risk of Bt rice return on earthworm *Eisenia fetida* via the 90 day experiment conducted in the laboratory. The life history traits (survival rate, relative growth rate, reproduction), physiological and biochemical changes (enzyme activity, gene expression) of earthworms, Bt protein concentrations in soil-straw mixture and earthworm, soil nutrients were detected after 7, 15, 30, 45, 60, 75, 90 d. The aim was to investigate whether Bt rice straw as cultivation base affects the earthworm *E. fetida*, and whether these effects are related to Bt protein or the nutrients in soil. Finally, the safety assessment standards of Bt and non-Bt rice straw as cultivation base for earthworms was established. Results will be presented and discussed.
The dynamics of a probable spread of cultivated algae

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Abstract

To assess the environmental risk of a possible escape of a potentially useful algal or cyanobacterial strain, experiments were conducted on invasiveness and persistence. The results can be applicable to devise protocols for assessing the risk associated with the cultivation of any promising non-native as well as genetically modified strain. An experiment was conducted with different cell concentrations inoculated in environmental water samples in the vicinity of the R&D Biofuels Site of Reliance Industries Limited (RIL), viz., from a cattle tank in a nearby village and a salt pan. These were incubated on an open shaker with 12 hours light. The samples were monitored periodically by microscopy and PCR analysis to examine the presence or absence of the introduced algae. On the 30th day of sample collection, enriched medium was added to a fraction of the inoculated water sample to assess the possibility of algae thriving under simulated favourable conditions. The cultures were monitored twice (on 15th day and 30th day) from the date of medium addition.

For a genetically modified strain, the same water samples were used in Phenometrics ePBRs (environmental photobioreactors) where the strain was inoculated. The monitoring by microscopy and PCR were carried out in periodic intervals. The results here are aimed to deduce if the strains are capable of invading, persisting or remain dormant in the existing environmental equilibrium. The risk of the strains’ potential for invasiveness will be discussed.
P - 09

An exposure-based risk assessment system for GM plants

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Abstract

Comparative risk assessment approaches are generally used to identify and evaluate differences between GM plants and their counterparts. In addition to traditional toxicological methods, molecular profiling have recently been added to comparative approach frameworks with the goal of increasing confidence in risk assessments of GMOs. Risk-benefit analysis approaches have been proposed to serve as an additional support tool for decision-makers, although current GMOs’ risk assessment systems are sometimes globally generalized. While food safety is a generalizable realm, ecological risk assessment is specific to regions and ecosystems. This Policy article stresses specific ecological risks and strategies to change the focus of potential environments to real environments within a regulatory system. To improve the relevance, logic, and comprehensiveness, we here propose a risk assessment system that is based on exposure mode for evaluating the ecological risks of releasing GM plants in specific environments. It does not consider laboratory testing of direct potential toxicity to non-target organisms prior to environmental release, but rather, focuses on the performance of GM plants in the receiving environment. The system includes five exposure modes: pollen flow, seed dispersal, litter movement, root exudates and food chain transfer in the environment. To assess ecological risks of GM plants in nature, we here only need to measure or detect “exposure characteristics” and potential “ecological effects” for each exposure mode. We propose integrating exposure characteristics and ecological effects to understand ecological risks of GM plants in nature.
Testing the invasiveness of a transgenic cyanobacterium

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Abstract

To assess the environmental risk of a possible escape of a potentially useful algal or cyanobacterial strain, an experiment was conducted on invasiveness and persistence. A genetically modified cyanobacterial strain, was inoculated in water samples from two environmental water bodies in Phenometrics ePBRs (environmental photobioreactors). Monitoring by microscopy and PCR were carried out in periodic intervals. The results here are aimed to deduce if the strains are capable of invading, persisting or remaining dormant in the existing environmental equilibrium. The discussion aims at devising a structured protocol for evaluating the invasiveness of any transgenic cyanobacterium, a key aspect that will define a product's biological safety.
Are genome edited products credence goods? Implications for regulation and governance

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Abstract

According to economic literature, credence goods have qualities which are expensive to judge even after purchase (Dulleck et al., 2011). In some cases, the specific feature is inherent to the production process and cannot be detected in the final product (Haas et al., 2010). This may lead to information asymmetries between sellers and buyers and create incentives for opportunistic seller behavior (Emons, 1997). As a consequence, credence goods markets are prone to inefficiencies (Kerschbamer et al., 2015) and need a suitable design of institutions and governance structures to prevent market failure.

As Baksi and Bose (2007) argue, genetically modified (GMO) products can be characterized as credence goods. However, the availability of testing methods to reveal the genetic nature of the product and thus to fulfil the requirements of traceability and labelling according to European regulation relaxes this assumption. With the introduction of genome editing as a new plant breeding technique, this situation has fundamentally changed. Now, products with genetic modifications can be obtained for which reliable detection methods are absent at the moment and unlikely to be developed before the first genome edited products will enter the market. After the ruling of the European Court of Justice in 2018, genome edited products fall under the European GMO regulation. These products need market approval and are likely to yield lower market prices because of consumer rejection. Since the characteristics are not detectable in the final product, there are incentives to disguise the true nature of the good in order to get unapproved market access or to obtain higher market prices. Against this background, the poster addresses the question whether the institutional framework currently in place at the European level can cope properly with these difficulties and which governance structures are likely to evolve in this context.

References

The Bt eggplant project in Bangladesh: present status, lessons learned and future prospects

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Abstract

Eggplant or brinjal (Solanum melongena) is a popular vegetable grown throughout Asia where it is attacked by the eggplant fruit and shoot borer (EFSB) (Leucinodes orbonalis). Yield losses in Bangladesh have been reported up to 86% and farmers rely primarily on frequent insecticide applications to reduce injury. Bangladesh has developed and released four brinjal varieties expressing Cry1Ac (Bt brinjal) and is the first country to do so. In this presentation we discuss the development and adoption of Bt brinjal in Bangladesh from an initial 20 farmers in 2014 to >27,000 farmers in 2018. Bt brinjal provides virtually complete control of BFSB, dramatically reduces insecticide sprays, provides a 5-6-fold increase in grower profit and does not affect arthropod biodiversity. A major focus of the project is to ensure its durability. Efforts include building capacity within Bangladeshi institutes that produce and distribute Bt brinjal, farmer training, implementing stewardship and communication. In order to ensure the long-term future of the partnership, we discuss the need to enhance involvement of the private sector in the production and stewardship of Bt eggplant. Bt brinjal is the first genetically engineered (GE) food crop to be commercially released in Bangladesh, and other GE crops are in the pipeline. Hence, success of the Bt brinjal partnership is likely to affect the future of other GE crops in Bangladesh, as well as other parts of the world where biotechnology is needed for food security and environmental safety. Bangladesh has shown great leadership in adopting biotechnology for the benefit of its farmers and serves as an example for other countries. The project is supported by USAID as the Feed the Future South Asia Eggplant Improvement Partnership.
Study of rice transgene flow

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Abstract

China is the largest rice producer worldwide and is one of the origins of Asian cultivated rice as well. Along with the rapid development of transgenic rice in China, the potential impact of rice transgene flow on the environment and food safety has become one of the major concerns. Gene flow is an important parameter in the risk assessment and regulation of transgenic rice on the scientific basis. In accordance with this situation, we have systematically studied the rice transgene flow. The results are as following:

The patterns of transgene flow and the major biological and meteorological factors controlling rice gene flow have been elucidated. Following the prevailing wind direction in rice flowering period, a rectangular design of field experiments were conducted at 3 locations in 2-3 years by using a homozygous transgenic line with bar gene inserted, resistant to herbicide Basta, as a pollen donor, and totally 19 non-transgenic rice as recipients, including male sterile (ms) lines, common rice cultivars (CRC), F₁ hybrid rice, and common wild rice (Oryza rufipogon). Results indicated that the frequency of transgene flow to ms lines was the highest, while gene flow to CRC and F₁ hybrids was the lowest. The frequency of transgene flow to O. rufipogon was in between. By comparison, the maximum frequency of gene flow to ms lines is one to three orders of magnitude higher than that to O. rufipogon and CRC. Gene flow frequency decreased exponentially as the distance increase, with a sharp cut off point at about 1-2 m in Guangzhou and Hangzhou, while it was approximately 5m in Sanya. It indicates that the sharp cut off point is closely related to the wind speed during rice flowering period at a given location. By using a concentric circle design of field experiment and an ms line BoA with higher outcrossing rate as a recipient, we have been able to clearly quantify the relationship between the gene flow frequency and the wind direction. In short, a general conclusion is that the order of magnitude of transgene flow frequency is basically the same as the outcrossing rate of the CRC (generally less than 1%), which means the gene transfer has not added a new additional risk.

A regional applicable rice gene flow model is established and used to predict the maximum threshold distances (MTDs) of gene flow during 30 years in 1026 major rice producing counties of southern China. The MTD 0.1% for rice cultivars is basically ≤5 m in the whole region, despite climate differs significantly at diverse locations and years. This figure is particularly valuable for the commercialization and regulation of transgenic rice.

We have artificially constructed four mixed populations of O. rufipogon with F₁ hybrids of CRC/O. rufipogon derived from transgene (either Bt or bar) flow to investigate the long-term fate of the transgene integrated into common wild rice. It was found that the F₁ hybrids of CRC/O. rufipogon totally disappeared within 5-8 years and the Bt or bar gene was not detectable in the mixed population. It is reasonable to speculate that the common wild rice possesses a mechanism of self-protection.

We have proposed to use principles of classification management and threshold-value management in the risk assessment and regulation of transgenic rice.
Variability of nutritional component levels in maize grain within individual hybrids is greater than the variability between a GE maize hybrid and its near-isogenic hybrid

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Abstract

Compositional equivalence studies are required by government regulatory agencies in many countries to inform the risk assessment of human and animal consumption of food and feed from a new genetically engineered (GE) crop. In these studies, the levels of nutritional and anti-nutritional components in food and feed derived from the GE crop are compared to those of the nontransgenic, near-isogenic crop. Any statistically significant differences are subsequently placed into context of the levels in conventional (non-GE) varieties of the crop documented in the scientific literature. Although a substantial amount of information concerning composition of maize (Zea mays L.) grain exists in the literature, the variability in compositional levels due to the growing environment of the crop is not well documented for individual maize hybrids. The objective of this work was to evaluate the variability of nutritional and anti-nutritional component levels within individual maize hybrids grown under different environmental conditions, and to relate the observed variability to differences detected between the GE crop and the nontransgenic comparator crop. Composition data were compiled for maize grain from eleven non-GE, commercial hybrids grown over the course of seven growing seasons (2009 to 2015) and in eighteen field trial locations across the U.S. Corn Belt region. To characterize the within-hybrid variability, the percent difference was calculated for each component, using the minimum and maximum mean values from among the environments for each hybrid. Percent differences were also calculated from literature values and internal data for cases when statistically significant differences were observed between the across-environment means of a GE maize hybrid and its near-isogenic comparator. The percent difference of the levels of each measurable component between a GE maize hybrid and its near-isogenic hybrid was less than that for an individual hybrid over multiple environments. For GE maize crops expressing a transgene that is not intended to result in a compositional change, this analysis confirms the expectation that differences in environmental growing conditions have a greater effect on crop composition than plant transformation.
Safety assessment of genome edited products

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Abstract

The use of genome editing in plant science raises numerous possibilities for advancing agricultural products. Harmonized global practices and/or regulations for establishing the safety of genome edited crops have not been established; however, producers of such products, like Syngenta, are committed to ensuring that genome edited crops are safe for humans, animals and the environment. Assessing the safety of genome edited crops can and should be undertaken independently of regulations. The most appropriate way to identify and evaluate genome edited products is to focus on the properties of the final product to which consumers and the environment will be exposed, and not on the process used to create or develop that product. This presentation identifies the types of information that should be considered to inform the safety assessment of genome edited products.
P - 16

Development of efficient information providing program for agricultural biotechnology

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Abstract

Although agricultural application of modern biotechnology has been successful, the public perception on its risk seems to be biased at least in Korea. Negative attitude on genetically modified crops could be a serious obstacle against the commercialization of agricultural biotechnology as well as its research activity. Therefore, risk communication becomes more and more important. One of the best ways for communication is to provide the public with the right scientific and objective information. In order to provide effective online agricultural biotechnology information, we surveyed public information gathering patterns and the preferred information contents. The survey was conducted on 698 middle and high school students and 650 researchers involved in agricultural biotechnology. For students, the information retrieval experience of agricultural biotechnology was 22%. The information retrieval contents were ‘Future and Prospects of Agricultural Biotechnology (28%)’, ‘What is Agricultural Biotechnology?’ (25%) and ‘Problems of Agricultural Biotechnology (19%)’. In the case of researchers, the information retrieval experience of agricultural biotechnology was 71% and the information retrieval contents were surveyed as follows: ‘Latest research technology of agriculture biotechnology (59%)’, ‘Approval trend of genetically modified organism development (13%)’, and ‘Introduction of agricultural biotechnology (13%)’. In the field of interesting agricultural biotechnology, students were interested in ‘Safety of agricultural biotech foods (22%)’ and ‘Future of agricultural biotechnology (20%)’, and researchers were ‘Latest research trends (25%)’, ‘New biotechnology (21%)’ and ‘Gene editing technology (11%)’. For the improvement of agricultural biotechnology homepage, students preferred ‘Convenient search method (26%)’, ‘Quick information confirmation (25%)’, ‘Real-time information provision like SNS (22%)’, and researchers preferred ‘Quick information confirmation (35%)’ and ‘Convenient search method (30%)’. When asked about the type of information provided by agricultural biotechnology, students preferred ‘SNS (49%)’ and ‘general homepage (38%)’, but the researcher preferred the ‘general homepage (65%)’. 
Untargeted metabolic profiling of components in a food chain of salt-tolerant transgenic plant and insects

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Abstract

In transgenic rice (Oryza sativa) plants, overexpression of AtCYP78A7, which encodes a cytochrome P450 protein, enhances tolerance to drought and salt stresses. This study was designed to examine the effects of a host transgenic plant on the life history traits and metabolite profiles of herbivorous and predatory insects in a food chain. We used a three-trophic level system consisted of the rice, its herbivore Sitobion avenae, and predator Harmonia axyridis. Transgenic and non-transgenic rice were cultivated under either salt-stressed or non-stressed conditions. Subsequently, they were fed to their herbivorous S. avenae, and predatory H. axyridis preyed upon S. avenae fed with transgenic or non-transgenic rice. The performance of insects including the survival, growth, and reproduction was investigated and untargeted metabolite profiling using GC-MS was analyzed for each trophic level. Application to 50 mM NaCl delayed the timing of development for S. avenae and decreased the body weight and size for H. axyridis. However, the life history traits in insects did not differ significantly between the groups fed on salt-tolerant transgenic rice and its non-transgenic counterpart. GC-MS-based metabolic analysis indicated metabolite profiles could be distinctly discriminated among three trophic levels. Salt stress also contributed to a clear division of profiles in the group of rice and H. axyridis. However, those metabolites did not distinguish between transgenic and non-transgenic rice. These results suggested that salt stress in a host plant reduces the growth and reproduction of herbivorous and predatory insects in a food chain and induces metabolic changes. Besides, the overexpression of AtCYP78A7 in a host plant did not affect the life history traits and metabolite profiles of insects.
Detection, identification and quantification of products resulting from the use of new plant breeding techniques

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Abstract

Plant breeding is one of the key elements of modernization of agriculture towards sustainable food, feed and fuel production. To achieve this goal new biotechnological techniques and especially new plant breeding techniques (NBTs) are continuously being developed. NBTs are a set of innovative methods used for genome improvement (intragenesis, cisgenesis, RNA-dependent DNA methylation, oligonucleotide directed mutagenesis, reverse breeding, zinc finger nucleases ZFN1-3, TALE nucleases, CRISPR-Cas9 system). Current legal definition of GMOs was elaborated when these techniques were not discovered so it is unclear which of them should fall under the GMO legislation. The ruling of the European Court of Justice (2018) regarding the mutagenesis clarified that the use of site specific genome editing technics would result in organisms which fall under the GMO regulations in EU. Such opinion is however not shared among all not EU countries especially where the classification is more product orientated. Development and validation of GMO determination methods are beside risk assessment essential part of GMO authorisation in EU. Placing of GM varieties on the EU market requires also post market environmental monitoring (PMEM). Here we present and discuss the possibility of application of molecular methods (PCR, real-time PCR, digital PCR, HRM, NGS, ELISA) for detection, identification and quantification of products resulting from the use of NBTs taking into account the level of introduced changes into the plant genome (insertion, deletion, single nucleotide polymorphism etc.). Development of specific and robust methods for detection of small changes introduced into plant DNA will be very challenging especially that this kind of mutation might occur naturally. Nevertheless, harmonization of both legal classification and the development of methods for GMO determination is a prerequisite for safe implementation of NBTs into plant breeding. It is also crucial for post market environmental monitoring and detection of unauthorized GMOs in the global trade.
P - 20

Monitoring and assessing the attack and injury level of *Ostrinia nubilalis* (European Corn Borer) and *Helicoverpa zea* (Corn Earworm) on Bt and conventional maize

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Abstract

Romania was among the pioneer countries, at global and European level, when in 1999 has adopted genetically modified (GM) crops for commercial cultivation. From almost half a million hectares cultivated with transgenic crops, 420,700 ha were cultivate with herbicide tolerant (HT) soybean (1999-2006) and 13,361 ha with insect resistant (IR) maize (2007-2015). From the legal point of view, the commercial cultivation of GM crops is still possible because Romania is one of the EU's eleven countries which have not restricted the cultivation on their territory, according to the provisions of the EU Directive 2015/412. Within the EU FP7 AMIGA project we monitored and assessed the environmental risks associated with the commercial cultivation of GM maize in Romanian agricultural ecosystem in specific local conditions and IPM practices. During three consecutive years (eight different locations/year) we monitored conventional maize fields. In two consecutive years we monitored, in the same location, transgenic (MON810) and conventional (near-isogenic) maize fields. Each year, just before harvesting, we assessed the attack and injury level of *Ostrinia nubilalis* (European Corn Borer) and *Helicoverpa zea* (Corn Earworm) on both conventional and Bt maize, in conjunction with the monitoring activities focused on non-target organisms (NTOs). Depending on the climatic conditions and IPM treatments applied, substantial levels of attack of both pests were recorded in conventional maize fields. We confirm that *O. nubilalis* remains a significant pest for maize in Romania. The MON810 maize it may not offer anymore the expected economic incentives as the Romanian farmers have ended the GM maize cultivation while waiting for more profitable genetically modified crops to become available that better fit their present needs.
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Development and evaluation of transgenic events independently expressing cry1Ac, cry2Aa, cry1F and cry1A for managing pod borer (Helicoverpa armigera) in pigeon pea (Cajanus cajan)

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Abstract

In cultivars ICPL87119 and BSMR736, MS medium supplemented with I BAP, TDZ and zeatin, separately, induced maximum shoot buds, 53.7, 46.1 and 40.9 respectively; any further increase in cytokinins levels resulted in reduced shoot buds. The MS basal with 0.5 mg/l IBA induced maximum and healthier roots (4.8±0.7). In planta transformation revealed 80.00, 85.00, 66.50% explant response, 53.75, 90.00, 90.98% explant survival and 3.0, 6.5, 12.0% transformation efficiency in Agrobacterium tumefaciens infection alone, A. tumefaciens culture with tobacco leaf extract and air evacuation, respectively. The 88 putative transformants carrying cry1Ac were developed, of which 48 showed 3:1 transgene segregation pattern in T2. Insect mortality ranged from 25.0 to 70.0% whereas, Cry1Ac protein level from 0.31 to 0.85 µg/g and cry1Ac transcript level from 15.6 to 165.1 ng/µl, validated through northern blotting in different tissues (leaf, flower and pod). In case of cry2Aa, 65 transformants developed, of which 16 showed 3:1 transgene segregation in T2. Insect mortality ranged from 5.25 to 65.75% whereas, Cry2Aa protein and transcripts ranged from 0.01 to 3.23 µg/g and 41.2 to 134.5 ng/µl, respectively. Southern and juncture analyses of selected three cry1Ac and five cry2Aa transformants confirmed T-DNA integration in plant genome. Fourteen transformants carrying cry1F were developed, of which seven showed 3:1 transgene segregation pattern in T2, wherein insect mortality ranged from 10.0 to 62.5%, Cry1F protein level from 0.113 to 1.032 µg/g and transcripts ranged from 45.2 to 105.3 ng/µl. Similarly, eleven cry1Acmb transformants were developed, of which seven showed 3:1 transgene segregation in T2. Insect mortality ranged from 35.0 to 62.5% whereas, protein level and transcripts ranged from 0.19 to 0.91 µg/g and 41.2 to 134.5 ng/µl respectively, in tested tissues. Pigeonpea transformation procedures and generated events of present study could be prospected for their further use.
Introgression of cry1Ac gene from transgenic chickpea into cultivated chickpea for pod borer resistance and identification of homozygous plants through marker assisted selection

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Abstract

Helicoverpa armigera is a polyphagous insect that damages many crops such as chickpea, cotton, pigeonpea, maize etc. (Gowda 2005). It leads to annual yield losses of > US $325 million world-wide (Yadav et al 2006). In India, loss in chickpea yield due to pod borer has been reported to be 10-60% under normal and 50-100% under favorable weather conditions, despite use of heavy doses of pesticides (Kumar and Kapur 2003). Towards controlling this insect, we incorporated cry1Ac gene from transgenic chickpea lines (T₅ generation), BS 100B-T₅ and BS 100E-T₅ into cultivated chickpea (Cicer arietinum L.) varieties PBG7, L552 through backcrossing. BC₁F₁ progenies, [(PBG7 x BS 100B-T₅) x PBG7], [(L552 x BS 100E-T₅) x L552] and BC₂F₂ progeny, BC₂F₁[{(PBG7 x BS 100E-T₅) x PBG7} x PBG7] selfed, were tested for the presence of cry1Ac gene through foreground selection (FGS). Insect bioassay was performed on cry1Ac positive plants and those resistant were analyzed for their protein content using ELISA. The data revealed that a fair number of BC₁F₁ plants contained cry1Ac gene and further analysis depicted their resistance to H. armigera and presence of high protein content (upto 11 µg/g leaf tissue). On the basis of FGS, insect bioassay and ELISA, resistant BC₁F₁ plants were used in the crossing programme. Out of 83 BC₂F₂, 10 were identified as cry1Ac positive through FGS, that were also subjected to background selection (BGS) using 25 polymorphic SSR markers to screen plants with maximum recurrent parent genome. On the basis of FGS and BGS, these 10 plants were selfed to raise BC₂F₃ population comprising 128 plants. Each BC₂F₃ line was tested using gene specific primers for presence of cry1Ac gene. The analysis revealed that 3 out of 10 cry1Ac positive plants were homozygous and remaining segregated in 1.25:1, 1.6:1, 2.3:1, 3:1, 3:1, 4:1 and 6:1 ratios.
P - 23

Evaluation of whole genome sequencing and an insertion site characterization method for molecular characterization of GM maize

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Abstract

Next generation sequencing (NGS) technologies, such as whole genome sequencing (WGS), have shown the potential to replace Southern blots for molecular characterization of GM crops. To determine if WGS could replace Southern blots for molecular characterization of GM maize, two GM maize events were sequenced using WGS in combination with an insertion site characterization (ISC) method. The sensitivity of the method was compared to that of Southern blot analysis through detection of each event junction and small artificially introduced insert fragments.
**Comparison of sequencing methods for the molecular characterization of genetically-modified crops**

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**Abstract**

Traditionally, sequencing of GM events has been carried out using PCR in combination with Sanger sequencing. Since the 1970s, the Sanger method has been the gold standard for sequencing; however this method has low-throughput, long turnaround time and high cost. Next generation sequencing technologies offer benefits relating to lower costs and increased workflow speed, in addition to advantages specific to each platform. We compare two NGS methods to Sanger sequencing, Illumina Miseq and Pacific Biosciences (Pacbio), for the molecular characterization of four GM maize events and highlight the advantages of each method for overcoming common challenges in GM event characterization.
Agrobacterium-mediated genetic transformation in green gram (Vigna radiata L.) for sustainable improvement

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Abstract

Optimization of Agrobacterium-mediated genetic transformation (aluminum-activated malate transporter 1; ATALMT1 gene) green gram (Vigna radiata L.) was established by using apical meristem and cotyledonary node. The transformation efficiency was maximum in OD$_{600}$ 0.6 of agrobacterium concentration, 3-day of co-cultivation time and 100 µM acetosyringone concentration. The putative transgenic plants which were histochemically expressed GUS activity. About 65% of thetranagenic plantlets showed positive. Transgenic crops, however, have not found ready acceptance among public at large. The ability to transfer and express genes from any organism into plants transgressing the sexual barrier has raised concerns about the possible hazards to human beings and the environment. Therefore, transgenic crops are subjected to elaborate tests to assess the risks, and to ensure safety, before they are approved for commercial cultivation. These tests include assessment of hazards to humans (allergenicity and toxicity), animals, non-target organisms and the environment. Allergens are proteins or glycoproteins that are recognized by immunoglobulin E (IgE) which is elicited by the immune system of an individual. Allergenic proteins must bind specific IgE molecules that are present on the surface of mast cells and basophiles to elicit an immune response. Utilization of bioinformatics tools for assessment of allergenicity of recombinant protein(s) from transgene has seen significant progress over the last decade. Bioinformatics analysis has been considered a preliminary part of the safety assessment for GMPs because it is the first step in supporting an assessment of the biosafety with food allergy. Bioinformatics analysis for allergenicity assessment of proteins is performed using different allergen databases. Allergen databases and computational tools are becoming important in the assessment of allergenicity of recombinant protein(s) synthesized by the transgene(s) of the genetically modified plants. The novel proteins produced in the genetically modified (GM) crops need to be evaluated for its potential allergenicity before their introduction into the food chain to address the safety concerns of consumers. The present study aims at the evaluation for the potential allergenicity of transgenic proteins of genetically modified (GM) mungbean containing aluminum-activated malate transporter 1; ARABIDOPSIS THALIANA ALUMINUM-ACTIVATED MALATE TRANSPORTER 1; AtALMT1 gene (AT1G08430) using bioinformatics tools. The transcriptional proteins protected membranes from oxidative stress-mediated damage and positively regulated antioxidant gene expression for ROS detoxification and their by counteract oxidative stress, maintain cell redox homeostasis, and enhance abiotic stress tolerance. The amino acid sequences were aligned using allergen online program (http://www.allergenonline.org) employing the FASTA algorithm in six allergen databases of FARRP, SDAP, ADFS, PSD, Allergome and AlgPred. The results showed neither significant alignment nor similarity of ALMT1 proteins at full sequence, domain, and epitope level with any of the known allergen proteins in the full sequence matching. Matching the amino acids illustrated no similarity to determine the epitope potential which confirmed that the transgenic mungbean plants do not have any allergenic effects and therefore safe for consumption.
Hybridization between maize (Zea mays) and teosinte Z. mays ssp. mexicana and Z. mays ssp. parviglumis

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Abstract

The presence of teosinte has been reported to occur in maize fields in Spain and France (Pardo et al. 2014, EFSA 2016). In the framework of the environmental risk assessment (ERA), the potential adverse effects of gene flow from GM plants to cross-compatible relatives must be assessed. In order to evaluate the potential gene flow between maize and teosinte, a cross-pollination experiment was conducted at INIA, Madrid (Spain), in 2017. The teosintes Zea mays ssp. mexicana L. (Schrad.) Iltis, accession Ames 21860, and Z. mays ssp. parviglumis Iltis & Doebley, accession Ames 21785, were provided by USDA. The maize variety was a Bt insect resistant maize (event MON810, DKC6451YG) which allowed the identification of hybrids by the detection of the cry1Ab protein on leaf disks using ELISA. To ensure the overlap in the flowering time, several sets of maize plants were sown periodically at six 2-3 week intervals. A total of 251 seeds were collected from Z. mays ssp. mexicana mother plants cross-pollinated with maize. From collected seeds, 24 plantlets were confirmed as positive hybrids using ELISA and by the phenotype of the hybrid plants, so a 19.2% potential hybridization rate was estimated considering that the maize variety employed as pollen donor was hemizygous for the dominant marker of insecticide resistance. However, despite the fact that maize was sown on different dates, it was not possible to overlap its flowering period with Z. mays ssp. parviglumis.

Our results agree with the fact that Z. mays ssp. mexicana forms frequent viable hybrids when growing in sympatry with maize in central and northern Mexico and differ with other studies that generalize that teosinte Z. mays ssp. mexicana crossed with maize pollen results only rarely in viable seeds. Data presented provide a step in acquiring the knowledge on the potential teosinte-maize hybridization.
Studies on root nodulation and associated bacterial community structure in insect resistant (IR) transgenic chickpea (Cicer arietinum L.)

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Abstract

Chickpeas (Cicer arietinum L.) are important protein-rich grain legumes widely grown in India, contributing 61.49% global production basket with productivity of 0.951 t/ha (FAOSTAT, 2018). Chickpeas can biologically fix nitrogen in symbiotic association with microorganisms converting atmospheric nitrogen into nitrogenous compounds that can be used by plants, while also improving soil fertility. Gram pod borer (Helicoverpa armigera Hubner) is the major devastating pest which attack chickpea starting from first fortnight after sowing resulted in yield loss of up to 20–30% annually. Transgenic chickpea harboring efficacious Bt gene can provide potential alternative to insect resistance breeding program. Five insect resistant transgenic chickpea (cv. DCP92-3) lines (IPCa2, IPCa4, IPCT3, IPCT10, IPCT13) harboring synthetic, codon optimized Bt genes were assessed for possible affects on biological nitrogen fixation (BNF) of chickpea directly by interacting with rhizobia, associated bacteria and/or indirectly through transgenic effects on host metabolism. Present investigation revealed that native Mesorhizobium of field soil initiated root nodulation in all five transgenic events similar to parental chickpea genotype, DCP92-3. Root nodules of DCP92-3 were colonized by Mesorhizobium to the maximum level of 79.52%. Transgenic event IPCa2 supported similar level of nodule occupancy by Mesorhizobium (82.01%), specifically the species M. amorphae which did not colonize any plants from other transgenic events as well as parent genotype. Interestingly, nodule occupancy of Mesorhizobium in IPCT 10 was very poor with the values of 27.05%. Species richness and Shannon diversity index was much higher in IPCT 10 (1196, 2.327) than that of parent genotype (197, 0.823) respectively. High Shannon index of root nodules of event IPCT 10 is similar to that of root tissues of parent genotype. It indicated that root nodules of transgenic event IPCT 10 lost their unique properties, and hence colonized by soil microorganisms in a similar pattern to root tissues. However, further conformational studies are in progress.
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Characterization of Bt Vip3Aa protein for GMO risk assessment

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Abstract

Most of the traits of transgenic crops imported to Korea are herbicide and insect resistance, and the proportion of Vip3Aa (Vegetative insecticidal protein) as an insect-resistant GMO crop has been gradually increased. However, few environmental risk study of the Vip3Aa releated GM crop has been undertaken compared with other insect-resistant GMOs in Korea. Therefore, we need to develop an ecological risk assessment system for Vip3Aa GMO crops that express Vip3Aa protein. In this study, we purified Vip3Aa recombinant protein and characterized the structure and function of Vip3Aa protein. And, we investigated bitrophic and tritropic bioassay using two herbivores, Plodia interpunctella and Sericus montella, natural enemy, Nesidiocoris tenuis and soil decomposer, Eisenia fetida as surrogate species. Although the Vip3Aa protein had no effect on P. interpunctella, N. tenuis and E. fetida survival, S. montella showed lower survival rate when fed with Vip3Aa protein contained artificial diet compared to butterflies fed with control artificial diet. Our case studies suggest that Vip3Aa protein does not harm these tried species except in one lepidopteran species under laboratory high concentration conditions.
Intensified and sustainable agriculture in developing countries: opportunities for, and role of, DNA-based crop improvement

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Abstract

The Australian Centre for International Agricultural Research (ACIAR) is the specialist agency of the Australian government supporting agricultural research for development through commissioned collaborative projects undertaken by developing countries research teams in partnership with Australian researchers. ACIAR supports research in the Pacific, South Asia, South East Asia and Eastern and Southern Africa. Innovations supported by ACIAR aim at improving food security and the livelihood of smallholder farmers, their sustainable use of natural resources, their connection to value chains and markets, adapting to climate change, and the empowerment of women and girls. The establishment of legal frameworks and national biosafety agencies in ACIAR partner countries is opening up opportunities for DNA-based crop improvement which ACIAR is ready to explore under its biotechnology policy. ACIAR support will be underpinned by the expertise of Australian public sector research on crop biotechnology, and Australia’s efficient regulatory regime. In the short term, Bt (insect protected) crops, such as chickpea in Bangladesh have a good potential for impact. However sustainable deployment of Bt crops will require effective stewardship to minimise the risk of the target insect developing resistance. Longer term opportunities reside in products improved for their nutritional or end-use value. Australian research agency CSIRO has developed omega-3 oil-producing canola which could supply the aquaculture feed needed in Bangladesh. Due to the expansion of dairy cattle, sorghum stover is now as valuable as sorghum grain in South Asia. The demand for animal feed is growing fast. CSIRO has developed crops producing oil in their leaves: deploying this technology in rice, sorghum, or forage grasses could improve the nutritional value of the straw and the supply of animal feed. Recent successes in manipulating plant reproduction towards apomixis, and increasing photosynthesis efficiency, open other new opportunities for long term improvement of smallholders productivity.
**Abstract**

The fall armyworm, *Spodoptera frugiperda* (J.E. Smith) (Lepidoptera, Noctuidae), was once confined to the western hemisphere but in early 2016 outbreaks were recorded in West and Central Africa. This devastating pest was confirmed in South Africa at the beginning of 2017. Since South Africa is one of the world’s largest genetically modified (GM) maize producers and insect resistant GM maize is planted on a wide scale throughout the country, the development of fall armyworm resistance to the insecticidal proteins in insect resistant GM maize is a real area of concern for South African regulators. The well-documented development of resistance of *Busseola fusca* (Fuller) (Lepidoptera: Noctuidae) larvae to first-generation, insect resistant GM maize in South Africa suggests that there were shortcomings in the insect resistance management programmes implemented in the past. An analysis of these insect resistance management programmes identified several shortcomings, both in the pre-marketing phase and the post-marketing phase. With the aim of significantly delaying or preventing the development of fall armyworm resistance to insect resistant GM maize in South Africa, an insect resistance management framework is presented that tightly integrates pre-marketing research and post-marketing monitoring.
Current applications of genome editing in agriculture: a systematic map

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Abstract

Plant breeding is a development process and new breeding methods have evolved continuously over time. Within few decades, genome editing techniques such as Clustered Regularly Interspaced Short Palindromic Repeats/CRISPR associated proteins (CRISPR/Cas), Transcription Activator-Like Effector Nucleases (TALENs), Zinc-Finger Nucleases (ZFN), Meganucleases (MN), Oligonucleotide-Directed Mutagenesis (ODM) and Base editing have been developed enabling a precise modification of DNA sequences in many plant species.

A systematic map provides a comprehensive overview about the fast growing available evidence for the application of genome editing in plants. It is based on two review questions targeting to current applications of genome editing in plants and the available evidence for any potential occurrence of associated off-target effects. Available academic and grey literature was collected and evaluated in a systematic and transparent manner covering the period between 1996 and May 2018.

Results of the systematic map cover the period between 1996 and May 2018 and show more than 1300 applications in model plants as well as in cultivated plants. The corresponding authors/leading institutions came by a considerable margin from China (612) followed by the USA (487), Japan (92) and Germany (88). The major part of applications are related to rice (475), followed by Arabidopsis (214), tobacco (107), tomato (87) and maize (77). Altogether, in the period until May 2018 applications in 46 different model and cultivated plants were documented. In most of the studies (92%) mutations comparable to spontaneous mutations or undirected mutagenesis were induced by genome editing. Besides many basic research studies, 98 applications with regards to plants and general traits were allocated as market-oriented developments, including improved growth characteristics and yield improvement, improved food and feed quality, increased tolerance to abiotic and biotic stress and herbicide tolerance.
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▶ Capacity building for regulatory compliance and product stewardship for commercialization and deployment of GM crops in Africa

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Abstract

Agricultural biotechnology offers great potential to enhance agricultural productivity, food security and livelihoods in Africa. Some countries in Africa have established functional biosafety regulatory systems and are moving towards commercialization of genetically modified (GM) crops. However, the general release of GM crops will require enhanced capacity for regulatory compliance and product stewardship to help ensure sustainable use of GM technology. The post-release management of GM crops encompasses trait performance, integrated pest management (IPM), seed quality, intellectual property, labelling, identity preservation, consumer acceptance and marketing. This poster will cover the key aspects of regulatory compliance and product stewardship for safe and sustainable use of GM technology. Bt cotton, Bt cowpea and drought tolerant maize, which are deployed or in pipeline in several countries in Africa, are included as case studies. The poster will highlight capacity building needs identified by stakeholders for addressing regulation and stewardship, and provide information resources.
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Current and future contributions to the work of the Cartagena Protocol on Biosafety (BSP) by the GIC

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Abstract

The Global Industry Coalition (GIC) for the BSP receives input and direction from trade associations representing thousands of companies from all over the world. Participants include associations representing and companies engaged in a variety of industrial sectors such as plant science, seeds, agricultural biotechnology, food production, animal agriculture, human and animal health care, and the environment. Since before the BSP entered into force, the Global Industry Coalition has been an active contributor to its implementation, in particular, its provisions on risk assessment and risk management of living modified organisms (LMOs). This work is done to support the safe and continued application of modern biotechnology in agriculture while ensuring the effective and efficient implementation of the Convention on Biological Diversity (CBD) and its Protocols in countries that are Parties to the CBD and BSP.

During the current intersessional period of the CBD (2019-2020), the GIC will engage in work programs on a range of topics coordinated by the CBD Secretariat: risk assessment and risk management (Articles 15 and 16); unintentional transboundary movements, including detection and identification of LMOs (Article 17); transit and contained use of LMOs (Article 6); socio-economic considerations (Article 26); public awareness, education and participation (Article 23); development of the post-2020 Biodiversity Framework; and synthetic biology.

In relation to the work programs on risk assessment and risk management, as well as synthetic biology, there are a number of opportunities for engagement, including through submissions of information to the CBD Secretariat, participation in online fora, and contributions to ad hoc technical expert groups. All of these points of engagement contribute to the draft decisions that will be presented to the Parties at their next meetings in late 2020. The planned program of work on these topics, relevance to ISBR participants, and expected GIC engagement will be presented.
Genetically modified insect-protected maize cultivation in the EU: the MON 810 case

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Disclaimer: Note that Monsanto has become a subsidiary of Bayer AG as of 21 August 2018. However, as the monitoring tasks described in this abstract were conducted before the specified date, the name ‘Monsanto’ is kept throughout the documents. The owner of this abstract is Bayer AG.

Abstract

In the European Union (EU), genetically modified insect-protected maize products have been approved for commercial cultivation since 1998. Maize event MON 810 produces the naturally occurring Bacillus thuringiensis (Bt) protein, Cry1Ab, which protects the maize plants from foliage feeding and stalk tunneling damage caused by certain lepidopteran insect pests such as the European corn borer (Ostrinia nubilalis) and the Mediterranean corn borer (Sesamia nonagrioides). MON 810 has consistently been cultivated in the EU (mainly Spain and Portugal) since 2003, which makes it possible to analyse the farmer experience in this period. More than 1,300,000 accumulative hectares of MON 810 have been cultivated and revealed consistent and substantial agronomic as well as economic benefits for farmers, and a favourable impact on the environment. However, the controversial and often emotionally loaded debate on the acceptance of genetically modified crops has led to their over-regulation and restricted cultivation in Europe. As a result, the cultivation of MON 810 has been subject to extensive monitoring efforts conducted by the authorization holder on an annual basis and using different tools including susceptibility evaluations of the target pests, farmer questionnaires, analyses from established farmer complaint systems and literature review. The overall conclusion of all the monitoring efforts confirms the validity of the outcomes of the initial safety assessments that MON 810 has no adverse effects on human, animal health or the environment. The MON 810 cultivation in the EU has provided efficient protection against the target pests resulting in higher yielding crop, a significant decrease in insecticide use and a reduced susceptibility to diseases and pests compared to conventional maize. The abovementioned evidence should be considered as valuable data for the risk management of this product, support its continued approval without additional but rather less extensive monitoring conditions that are in proportion to the risk.
Socioeconomic impacts of the gene editing regulation in Argentina: preliminary statistics.

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Abstract

The regulatory framework in Argentina is based on Resolution 763/11 which involves all activities related to GMOs. From the moment that Gene Editing techniques started to develop globally, Argentina decided to work in a special regulatory regime to determine if a product obtained through these innovation techniques could be contemplated or not by the GMO resolution. After two years of debate a resolution becomes official and the first consultations of products genetically edited to be analyzed by CONABIA. Until now, almost twenty cases have been presented, this includes annual crops as well as ornamental plants and fruit tree, some animals and microorganisms. The evaluation of the cases presented allowed us to obtain preliminary statistics related to the socio-economic impact of the Gene editing products for agroindustry use. First of all, large part of the consultations carried out with CONABIA belonged to small companies and public institutions, while a smaller proportion corresponded to multinational companies. This shows that an opportunity opens up for small companies and public institutions to reach the market with product obtained through these technologies. Secondly, it was observed that most of the queries presented to the committee were made when the product was in the “design stage” and not as a final product. As the resolution for Gene Editing products offers the possibility to make the query when the product is in in “design stage” allows the developer to anticipate the development costs of the products to reach the market. Finally, it was important to consider the GM and Gene Editing crops trajectory to know the speed of innovation. At this point it was seen that the speed of innovation for GM crops remains stable while Gene editing products are blooming.
Safety evaluation and approval status of genetically modified foods in Korea

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Abstract

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. In which cases a person who imports, develops or manufactures GM foods for the purpose of eating imports GM foods for the first time, he/she shall undergo a safety evaluation of the relevant foods, etc. by MFDS. And in which cases ten years have elapsed since GM foods underwent safety evaluation, they shall be re-evaluated for their safety. Safety of GM foods is evaluated according to 「Food Sanitation Act」 and 「Regulation on safety evaluation for GM foods (MFDS Notice No. 2018-6)」 based on the concept of substantial equivalence suggested by CODEX and OECD. To conduct environmental risk assessment, 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. 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 according to LMO Act. As of January 2019, a total of 199 events have been approved by MFDS and they are 169 events of GM crops including soybean (29), maize (87), cotton (29), canola (14), sugar beet (1), potato (4), alfalfa (5), 6 events of GM microorganisms and 24 events of GM food additives originated from GM microorganisms. The re-evaluation of 31 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.
Asia forum: an information exchange initiative by Korea BCH

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Abstract

Asia-Pacific region, is home to nearly 60% of the world’s population with growing demand for food and feed. Biotechnology offers an array of powerful tools and among them, genetic engineering and more recently gene editing holds the promise of improving productivity, profitability and sustainability of farm production systems. Biosafety regulatory systems for use of biotech products are at different stages of development and implementation in countries of the Asia-Pacific region, the processes having been initiated at different times and following different approaches. Countries of the Asia-Pacific region have in general adopted a cautious approach to field trials and commercial cultivation of GM crops. Those that have approved such cultivation have mostly experienced benefits through improved yields, fewer applications of pesticides and higher farmers’ income. Public sector research involving GM technology for crop improvement is also being widely pursued, though majority of the research results are still at the laboratory or greenhouse stage, with limited number progressing to field testing stage.

Korea Biosafety Clearing House (KBCH) has initiated convening of an ‘Asia Forum’ as an information sharing mechanism among the Asian countries, since 2017. The first Asia Forum organized in 2017 focused on environmental release of GM crops and the second on gene editing. The information exchange among regulators and experts has been extremely useful and expected to lead towards cooperation among Asian countries in dealing with new and advanced technologies in a collective manner. This presentation will cover conceptualization of the Asia Forum and key findings from two meetings based on analysis of the presentations made.
Positive impacts of the new Brazilian regulatory scenario for commercialization of genetically modified microorganisms and their derivatives: amyris case

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Abstract

Amyris’ proprietary yeast engineering process uses renewable-sourced carbon from plants to create products including cosmetic emollients and fragrances, fuels, solvents, lubricants and nutraceuticals. Amyris’ subsidiary located in Brazil plays the fundamental role in developing and transferring process technology from pilot plant to manufacturing scale ensuring biosafety compliance. According to the current Brazilian Biosafety Legislation, to commercialize genetically modified microorganisms (GMMs) and their derivatives, it is mandatory to assess their safety to the environment and human and animal health, depending on the intended use, and to submit commercial approval proposals to the Brazilian National Biosafety Technical Commission (CTNBio). In 20 years of genetically modified organisms use in Brazil, GMMs have been shown to be safe and efficient, providing a History Of Safe Use (HOSU) that enables the development and evolution of the current regulation. In 2018, CTNBio’s Normative Resolution 21 was published specifically for genetically modified microorganisms (GMMs) commercialization purposes, recognizing the advances and development of biotechnology. The regulation for GMMs follows the pace for development of new strains and complexity of such organisms. In this context, this presentation intends to demonstrate the positive impacts of the publication of a specific regulation focused on microorganisms, enabling the increase of the competitiveness of the products originated with this innovative technology, while also maintaining safe practices.
The concept of pure and chemically defined substances and implications for their risk assessment

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Abstract

Chemistry defines “pure substances” as matter made of only one type of molecule or atom which presents constant and well-defined physical-chemical properties. Therefore, pure substances have always the same composition regardless their origin source or production mode. Modern biotechnology has the potential to enable the development of virtually all kinds of molecules using more sustainable sources. Human insulin was the first commercial molecule produced from a GMO, resulting in a better life quality for patients. Since then, several other substances have been produced, including ingredients used in the food industry, fine and commodity chemicals, biofuels, etc. The Brazilian Biosafety Law N° 11.105 states that “pure and chemically defined substances obtained by means of biological processes and which do not contain GMOs, heterologous protein or recombinant DNA shall not be deemed GMO by-products”. If this requirement is met, the Brazilian regulators recognize that such class of substances are indistinguishable from substances produced by means of “conventional” processes and do not pose any additional risk to environment or consumers compared to their conventional counterparts. In this poster we discuss the concept of pure substance adopted by the Brazilian regulators and the implication of this classification for their risk assessment. The harmonization of this concept among regulatory agencies would correctly assess the biosafety of such substances according to their intrinsic risk instead of their production route.
Argentinian expertise in regulatory cooperation

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Abstract

Argentina was one of the first countries in Latin America to implement a system of evaluation of the biosafety of GMOs for agriculture use. This regulatory system not only is recognized worldwide, but also it provides bilateral and multilateral cooperation with other countries to develop their own regulatory frameworks. With a 27 years trajectory in biosafety expertise the National Advisory Commission on Agricultural Biotechnology (CONABIA by its Spanish acronym) has been recognized by FAO as a reference center in biosafety of GMO. In relation to the aforementioned, CONABIA actively participate in two kinds of cooperation. O one hand bilateral activities: Conformed by diverse initiatives, such as work groups, agreement memorandums and FOAR. This last initiative aims to trained technicians of under developed countries in biosafety and biotechnology. And on the other hand, multilateral activities that involve training and capacity building activities by international organization like FAO, ICGEB, IICA, ILSI, OECD, UN University, MERCOSUR and CAS. Furthermore, CONABIA is constituted by members of different institutions, like ministries, public universities, research centers with interdisciplinary representatives which evaluate the environmental biosafety of GM crops, which involves the different procedures for GM plants, animals and microorganisms. Finally, concerning the scientific-technical evaluations of CONABIA, more than 2000 field trials and 50 evaluations for the commercial release, were granted for six different species.
Prospective strategy of communication for biotechnology in Argentina

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Abstract

Biotechnology has a real potential to solve particular problems in agriculture that have not been determined by conventional methods. Currently, there is a lot of innovative capacity that will be needed to be channeled as these technologies take an increasing role in the development process. Due to the speed with these products with adding value are generated and inserted into society worldwide that is important to evaluate the possible impacts that scientific communication and outreach strategies can generate to achieve a positive reception of these technologies.

Based on different experiences in scientific communication and divulgation events carried out by the Biotechnology Directorate in recent years, intended for children and adults which had wide acceptance, we propose to develop a strategic prospective plan of communication for biotechnology in Argentina. The elaboration of said plan will be built based on the proposed scenario considering the evolution of the technological, economic and sociopolitical variables.
Determinants of attitude and perceptions towards GMOs and biosafety policy in Uganda

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Abstract

Attitudes and perceptions of key stakeholders towards genetically modified organisms (GMOs) can affect decision making for critical policies for biosafety as well as adoption of relevant technologies. This paper analyzes factors that contribute to the attitudes and perceptions towards GMOs and biosafety in Uganda based two studies that were conducted between 2016 and 2017. The surveys were conducted in 12 districts targeting 1660 respondents using questionnaires with five-point Likert scales. Based on the results of the surveys, 73% of the respondents agreed that Uganda should set-up systems to regulate GMOs, 9% disagree while 18% were uncertain. Using in-depth questions and feedback received during other stakeholders’ outreach engagements regarding biosafety, we identified patterns of association between the attitude groups and the contributing factors. Prior knowledge and trust in the information sources were the major driving factors for attitude and perceptions for most stakeholders’ categories. Thus timely identification and continuous engagement of the “right” opinion leaders is pertinent otherwise efforts may be counterproductive. The role of mass media outlets in shaping public opinions, regardless of the messenger, cannot be underestimated. Influencing policy and the regulatory system requires a multi-faceted and flexible communication strategy that accommodates the ever changing needs of the various stakeholders’ categories. We also discuss the implications of this knowledge for future education and outreach efforts that would foster appreciation of and informed decision-making on adoption of scientific innovations and bio-policies in Africa.
Evolution of the environmental risk assessment of stack GM crops in Argentina

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Abstract

Argentina is one of the countries with the longest trajectory in the field of biosafety. Its beginning dated in 1991, year in which the National Advisory Committee on Agricultural Biotechnology (CONABIA) and the Biotechnology Directorate have started to regulate activities with GM crops. In 1996, the first single event (soybean resistant to glyphosate) was approved for commercial release. From that moment, it has been an increase in the number of applications for commercial authorization of GM crops, including single and stacked events. In 2007, a specific resolution for stacked events became official. This Resolution proposes a simplified environmental risk assessment (ERA) for stacked events whose parental events have already passed through the regulatory system and have been approved for commercialization. Due to the growing demand of cases presented and the experience that the Argentinian framework was acquiring in the ERA of GMOs, it was necessary to make an expedited assessment for stacked events whose parental events have commercial approval. Moreover, the experience that the Argentinian regulatory system has in assessing the risk of liberating into the agro ecosystem stacked GM crops, enables regulators to make an even faster and simpler ERA for them, focusing on the interaction of the expression products.
The regulation of GMOs in New Zealand

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Abstract

The concept of a ‘new organism’ in the New Zealand context came into being with the Hazardous Substances and New Organisms Act, 1996 (The HSNO Act), and is defined as any organism not present in New Zealand on or immediately before 29 July 1998, as well as any genetically modified organism. The Environmental Protection Authority is responsible for administering the HSNO Act, and as such regulates all New Organisms, including GMOs. A GMO in New Zealand has a broad definition, but refers to Regulations specifying those organisms that meet the definition, but are considered exempt. These regulations were reviewed and redrafted in 2016 in response to a High Court challenge to the result of another of EPA’s functions, the statutory determination of whether or not any organism is a New Organism under the HSNO Act. The EPA has the power to grant various types of approvals for GMOs, which mostly involve the importation into containment, or the development of GMOs in containment. However, the EPA also has given approvals for the field trials and release of various GMOs since the inception of the HSNO Act. I will discuss the aspects of the law that EPA must consider in coming to a decision for any approval for the release of a GMO, or a determination as to whether or not an organism is or is not a GMO for the purpose of the HSNO Act, using recent EPA decisions as examples.
A simple problem formulation framework to create the right solution to the right problem

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Abstract

A systematic approach to formulate consistent, technically robust and scientifically tractable problems will facilitate achieving innovative and effective solutions in risk evaluation. The fundamentals of problem formulation have been adapted from environmental and human health risk assessments. A structured problem formulation enables focus on describing and evaluating the specifics of the problem to be solved, instead of immediately creating solutions. First the problem should be framed to provide clarity and gain agreement on the problem to be addressed, resulting in a specific problem statement. Second the problem is explored in order to transform it into an operational state through questions to answer, hypotheses to test, and represented by a conceptual model. Finally the approach to testing hypotheses is mapped and the analysis plan is developed to address the problem statement. This simple adaptable framework can be applied to any circumstance to resolve a specific problem and describe a path to resolution.

Reference

Assessment of effects from Bt maize on non-target Lepidoptera: towards improvement of test protocols and risk assessment

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Abstract

European legislation requires ecotoxicology tests on non-target (NT) organisms, as part of the risk assessment of genetically modified (GM) crops. However, the lack of clear guidelines and standards regarding test protocols lead applicants to focus on pest species and to use different test protocols, possibly overlooking risks to NT organisms. This project addresses the need for common standards of non-target Lepidoptera laboratory studies for risk assessments of insect resistant (Bt) maize.

Firstly, we developed a way to select a representative set of non-target Lepidoptera suitable for ecotoxicity tests by applying relevant selection criteria such as exposure probability and breeding possibility. By applying the method to the Lepidoptera fauna of Germany we were able to identify 31 possible candidate species.

Secondly, we scrutinized available test protocols for testing the effects of Bt protein on non-target Lepidoptera. By doing so we identified a number of issues requiring standardisation of the experimental conditions and/or the approach and provide suggestions for a harmonized procedure such as the application of Bt maize pollen or synthetic toxins, larval diet, experimental controls, magnitude and duration of exposure to Bt, the assessment endpoints and sufficient statistical power.

Finally, laboratory studies were carried out on relevant NT Lepidoptera species to assess key aspects of the testing methodology that we had identified in the previous steps; and to obtain currently lacking results on species’ response to Bt toxins, necessary for risk assessment simulation models.

The results from this project contribute to the necessary development of precise guidance for the authorities and companies alike, supporting the operalisation of the required laboratory tests for the evaluation of non-target effects of Bt maize on Lepidoptera.
Biosafety status and socioeconomic effects of Bt-brinjal cultivation and its public perception in Bangladesh

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Abstract

Bangladesh released genetically modified Bt Brinjal which is resistant to its most devastating pest, the fruit and shoot borer (FSB). This landmark occasion marked the beginning of cultivation of South Asia’s first genetically modified food crop. Conventional brinjal varieties are highly susceptible to damage caused by the FSB for which farmers spray 60 to 180 times per season that can leave harmful residues on the crop and also expose farmers to dangerous toxins in pesticides. Adoption of Bt brinjal is expected to positively impact the income of the farmers; improve environment and human health. A study was conducted to analyze the biosafety maintenance and management during bt-brinjal cultivation its socioeconomic effect and public perception in Bangladesh. The study comprised of visiting the bt-brinjal fields, interview of 101 farmers from 26 Upazilla under 20 districts of Bangladesh, analysis and interpretation of the data. It was found that 66.67% of the bt-brinjal farmers marginal farmers who cultivated less than 0.1 ha of land for bt-brinjal. Annual income from bt-brinjal cultivation varied among the farmers. Most of the farmers belonged to the low income group. Among the 4 varieties released in Bangladesh, 35.29% of the farmers cultivate Bt-brinjal2 (Kazla) variety. It was found that more than half of the farmers (51.96%) maintain border crop while growing bt-brinjal in their fields. Other farmers either do not manage border crop or have no idea about border crop management. It was found that 50% of the farmers use fence around the bt-brinjal field to protect the crop from animals and being theft. In some cases there were watch men employment for the protection of the crops. The survey revealed that 52% farmers label the bt-brinjal for sale. In this survey 85.29% of the farmers opined that cultivation of bt-brinjal improved insect control. Majority of the farmers (77.45%) found that bt-brinjal reduced labor and chemical costs and 75.49% farmers found increase of yield and 71.57 % growers were benefitted with the increase of income. This survey found that 89.22% of the consumers reported that cultivation of bt-brinjal improved quality of brinjal. Again, 58.82 % consumers opined that price was reduced due bt-brinjal cultivation, while 41.18% did not agree with this opinion. Most of the consumers (97.06%) believe that bt-brinjal cultivation reduced pesticide use and consequently reduced health and environmental concerns of insecticide use (96.08%) and bt-brinjal is safe for human health (96.08%). The information gained is valuable for future GM crop development, release and cultivation in Bangladesh.

Keywords: Biosafety, Bt-brinjal, GE crops, Management, Socioeconomic.
Towards developing science based regulation on genome editing in India

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Abstract

The advent of site-specific nucleases like ZFN, TALEN, CRISPR-Cas has transitioned genetic engineering (GE) into the era of genome editing (GEd) by introducing higher precision towards modification of genome of plants, animals, humans, and microbes. From introducing a single base change to insertion of foreign gene(s), genome editing technologies offer solutions to a wide range of problems. As such, adoption of regulations and risk assessment mechanism of GE organisms for GEd shall overburden and impede timely adoption of the technology to reap its benefits. Globally efforts have been made to revisit, revise or update the existing regulatory risk assessment mechanisms for the regulation of GEds. In this regard, some countries have already clarified their legal position(s) on regulating genome editing and others are in the process, although there is still limited clarity on its operationalization i.e. determining the underlying process of risk assessment and the data required for the assessment. In this context, in India, Section 3 of Rules 1989 of Environment (protection) Act, 1986 has defined GE in a way that will require implementation of biosafety regulation on GEd in the process, product and product thereof level by a mechanism defined under the Rules. As per the Rules, the GEd will trigger regulation and hence, Indian regulatory authorities are working on a policy specific to GEd for its adoption to various applications. Also, keeping in view of the technical and procedural differences between the GE and GEd technologies, the GEd risk assessment shall require data proportional to the complexity and risk(s) of types of GEd namely SDN1-3. It will help to develop a functional risk evaluation matrix on GEd that will allow determining the scope of regulation or exemption on the quantum of data requirement and assessment framework.
Concept of familiarity in risk assessment - experience of the Americas

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Abstract

The International Life Science Institute (ILSI) is structured, in all countries where it operates, in Scientific Committees, among which Biotechnology. The ILSI Biotechnology Committees of Argentina and Brazil have been working together for a few years to identify issues of greatest interest for development and training in the various countries of the Americas. Due to their intrinsic importance for the problem formulation (the starting point of the risk analysis), the topics “familiarity” and “history of safe use” (HOSU) have stood out as shared topics of interest for this collaboration in the last 5 years. Particularly, the familiarity topic has been deeply discussed by the Committees to explore related concepts as stacked events, data transportability and similar constructs. Both topics have therefore been further elaborated, culminating in a harmonization workshop held in September / 2018 in São Paulo. The main topics addressed at the workshop were: (*) concepts of “familiarity” and HOSU in a risk analysis of GMOs; (*) applicability of these concepts; (*) some experiences of regulatory agencies in the Americas in the use of these concepts. Among the main conclusions and recommendations are: (1) The need to formalize definitions of HOSU and “familiarity”; for its relevance and its impacts on the Problem Formulation process and further harmonization; (2) The approaches and practice of agencies in the Americas are important for understanding the relevance and impacts of the terms and tools discussed; (3) Collaboration among regulatory agencies is essential to harmonize processes and verify the applicability of the terms and tools discussed; (4) The publication of the terms and definitions is essential, and therefore need to be presented in peer-reviewed scientific journals.

A Memory of the event will be made available at the ISBR2019, where a Parallel Session on “Familiarity” will also take place.
WORKSHOPS
W1: Gene editing and gene drives for managing unwanted vertebrates - current status and biosafety consideration

Organizers:
Allison Snow, Ohio State University, USA and Tim Harvey-Samuel, Pirbright Institute, United Kingdom

WS I - 1

Ecological context for the proposed release of Lyme-resistant, white-footed mice: a case study of gene editing

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Abstract

Genetic engineering of wild populations has been proposed as a way to reduce human diseases by altering pathogens’ hosts. For example, gene editing may be used to create white-footed mice (Peromyscus leucopus) that are resistant to the Lyme spirochete vectored by blacklegged ticks (Ixodes scapularis) in the USA. Towards this goal, Kevin Esvelt and colleagues began working with residents of Nantucket and Martha’s Vineyard islands, Massachusetts, in 2016 to discuss genetically engineering local white-footed mice, which are the primary reservoir host for Lyme. As proposed, if field trials with gene-edited mice on small islands show that the incidence of spirochetes in mice is reduced substantially, the project would scale up to Nantucket and Martha’s Vineyard and possibly the mainland (perhaps by adding a localized gene drive), pending approvals from relevant constituents. White-footed mice are abundant in forest habitats and they play a major role in natural predator-prey-herbivore interactions. To evaluate possible hazards of releasing GE mice, detailed information is needed about the inserted genetic elements, the efficacy of these genetic alterations in conferring resistance, and how the introduced GE mice differ from wild mice with regard to their genetic diversity, behavior, survival, and reproduction. In addition to effects associated with engineered resistance and any founder effects from lab-reared populations, it is possible that insertion of the resistance cassette(s) would have unanticipated pleiotropic effects on mouse phenotypes. A key question is whether the GE mice will have lower or greater fitness than their non-GE counterparts. Fitness experiments carried out under semi-natural conditions can offer insights about such effects, although the full range of such outcomes may not be evident in small-scale, short-term studies. Ideally, the proposed Lyme-resistant, white-footed mice would be very similar to local white-footed mice in their genetic diversity, physiological ecology, fitness, and ecological interactions in local habitats.
Determining the feasibility of gene drives for feral cat control in Australia

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¹CSIRO, Perth, Australia; ²Australian Wildlife Conservancy, Perth, Australia; ³CSIRO, Canberra, Australia; ⁴Island Conservation, Galapagos, Ecuador

Abstract

CRISPR-Cas9 genome editing has opened up a new frontier of exploring genetic pest control technologies including gene drives, which can be used to force deleterious traits through target pest populations. Gene drives are delivered and spread through sexual reproduction, which makes population eradication theoretically possible from a small number of released gene drive-carrying individuals. This powerful technology could form part of a fresh new approach to control intractable yet highly damaging invasive species including the feral cat, which in Australia is a key driver of native species extinctions. Indeed, feral cats are estimated to kill over a million birds each day across Australia, and are responsible for 30 endemic mammal extinctions in Australia in the last 200 years. To date, gene drives have been demonstrated effective only in insect and yeast models, and only under controlled laboratory conditions. The GBIRd (Genetic Biocontrol of Invasive Rodents) consortium are developing a gene drive technology to deploy against invasive mice on islands. Once developed, optimised, and proven safe and effective in mice, this technology should be adaptable to target other invasive mammals, including feral cats. In the interim, we are focused on improving our understanding of feral cat biology, ecology, genetics and behaviour in order to determine whether a gene drive would spread effectively within and between feral cat populations, and if so how long it would take to reach and control feral cat populations across Australia. Understanding genetic diversity, population dynamics, dispersal patterns, mating strategies, etc. is essential to inform release strategies, and any genetic control strategy against cats will need to take into account their territorial nature. We are also engaging with relevant stakeholders and communities across Australia to determine whether, and under what conditions, the Australian public may accept the use of gene drives for feral cat control.
A CRISPR-Cas9 split drive targeting female reproduction in mice

Gus McFarlane, Bruce Whitelaw, Simon Lillico
University of Edinburgh, Roslin Institute, United Kingdom

Abstract

Invasive pests impact the environment, economy and society. Current control methods are costly and largely inadequate, and they often lead to unwanted suffering in target and non-target species. Gene drives that enable super-mendelian inheritance of a transgene may offer a more cost-effective, humane and species-specific alternative than current methods. We set out to develop and test a safe-guarded gene drive system, known as a split drive, that could spread female infertility through a laboratory-contained mouse population. Using mouse embryonic stem cell technology, we developed a Cas9 split drive system which disrupts an essential female fertility gene and confers a recessive female-infertility phenotype. Split drive harbouring embryonic stem cells were developed using plasmid donor-DNA and a combination of Cas9 ribonucleic protein and plasmid-based Cas12a endonuclease. Engineered cells were validated using digital PCR and traditional Southern blotting techniques. A breeding population of split drive mice is being established to study the transmission frequency and phenotypic impact of the drive system in a model mouse population. The findings could help guide the development of safe gene drive systems for vertebrate pest management.
Safe development of CRISPR gene drives for invasive rodent population suppression

Chandran Pfitzner, Sandra Piltz, Fatwa Adikusuma, Paul Thomas
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Abstract

Invasive mammalian pests including mice and rats cause significant environmental damage and loss of agricultural productivity. Landscape-scale rodent control relies on widespread distribution of toxic bait and is relatively expensive, labour-intensive and inhumane. Recent advances in genome editing technology suggest that CRISPR-Cas9 gene drives could be used as an alternative, humane strategy for invasive rodent population control. A CRISPR-Cas9 gene drive is a genetic construct that promotes its own inheritance through self-replication and can therefore spread through a given population. Our recent in silico modelling indicates that CRISPR-Cas9 gene drives that induce female sterility or embryonic lethality have potential for eradication of rodents on islands. Our modelling also suggests that a Y chromosome “shredding” drive could be used for invasive rodent population suppression. However, despite their potential, CRISPR-Cas9 gene drives have only been developed in a small number of species including flies, mosquitoes and yeast. Our goal is to develop efficient mouse CRISPR-Cas9 gene drive technology, incorporating stringent safeguards against unintentional release. Using a ubiquitous Cas9-expressing strain, we have shown that gene drive activation in mouse zygotes promotes generation of indel mutations and not self-replication. We are also developing a proof-of-concept “germline-active” gene drive using a similar strategy to that employed in insects. We anticipate these experiments will provide an important step towards development of new tools for population suppression of invasive rodent pests.
WS I - 5

▶ Engineering genetic incompatibility and applications for controlling invasive fish populations

Siba Das, Samuel Erickson, Przemek Bajer, Maciej Maselko, Michael Smanski
University of Minnesota, Saint Paul, Minnesota, United States

Abstract

We introduce a novel approach to engineer a genetic barrier to sexual reproduction between otherwise compatible populations. Programmable transcription factors drive lethal gene expression in hybrid offspring following undesired mating events. In this talk, I describe the technology, demonstrate a proof-of-concept in yeast, and share recent progress in translating the approach to fish with applications for invasive species control.
**WS I - 6**

**Principles of probabilistic risk assessment for genetic biocontrol**

**Keith Hayes**  
CSIRO DATA61, Hobart, Australia

**Abstract**

National regulations that mandate environmental risk assessments for the contained use and release of Living Modified Organisms (LMOs) typically stipulate the use of qualitative methods. The advent of gene drives, however, have led some agencies to question the adequacy of qualitative risk assessments methods, and The United States National Academies of Science Engineering and Medicine (NASEM) and the Australian Academy of Sciences (AAS) have recently recommended quantitative probabilistic risk assessments in this context. This presentation provides an overview of the principles of probabilistic risk assessment for genetic biocontrol, whilst briefly highlighting a range of methods that enable these principles to be applied. The presentation will draw on examples of hazard analysis and risk assessments completed by the CSIRO DEERA team for real (malaria vector control) and hypothetical (eradication of non-native populations of mice and carp) situations.
A review of baseline information on RNAi that supports the environmental risk assessment of some RNAi-based GM plants

Olivier Christiaens¹, Teodora Dzhambazova², Kaloyan Kostov², Salvatore Arpaia³, Mallikarjuna Reddy Joga¹, Isabella Urru³, Jeremy Sweet⁴, Guy Smagghe¹

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²Agrobioinstitute (ABI), Sofia, Bulgaria;
³Italian National Agency for New Technologies, Energy and Sustainable Economic Development (ENEA), Roma, Italy;
⁴JT Environmental Consultants Ltd, Cambridge, United Kingdom.

Abstract

A systematic literature search was performed to collect all available peer-reviewed studies on RNAi in invertebrate species (Nematoda, Arthropoda, Mollusca and Annelida) to provide a baseline information on this technology for EFSA that could support the environmental risk assessment of RNAi-based GM plants. In this literature search, we retrieved a total of 5,076 publications. Based on this database, an overview was compiled of all studies using oral delivery of small RNAs (sRNAs) to these invertebrates. This overview includes information on tested species, life stage, sRNA molecule type, target gene, concentrations used, outcomes, etc. A second part of our assignment was to provide several narrative reviews on different topics such as environmental and cellular uptake of sRNAs, RNAi efficiency and factors involved in sensitivity, possible exposure routes of small RNAs to (non-)target organisms, potential unintended effects by sRNAs on invertebrate species in the agroecosystem and also on the availability and use of genomic data in risk assessment of RNAi-based GM crops. The analysis of the studies shows that in most cases, information on dsRNA expression in GM plants is not adequate for an exposure analysis and in some studies, no detection of dsRNA in plants was carried out. We conclude that it is necessary to characterize expression levels in each GM event in order to determine exposure levels to both target and non-target organisms. Movement of dsRNA along trophic chains and the persistence of its biological activity have been shown only in a few multi-trophic systems. We conclude that fate of dsRNA originating from GM plants in different trophic levels needs to be determined in order to assess effects at higher trophic levels. The use of bioinformatics to predict off-targets and non-target effects is problematic because there is no real consensus yet on the ‘rules’ for siRNA/RISC binding to the homologous mRNA and there is limited sequence information in both targets and off targets. There is no certainty on the number of nucleotides that must match the target sequence and on the allowed number or types of mismatches. In addition there is no clear evidence on the number of siRNAs processed from dsRNA that are necessary for gene silencing. Thus we conclude that genomic data alone is unlikely to be sufficient to predict silencing effects.
Phage-based bacterial production and exogenous application of dsRNAs for plant protection

Annette Niehl\textsuperscript{1}, Marjukka Soininen\textsuperscript{2}, Minna Poranen\textsuperscript{2}, Manfred Heinlein\textsuperscript{1}

\textsuperscript{1}Université de Strasbourg, Strasbourg, France; \textsuperscript{2}University of Helsinki, Helsinki, Finland

Abstract

Virus infection causes severe damage on cultivated plants and therefore represents a serious threat to global food production. Recent experiments demonstrate the ability of exogenously applied double-stranded (ds)RNAs to protect plants against virus infection by triggering RNA interference. We engineered bacterial cells containing a phi\textsuperscript{6} phage-derived RNA replication system for the efficient in vivo production of large amounts of high-quality dsRNA sequences homologous to Tobacco mosaic virus (TMV). The produced TMV-derived dsRNAs inhibited infection by TMV when applied to Nicotiana benthamiana plants. The established dsRNA production system enables the cost efficient production of dsRNAs and application of dsRNA molecules as a highly flexible and nontransgenic approach for protecting crops against viruses and other pathogens.

Reference

Viral-based dsRNA delivery systems for use in pest and disease control

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Abstract

RNA interference (RNAi), a gene silencing mechanism triggered by double-stranded RNA (dsRNA), holds great promise as a novel and environmentally friendly pest and disease control strategy. The first insect control strategies which are expected to be commercialized are specifically targeting certain beetle species. While most beetles appear to be very sensitive to orally delivered dsRNA, this is not the case for many other insects. A great amount of research is being conducted to develop efficacious dsRNA delivery strategies in an attempt to overcome some of the barriers which have been identified as impeding efficient RNAi in these insects. One of these delivery approaches is viral delivery of dsRNA. Viruses can be modified to express insect-specific dsRNA, either in plants or in the insect itself. This approach has several benefits which allow a more efficient control of the target pest or disease. Alternatives, such as the use of viral-like particles to enhance the delivery of dsRNA are now also investigated and might provide a less controversial alternative to the use of engineered viruses as well. Here, an overview will be given on the state of the art and the possibilities of these virus-based delivery systems and a proof-of-concept of an engineered insect virus expressing a fruitfly-specific dsRNA will be presented.
Problem formulation for environmental risk assessment of spray applications of insecticides containing double-stranded RNA

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Abstract

Risk comprises the probability and severity of harm that may result from taking a course of action, such as applying a pesticide. Risk is high when severe effects are likely and low when harmful effects are predicted to be rare or trivial, or both. Estimates of risk contribute to decisions about whether to take certain actions; other relevant factors may be estimates of the likely benefits of those actions and the risks from not taking action. Efficient and effective risk assessment relies on problem formulation, which includes several vital steps: 1. agreement on what effects should be regarded as harmful; 2. formulation of hypotheses about how the proposed activity may lead to such harmful effects; 3. tests of those hypotheses with existing data; and 4. a plan to acquire new data for hypothesis testing should tests with existing data be insufficient for decision-making. By concentrating on predicting harm, problem formulation guides risk assessment away from haphazard collecting of data of unknown relevance for decision-making. Problem formulation is particularly valuable when considering products of new technology, when there is a temptation for risk assessment to become basic research into the properties of the technology, rather than a method for evaluating whether particular uses of specific products of the technology are likely to be harmful. We illustrate how problem formulation can guide the ecological risk assessments for spray applications of insecticides containing dsRNA active ingredients that induce RNAi in target insects.
Authorisation of sprayable RNAi based plant protection products: Challenges for environmental risk assessment and risk management

Achim Gathmann
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Abstract

RNA interference (RNAi) is a means of reducing or switching-off the expression of individual genes, often described as ‘gene silencing’. RNAi is a natural process with important defence and regulatory functions in animals, plants and fungi. RNA technology is widely used in GM plants. Prominent examples are virus resistances, e.g. in squash, papaya or plum, quality traits, e.g. in potato and apple, oil composition of soybeans, and pest regulation of the western corn root worm.

Additionally, sprayable RNAi based plant protection products are in the pipeline aiming at different targets such as flea beetles in oil seed rape, fusarium diseases in barley or weed control to overcome resistant weeds.

RNAi is a new mode of action in “conventional plant protection products”. This might challenge the risk assessment and risk management. For some aspects/areas, the characteristics of RNAi as active ingredient, needs adaptions of existing or the development of new risk assessment tools. For other parts, it might on the other hand ease the risk assessment. Additionally, new formulations to resist degradation of sRNA such as liquid encapsulation, conjunction with polymers or nanoparticles might challenge risk assessments.

The presentation will introduce the new challenges, identify similarities and differences in risk assessment of biotechnical and classical plant protection products, and discuss how these challenges might be considered in the authorisation process of sprayable RNAi plant protection products.
Silencing an essential gene involved in infestation and digestion in grain aphid through plant-mediated RNA interference generates aphid-resistant wheat plants

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⁴Functional and Evolutionary Entomology, Gembloux Agro-bio Tech, University of Liege, Liege, Belgium

Abstract

Grain aphid (Sitobion avenae F.) is the most dominant and destructive pest of wheat causing significant yield loss of cereal plants each year. Expression of double strand RNA (dsRNA) in transgenic plants designed against insect target genes has been shown to give protection against pests through RNA interference (RNAi). In this study, we identified a novel potential RNAi target gene (SaZFP) which was involved in ingestion and digestion in grain aphid based on transcriptomic profiling of the alimentary canal of grain aphid upon feeding on wheat plants and in vitro dsRNA artificial diet assay. We generated stable transgenic wheat lines expressing dsRNA for targeted silencing of SaZFP in grain aphid. After feeding on transgenic wheat plants expressing SaZFP-dsRNA, attenuated expression levels of SaZFP mRNA in aphids were observed compared with those of aphids feeding on wild-type plants. The decreased SaZFP expression levels were correlated with significantly prolonged development, reduced fecundity and survival, and dramatically decreased reproduction of aphids. We also observed altered aphid feeding behaviour such as delayed delivery of saliva into sieve element and shorter ingestion phase. Furthermore, we found the silencing effect was persistent and transgenerational as decreased survival and fecundity were observed in both surviving aphids and their offspring. Taken together, we not only identified a novel effective RNAi target in grain aphid, but also demonstrated that plant-mediated RNAi of an essential gene involved in infestation and digestion can be exploited as an efficient strategy for aphid control in wheat.
Problem Formulation in the ERA of RNAi-based GM Wheat with Resistance to *Fusarium* Pathogens

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²Julius Kühn-Institut, Braunschweig, Germany

Abstract

Genetically modified (GM) organisms are becoming ever more complex through the application of new molecular techniques. One of these techniques uses RNA interference (RNAi) for pathogen control. RNAi-based GM plants can produce species-specific double-stranded RNA (dsRNA) to disrupt essential physiological functions of plant pathogens via host-induced silencing of gene expression (HIGS). This innovative, highly specific technology combines pronounced selectivity for the target organism with minimal side effects as compared with chemical treatments, and has the potential to introduce novel pest and disease resistance, thereby increasing crop productivity and reducing post-harvest losses. Evidently, it is critical to ensure that the dsRNA and corresponding small-interfering RNA species do not result in any unintended gene silencing (often referred to as off-target gene silencing) that can negatively impact the physiology of the host plant, any plant-associated beneficial fungi, potential non-target herbivores, and/or their predators. However, current understanding of the susceptibility of organisms to environmental exposure to dsRNA, as well as the likelihood of off-target gene effects, is incomplete. In this study, European environmental protection policy objectives formed the starting point of an assessment of potential impacts from the cultivation of RNAi-based GM wheat designed to resist *Fusarium* pathogens via HIGS. We have applied Problem Formulation, consisting of a catalogue of risk hypothesis and their causal pathways to potential environmental harms, as the first step towards their science-based environmental risk assessment (ERA). The results support: (i) the identification of knowledge gaps arising in the area of potential environmental harms specific to RNAi-based fungus resistance, and; (ii) the development of risk assessment guidelines which relate to specific effects of RNAi crops on the environment. Certainly, these outcomes will prove valuable for informing future ERAs of RNAi-based pathogen-resistant GM plants.
Data requirements for the environmental assessment of RNAi plants: introduction to a discussion

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²ENEA Research Centre Trisaia, Division Bioenergy, Biorefinery and Green Chemistry, Rotondella, Italy;
³JT Environmental Consultants Ltd, Cambridge, United Kingdom;
⁴Ghent University, Department of Crop Protection, Ghent, Belgium

Abstract

RNAi-based genetically modified (GM) plants have been in use for a long time, starting with the development of the FLAVR SAVR tomato and of several virus resistant crops, e.g. papaya resistant to papaya ring spot virus. More recently control of plant pests and fungal pathogens has been achieved in host-induced gene silencing (HIGS) approaches. Especially these new types of applications raise specific environmental biosafety issues like potential unintended effects on non-target organisms caused by pest- or pathogen-specific dsRNA produced in RNAi plants. Current approaches to environmental risk assessment of RNAi plants within the EU legal framework will be presented in comparison with a case study from the US. Relevant questions will be addressed as an introduction to a discussion on data requirements to determine possible harm, exposure and eventually risk of RNAi-based GM plants.
BOBO JACK  
Vice President for Global Policy and Government Affairs, Intrexon Corporation, USA

Jack Bobo serves as the Vice President for Global Policy and Government Affairs for Intrexon Corporation, a synthetic biology company developing revolutionary solutions to the world’s most pressing problems—in food, energy and health. In 2015, he was named by Scientific American one of the 100 most influential people in biotechnology. He joined Intrexon from the U.S. Department of State where he worked for thirteen years as a senior advisor on global food policy, biotechnology and agricultural trade. He is an accomplished communicator, having delivered more than 300 speeches on the future of food, the role of science and technology in feeding the world and how to build consumer trust. Prior to his career at the State Department, he was an attorney at Crowell & Moring LLP. He received a J.D., an M.S. in Environmental Science, a B.A. in psychology and chemistry and a B.S. in biology from Indiana University.

HORSCH ROB  
Deputy Director, Agricultural Development, Bill & Melinda Gates Foundation, USA (recently retired)

Dr. Rob Horsch recently retired from the Bill & Melinda Gates Foundation which he joined in November 2006 to develop and lead the science and technology initiative of the agricultural development program. He managed a team of program officers and other staff that makes and managed a large and diverse portfolio of research and development grants aimed at improving the productivity of small holder farmers by improving the crops that poor farmers raise, and poor consumers eat. He also serves on the Board of Directors of the Foundation for Food and Agricultural Research, and as an Advisor to the Global Commission on Climate Adaptation.

Rob is a leader in the effort to create agricultural technologies that help improve yields and incomes for farmers around the world. He joined Monsanto in 1981 and led the company’s plant tissue culture and transformation efforts until 1995. In that capacity, he contributed to the development of the Bollgard, Yieldgard, and Roundup Ready traits in broad use today and directed an expanding research group to apply genetic transformation technology to many important crops, including potato, tomato, cotton, soybean, corn and wheat. He served most recently as Vice President of International Development Partnerships with responsibility to help small-holder farmers in developing countries gain access to better agricultural products and technologies.

Rob received his Ph.D. in Genetics at the University of California, Riverside, in 1979, and then conducted postdoctoral work in plant physiology at the University of Saskatchewan. He has served on the editorial boards of several leading journals in the plant sciences and as an advisor to the National Science Foundation and the Department of Energy. He was awarded the 1998 National Medal of Technology by President Clinton for contributions to the development of agricultural biotechnology.
VAN EENENNAAM ALISON  
Department of Animal Science at University of California, Davis, USA

Dr. Alison Van Eenennaam is a Cooperative Extension Specialist in the field of Animal Genomics and Biotechnology in the Department of Animal Science at University of California, Davis. She received a Bachelor of Agricultural Science from the University of Melbourne in Australia, and both an MS in Animal Science, and a PhD in Genetics from UC Davis. Her publicly-funded research and outreach program focuses on the use of animal genomics and biotechnology in livestock production systems. Her current research projects include the development of genome editing approaches for cattle. She has given over 600 invited presentations to audiences globally, and uses a variety of media to inform general public audiences about science and technology. She frequently provides a credentialed voice on controversial scientific topics and has appeared on national media including The Dr Oz Show, NPR, Science Friday, and the Intelligence Squared debate series. She appeared in the documentary “Food Evolution” narrated by science-communicator Dr. Neil deGrasse Tyson. A passionate advocate of science, Dr. Van Eenennaam was the recipient of the 2014 Council for Agricultural Science and Technology (CAST) Borlaug Communication Award, the 2016 BIO Future Maker Award, and in 2017 was elected as a Fellow of the American Association for the Advancement of Science (AAAS).

WOLT JEFF  
Professor Emeritus of Agronomy at Iowa State University, USA

Jeff Wolt is Professor Emeritus of Agronomy at Iowa State University where he was affiliated with the Biosafety Institute for Genetically Modified Agricultural Products (BIGMAP) and served as the co-director of the Crop Bioengineering Center. As an agricultural risk analyst, Wolt focuses on the evaluation and communication of the risks and benefits associated with the products and processes of new technologies in plant agriculture. His research seeks to apply formal risk analysis approaches in biotechnology with efforts keyed to genome engineering for novel plant traits; plants as production systems for novel proteins; and food and environmental safety issues pertaining to genetically engineered plants and their products. Wolt additionally trains and consults on biosafety risk assessment for interested and affected parties locally, nationally, and internationally. He has taught graduate courses in risk assessment and regulatory toxicology and an undergraduate course in agricultural sustainability; and he currently teaches food safety as a contributing professor to the University of Iowa College of Public Health. Wolt is a Fellow of the American Society of Agronomy. He has a B.S. degree from Colorado State University and M.S. and Ph.D. degrees from Auburn University.
ABRAHAMSEN MITCH

Previously to joining Recombinetics, Dr. Abrahamsen was the Senior Vice President of Research and Development at Cobb-Vantress for Tyson Foods, Vice President of Research at Hill’s Pet Nutrition for Colgate-Palmolive, Vice President of Research and Development, Chief Scientific Officer of Pyxis Genomics, Inc, and a professor in the Department of Veterinary Pathobiology and Director of Graduate Studies, Molecular Veterinary Biosciences at University of Minnesota. Dr. Abrahamsen received a bachelor’s degree in Biochemistry from the University of Minnesota and a PhD in Biochemistry from the University of Washington.

ADEYEMO MODUPE

Mrs. Modupe B. Adeyemo is the Programme Officer: Food Safety with the African Biosafety Network of Expertise (ABNE) of AUDA-NEPAD, Dakar, Senegal. She holds a Bachelor of Science degree in Food Science and Technology and a Master of Science degree in Food Microbiology. She was a VLIR-UOS scholar at the Ghent University, Belgium and a recipient of the Australia Awards Africa Fellowship (University of Sydney). She provides technical expertise to AU member states with regards to biotechnology, biosafety and food safety issues. She also coordinates ABNE’s Food Safety Resource Network.

AHUJA VIBHA

Dr. Vibha Ahuja is M.Sc. (Hons.) and Ph. D in Microbiology from India. She has more than 20 years of experience in the area of biotechnology and biosafety capacity building. These include undertaking planning and implementing capacity building activities, imparting training through seminars/workshops/national and international training programs and preparing well researched publications for various stakeholders related to biosafety issues etc. She has been actively engaged in providing support to regulatory authorities in India, has expertise in development of guidelines and also implementation of regulatory system including processing of applications etc. She has wide experience in issues related to the Cartagena Protocol on Biosafety and is well versed with relevant decisions/developments.

ARUJANAN MAHALETCHUMY

Mahaletchumy Arujanan is the Executive Director of Malaysian Biotechnology Information Centre (MABIC) and founder and Editor-in-Chief of The Petri Dish – the first science newspaper in Malaysia. She has a degree in Biochemistry and Microbiology from Universiti Putra Malaysia, Masters in Biotechnology and PhD in science communication from University of Malaya. Maha is listed as the world’s 100 most influential people in biotechnology by Scientific American Worldview 2015. She is also listed in the honorific list of Women in Biotechnology Law and Regulation as part of Biotechnology Law Report 2015 published by Mary Ann Liebert Inc, among 23 other women scientists and lawyers. Maha won the 2010 Third World Academy of Science Regional Prize for Public Understanding of Science for East, Southeast Asia and Pacific Region. Maha developed the 1st science communication training module for scientists in Malaysia and runs training workshops and established the Asian Short Course on Agribiotechnology, Biosafety Regulations and Communication with a pilot course in Aug 2018. She has published chapters, papers and articles on science/biotech communication and biotechnology development.
Dr. Pamela Bachman is an Associate Science Fellow and the Environmental Strategic Engagement Lead for Bayer Crop Science based in Saint Louis, Missouri, USA. Pamela is currently responsible for many of Bayer’s monarch butterfly and biodiversity initiatives with the goal to increase agricultural sector participation in habitat conservation. Prior to her current role Pamela led an ecotoxicology and risk assessment team that evaluated potential and risk of biotechnology-derived crop protection products on non-target terrestrial and aquatic wildlife. In her 10 years in the agriculture industry, Pamela has served on a variety of industry task forces, workshops and scientific committees to develop guidance for ecological risk assessment and further develop and refine these assessments for crop protection products such as Bts and RNAi-based products. Pamela is trained as an aquatic toxicologist/ecologist and received her Ph.D. from Florida International University in Miami.

Prof. Dr. Detlef Bartsch studied biology at the Universities Münster and Göttingen in Germany. His research carrier covers plant ecology at Berlin & Aachen Universities of Technology as well as plant population genetics at University of California Riverside. He is currently working for the German Government being head of the Department “Genetic Engineering” at the Federal Office of Consumer Protection and Food Safety (BVL) in Berlin. His experience includes risk assessment & management, population biology of cultivar/wild plant complexes, conservation of plant genetic resources, environmental biosafety research, and monitoring of GM plants with resistance to insects, viruses, nematodes and herbicides. As sideline activities, he is lecturer for Botany at the RWTH Aachen University - Institute for Environmental Research - since 2002. The European Food Safety Authority (EFSA) appointed him for the GMO Panel from 2003 – 2012 and GMO Environmental Working Group 2012-2015.

John C. Besley studies public opinion about science and scientists’ opinions about the public in the context of trying to help science communicators be more strategic. He seeks to understand how views about decision-makers and decision processes affect perceptions of science and technology (S&T) with potential health or environmental impacts. He has published more than 80 peer reviewed articles, chapters, and reports and is on the editorial boards of the journals Science Communication, Public Understanding of Science, and the Journal of Risk Research. He is the associate editor for risk communication for Risk Analysis and has written a biennial report on public opinion about S&T on behalf the U.S. National Science Board for Science and Engineering Indicators since the 2014 edition. He is a fellow of the American Association for the Advancement of Science.

I am a Principal Plant Breeder in the Bangladesh Rice Research Institute. I have been working here since 1998. During my long breeding career I worked to develop rice varieties with increased yield and enhanced nutritional quality. I have also worked for the development of high yielding rice varieties for cold prone areas in Bangladesh. So far, my breeding programs have developed several thousands of breeding lines and released 10 high yielding rice varieties, of which five are zinc biofortified rice. I have been working with Golden Rice (GR) since 2008. We introgressed GR2 locus from Golden Rice event GR2E into BRRI dhan29, a widely cultivated rice variety in Bangladesh during my PhD thesis research at IRRI, Philippines. The introgression lines were then transferred to Bangladesh and evaluated in the screenhouse, and confined field trials in different locations across the country. We have already identified superior lines that are identical to the recipient parent and have higher carotenoids levels in the grains. I have published 35 research articles in reputed journals. I served as the research supervisor of many MS and PhD students of different universities in Bangladesh. I am connected with different professional organizations that promote breeding and biotechnology for crop improvement.
BRONDANI ADRIANA

Adriana Brondani is the Executive Director of the Biotechnology Information Council (CIB). Biologist, graduated from the Federal University of Rio Grande do Sul, where she also holds a master's and doctorate degree in Biochemistry and Molecular Biology. She has worked as professor at the Lutheran Brazilian University, Federal University of Rio Grande do Sul and at the Pontifical Catholic University. Currently, she is also professor at the MBA of Agribusiness at the University of São Paulo (USP) and at the postgraduate course of the Brazilian Association of Nutrology (ABRAN). Working in the Plant Biotechnology area for the last eight years, she had acquired great experience in science communications, ability to promote engagement and skills to manage projects across different geographies. During this time her biggest challenge was to improve CIB Brazil's presence on media in a context of unfavorable public opinion and implement the social media program when there were few experiences to learn from.

CAMARGO ANA MARTÍN

Ana Martín Camargo is currently a trainee at the Genetically Modified Organisms (GMO) Unit of the European Food Safety Authority (EFSA, Parma), where she contributes to the assessment of the 2017 insect resistance management and monitoring data reported in the annual post-market environmental monitoring report on the cultivation of transgenic maize MON 810 in the EU. She also supports the activities of EFSA's Working Group on the environmental risk assessment of gene drive modified insects. Ana has a background in applied entomology, and she holds a PhD in Biology from the Universidad Complutense de Madrid. Her doctoral research focused on assessing resistance evolution to Bt-proteins expressed in transgenic maize by target and non-target lepidopteran pests.

CHEN MAO

Chen, Mao is the Biotech Regulatory Affairs Lead for Asia Africa at Bayer Company. In his current role, Mao provides leadership for developing regulatory strategies to secure import and cultivation approvals for Bayer's biotech products across crops in Asia and Africa. Mao received his Ph.D. degree in Entomology at Zhejiang University (2005) and a 3-year post-doc training at Cornell University (2005-2008). Mao also worked as a Research Scientist at Cornell University for 2 years (2008-2010) primarily focusing on insect resistance management (IRM) and ecological risk assessments. Mao joined Monsanto USA in 2010 leading the high throughput gene discovery testing team. Between 2012 and 2014, Mao led the Global IRM for Corn Rootworm Project at Monsanto focusing on corn rootworm genome sequencing, molecular marker development, and biochemical, behavioral, and physiological characterization. From 2014 to 2016, Mao led the IRM efforts at Monsanto Singapore for Asia-pacific & China. Mao has published more than 40 peer-reviewed research articles and wrote 3 book chapters on Ag-biotechnology, ecological risk assessments, and IRM/IPM in international scientific journals including Annual Review of Entomology, PLoS Genetics.

CRAIG WENDY

Dr. Wendy Craig is currently the Group Leader of the ICGEB’s Biosafety Group which is principally involved in biosafety capacity enhancement in their Member States (primarily developing countries). She is actively managing projects targeting locally-identified needs in GMO regulation and information dissemination, focusing on the governmental, institutional and individual levels. These activities rely on strengthening collaborations and creating synergies with international organisations and experts operating in similar or associated arenas. Dr. Craig gained her PhD at Nottingham University, UK in 1996 studying approaches for the genetic manipulation of oilseed rape. This led to her conducting a series of plant biotechnology-based post-doctorate studies in various parts of the world before joining the ICGEB Biosafety Group in January 2005. She regularly authors articles and reviews in the field of GMO biosafety.
DASS BRINDA

Dr. Dass is the Policy Lead in the Gene Drive Research team at FNIH working to assist scientific and regulatory capacity building in African countries determining the feasibility of using genetically modified and/or gene drive mosquitoes for malaria control or elimination within their independent regulatory framework. They bring expertise gained at the US Food and Drug Administration working as a master reviewer on the review, approval, and regulation of genetically engineered animals especially investigational GM insect products (bees and mosquitoes). They have provided expert advice and guidance on a variety of topics related to the policy, regulation, and risk assessment of GE insects especially mosquitoes that spread human diseases such as Zika and Dengue, both within FDA as well as across US federal agencies, international organizations, and other stakeholder groups including the public. They also represented the US FDA on various task forces related to the Zika health emergency both at the national and international level. Additionally, they also represented the US government as an expert on an International Ad Hoc Expert Group organized by the Organization for Economic Cooperation and Development (OECD) for the preparation of the biology document on Aedes aegypti. They hold a B.Sc. and M.Sc. in Zoology, an MPH in epidemiology, post-masters certificate in Clinical Research Management, and a Ph.D. in cell and molecular biology.

DAWSON KENNETH

Professor Kenneth A. Dawson is Director of the Centre for BioNano Interactions (CBNI). The scientific focus of this Centre is to understand the interaction of nanoparticles with living systems (www.ucd.ie/cbni). The Centre seeks to clarify the fundamental controlling factors for these interactions and seeks to support applications in nanoscale impacts in humans and the animate environment. Prof. Dawson is a founder and leading thinker in the modern concept of biological identity and action at the nanoscale, has pioneered such concepts as biomolecular (protein) corona, and other aspects of how nanoscale interacts at cell level. He is Chair of Physical Chemistry at University College Dublin, has served as co-ordinator of the European Infrastructure in the arena, and has served in many regulatory, advisory and industry bodies world-wide. He has experience in the management of large scale projects, including multi-sectoral cross-disciplinary research projects and other international programs. He has received several international prizes, including the 2007 Cozzarelli Prize from the National Academy of Sciences USA (for the description of the Biomolecular Corona), as well as IBM, Packard, Canon, Sloan and Dreyfus prizes. He is among the top 1% of cited authors (Clarivate Analytics) in science for 2018.

DEVOS YANN

Yann Devos is a senior scientific officer – ecology at the European Food Safety Authority (EFSA; Italy) where he is involved in the risk assessment of genetically modified organisms (GMOs) and the development of risk assessment guidelines. He is employed by EFSA since 2008, and previously worked at the Biosafety and Biotechnology Division of the Scientific Institute of Public Health (Belgium). Through his career, Yann has gathered extensive experience in the environmental risk assessment of transgenic plants and their associated farm management practices. In 2015, he joined the OECD Steering Group drafting the consensus document on planning risk/safety assessments for the release of transgenic plants – The use of environmental considerations. Currently, he coordinates the activities of EFSA’s Working Group on the environmental risk assessment of gene drive modified insects. He regularly authors peer-reviewed articles and reviews in the field of GMO biosafety. Yann has an MSc in Biology (ecology) and a supplementary degree in Environmental Sciences from the University of Antwerp, and a PhD in Applied Biological Sciences from the Ghent University.
Ben Durham is Chief Director: Bio-innovation at the National Department of Science and Technology in South Africa. His responsibilities include the implementation of the South African Bio-economy Strategy, launched in January 2014, and he now is overseeing implementation of the bio-innovation themes for Agriculture, Health, Industry & Environment, and IKS. Ultimately, the purpose is to develop and improve the efficiencies of the National System of Innovation, ensuring science-based contributions to the Bioeconomy.

Amongst others, Ben has been appointed to:

- The position of vice chair of the Executive Council of the GMO Act (1997), managed by the Department of Agriculture, Forestry and Fisheries;
- Board membership of the National Health Laboratory System, and the vice chair of the Research and Innovation sub committees;
- The International Advisory Committee of the Global Bioeconomy Summit

Esther Esteban

From April 1999 to March 2001 she held a postdoctoral fellowship at Michigan State University (USA)

Doctor Agricultural Engineer from the University of Córdoba in 1998, having completed the doctoral thesis at the Institute of Sustainable Agriculture (CSIC) of Córdoba with a grant from the Ministry of Education and Science.

She has completed a stay at the Michigan State University (USA) in 1996 and another one at the University of Guelph (Canada) in 1994.

Agricultural Engineer from the Polytechnic University of Madrid in 1994.

She joined the State Agronomist Engineers Corps in 2003 performing different functions in the Ministry of Agriculture, Fisheries and Food.

From 2009 to 2018 she was Secretary of the Inter - ministerial Council of Genetically Modified Organisms in Spain.

From September 2014 to September 2018 she was Deputy Director General of Means of Agricultural Production and Spanish Office of Plant Varieties of the Ministry of Agriculture, Food and Environment. The two previous years she held the position of Assistant Deputy Director in the same Unit.

Sarah Evangela

Sarah serves as Director of the Cornell Alliance for Science—a global communications effort that promotes evidence-based decision-making in agriculture. She teaches courses on agricultural biotechnology at the graduate and undergraduate level and is part of an interdisciplinary team that developed a massive open online course (MOOC) on the science and politics of GMOs on Cornell’s EdX platform. Sarah serves as Senior Associate Director of International Programs in the College of Agriculture and Life Sciences (CALS) and holds an adjunct appointment in the Section of Plant Breeding & Genetics in the School of Integrative Plant Sciences at Cornell. In addition, she is a Senior Fellow at the Breakthrough Institute. Sarah was instrumental in launching the CALS initiative, AWARE (Advancing Women in Agriculture through Research and Education) which promotes women in agriculture.

Sarah received her PhD in Plant Biology from Cornell University in 2009, for which she conducted an interdisciplinary study combining work in plant molecular biology with science communication. She came to Cornell after completing a BA in Biology at Reed College. Sarah grew up in a small agricultural village in northwest Illinois and enjoys life in the Finger Lakes with her husband and young children.
FALDA THIAGO

Thiago Falda is the Technical and Regulatory Affairs Director of the Brazilian Bioinnovation (ABBI) where is responsible for the interlocution with the brazilian government and sectoral representative entities aiming the development of public policies that contribute to the consolidation of the Industrial Biotechnology Sector in Brazil. Prior to this he served as a Technical Adviser of The Association of Biotechnology Companies in Agriculture and Agribusiness - AgroBio (2012 – 2015) providing technical and scientific support in regulatory affairs for Ag biotech products. Thiago Falda holds his Ph.D in Genetics and Plant Breeding, with an emphasis on Molecular Plant Microbe Interactions, from University of São Paulo (2012) and a B.S. in Biology from Londrina State University (2006).

FERNANDES PATRICIA

Patricia Machado Bueno Fernandes completed her Ph.D. in Biochemistry from the Federal University of Rio de Janeiro and Princeton University in 1997 and her postdoctoral studies at Princeton University in 2011. She worked at the Scripps Clinic & Research Foundation, USA, between 1990-1992. Currently she is Full Professor and President of the Biosafety Commission (CIBio) of the Federal University of Espirito Santo - UFES. Dr. Patricia Fernandes is a member of the Brazilian National Technical Committee on Biosafety (CTN-Bio) of the Ministry of Science, Technology and Innovation since 2005, being currently the coordinator of the plant-environmental sector. She has published over 100 articles in international specialized periodicals, in annals of events and book chapters. Organized events in Brazil, in addition to participating in national and international events as a speaker or moderator. Supervises postdoctoral fellows as well as doctoral, master’s and scientific initiation students in the areas of Biotechnology, Biochemistry and Molecular Biology, with emphasis in response to stress in microorganisms and plants.

GLANDORF BOET

Dr. Boet Glandorf works as senior risk assessor and policy advisor at the Department of Gene Technology and Biosafety at the Dutch National Institute of Public Health and the Environment. She is responsible for the environmental risk assessment of GMOs including the ERA of organisms obtained by new technologies.

She is also active as an ERA expert at the national and international level, such for the EFSA, the WHO and in the frame of the Convention of Biological Diversity on the topics of LMOs and synthetic biology.

GOODMAN RICHARD

Dr. Goodman has been a Professor at the University of Nebraska Lincoln since August, 2004. He manages the http://www.AllergenOnline.org database that is a free-peer reviewed allergen risk assessment tool. Version 19 was posted February 2019 and includes a Celiac Disease risk assessment database to evaluate novel dietary proteins. The purpose is to compare new proteins to known allergens and celiac peptides to identify those requiring additional testing to ensure minimal risk of allergy or celiac disease from novel proteins in GMOs and novel foods.

Dr. Goodman participated in the CODEX Alimentarius working group (2001) that developed the CODEX 2003 guidelines for the safety assessment of GM Organisms. He participated in many international GM food safety workshops in the USA, India, China, the EU, Africa and South America. He has performed bioinformatics safety evaluations for allergenicity and toxicity of many insect resistant, herbicide tolerant and nutritionally enhanced plants and animals. His graduate students have tested stability of proteins in pepsin and in simulated intestinal fluid, and tested animal models to determine whether they might predict allergenicity of dietary proteins or celiac disease. He is Chair of the WHO/IUIS Allergen Nomenclature Subcommittee that names allergens (www.allergen.org).
GREEN ALLAN

Dr Allan Green has devoted his lifetime research career at CSIRO to understanding the genetic control of oil and fatty acid biosynthesis in plants, and using this knowledge to develop new and improved oil crop products for Australian and global agriculture. He has been a pioneer in using increasingly sophisticated genetic technologies for the modification of fatty acid composition in oilseed crops to provide improved nutritional value, enhanced functionality, and novel industrial end uses. The CSIRO Plant Oil Engineering research group that he established and led has for over two decades been at the forefront of global research on metabolic engineering of plant oil composition and is creating significant opportunities for innovation in the Australian and global oilseeds industries. The culmination of this work has been the development and recent deregulation of Australia’s first two oilseed crops carrying GM oil quality (output) traits - a super-high oleic acid safflower oil and a DHA-containing canola oil - as well as the development of potentially game-changing technology for producing oils in plant leaves. Allan has recently retired and taken up a Research Fellow role at CSIRO Agriculture & Food, based in Sydney.

GUSSOU CHARLES

Dr. Charles Guissou is a public health physician at the Institute of Research in Health Sciences affiliated with the Ministry of Scientific Research of Burkina Faso. He currently works for Target Malaria project in Burkina Faso as one of his co-principal investigators. The project aims to develop and share new technology for malaria control in Africa. As a matter of fact, malaria represents a major public health burden in many countries and the African continent is the most affected by malaria, with 90% of the world’s 216 million cases in 2016 recorded in sub-Saharan Africa (WHO, 2017). Gene drive technologies have been identified to having the potential to address this public health challenge the continent faces, by offering new solutions that are long term, sustainable and cost effective.

HAMBURGER DAVID

David Hamburger is a Ph.D. candidate at the Chair of Constitutional and Administrative Law, Public International Law, European and International Economic Law at the University of Passau (Germany) and holds a LL.M. degree in International Law from the University of Glasgow. As part of a project funded by the German Federal Ministry of Education and Science (BMBF), he is conducting research on the international aspects of the regulation of plants derived from genome editing.

HERMAN ROD

Rod has been an agricultural scientist for 35 years. He currently acts as a Science Policy Leader within the regulatory function of Corteva Agriscience™, Agriculture Division of DowDuPont. Rod obtained a M.S. at Rutgers University and served for more than 16 years in discovery research. Since 1999, he has been involved in the safety assessment and regulation of GM crops and has published more than 75 peer-reviewed papers. In his spare time, he helps his wife with a market-vegetable farm and restoration of wildlife habitat on the farm.
HUÉSING JOSEPH

Joe Huesing serves as the Lead Scientist for the U.S. Government Fall Armyworm Task Force. He has also served as the USAID Senior Biotechnology program manager for USAID’s global USAID biotechnology portfolio. His career in the biotechnology industry included positions in Gene Discovery, Intellectual Property and Regulatory Affairs. He was also Director of the Science Project Management and Leadership Program at Webster University. As an Adjunct Associate Professor of Entomology at Purdue University he supported biotechnology efforts in the developing world. He works with academic, regulatory, industry scientists and policy makers to develop products for small holder farmers in the developing world.

JEPPSON PAUL

Dr. Jepson serves as Director of the Integrated Plant Protection Center, an international research, extension and policy development center, that addresses problems in sustainable crop production intensification, human health, IPM, extension education capacity development, climate and weather-based decision support, ecotoxicology, risk assessment, regulation, and risk-based decision making. Dr. Jepson has served as State IPM Coordinator for Oregon; Co-Director USDA NIFA Western IPM Center; member, International Standards Committee (ISC) of Sustainable Agriculture Network (SAN). He is currently active in program leadership, capacity development, policy, research and extension in the Western USA, West Africa and Central America. Dr. Jepson’s specialties include research and extension program leadership, capacity development in research, education, extension, policy, and regulation associated with food security, human health, conservation and management of ecological services in agriculture; risk assessment and management associated with pesticides, genetically modified crops, cropping systems, climate and weather; adult education theory and practices that address risk-based decision making; and design of rational and ecologically literate crop certification systems.

JOHN LIJO

Dr. Lijo John is working as Assistant Director (Technical) at Export Inspection Agency - Kochi, Laboratory under Export Inspection Council, Ministry of Commerce and Industry, Govt. of India since May 2012. He is responsible as Technical Manager for Molecular Biology division of EIA-Kochi Laboratory, the National Referral Laboratory for the detection of GMOs. He is also involving in developing test facilities and validating test methods for GMO testing, detection of viruses/pathogens, meat authenticity and basmati rice authenticity testing using PCR, Real Time PCR and DNA Sequencer. He has completed his Doctor of Philosophy on Molecular Genetics from Cochin University of Science and Technology in the year 2010. He is having 16 years’ total experience in the field of Molecular Biology including research and testing. He also has nine years of research experience with ten International publications on peer-reviewed Scientific Journal, two papers in National Scientific Journals and few abstracts presented in various national and international conferences and more than 250 nucleotide sequence submissions in GenBank database.

Dr. John was associated with UNEP-GEF supported capacity building project on Biosafety being implemented through Ministry of Environment, Forest and Climate Change, Govt. of India. He has undergone training on Detection of LMOs at Intertek ScanBi Diagnostics, Sweden, and also participated in the Asia Pacific Workshop on Detection and Identification of LMOs, organized by The Secretariat of the Convention on Biological Diversity (SCBD), UNEP at Kuala Lumpur, Malaysia. He also delivered presentations on detection of GMO in various trainings workshops organised at national level. He is also a trained and qualified assessor as per ISO/IEC 17025:2017.
**JONES HUW**

I have a global reputation in the development of cereal transformation systems and the application of biotechnology approaches to study gene function. I have research and teaching interests in applied crop genome editing and functional genomics but also in risk assessment and regulatory policy of biotechnology. I was vice-chair of the GMO panel, European Food Safety Authority on which I served 2009-2018, and am Honorary Professor in the School of Biosciences, Nottingham University and Honorary Researcher at Rothamsted Research. I moved to Aberystwyth in 2016 after almost 20 years at Rothamsted then before that, Long Ashton Research Station. In addition to my work in GMO risk assessment, I have held two UK government licences to conduct non-commercial, field trials of GM wheat in the UK to investigate gluten quality and aphid resistance. Although an independent research scientist, I maintain excellent links with a range of stakeholders in industry and policy. For instance, I spoke on ‘Gene editing and its application to fruit and vegetable breeding’ at the UK Fruit & Vegetable Congress, Ricoh Arena Coventry UK on 9th Oct 2018 [https://www.fpjlive.com/speakers](https://www.fpjlive.com/speakers) and chaired an international discussion on the regulation of gene editing for the OECD in Paris 28th-29th June 2018. [http://www.oecd.org/environment/genome-editing-agriculture/](http://www.oecd.org/environment/genome-editing-agriculture/) I am currently on the Management Committee and a Work Group leader of the iPlanta (crop RNAi) COST action and have co-authored 152 scientific risk assessment opinions and guidance documents with EFSA and published more than 100 research papers, books and other articles in the field of plant molecular genetics. A full list of my research papers can be found at [https://www.aber.ac.uk/en/ibers/staff-profiles/listing/profile/hdj2/](https://www.aber.ac.uk/en/ibers/staff-profiles/listing/profile/hdj2/) and EFSA publications can be found at: [http://www.efsa.europa.eu/en/search/site/%22huw%20jones%22](http://www.efsa.europa.eu/en/search/site/%22huw%20jones%22)

**KELLY LISA**

Dr Lisa Kelly is a Principal Scientist in the Microbiology and Biotechnology section of Food Standards Australia New Zealand (FSANZ). Lisa’s has responsibility for overseeing the assessment of applications for the approval of genetically modified (GM) foods in Australia and New Zealand, and also FSANZ’s strategic projects related to GM foods, including the current review of food derived using new breeding techniques. Lisa regularly represents the Australian government on GM food matters at an international level and is currently serving as a member of the Bureau of the OECD Working Group for the Safety of Novel Foods and Feed, having previously chaired the group. Lisa also previously led the Australian delegation to the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology (2005-2009) as well as participated in two FAO/WHO expert consultations on GM animals (2003 & 2007).

Lisa has a PhD in molecular plant virology from the Australian National University and worked as a post-graduate research fellow at CSIRO Plant Industry before joining FSANZ in 1997.

**KIGGUNDU ANDREW**

Dr. Andrew Kiggundu is the Project Manager for the Virus Resistant and Nutritionally Enhanced Cassava for Africa Project (VIRCA-Plus) at the Donald Danforth Plant Sciences Center. He earned his Bachelor of Science from Makerere University in 1994, his Master of Science in Plant Breeding from the University of the Free State, South Africa in 2000 and his PhD in Plant Biotechnology from the University of Pretoria, South Africa in 2015. He returned to Uganda and was part of a vibrant team working to develop plant biotechnology capacity at the National Agricultural Research Laboratories, Kawanda. Before joining the Donald Danforth Plant Sciences Center, he was a Principal Research Officer and Program Leader of the Biodiversity and Biotechnology Programme at the National Agricultural Research Laboratories. He led teams on plant genetic resource conservation, biological control and plant biotechnology including genetic engineering of African crops. He was also involved in the development of GE crop regulatory and biosafety frameworks, capacity building and public awareness in Uganda and other parts of Africa.
KOO OKJAE

Okjae Koo is a veterinarian, having received his DVM and Ph.D. in veterinary medicine from Seoul National University. He has more than 15 years of experience working on transgenic animals and has been a research partner with ToolGen since 2009. ToolGen is a biotechnology company focused on the development and application of genome editing technologies. It creates, and holds intellectual property rights for, essential tools and technologies for editing the genetic information in microbial, plant, animal and human cells.

Prior to joining the staff at ToolGen, he trained as a visiting fellow in NIH and worked as assistant professor in GBST, Seoul National University and as a researcher in Samsung SAIT.

Throughout his research, he has worked on the use of ZFN, TALEN and CRISPR/Cas9 technologies for targeted modification of various animals (from rodents to livestock). Since joining ToolGen, he has focused his efforts on optimizing genome editing platforms for both animals and plants.

He currently leads plant and animal genome editing R&D projects in ToolGen as well as having a role in business development/partnering in the agricultural genome editing field. Since 2018, he has also served as a Director for GenStorm, a joint venture company of ToolGen (Korea) and Genovo (China) for developing genome edited crops.

KUMAR SANDEEP

Sandeep Kumar is the Principal Investigator & Senior Scientist at Corteva Agriscience™, Agriculture Division of DowDuPont. He holds B.S. and M.S. degrees in Agriculture & Forestry from India, and Ph.D. in Forest Biotechnology from FRI University, India. Sandeep currently leads research projects to develop innovative technology and intellectual property to achieve targeted genome editing in maize and key dicot crops. He is also involved in developing strategic roadmap for systematic evaluation of CRISPR-Cas specificity and its relevance in plants. Sandeep is certified Six Sigma Greenbelt project leader and registered patent agent to practice before the U.S. Patent Office. He has published 30 journal articles, seven book chapters and edited two books. He is a lead inventor in >50 patents and patent applications. Sandeep is the editorial board member of several journals including Plant Biotechnology Journal.

LEGGEWIE GEORG

Dr: Georg Leggewie studied biology at the Universities of Würzburg and Heidelberg in Germany and at the University of Kentucky in Lexington, Ky, USA. He received his Ph.D. from the Humboldt-University in Berlin. His research carrier focussed on the molecular biology of plant mineral nutrition at the Max-Planck-Institute of Molecular Plant Physiology in Golm, Germany, and at the IACR Rothamsted in Harpenden/UK. Since 2005, he is working for the German Government at the Federal Office of Consumer Protection and Food Safety (BVL) in Berlin. As scientific officer in the Department “Genetic Engineering”, he is regularly involved in risk assessment on applications for deliberate release and applications for placing on the market of GMOs according to Directive 2001/18/EC and Regulation (EC) 1829/2003. His experience includes molecular biology, food and feed safety, risk assessment & management of GMO and environmental biosafety research.
LEMA MARTIN

Since 2012, Martin Lema holds the position of Director of Biotechnology in the Ministry of Agroindustry of Argentina, where he began working as the Coordinator for Policy Making in Agricultural Biotechnology in 2004. He is the Chairman of the Argentine National Advisory Commission on Agricultural Biotechnology (CONABIA). During his mandate, the United Nations Organization for Food and Agriculture (FAO) has designated CONABIA as a Centre of Reference for the Biosafety of Genetically Modified Organisms. He is also a member of the Argentinian GMO Food Safety Assessment Committee at the National Agrifood Health and Quality Service. More recently, he has been appointed as Chairman of the Committee on Microbial Agricultural Inputs (CABUA) and the National Advisory Commission on Biomaterials (COBIOMAT).

In the recent past, he has served as Delegate to the COP-MOPs of the Cartagena Protocol on Biosafety, the OECD fora on both the safety of novel foods and feeds and on the harmonisation of regulatory oversight in biotechnology, the WTO case on biotechnology products, the Argentinian Delegation Head to the Codex Task Force on Foods derived from Modern Biotechnology, and similarly to the Codex Committee on Methods of Analysis and Sampling. In both subsidiary bodies, he was chosen to co-chair the elaboration of guidelines applied to products derived from recombinant-DNA organisms. He is currently the national focal point for the FAO GM Foods Platform. Further, he has been involved as staff or coordinator in over 30 multilateral or bilateral initiatives for capacity building in the field of GMO regulation.

In the academic field, he holds an Ordinary Adjunct Professorship in the School of Biotechnology at the National University of Quilmes, Argentina. Since 2000, he has been teaching graduate and post-graduate courses on agricultural biotechnology, introductory biotechnology and biosafety. He has also authored several publications pertaining to biotechnology research, teaching, biosafety and policymaking.

LEWI DALIA

Dalia Lewi Agricultural Ingeneering graduate with a specialty in plant breeding at the University of Buenos Aires (UBA), Argentina. Completed the PhD in biological sciences “Genetic transformation of sunflower” at the Faculty of Exact and Natural Sciences (UBA). As postdoctoral subject at the Genetics Institute INTA (National Institute of Agricultural Technology) developed the maize genetic transformation for “Mal de Rio Cuarto Virus” resistance and then for abiotic stress. More recently, since 2010 lead the development of the cotton genetic transformation protocols at INTA to obtain events with the cotton boll weevil resistance. Researcher in plant biotechnology, currently responsible for the development of maize and transgenic cotton and leads the Plant Genetic Transformation Group at the Genetic Institute, INTA. Represents INTA at CONABIA (National Advisory Commission on Agricultural Biotechnology) since 2009. Has participated in the revisions of the regulations and proposed specific regulations for the GMOs management in local institutions. Has published works in international journals, books and books chapters. Has directed graduate and postgraduate thesis, and coordinates projects on plant biotechnology. Is a professor of “Biosafety and risk assessment of GMOs” in the Agrobiotechnology Engineering career at the National University of San Martín.

MACDONALD PHIL

I have worked for nearly 20 years in government regulation, mostly related to biotechnology. In my current position, I supervise and lead a group of scientists that coordinate the Canadian Food Inspection Agency’s plant health research and diagnostic initiatives, especially those related to the applications of genomics and how these tools can inform policy.

I have acted as the CFIA spokesperson on a number of scientific issues related to the environmental risks posed by GM crops, delivered risk assessment workshops and capacity building to the international regulatory and scientific community. I have also represented the Canadian Food Inspection Agency in national and international discussions on the environmental risks posed by plants modified by modern biotechnology, the application of genomic based plant breeding technologies and regulatory approaches to emerging technologies such as nanotechnology and synthetic biology. I represented Canada as a technical expert on the Ad-Hoc Technical Expert Group on Risk Assessment and Risk Management that developed further Guidance for Annex 3 on risk assessment of the Cartagena Protocol.

I have come to the regulatory environment after ten years in a research laboratory first working on herbicide tolerant plants, then transgenic animals. My graduate Studies were completed at Carleton University in Ottawa where I worked on molecular models for herbicide resistance.
MACKENZIE DONALD

Dr. Donald MacKenzie is the Executive Director of its Institute for International Crop Improvement (IICI). He manages the IICI’s programs and partnerships dedicated to translating key discoveries in plant health, disease and pest management, genomics, advanced breeding and nutrition to staple crops that impact food security around the globe. Don also provides guidance on navigating through the practical, safety and regulatory processes necessary to demonstrate that new crop varieties are proven safe and effective for the farmers who will benefit from them.

Don is an international expert in regulatory systems for agriculture, including environmental risk assessment, biosafety and food safety assessments. His extensive experience in plant product development and global regulatory processes aligns with the Institute’s commitment to collaborate with international and local partner organizations to deliver crops with improved nutritional content and disease resistance to places where people are in most need. In addition to feeding the hungry, these efforts have the potential to contribute to environmental health and empower farmers to become more self-sufficient.

MIRANDA PATRICIA

- Degree and Ph.D. in Chemistry, Faculty of Sciences, University of Buenos Aires
- Post-Doctoral activities in Canada, Chile and the United States
- Member of the National Research Council (CONICET) of Argentina since 1998
- 1987 - 2008: Scientific Research, Protein chemistry, Instituto de Biología y Medicina Experimental (Institute of Biology and Experimental Medicine), Buenos Aires, Argentina.
- In 2008 joins to the Instituto de Agrobiotecnología Rosario (INDEAR) (Institute of Agrobiotechnology) as Lead of the Laboratory of Protein Technology until 2014.
- In 2014 – present as Manager of Regulatory Affairs

NAPIER JOHNATHAN

- Johnathan obtained his BSc (hons) in Agricultural Sciences from the University of Nottingham, followed by a PhD in plant biochemistry from King’s College, London. He carried out post-doctoral research at the University of Cambridge, then taking up a position at Long Ashton Research Station in Bristol. His research group relocated to Rothamsted Research in 2003 where he is currently Flagship Leader.
- Johnathan is also an Affiliated Lecturer at the University of Cambridge and Visiting Professor at the University of Nottingham, who also awarded him a DSc in 2006. He has published over 170 peer-reviewed papers, and is the inventor on multiple patents relating to the biotechnology of lipid metabolism. He is currently running the only GM field trials in the UK, evaluating the performance of metabolically engineered oilseeds to accumulate omega-3 fish oils, as well as carrying out the first field trials of gene-edits crops.

ONYEKACHI FRANCIS

- Onyekachi Francis Nwankwo is the Programme Officer, West Africa at African Agricultural Technology Foundation (AATF) and a strong advocate of the critical role of technology and innovation in agricultural systems in Africa. The last 8 years of Francis has been committed to the complex process of developing and deploying podborer resistant (Bt) cowpea in West Africa – taking the potential product from laboratory, through field trials to successful deregulation in Nigeria. He is passionate to see the product in farmers’ fields across the project countries in West Africa. Francis is a Nigerian national.
PAVELY CHLOE

Chloe started her career at Pioneer-DuPont in Des Moines, IA, USA as the 7th person hired into the Pioneer/DuPont Regulatory team; when she left 8 years later, the group had grown to 150 people. She then moved to Monsanto (St Louis, MO, USA) where she worked for 7 years in various roles, including a 3-year assignment based in Buenos Aires, Argentina leading the Regulatory Affairs team for Latin America South that was responsible for obtaining Regulatory approvals for all Monsanto’s biotech crops, crop protection and seed & vegetables products. Chloe joined Genective (a JV between Limagrain and KWS based in Paris, France) in September 2014 as Head of Regulatory where she was responsible for developing and implementing the regulatory strategy for getting Genective’s biotech corn products to market, including business development as well as establishing processes for product advancement and selection. In November 2017, Chloe moved to Minneapolis, MN, USA to join Calyxt as Global Regulatory Director. Her role at Calyxt is to bring new gene-edited products to market by developing pragmatic regulatory strategies and working with government authorities in the countries of interest. Her role also includes establishing and maintaining Calyxt’s Quality Management System and ensuring optimal product quality and traceability throughout the supply chain from growers to food customers with an Identity-Preserved process.

PETRICK JAY

Dr. Jay Petrick leads the Macromolecule Toxicology team in Regulatory Sciences within Bayer Crop Sciences. Prior to joining Bayer as part of the acquisition of Monsanto, he was with Monsanto Company for 13 years was appointed a Fellow in the Monsanto Science Fellow program. Dr. Petrick has been board certified in General Toxicology by the American Board of Toxicology (DABT) since 2011 and is a full member of the Society of Toxicology, having joined in 2000. He earned his B.A. in Molecular, Cellular, and Developmental Biology from the University of California, Santa Cruz and his Ph.D. in Pharmacology and Toxicology from the University of Arizona. Dr. Petrick completed his postdoctoral fellowship in toxicology with Dr. Curtis D. Klaassen at the University of Kansas Medical Center. Dr. Petrick works in the areas of food safety and pesticide toxicology with an emphasis on food safety of GM crops and the safety of RNAi-based agricultural products. He has authored more than 20 peer-reviewed scientific papers. Outside of work, Jay enjoys spending time with his family, cycling, hiking, travel, and brewing beer.

QUEMADA HECTOR

Dr. Hector Quemada is Principal Research Associate at Western Michigan University, working with the Foundation for the National Institutes of Health on a project aimed at strengthening capacity of regulators in Africa, for regulating gene drive technologies. Prior to this, he was Director of the Biosafety Resource Network at the Donald Danforth Plant Science Center, a project that provided regulatory and product development expertise for publicly funded transgenic crop development projects. Before joining the Danforth Center, he was the manager of the Biotechnology and Biodiversity Interface grant component of the Program for Biosafety Systems, a USAID project supporting research to generate data relevant to risk assessments of crops in developing countries. He was the founder of Crop Technology Consulting, Inc., a consulting firm conducting technical and biosafety assessment for biotechnology programs in developing countries, and developing regulatory approval dossiers for public and private crop development organizations. He has experience developing transgenic crop varieties for the private sector.
RAYBOULD ALAN

Alan Raybould is a Senior Science and Technology Fellow at Syngenta in Basel, Switzerland. Alan joined Syngenta in 2001 and until 2014 worked in its Product Safety department at Jealott’s Hill International Research Centre in the United Kingdom. There he led the preparation of environmental risk assessments as part of worldwide regulatory submissions for Syngenta’s transgenic crops. Alan moved to Basel in 2014 where he currently works on risk assessment and societal acceptance of agricultural products of new technology. Before joining Syngenta, Alan was a Principal Scientific Officer at the UK’s Centre for Ecology and Hydrology, where he led a research group developing methods for estimating gene flow among populations of wild plants, and studying the ecological genetics of insect and virus resistance in wild relatives of crops.

ROBERTS AARON

Aaron Roberts is a PhD student studying applied ethics at McMaster University and a Research Assistant at the Institute on Ethics & Policy for Innovation (IEPI). Core areas of Aaron’s research interest include the ethical, social and cultural issues surrounding implementations of gene drive technologies. Additionally, he is interested in ethics as they relate to development and implementation of artificial intelligence (A.I.). At IEPI he assists the Director and other team members in developing specific project deliverables by providing research support, critical analysis, and high-quality synthesis on a wide range of topics related to ethical issues in global health and development research. Previously, Aaron held various positions at the College of Physicians and Surgeons of Ontario, including work on their Investigations and Resolutions teams. Aaron holds Hons. BA and MA degrees in philosophy from Wilfrid Laurier University.

RUBINSTEIN CLARA

Dr. Rubinstein is a Biologist (University of Buenos Aires). She completed her scientific training in Argentina and abroad, at Michigan State University (US) and the Pasteur Institute in France. Clara received her PhD in Bacterial Genetics from the University of Buenos Aires and as a staff scientist for the National Research Council (CONICET), she conducted research on molecular biology and microbiology and published her work in international peer reviewed journals. Dr. Rubinstein began collaborating with ILSI Argentina as a volunteer leader in 1999, starting the Biotechnology Task Force and is currently ILSI Argentina’s President. In 2002, joined Monsanto Argentina (as of August 2018, Bayer Crop Science), to lead the Scientific Affairs area for the Latin American South region; in 2015, Clara became a member of the Science Fellows Program. During this period, Clara specialized in Science Based Risk Assessment with focus on Biotechnology, was part of the Scientific Advisory Committee for the Food and Feed Safety of transgenic crops at the AgriFood Quality Service (SENASA) on behalf of the Argentine Seed Association until 2016. She publishes on the topic, organizes and participates in capacity building programs in several countries of the Latin American region, frequently in partnership with other ILSI entities, academic, governmental and non-governmental organizations.
RÜDELSHEIM PATRICK

After obtaining his PhD in biology/botany at the University of Antwerp, Belgium, He started his career in D.J. Vanderhave B.V., a Dutch Seed company where he was involved in the application of plant cell biology in classical breeding. In 1990, he joined Plant Genetic Systems N.V., Ghent, Belgium as Field Trial Supervisor. After being in charge of Product Development and Registration, he was appointed Director Regulatory Affairs and Member of the PGS Board. In 1996, following the acquisition of PGS by AgrEvo, he became Global Head of Biotechnology Regulatory Affairs for the AgrEvo group. In this function, he ensured the scientific argumentation for Product Safety and Quality as well as the compliance with all regulatory acquirements related to genetic engineering. After the creation of Aventis S.A. due to the merger of Hoechst and Rhône-Poulenc, Patrick Rüdelsheim became Global Head Regulatory Affairs BioScience of Aventis CropScience and following the acquisition of Aventis CropScience by Bayer in 2002, he was confirmed in that position for Bayer CropScience. In 2003, he founded and became General Partner of Perseus BVBA, a service company focused on bio-safety and related regulatory requirements. Since mid 2015, he is also Senior Regulatory Advisor and Managing Director of ABS-int, a multi-disciplinary service provider dedicated to Access and Benefit Sharing requirements. Prior to joining ABNE, Mrs. Adeyemo was a Chief Regulatory Officer in the Food Safety and Applied Nutrition Directorate of the National Agency for Food and Drug Administration and Control (NAFDAC), Nigeria. She represented NAFDAC in the National Biosafety Committee, where she served as the Secretary and actively participated in various biosafety application reviews. As the Biosafety Desk Officer in NAFDAC, she contributed to policy development and the regulation of GMOs. She was also a member of the National Food Safety Management Committee (NFSMC), Nigeria and served as the Secretary of its technical committee on Risk Analysis.

SAAH ROYDEN

J. Royden Saah, of Island Conservation, coordinates the Genetic Biocontrol of Invasive Rodents Partnership (GBIRd) to safely, effectively, and ethically develop and evaluate the suitability of engineered mice with the potential control, or even eradicate, introduced, damaging (invasive) populations on islands. Royden knows that 500+ island rodent eradications have demonstrated how controlling invasive species protects island communities and prevents extinctions of at-risk wildlife and ecosystems. By working with GBIRd to responsibly develop novel gene drive technology, we can reduce the risks posed by anticoagulant pesticides, the primary tool currently used for rodent eradication on islands today. GBIRd is a complex effort in terms of the science and social concerns/consequences. Royden has a wealth of experience in multifaceted projects that includes leading the construction of a children’s hospital lab in Monrovia, Liberia during the West African Ebola outbreak and managing a multi-agency health-preparedness effort during a 2012 national political convention. He has spoken at the White House Conference Center and at United Nations Conventions on the importance of this technology investigation and the required safety mechanisms needed during development. Royden holds a Bachelor of Science in Zoology and a Master of Science in Microbiology from North Carolina State University, USA.

SHELTON ANTHONY

Professor Anthony (Tony) Shelton is an International Professor of Entomology and Associate Director of International Programs for Cornell’s College of Agriculture and Life Sciences (CALS). His research program is responsible for developing sound integrated pest management (IPM) strategies for vegetables with spin-offs for other crops. Components of his program stress insect population ecology, biological control, plant resistance, agricultural biotechnology and risk assessment, insecticide resistance, insect movement, trap cropping, and plant productivity and marketability as a function of insect infestations. Tony is also Director of the USAID-funded project on using insect-resistant Bt eggplant in Bangladesh and the Philippines. More than 27,000 farmers are growing Bt eggplant in Bangladesh and it is dramatically reducing insecticide use while increasing farm income and improving the environment. Among the awards he has received are the Entomology Society of America’s (ESA) National Award for IPM (1995), the NYS Award for Excellent in IPM (2007), the ESA National Recognition Award for Research (2005), Cornell (CALS) Award for Applied Research (2007), the ESA L.O. Howard Award (2011) and the ESA National IPM Team Award (2013). In 2010 he was elected an ESA Fellow. His program has a strong commitment to outreach education for the agricultural community and the general public.
SILVANOVICH ANDRE

Prior to joining the Regulatory Science Group at Monsanto in 1999 Andre Silvanovich received his B.Sc. (H) in Chemistry and Microbiology and M.Sc. in Chemistry from the University of Manitoba; subsequently he received a Ph.D. in Cell and Developmental Biology from the University of Minnesota. Andre has held several individual contributor and management roles in the Legacy Monsanto Regulatory Science organization including leading teams responsible for conducting the Protein Characterization and Safety assessments, Immunoassay Development and Protein Expression analysis and Production Bioinformatics. Currently Andre leads the Bioinformatics and Sequence Analysis team where he is responsible for advancing the use and acceptance of Next Generation Sequencing Technologies as a means for conducting genetically enhanced crop molecular characterization. Additionally, Andre has been involved in developing software tools and implementing strategies related to the assessment of protein allergenicity and toxicity and has led efforts to identify and implement computer automation to produce complex technical documents. Andre was appointed a Monsanto Scientific Fellow in 2017, he has authored greater than 300 technical documents that are used to support the deregulation of Legacy Monsanto and Bayer Crop Science Biotech product portfolio. Andre lives in Chesterfield, Missouri with his wife Sheila.

SOARES FELIPE MARIA SUELI

Maria Sueli Soares Felipe is the current President of Brazilian National Biosafety Technical Commission (CTNBio) where she represents the Brazilian Ministry of Science, Technology, Innovation and Communication. She is also a Professor of Catholic University of Brasilia (UCB) and a retired Professor of University of Brasilia (UNB). During her career she have been establishing several collaborations with national and international scientific and research institution and held various positions in the Brazilian government in strategic organs related to research, industrial and technological development working to the development of science and technology public policies. Maria Sueli holds a Ph.D. in Biochemistry (1992) from University of São Paulo, a Master’s degree in molecular biology (1978) and a BS Degree in Chemistry (1975) from University of Brasilia.

SONG PING

Ping Song is a senior research scientist at Corteva AgriScience™, the Agricultural Division of DowDuPont Company. He has a Masters in Plant Genetics and Breeding from Zhejiang Agricultural University in China and a PhD in Agronomy from Texas Tech University, USA. He has been working in the agricultural biotechnology industry for more than 20 years with focus on safety assessment of GM crops to achieve regulatory approval and product registration. He worked on the regulatory approval of GM crops launched by Corteva AgriScience including Widestrike™ cotton, Herculex® corn, Enlist™ corn, soybean, and cotton. Over the past 20 years, Dr. Song has authored more than 20 peer-reviewed publications and book chapters. He specializes in applying bioinformatics to the risk assessment of GM crops and serves as a steering team member for the peer-reviewed allergen database COMPARE.

STUPAR ROBERT

Robert Stupar is an Associate Professor in the Department of Agronomy and Plant Genetics at the University of Minnesota, USA. He received a B.S. degree in Biology from the University of Minnesota and a Ph.D. degree in Plant Breeding and Plant Genetics from the University of Wisconsin. His current appointment includes 75% research and 25% teaching responsibilities. Dr. Stupar's research program focuses on the genetics and genomics of legume crop species, with an emphasis on soybean. His group uses classical mutagenesis and modern plant biotechnology to study the functions of genes in plants. He has co-authored over 60 scientific research articles in the field of plant genetics. In 2011, his team was the first to publish successful gene editing in soybean. Dr. Stupar's awards include the American Society of Agronomy Early Career Professional Award and the Crop Science Society of America Young Crop Scientist Award.
TABEI YUTAKA

I am a director of Division of Applied Genetics in Institute of Agrobiological Science, NARO (National Agriculture and Food Research Organization), in Japan. I am a member of research committee on genetically modified foods under Japanese Ministry of Health, Labor and Welfare. My background research field is plant breeding using biotechnology. I entered National Institute of Vegetable Research and was engaged in the biotechnology research of Cucurbitaceae. I received a PhD degree from Tsukuba University for my study in the application of biotechnology in Cucurbitaceae vegetable breeding. Then, I worked on the regulatory affairs concerning environmental risk assessment of genetically engineered organisms (GMO) in Ministry of Agriculture and Forestry, Fishery (MAFF), Japan (1997-2000). I was also engaged in the development of plastid transformation systems in plants. Meanwhile, I have continued as leader the science communication with public and stakeholders to provide accurate information about GMO and New Plant Breeding Technology.

TEEM JOHN

Dr. Teem received his doctorate in Biology from Brandeis University, where he was trained in yeast molecular biology and genetics. Following post-doctoral fellowships at MIT (Boston), the Hospital for Sick Children (Toronto) and the University of Iowa (Iowa City), Dr. Teem took an assistant professor position at Florida State University where he used yeast genetics to conduct research on the human genetic disease cystic fibrosis. He later joined the Florida Department of Agriculture and Consumer Services where he specialized in genetic biocontrol of invasive species. His research there focused upon the development of genetic strategies to eradicate and control invasive aquatic species. His work included development of mathematical models to predict the outcome of genetic approaches to eradicate invasive fish, and laboratory methods to produce transgenic organisms for invasive species control. As a result of his combined experience in genetic research, data analysis and risk assessment, Dr. Teem has published 20 peer-reviewed articles related to molecular biology and genetics, reaching international audiences.

As a Scientific Program Manager at the ILSI Research Foundation, Dr. Teem contributes to the design and implementation of programs that promote science-based approaches to the safety assessment of genetically modified organisms, with a strong emphasis on the use of gene drives in biotechnology. He is also involved with activities to promote the sharing of confined field trial data between countries that are making regulatory decisions regarding approvals of GE plants for cultivation.

THIZY DELPHINE

Delphine Thizy is the Stakeholder Engagement Manager of Target Malaria, a non-for-profit consortium of researchers developing an innovating vector control approach to save million of lives from malaria. She has over 10 years’ experience in the field of stakeholder engagement in lower-income countries, with a particular attention on conflict drivers.

After receiving her Master’s Degree in Economic development studies and project management from the Pierre Mendes University, France (Grenoble, France), she worked in advocacy for Palestinian farmers’ rights before holding several positions within PlaNet Finance in the Middle East and South Asia. There she was responsible for technical assistance to microfinance institutions in post-conflict countries as well as leading a team for capacity strengthening of various civil society groups.

Afterwards she joined a consultancy company, Channel Research, specialising on social impact of projects. In that role she conducted a number of projects evaluations in the field of humanitarian aid and development for a variety of donors and organisations – including the European Commission, members of the Red Cross and Red Crescent Movement and private foundations. After creating her own consultancy company she specialised in social performance and stakeholder engagement for infrastructure and extractive industries. She led several teams for large social impact assessments across Africa.

Since 2014 she became the Stakeholder Engagement Manager of Target Malaria and works with teams in Mali, Uganda, Burkina Faso and Ghana, as well as at the global level to engage stakeholders to co-develop and share an innovative long-term, sustainable and cost-effective vector control technology.
 TIMPO SAMUEL

Samuel E. Timpo is a Principal Programme Officer with AUDA/NEPAD African Biosafety Network of Expertise (ABNE), which supports African Union member states in building functional biosafety regulatory frameworks. He is responsible for the socio-economic aspects of biosafety and biosafety communication. He has been involved in biosafety capacity building efforts in Africa for over a decade and is the focal person in AUDA/NEPAD for the Convention on Biological Diversity and its Protocols. He also served as research lead for a team of researchers who examined factors influencing the differential ability of sub-Saharan African countries to implement functional regulatory systems for modern biotechnology. Prior to this, he worked as a socio-economist with the Biotechnology and Nuclear Agriculture Research Institute (BNARI) of the Ghana Atomic Energy Commission during which period he also coordinated biosafety capacity development activities in Ghana. He has a Master of Philosophy degree in agricultural economics from the University of Ghana, Legon.

 TSUDA MAI

Mai Tsuda is the Assistant Professor of Tsukuba-Plant Innovation Research Center (T-PIRC) in University of Tsukuba. She belongs to Risk Assessment and Management group under the Plant Transgenic Design Initiative in T-PIRC. She earned a degree of Master's from Utsunomiya University, and PhD in agriculture from United Graduate School of Agricultural Science Tokyo University of Agriculture and Technology in Japan. She studied on gene flow from Brassica napus to B. juncea at the National Agriculture and Food Research Organization in the doctoral dissertation.

 TURNER GEOFF

Geoff Turner is a regulatory professional with over 20 years of technical and strategic regulatory experience in both government and the private sector in Canada and the UK. He provides support and guidance to the Target Malaria project in navigating regulatory processes in project countries through ensuring project activities are well grounded in sound principles of risk analysis. Before joining the Target Malaria project he worked in the private sector leading technical regulatory processes for transgenic insects across multiple jurisdictions. Notably Mr. Turner led the development of the technical dossier and risk assessment processes which led to the first positive biosafety evaluation of a GM mosquito against the European risk assessment framework (NL government), and further supported the territory wide approval for the operational use of a GM mosquito in the Cayman Islands. In the commercial sector, he also led regulatory processes supporting the first open trial of a GM self-limiting insect for agriculture pest control in the USA. His work in GM insect regulation goes back further to 2006 when he was the Canadian government lead on the development of a North American Standard on the importation and confined field release of GM arthropods under the North American Plant Protection Organisation (NAPPO). Mr Turner’s early experience is grounded in over 10 years’ of hands-on molecular biology laboratory work supporting regulatory programs in a Canadian science based regulatory agency, where he went on to management positions in Canadian government plant health regulatory and strategic policy programs, overseeing operational program delivery, technical trade agreements, and bilateral regulatory cooperation.
Van Ree Ronald

Ronald van Ree defended his thesis at the University of Amsterdam in 1994 on the topic of grass pollen allergens and their interaction with the immune system. From 1994 until 2005 he headed the Allergy Research Laboratory at Sanquin Blood Supply Foundation in Amsterdam. In July 2005 he moved to the Academic Medical Center in Amsterdam where he was appointed as Associate Professor at the Department of Experimental Immunology. There he is head of the Laboratory for Allergy Research. In June 2009 Ronald van Ree was appointed as Full Professor of Molecular and Translational Allergology. The main areas of interest of the Allergy Research group are:

- Protein-chemistry and molecular biology of respiratory and food allergens: what makes an allergen an allergen?
- Innovative approaches for in vitro and in vivo diagnosis of IgE-mediated allergy: from allergen extracts to molecular diagnostics.
- Innovative biopharmaceutical approaches for allergen-specific immunotherapy: recombinant technology, novel adjuvants and administration routes.
- Immuno-epidemiology of respiratory and food allergies: the role of allergen exposure, environment, diet, infections and lifestyle in the development of allergy.
- Mouse models of allergy and asthma: how are sensitization and disease expression regulated?

Ronald van Ree has participated in many EU Framework Program projects, amongst which as co-ordinator of the CREATE project (FP5) developing certified reference materials for allergen products, as vice-coordinator in the Integrated Project (FP6) on Food Allergy, EuroPrevall, in the GLOFAL project (FP6) aiming at integrating food allergy research in developing countries in EU framework program, as co-ordinator of the ongoing project (FP7) on immunotherapy for food allergy FAST (2008-2017), and as ExCom member of the iFAAM project (FP7; 2013-2017) on risk management of food allergy. In February 2014 he took up the coordinator ship of another EU project BM4SIT targeting at innovative approaches for allergen-specific immunotherapy (novel adjuvant in combination with a designed hypo-allergen). He has been Vice-President for Congresses in the Executive Committee of the European Academy of Allergy and Clinical Immunology (2013-2015). He is on the editorial board of several leading journals in the field of allergology, and has been associate editor of International Archives of Allergy and Immunology. Ronald van Ree has published over 300 papers in peer-reviewed journals, and several book chapters. His Hirsch-index at the end of 2018 was 65.

Vesprini Facundo

Facundo Vesprini serves in the Argentinean Government Secretariat of Agroindustry. He began, in 2012, as a GMO Risk Assessment Specialist in the Biotechnology Directorate, and since 2016 he leads the area of Environmental Risk Assessment of Genetically Modified Plant Organisms (GMPOS).

In this position, he provides support to the Biotechnology Directorate, the National Advisory Committee on Agricultural Biotechnology (CONABIA) and other technical advisory bodies. In addition, he conducts trainings on the regulation of GMOs in different countries. Before joining the Ministry of Agroindustry, Facundo Vesprini worked as a specialized technician in the Certification and Control Directorate at the National Seed Institute and as researcher in the field of biotechnology at the Chair of Biochemistry of the School of Agriculture (University of Buenos Aires).

In the academic field, he teaches on post graduate courses on biotechnology and biosafety and he also has authored publications about biotechnology, biosafety and Insect Resistance Management (IRM).

Facundo Vesprini earned a Degree in Agricultural Engineering from the University of Buenos Aires in 2013 and later completed an Specialization on Management of New Technologies in Science and Engineering at Ajou University in South Korea. Currently he is studying a Master in Policy and Management of Science and Technology at the University of Buenos Aires. He has also taken international post graduate courses on biotechnology and regulatory.
**WHARTON PHILIP**

Dr. Phillip Wharton is currently associate professor of potato pathology at University of Idaho and has been a research/extension specialist since 2008. Wharton earned his doctorate in plant disease resistance in 1997 at the United Kingdom’s University of Reading. He spent the following two years as a post-doctoral researcher at Purdue University, where he investigated biochemical mechanisms of plant disease resistance in sorghum. In 1999, he moved to Michigan State University, where he studied the biology and epidemiology of diseases of tree and small fruit (cherries, blueberries, strawberries, and grapes) before concentrating his efforts in 2004 on late blight, Rhizoctonia, Fusarium dry rot and other diseases of potato. Wharton currently has several international projects developing late blight resistant potatoes in Indonesia and Bangladesh and conducts research on disease forecasting, crop protection, host-pathogen interactions, post-harvest disease management of vegetable crops and fungicide resistance.

**WHELAN AGUSTINA**

Agustina Whelan serves in the Argentinean Ministry of Agroindustry. She began in 2010 as GMO Risk Assessment Specialist, then in 2013 she was designated coordinator of Risk Assessment of Genetically Modified Plant Organisms (GMPOs) for commercial release, and since 2015 she is the Head of the Biosafety and Food Safety assessment teams in the Biotechnology Directorate of the Ministry of Agroindustry. In these positions, she provides technical and operational support to the Biotechnology Directorate and to the National Advisory Committee on Agricultural Biotechnology (CONABIA) and other technical advisory bodies in activities related to her area of work. These activities include the management of applications, participation in internal and external meetings, and drafting safety assessment and other reports pertaining scientific advice in biotechnology and biosafety. She has also been appointed to participate in Biosafety related fora such as the Cartagena Protocol. Before entering the Ministry of Agroindustry, Agustina Whelan worked in the field of biotechnology applied to human health, as Cytotechnology Specialist in the Cosme Argerich Hospital of Buenos Aires. In the academic field, she performed as Visiting Scholar at National University of Quilmes, Argentina during the years 2014-2016, for teaching graduate and postgraduate courses on biotechnology and biosafety. In addition, she has authored publications pertaining biotechnology, biosafety and policymaking. Agustina Whelan completed a Bachelor Degree in Biotechnology in the University of Quilmes in 2009. She also has magister post graduate studies in Policy and Management of Science and Technology at the University of Buenos Aires (UBA).

**WITWER KENNETH**

Dr Witwer and his laboratory study noncoding RNAs (ncRNAs), extracellular vesicles (EVs), and their regulatory roles in health and disease in the Department of Molecular and Comparative Pathobiology at The Johns Hopkins University School of Medicine. Special areas of focus in the Witwer group are HIV disease, including central nervous system effects of HIV infection; non-HIV neurodegenerative diseases; and delivery of RNA for therapeutic purposes. Dr. Witwer directs a US NIH-funded course on Rigor and Reproducibility in Research at Johns Hopkins and has helped to lead standardization initiatives of the International Society for Extracellular Vesicles (ISEV) as a past Secretary General of the society and was co-coordinator of the recently released “MISEV2018” guidelines for studies of EVs. He has also served regularly on RNA-related panels of the US NIH, US EPA, EFSA, and others.
Fred Wondergem is Sr Manager Product Stewardship and Regulatory at DuPont Industrial Biosciences Division. He has a special focus on biotechnology innovation projects for the food industry as well as on food enzymes advocacy. He has been working with the development and implementation of EU Enzymes legislation under FIAP (Food Improvement Agents Package) as well as the subsequent filing of food enzyme dossiers to the EU Commission and EFSA.

Fred graduated as Medical Biologist from University Utrecht. He started his professional career as a toxicological assessor at the Dutch RIVM to support evaluations at both the Dutch Medicines Evaluation Board and the European Medicines Agency. He then moved to the pharma biotechnology industry to work as a Regulatory Affairs Associate at Centocor (currently Janssen Biologics BV). Followed by a transition into the food biotechnology at Genencor, which finally merged into DuPont.

He devotes most of his free time to a wide range of music, and cycling.

María Luz Zapiola is the Scientific Affairs Manager at ArgenBio. She is in charge of the technical content developed for publications, web page and social networks of ArgenBio and the topics related to Biotechnology in Infoalimentos. She is also responsible of the “train the trainers program” of ArgenBio, training 800-900 trainers per year. María Luz also teaches seminars and classes within graduate programs.

Together with ArgenBio’s Communications department, she generates materials to answer the difficult questions and concerns of the different publics regarding biotechnology, agrochemicals and glyphosate, among others. These resources are then used in role-playing workshops with communicators and influencers regarding answering difficult questions. Also, she actively participates in the IRM (Insect Resistance Management) program, which generates and communicates management recommendations of the technologies.

María Luz is and Agronomist from the Universidad Católica Argentina (UCA), with a Master of Science (specialization in crop ecophysiology) and a PhD (specialization in crop science and genetics) from Oregon State University (OSU), USA. As a complement to her vast teaching and research activities at UCA and OSU, she also worked in technology development in the private sector.
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