BIOSAFETY SYMPOSIUM PROGRAM

1.2.2018

ENABLING SUSTAINABLE BIOTECH INNOVATION

biosafety SOUTH AFRICA

science & technology
Department:
Science and Technology
REPUBLIC OF SOUTH AFRICA

PROGRAM

07:30-08:30	Registration, coffee and networking	
Plenary Session (Chair – Ben Durham)		
08:30-08:35	Welcome & goal	Hennie Groenewald
08:35-09:00	Opening	DST – Ben Durham
09:00-09:35	Challenges to biotech innovation for small companies and the public sector	Keith Redenbaugh, Arcadia Biosciences
09:35-09:45	Discussion	
Theme 1 – Biosafety Communication & Engagement (Chair – Ben Durham)		
09:45-09:55	Biosafety SA's C&E initiative	Liezel Gouws
09:55-10:10	Science communication and biotech innovation	Marina Joubert
10:10-10:20	Discussion	
10:20-10:50	**Coffee break and networking**	
Theme 2 – Biosafety Governance (Chair – Sandy Snyman)		
10:50-11:05	Food/feed safety issues related to GMOs	Penny Campbell
11:05-11:20	A practical perspective on environmental risk assessment	Wadzi Mandivenyi
11:20-11:35	Socio-Economic issues related to GMOs	Ben Durham
11:35-11:50	Regulatory best practice in the SA context	Nompumelelo Mkhonza
11:50-12:00	Discussion	
Theme 3 – GMO Sustainability R&D (Chair – Johnnie vd Berg)		
12:00-12:15	SANBI's GMO related R&D	Tlou Masehela
12:15-12:30	Insect Resistance Management in Bt crops	Andri Visser
12:30-12:45	Modelling refugia requirements for insect resistant sugarcane	Dirk Human
12:45-13:00	Assessing the likelihood of gene flow from sugarcane (*Saccharum* species hybrids) to wild relatives in South Africa	Hlobisile Khanyi
13:00-13:15	Discussion	
13:15-14:00	**Lunch and networking**	
14:00-14:15	Overview of food/feed safety research - GRACE results	Eugenia Barros

14:15-14:30	Maize seed choices in Eastern Cape	Siphokazi Ngcinela
14:30-14:45	Review of two decades of GMO socioeconomic research in the SA context	Marnus Gouse
15:15-15:30	Discussion	
Theme 4 – Emerging Biosafety/Sustainability Issues (Chair – Wadzi Mandivenyi)		
15:30-15:40	Sustainable biotech innovation from an entrepreneur's perspective	Mauritz Venter
15:40-15:50	GM forestry	Sanushka Naidoo
15:50-16:00	GMO sugarcane sustainability R&D	Sandy Snyman
16:00-16:10	Induced genetic variation: Innovation opportunities & challenges	Hennie Groenewald
16:10-16:20	Regulators' perspective	Wadzi, Ben and Penny
16:20-16:30	Discussion	
16:30-16:40	Closing	Hennie Groenewald
16:40-18:00	Networking cocktail	
18:00-19:30	Screening of the movie "Food Evolution"	

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ABSTRACTS

Challenges to Biotech Innovation for Small Companies and the Public Sector

Keith Redenbaugh

Director of Regulatory Affairs, Arcadia Biosciences, Inc., Davis, California USA

Since the launch in 1994 of the first, commercial, genetically engineered (GE) crop (Calgene's FLAVR SAVR tomato), the agricultural biotechnology industry has consolidated from dozens of companies to four large ones: BASF Plant Science, Bayer CropScience (soon to incorporate Monsanto), the Agriculture Division of DowDupont and Syngenta (part of ChemChina). Although small companies played major roles early in the development of agbiotech and the commercial launch of some of the first products, very few small companies are able to do this today. Two of the most significant hurdles are the high cost of obtaining global approvals and meeting the necessary stewardship requirements, which include global movement of products from the GE crops. This talk will focus on small companies and strategies for dealing with these hurdles. Examples include several identity-preserved, commercial GE crops contrasted against a major global commodity crop.

Biosafety SA's Communication and Engagement Initiatives

Liezel Gouws

Biosafety South Africa, 105 Wentworth, Somerset Links Office Park, Somerset West, South Africa 7130

In many countries the biggest current hurdle to the deployment of GM crops is not governance or technical development and sustainability issues, but rather negative public perceptions. The necessity and value of science-based "biosafety" or "risk" communication to ensure public trust in GM governance systems, already approved GM crops and the value of GM technology as a research and developmental tool is therefore more crucial than ever. Biosafety South Africa has accepted the responsibility to facilitate the development of a biosafety communication strategy that would ensure a coherent and effective approach to biosafety communication in South Africa. At first the context in which the strategy had to be developed was established in close collaboration with various stakeholders and with the assistance with appropriately skilled science communication experts, which ensured a suitable framework in which to develop the strategy. Moreover, in order to develop a sustainable and effective biosafety communication strategy three important questions were considered: who should participate in the communication efforts (defining the biosafety communication ecosystem), what should be communicated to whom (biosafety message development) and how should the identified messages be communicated (developing a biosafety communication approach)?

The goal of a biosafety communication strategy was identified as the positive influencing of the national conversation around genetically GMOs from a science perspective; in order to increase awareness and build confidence in the biosafety systems in place to ensure the safety and sustainability of GM activities and products. Such confidence will not only impact on the acceptability of the current products in the market, but more importantly also support the objectives of the national bio-economy strategy. While this strategy defines the broad goal and actions that would realise it, these were further concretised into an adaptive tactical plan with coalescing strategic objectives and well-defined, actions that will lead to the realisation of the strategic goal. This presentation will give a glimpse into the communication and engagement initiatives of Biosafety SA thus far and highlight success and lessons learnt.

Believing is seeing: The challenges of communicating unpopular science

Marina Joubert

Centre for Research on Evaluation, Science and Technology (CREST), Stellenbosch University

Innovations in biotechnology promise novel solutions to complex problems related to health, food and the environment, but are typically characterised by some uncertainty, along with ethical questions, economic interests and high policy stakes. Consequently, these emerging technologies have intensified societal debate and polarised public opinion about its acceptability and desirability. These debates often focus on political, ethical, moral, legal and economic dimensions, rather than the science itself.

Based on a desire for political support and public acceptance of cutting-edge science, the notion that publicly funded scientists have a duty to engage with the public has become widely accepted. This perception of a moral duty to communicate is particularly strong for researchers who work on topics that have moral or ethical implications. However, scientists who actively participate in public communication about contested topics may find themselves negotiating a fine line between public communication, advocacy and even activism, and may face a series of reputational risks, tensions and trade-offs. It is also clear that, no matter how well intended public engagement activities may be, they are by no means a guarantee of public support and may even lead to greater public opposition to new innovations.

In my talk, I will present a few theoretical concepts that are useful for understanding public trust in science and how public opinion about biotechnology is formed, including a brief reflection on the effects of societal risk–benefit calculations, media coverage, culture and ideology. I will conclude with relevant insights from a new field of study known as the 'science of science communication' which emphasises effective, responsible and ethical public communication of science.

Socio-economic issues related to GMOs

Ben Durham

National Department of Science and Technology, Pretoria, South Africa.

GMOs – like any new product - are designed to have socio-economic impact. In the contentious global debate over GMOs, however, the 'socio-economic considerations' issue is a battlefield, with widely differing interpretations as to how they could be used to further the entrenched polarized approaches. The presentation will provide a brief overview of 'socio-economic considerations', what the underlying issues are, and how South African regulators deal with the topic.

Regulatory best practice in the SA context

Nompumelelo Mkhonza, Noluthando Netnou-Nkoana and Julian Jaftha

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South Africa has twenty years' experience in the regulation and commercialisation of Genetically Modified Organisms (GMOs). Compliance with regulatory requirements is fundamental in maintaining an effective regulatory system. The Office of the Registrar which is responsible for the administration of the GMO Act, 1997 (Act No.15 of 1997) has observed that, despite the well-established and tested regulatory system, some of the applications submitted for approval of GMO events in terms of the Act are non-compliant. This results in delays in processing of the applications and subsequently in decision-making regarding such applications.

The main challenge mostly encountered is around incomplete information supplied by applicants, including but not limited to: use of outdated application forms, insufficient risk assessment data and aggregated field trial data. It is the responsibility of both the regulators and the applicants to improve regulatory compliance by reducing factors leading to non-compliance. This presentation will highlight best practices with regard to information required from the applicants in relation to permit applications for Contained Use, Commodity Clearance, Field-trial Release and General Release. Information on the obligations of applicants and the interface with Inspection Services and the Appeal Board will also be shared.

SANBI's GMO monitoring and research programme: role and contribution to GMO sustainability, research and development

Tlou S. Masehela
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South Africa has adopted biotechnology and its related products within a risk assessment framework in which Genetically Modified Organisms (GMOs) are strictly regulated and subjected to a risk assessment prior to environmental release. Linked to this process, is the need to manage and monitor potential environmental effects that may arise due to the presence of any GMOs released into the environment. As a result, SANBI is mandated to monitor and report on any impacts of GMOs after their release into the environment and research is necessary to support this function. Since the inception of SANBI's GMO monitoring and research programme in 2005, several contributions have been made and various milestones achieved in support of the agricultural biotechnology research and development space, specifically, for the environmental release of genetically modified crops in South Africa. This pertains to industry monitoring protocols, environmental risk assessment processes, the development of a monitoring framework, conducting several desktop based studies on GM crop trends and the establishment of new studies within the scope of GM crops. The GMO programme values partnerships and collaborations in order to continue providing the necessary support towards sustainable GMO research and development in South Africa. At the same time, the programme upholds a long term goal of generating credible scientific based evidence that will support various frameworks and legislative tools that regulate the safe use, research and development of GMOs.

Guess or know? How assumptions about the behaviour of lepidopteran pests affects IRM strategy and sustainability for Bt crops.

Andri Visser[1], Hannalene Du Plessis[1], Annemie Erasmus[2], Johnnie Van den Berg[1]

[1]North-West University, Potchefstroom, North West Province, South Africa, [2]ARC-Grain Crops Institute, Potchefstroom, North West Province, South Africa

The use of genetically modified (GM) Bt-crops has increased exponentially over the past four decades. These crops contain genes from the bacterium *Bacillus thuringiensis* (Bt) that allow the expression of Cry (crystal) proteins, which are toxic to specific target insect pests. Because of the effectiveness of these toxins, the selection pressure for evolution of resistance is high. Although various insect resistance management (IRM) strategies have been considered to delay the evolution of resistance, the high-dose/refuge strategy is favoured. This strategy accepts that Bt-plants produce toxin levels high enough to kill heterozygous (RS) resistant individuals. It also accepts that a susceptible (SS) population persists in non-Bt maize refuges to mate with the rare homozygous (RR) resistant individuals that survive the high doses of Bt-toxin in Bt maize fields. Although this IRM strategy has contributed to limiting the evolution of Bt-resistance, it is based on several assumptions that are not consistently met for different target species. These include assumptions about the interactions between insect pests and Bt-crops, as well as between resistant and susceptible individuals in the pest population. For example, it is assumed that the pest shows no ovipositional or feeding preference for either Bt- or non-Bt plants, that larvae do not migrate extensively, and that factors such as plant density, plant age, and the presence of wild hosts do not hamper the efficacy of the IRM strategy. This presentation also reviews the knowledge regarding larval migration of lepidopteran pests, their wild host plants and Cry protein expression levels, and relates this to IRM in an African context.

Modelling refugia requirements for insect resistant sugarcane

DJ Human and Linke Potgieter

Department of Logistics, Stellenbosch University

Crops expressing genes from the bacterium Bacillus Thuringiensis (Bt) produce a protein toxic to members of the order Lepidoptera and are a popular alternative to sprayed insecticides. Although these Bt crops are considered to be an effective pest control method, reckless usage adds environmental pressure on the pest population to develop resistance to the toxin over time. One method of limiting the rate of resistance development is to keep small portions of the cultivated land planted with the non-GMO crop which then acts as a refuge area for the pest, limiting its exposure to the toxin and removing the pressure to develop resistance. Strains of Bt sugarcane for the South African market that should limit the damage caused by the stalk borer moth, Eldana Saccharina Walker, are being developed, and a prerequisite to releasing such a product is a recommendation on the size and layout of the refuge areas to be planted, as an area too small may not curb the rate of resistance development enough, but an area too large may not be economically viable for the end user. A simulation-based model is presented where individual moths are modelled as agents on an underlying sugarcane field. To reduce the complexity of the model, the field is divided into a series of smaller cells that can interact with each other, which allows us to model the impact of a severe infestation on an area the size of an average sugarcane farm. Preliminary results show that refugia requirements will be large, as the moth is not known to fly far from where it hatched, leading to possibly homogeneous population bubbles that diminish the effectiveness of widely spread refuge areas.

Assessing the likelihood of gene flow from sugarcane (Saccharum hybrids) to wild relatives in South Africa

H. Khanyi[1], S. J. Snyman[2,3], D. M. Komape[1], J. van den Berg[1], D. Cilliers[1], D. Lloyd Evans[2,3,4], S. Barnard[1], S. J. Siebert[1]

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Gene flow between crops and their cross-compatible wild relatives is undesirable in commercial production systems. The transfer of transgenes from genetically modified (GM) crops to wild relatives may enhance their capacity for invasiveness or may affect non-target herbivore species. Therefore, biosafety assessments are a legal requirement to evaluate the potential impact of GM crops on the environment before their approval for commercial release. The aim of the study was to assess the gene flow potential from sugarcane (Saccharum hybrids) to wild relatives in the sugarcane production regions of Mpumalanga and KwaZulu-Natal provinces South Africa. In the first instance, an assessment of Saccharum wild relatives was conducted based on prevalence, spatial overlap, proximity, distribution potential and flowering times. The presence of wild relatives in sugarcane production regions based on herbaria records and field surveys were Imperata, Sorghum, Cleistachne and Miscanthidium species. Eleven species were selected for spatial analyses based on their presence within the sugarcane cultivation region: four species in the Saccharinae and seven in the Sorghinae. Secondly, fragments of the internal transcribed spacer (ITS) regions of the 5.8s ribosomal gene and two chloroplast genes, ribulose-bisphosphate carboxylase (rbcL) and maturase K (matK) were sequenced or assembled from short read data to determine relatedness between Saccharum hybrids and its wild relatives. Phylogenetic analyses of the ITS cassette showed that the closest wild relative species to commercial sugarcane were Miscanthidium capense, M. junceum and Narenga porphyrocoma. Sorghum was found to be more distantly related to Saccharum than previously described. Field assessment of pollen viability of 13 commercial sugarcane cultivars using two stains, iodine potassium iodide and triphenyl tetrazolium chloride, showed decreasing pollen viability (from 85 - 0%) from the north to the south eastern regions of the study area. Future work will include aspects influencing gene flow such as cytological compatibility and introgression between sugarcane and Miscanthidium species.

Overview of food/feed safety research - GRACE results

Eugenia Barros

Eugenia Barros Biosciences and Consulting, Johannesburg, South Africa

The safety of plant derived foods and feeds has focused mainly on genetically modified (GM) crops. Methodologies have been developed to assess the potential risk of genetic modification and its impact on human and animal health, on the environment and on society at large. The common element in the evaluation of GM crops is based on a comparative analysis of the GM plant with its non-GM (conventional) counterpart and it focus on two aspects of the GM plant – the intended effects and the potential unintended effects of the genetic modification. The assessment of the intended effects targets the new characteristic/s that were introduced into the GM plant and tests for specific, key compounds, using well established and validated protocols. In addition to these, the detection of potential unintended effects is done through non-targeted analysis and uses profiling technologies such as the omics technologies. The European Union-funded project GRACE (GMO Risk Assessment and Communication of Evidence) pursued two key research objectives: (i) to provide comprehensive systematic reviews on the health, environmental and socio-economic impacts of GM plants taking into consideration the risks and potential benefits; (ii) to test various types of animal feeding trials and alternative in vitro methods to determine their suitability and what scientific information they provide for health risk assessments of GM food and feed. The results of the feeding trials (90-day and 1-year) and of the in vitro / omics studies with whole food / feed using MON810 maize as GRACE explored the value of the different approaches to risk assessment of whole GM food / feed will be discussed.

Assessment on farmers' choice of maize varieties, awareness and compliance to GM maize permit conditions in OR Tambo District, Eastern Cape Province

Siphokazi Ngcinela[1], Abbyssinia A. Mushunje[1], Amon Taruvinga[2], Charles Mutengwa[2]

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Understanding determinants of farmers' maize seed choices by professional plant breeders is critical, more especially underlying successful adoption of improved maize varieties. On the other side, farmers' knowledge and awareness of GM maize is a fundamental decision making process and it's ultimately adoption. Farmers' choice of maize varieties at small scale level is not clearly determined. Little is known about smallholder farmers' awareness and compliance to GM maize permit conditions. This study therefore sought to identify smallholder farmers' maize varieties choice, awareness and compliance to GM maize permit conditions. A structured questionnaire was administered to 704 respondents through a multistage random sampling technique. The respondents were selected from three study sites of Mqanduli, Port St Johns and Flagstaff. SPSS version 24 was used to analyse the data.

The results revealed that different maize varieties were being produced by smallholder farmers. Farmers were mainly choosing unimproved maize (Landrace) than GM maize and conventional hybrid maize varieties. For empirical results, gender, highest educational level, household size, employment status, access to land, access to market, access to credit, membership to farmers' group were positive and the significant variables for adoption of GM maize varieties. The results further showed that smallholder farmers were neither aware nor complying with GM maize permit conditions. Permit conditions are being violated, which is likely to result in numerous undesirable effects. It is recommended that more research will be necessary on landrace maize variety as farmers prefer that variety most. Policy should target farmers groups and organisations since more farmers who are producing GM maize varieties at the small scale level are from these organisations. Access to market and credit need to be promoted. All stakeholders, including government and the private sector, should educate farmers about permit conditions.

Two decades of GMO socio-economic research in the SA context

Marnus Gouse

Bureau for Food and Agricultural Policy (BFAP). Department of Agricultural Economics, Extension and Rural Development, University of Pretoria

In 2018 South African farmers will harvest the country's 22^{d} GM cotton crop, the 21st GM maize crop and the 18th GM soybean crop. It is estimated that in the 18 year period from 1998 to 2015, the use of Insect Resistant (IR) and Herbicide Tolerant (HT) GM traits in maize and cotton and HT in soybeans resulted in a direct cumulative farm income gain of $2.04 billion. This enormous amount of money excludes indirect and non-pecuniary benefits like labour and fuel saving, health benefits, managerial freedom and the environmental and production benefits of a move towards conservation tillage practices. Also excluded are the benefits of increased food security and decreased drudgery for smallholder maize producers.

The presentation will provide background on the GM crop technologies and the impacts they've had on the different industries. The presentation will also highlight some lessons from two decades of GM crops in South Africa to inform current and future research and decision-making.

Sustainable biotech innovation from an entrepreneur's perspective

Mauritz Venter

Co-founder & CEO, AzarGen Biotechnologies

Building a sustainable business and positioning for long-term success, AzarGen focuses on finding business opportunities in the biopharmaceutical market where uncertainty and risk is traditionally very high but offers the greatest potential rewards in the biotechnology industry. Compared to hi-tech start-ups, biotech is not a typical 'started in the garage' type venture. The business of biotechnology is risky due to the additional biological uncertainty which usually leads to highly regulated go-/no-go milestones prior to product release. Based on typical start-up business models and development cycles, it is clearly evident that an integrated approach and communication between all relevant stakeholders, including: innovators, regulators, investors and consumers, need to be established early from concept phase through development to product release.

From a biotech entrepreneur's perspective, the drive to start a high-risk venture should be based on a defined solution to a specific problem while a market demand exists. The start-up entrepreneur's passion alone (combined with wild imagination and some naivety) will not be sufficient for business success. Sustainable biotech innovation, whether the business is built on the premise of new platform technology (e.g. recombinant DNA or genome editing technology) or a specific product, depends on a multitude of different factors, including many which do not relate directly to the technical ability to understand, manipulate, develop and utilise the specific biology system. These non-biological factors include policy and regulatory frameworks, access to IP and freedom to operate considerations, a wide range of capacity and skills requirements and consumer acceptance - many of which are highly context specific. It is therefore important to identify, understand and address, as appropriate, all these underlying factors within a particular biotech innovation system to help ensure success.

GM Forestry

Sanushka Naidoo1 and Zander Myburg

Department of Genetics, Forestry and Agricultural Biotechnology Institute (FABI), University of Pretoria, Private bag x20, Pretoria, 0028, South Africa

Globally, forestry is an important resource for goods and services. Diseases and pests are among the key competitive challenges facing forestry and incidences are expected to increase with changes in climatic conditions. The threat posed by new, highly virulent pathogens in future may necessitate the use of genetically modified material, if resistance is not present in the breeding population. An extreme example of this is the case of the American Chestnut which is highly susceptible to Cryphonectria parasitica. The introduction of the wheat oxalate oxidase gene to neutralise the copious amounts of oxalic acid produced by the fungus, has demonstrated the success of GM technology in trees.

GM Eucalyptus trees have been developed and assessed in field trials. In the US, ArborGen has produced Eucalyptus trees with enhanced frost tolerance while in Brazil, the biotechnology company FuturaGene has produced GM Eucalyptus containing the Arabidopsis endo-1,4-b-glucanase (cel1) gene conferring enhanced growth properties and increase in biomass. These products are at various stages of de-regulation. South Africa lags behind in the development of GM technology in forestry, which may become an important avenue to enhance tree defence in future, as well as engineer novel wood properties for use in biofuels and biomaterials. We present recent progress in adopting GM technology and discuss anticipated challenges in this area.

Biosafety and sustainability aspects being considered in the pre-commercialisation phase of developing genetically modified sugarcane in South Africa

SJ Snyman[1,2], M Gouse[3], L Potgieter[4], S Siebert[5] and J Van den Berg[5]

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The South African Sugarcane Research Institute (SASRI) has conducted research on genetic modification (GM) of sugarcane for traits such as insect resistance, herbicide tolerance and improved nitrogen use efficiency. The sugar industry recently made a strategic decision to invest in the development of an enabling environment to commercialise a GM sugarcane variety. It subsequently commissioned a business case study for insect resistant GM sugarcane (identified as the most appropriate GM trait in an industry workshop held in 2013), which identified several commercialisation scenarios and high-lighted gaps in biosafety-sustainability research and data as one of the hurdles to commercialisation. Several collaborations are underway to undertake research in the following fields: (1) efficacy studies using diet feeding bioassays to determine base-line susceptibility of South African (SA) Lepidopteran stalk borers that are pests of sugarcane and maize e.g. *Chilo partellus* (a surrogate for *C. sacchariphagus*), *Eldana saccharina* and *Sesamia calamistis* using selected *Bacillus thuringiensis* (Bt) Cry proteins in order to determine high-dosage and possible 'gene stack' combinations necessary for insect resistance management; (2) a phylogenetic analysis based on the DNA barcode fragment of the internal transcribed spacer (ITS) regions of the 5.8s ribosomal gene and a spatial assessment of wild relatives of the *Saccharum* species complex viz. *Miscanthidium capense and M. juncuem*, to assess the likelihood of outcrossing; (3) an ex ante socio-economic analysis to support adoption of Bt GM sugarcane in all grower sectors and consideration of local and international market/trade implications for sugar derived from GM cane; and (4) determination of optimal size and distribution of refugia using simulation models to minimise the development of resistance in target insects. In addition to generating biosafety data necessary to support regulatory dossiers, it is anticipated that the development of human capacity skills will enable a wholly SA-developed GM crop in the near future.

Induced genetic variation: Innovation opportunities & challenges

Jan-Hendrik Groenewald

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A wide and evolving range of more accurate and efficient techniques, aimed at modifying genomes and/or gene expression, have recently been developed. In turn, these have enabled genetics-based applications, which previously were considered unpractical. These developments have not only lead to excited speculations on the potential and usefulness of these applications in medicine, breeding, pest management and other biotechnologies, but also intense international discussions of their possible ethical, regulatory and safety implications. In addition, the conceptual and technical similarities and overlaps between these techniques and GM technology often imposes a "GMO-frame" on these discussion, which often leads to inaccurate clumping of distinct techniques, genetic impacts and/or – outcomes and/or risk implications, which significantly impedes on evidence-based decision making. Instead, this international debate should be used to re-establish sound parameters for science-based risk regulation, including a contextually appropriate trigger and threshold for the regulation of organisms whose genetic material has been modified. These discussions are in urgent need of conclusion to fill the vacuum left by the high rate at which the field is developing and in order to ensure the safety and sustainability of research, development and commercialisation while not unduly constraining biotech innovation.

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