*Regional Expert Consultation on*

# Gene Editing in Agriculture and its Regulation

**Hyderabad, India**
**October 10-11, 2019**


# Proceedings and Recommendations

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***Citation:***

Rishi K. Tyagi, Rajeev K. Varshney, Pooja Bhatnagar-Mathur, Shivendra Bajaj, Ratna Kumria and Ravi K. Khetarpal (2019). **Regional Expert Consultation on Gene Editing and its Regulation - Proceedings and Recommendations**. Asia-Pacific Association for Agricultural Research Institutions (APAARI), Bangkok, Thailand, xvii+44 p.

***Published by:***

**Asia-Pacific Association of Agricultural Research Institutions (APAARI)**
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# Foreword

The latest progress in achieving Sustainable Development Goals as brought out by United Nations shows a dismal picture for Asia-Pacific where we are not even close to half way mark of what should have been achieved towards Zero Hunger by 2018. This calls for accelerated actions to be taken in the region by various stakeholders. Sustained and innovative crop and livestock improvement addressing also the biotic and abiotic stresses is the need of the hour to enhance agricultural production and productivity. Gene editing is one such innovative and precise approach to safely improve the efficiency of breeding, and increase genetic diversity for crop and livestock breeding programs.

In the above backdrop, it was considered important by APAARI to review the status of regulatory policies around gene editing across the globe particularly in countries of Asia-Pacific region; to provide a platform to discuss the impact of regulatory hurdles, delays and associated high cost on technology adoption; and to discuss on communication strategies, enabling policies for plant and animal breeding innovations. Keeping this in view APAARI through its program of Asia Pacific Consortium on Agricultural Biotechnology (APCoAB) organized a Regional Expert Consultation on Gene Editing and its Regulation in partnership with International Crop Research Institute for the Semi-Arid Tropics (ICRISAT) and Federation of Seed Industry of India (FSII) at Hyderabad, India from October 10-11, 2019.

It is heartening to mention that a total of 110 experts belonging to 9 countries (Australia, India, Japan, Philippines, Papua New Guinea, Switzerland, Taiwan, Thailand, Vietnam) attended the meeting. Participants included researchers, representatives of various public institutions and private sector; policy makers and scientists from member countries of APAARI; FAO; CGIAR Centers; government departments and bodies including Department of Biotechnology, Ministry of Agriculture & Farmers' Welfare of India. Deliberations were made on status and advances in gene editing in various national and international Institutions including regulatory status of gene editing in Asia-Pacific region and perception of gene editing by different stakeholders. Panel Discussion were also held to prioritize research areas, capacity and Infrastructure Development, regulatory policy development and public awareness, and Possible Partnerships. One of the important outcome of the 2-day deliberations was the need for a clear regulatory policy on gene editing in the region and to achieve consistency by not regulating products of plant varieties developed through the latest breeding methods if they are similar or indistinguishable from varieties produced through earlier breeding methods. The overall recommendations made would facilitate taking a regulatory stand on gene editing by the developing countries and would accelerate the process of enhancing agricultural productivity.

I take this opportunity to thank Dr Rishi Tyagi (APCoAB Coordinator) for bringing the important partners on one platform in partnership with two other APAARI members (ICRISAT and FSII), and ensuring that the deliberations are well captured in the proceedings. Finally,

I thank one and all who have contributed for the success of the Expert Consultation and in drafting the proceedings. I am sure the recommendations made would be a valuable source of strength for many of the countries in the region who are intending to adopt or streamline their gene editing related research and development.

**(Ravi Khetarpal)**
Executive Secretary, APAARI

# Acknowledgements

On behalf of Asia-Pacific Association of Agricultural Research Institutions (APAARI), Asia Pacific Consortium on Agricultural Biotechnology (APCoAB) and my own behalf, it is my great pleasure to acknowledge and profusely thank all the Co-Organizers - International Crops Research Institute for the Semi-Arid Tropics (ICRISAT), Hyderabad, India; Council of Agriculture (COA), Taiwan; CGIAR Research Program - Grain Legumes and Dryland Cereals (CRP-GLDC), ICRISAT, India; Federation of Seed Industry of India, New Delhi, India; and Alliance for Agri Innovation, New Delhi, India for organization of the Regional Expert Consultation on Gene Editing in Agriculture and its Regulation'. Besides organizational support, strategic and technical input of individuals is equally important. Profound thanks are accorded to Dr Renu Swarup, Secretary, Department of Biotechnology, Government of India, New Delhi, India, for encouraging the organization of this meeting and delivering the inaugural address during Opening Session of the meeting and setting the tone of the deliberations. I am extremely thankful to Dr Peter S Carberry, Director General, and Dr Kiran K Sharma, Deputy Director General – Research, Dr Rajeev K Varshney, RP Director, Genetic Gains and Dr Pooja Bhatnagar-Mathur, Theme Leader - Cell, Molecular Biology & Genetic Engineering of ICRISAT, for agreeing to organize this meeting at ICRISAT and their various contributions in form of logistics and other technical inputs for developing the agenda. Inputs from Dr Sharma and Dr Vibha Ahuja, BCIL, are also acknowledged to draft the major recommendations. I am equally thankful to Dr Shivendra Bajaj, Executive Director, FSII, for his technical inputs to help in developing the agenda. Encouragement, timely inputs and overall leadership of Dr Ravi Khetarpal, Executive Secretary, APAARI, is gratefully acknowledged.

I place on record my gratitude to all Heads and/or their nominees from National Agricultural Research Systems (NARS) of Asia-Pacific region for their presence, sacrificing precious time for providing inputs in the consultation. Grateful thanks are extended to all the Co-Chairs for conducting the respective sessions efficiently and steering the discussions, which resulted in important and useful recommendations presented in this document. All the speakers and panelists of various technical sessions and panel discussion are thanked immensely for their excellent contributions, and participants/discussants for their insightful interventions. All the rapporteurs and facilitators of technical, panel discussion and plenary session are acknowledged for meticulously capturing the salient points that emerged from the presentations/discussion.

Most sincere appreciation is extended to all staff members of APAARI Secretariat, particularly Mr Vishwanath Sah, Mr Manish Rai and Ms Thansita Tanaphatrujira, for their concerted efforts and valuable contributions in the preparatory phase of the event. Sincere thanks are due to the Co-editors, Drs Rajeev K Varshney, Pooja Bhatnagar-Mathur, Shivendra Bajaj, Ratna Kumria for their intensive involvement in collation, compilation of content of the proceedings.

Financial support provided by CRP-GLDC and FSII is also gratefully acknowledged.

**Rishi K. Tyagi**
Coordinator, APCoAB

# The Organizers

## The Asia-Pacific Association of Agricultural Research Institutions (APAARI)

The Asia-Pacific Association of Agricultural Research Institutions (APAARI), with its headquarters in Bangkok, is a unique voluntary, membership-based, self-mandated, apolitical and multi-stakeholder regional organization in the Asia-Pacific region. It promotes and strengthens agriculture and agri-food research and innovation systems through partnerships and collaboration, capacity development and advocacy for sustainable agricultural development in the region. Since its establishment in 1990, APAARI has significantly contributed towards addressing agricultural research needs and enhancing food and nutritional security in the region. The close links, networks, partnerships and collaboration with stakeholders that APAARI has developed over the years, as well as its goodwill, authority and focus on results, make the Association an important actor in the region. The ultimate aim of APAARI is to help realising sustainable development goals in Asia and the Pacific. For more details, please visit the website: http://www.apaari.org

## International Crops Research Institute for the Semi-Arid Tropics (ICRISAT)

The International Crops Research Institute for the Semi-Arid Tropics (ICRISAT) is a non-profit, non- political organization that conducts agricultural research for development in Asia and sub-Saharan Africa with a wide array of partners throughout the world. Covering 6.5 million square kilometers of land in 55 countries, the semi-arid tropics are home to over 2 billion people, and 644 million of these are the poorest of the poor. ICRISAT and its partners help empower these poor people to overcome poverty, hunger and a degraded environment through better agriculture. ICRISAT is headquartered near Hyderabad, Telangana State, India, with two regional hubs and four country offices in sub-Saharan Africa. It belongs to the Consortium of Centers supported by the Consultative Group on International Agricultural Research (CGIAR). For more information, please visit: www.icrisat.org/

## Asia-Pacific Consortium on Agricultural Biotechnology and Bioresources (APCoAB)

The Asia-Pacific Consortium on Agricultural Biotechnology and Bioresources (APCoAB) was established in 2003 under the umbrella of APAARI. Later in 2017, it was renamed as Asia-Pacific Consortium on Agricultural Biotechnology and Bioresources (APCoAB). APCoAB has the mission to harness the benefits of agricultural biotechnology bioresources for human and animal welfare through the application of latest scientific technologies while safeguarding the environment for the advancement of society in the Asia-Pacific region. For more details please visit the website: http://www.apcoab.org; http://www.apaari.org/web/our-projects/apcoab/

## Council of Agricultural Research (COA)

The Council of Agricultural Research (COA), Taiwan is the competent authority on the agricultural, forestry, fishery, animal husbandry and food affairs in Taiwan. Its responsibilities include guiding and supervising provincial and municipal offices in these areas. Under the council, there are Department of Planning, Department of Animal Industry, Department of Farmers' Services, Department of International Affairs, Department of Science and Technology, Department of Irrigation and Engineering, Secretariat, Personnel Office, Accounting Office, Civil Service Ethics Office, Legal Affairs Committee, Petitions and Appeals Committee and Information Management Center respectively in-charge of related affairs. For more details, please visit the website: http://eng.coa.gov.tw

## CGIAR Research Program - Grain Legumes and Dryland Cereals

The CGIAR Research Program on Grain Legumes and Dryland Cereals (GLDC) builds on the work done by three CGIAR Research Programs from 2012 to 2016: Grain Legumes, Dryland Cereals and Dryland Systems. GLDC aims is to increase the productivity, profitability, resilience and marketability of critical and nutritious grain legumes and cereals within the semi-arid and sub-humid dryland agroecologies of sub-Saharan Africa and South Asia. These agroecologies are where poverty, malnutrition, climate change and soil degradation are among the most acute globally. For more details, please visit the website: http://gldc.cgiar.org/

## Federation of Seed Industry of India (FSII)

The Federation of Seed Industry of India (FSII) is a 40-member led association of R&D based plant science industry, engaged in the production of high-performance quality seeds for food, feed and fibre in the country. Member companies are engaged in research-based breeding applications and seed technologies, enabling farmers to adopt technology driven farming solutions to improve agricultural productivity in a sustainable manner, minimizing pre and post-harvest losses. FSII is affiliated to International associations including International Seed Federation (ISF), Croplife Asia (CLA) and The Asia Pacific Seed Association (APSA). For more details, please visit the website: http://fsii.in

## Alliance for Agri Innovation

Alliance for Agri Innovation is a leading agri-tech industry body, working towards accelerating agriculture growth by promoting new and emerging technologies for the benefit of farmers and consumers. The association is created by like-minded agricultural organizations driven by research and innovation, committed to investment in India and respect for intellectual property rights. The focus of the association is to create awareness amongst farmers and stakeholders regarding the advances in agri-technology, seeds, plant-breeding innovations around the world and the benefits it could provide to the farmers of a developing country like India. The objective of AAI is to encourage investment in research in agricultural technologies, to protect the IP rights of these innovations and bring farmers close to biotech crops, thus, leading to a sustainable agricultural ecosystem. For more details, please visit the website: https://agriinnovation.in/

# Abbreviations and Acronyms

| | |
|---|---|
| AAI | Alliance for Agri Innovation |
| APAARI | Asia-Pacific Association of Agricultural Research Institutions |
| APAC | Asia-Pacific |
| APCoAB | Asia-Pacific Consortium on Agricultural Biotechnology and Bioresources |
| APR | Asia Pacific Region |
| APSA | Asia Pacific Seed Association |
| BCIL | Biotech Consortium India Limited |
| BIRAC | Biotechnology Industry Research Assistance Council |
| BLB | Bacterial Leaf Blight |
| Bt/RR | *Bacillus thuringiensis* / Roundup Ready |
| Cas9 | CRISPR-associated protein 9 |
| CGIAR | Consultative Group for International Agricultural Research |
| CIMMYT | International Maize and Wheat Improvement Center |
| CIP | International Potato Center |
| CLA | Crop Life Asia |
| COA | Council of Agriculture |
| CPB | Cartagena Protocol on Biosafety |
| CRISPR | Clustered Regularly Interspaced Short Palindromic Repeats |
| CRP-GLDC | CGIAR Research Program on Grain Legumes and Dryland Cereals |
| DBT | Department of Biotechnology |
| DG | Director General |
| DGR | Directorate of Groundnut Research |
| DNA | Deoxyribonucleic Acid |
| DOA | Department of Agriculture, Thailand |
| FAO | Food and Agriculture Organization |
| FAO-RAP | FAO Regional Office for Asia and the Pacific |
| FSANZ | Food Standards Australia New Zealand |
| FSII | Federation of Seed Industry of India |
| FTO | Freedom to Operate |
| GDP | Gross Domestic Product |

| | |
|---|---|
| GE | Gene Editing |
| GHG | Green House Gases |
| GM | Genetically Modified |
| GMO | Genetically Modified Organism |
| GWAS | Genome-Wide Association Study |
| IARI | Indian Agricultural Research Institute |
| ICAR | Indian Council of Agricultural Research |
| ICARDA | International Center for Agriculture Research in the Dry Areas |
| ICGEB | International Centre for Genetic Engineering and Biotechnology |
| ICRISAT | International Crops Research Institute for the Semi-Arid Tropics |
| IIAB | Indian Institute of Agricultural Biotechnology |
| IIHR | Indian Institute of Horticultural Research |
| IIMR | Indian Institute of Millets Research |
| IITA | International Institute of Tropical Agriculture |
| INDELS | Insertions/Deletions |
| IPR | Intellectual property rights |
| IRRI | International Rice Research Institute |
| ISF | International Seed Federation |
| JDC | Joint Department Circular 1 |
| JIRCAS | Japan International Research Center For Agricultural Sciences |
| LMO | Living Modified Organism |
| M | Million |
| NABI | National Agri-Food Biotechnology Institute |
| NBPGR | National Bureau of Plant Genetic Resources. |
| NBT | New Breeding Technology |
| NCBP | National Committee on Biosafety of the Philippines |
| NGGF | National Genomics and Genotyping Facility |
| NHEJ | Non Homologous End Joining |
| NIAB | National Institute of Animal Biotechnology |
| NIPGR | National Institute of Plant Genome Research |
| NPBT | New Plant Breeding Technology |
| NTU | Nanyang Technological University |
| ODM | Oligo-Directed Mutagenesis |
| OECD | Organisation for Economic Co-operation and Development |
| OGTR | Office of the Gene Technology Regulator |
| Pacific SIDS | Pacific Small Island developing States |
| PBI | Plant Breeding Innovations |
| PNG | Papua New Guinea |

| | |
|---|---|
| QAFFI | Queensland Alliance for Agriculture and Food Innovation |
| R&D | Research and Development |
| RNA | Ribonucleic Acid |
| RNAi | RNA Interference |
| SABC | South Asia Biotechnology Centre |
| SDG | Sustainable Developmental Goals |
| SDN1 | Site Directed Nuclease 1 |
| SDN2 | Site Directed Nuclease 2 |
| SDN3 | Site Directed Nuclease 3 |
| SME | Small and Medium-sized Enterprises |
| SOP | Standard Operating Protocol |
| TALENS | Transcription Activator-Like Effector Nucleases |
| TBC | Technical Biosafety Committee |
| USA | United States of America |
| USD | United States Dollar |
| VAAS | Vietnam Academy of Agricultural Sciences |
| WHO | World Health Organization |
| WTO | World Trade Organization |
| ZBNF | Zero Budget Natural Farming |

# Executive Summary

**Regional Expert Consultation on Gene Editing and its Regulation** was held on October 10-11, 2019 at the International Crop Research Institute for the Semi-Arid Tropics (ICRISAT), Hyderabad, India. The Expert Consultation was organized by Asia-Pacific Association of Agricultural Research Institutions (APAARI), under a program on Asia-Pacific Consortium on Agricultural Biotechnology and Bioresources (APCoAB), Thailand in collaboration with ICRISAT, India; Federation of Seed Industry of India (FSII), Alliance for Agri Innovation (AAI), India with support from the CGIAR Research Program on Grain Legumes and Dryland Cereals (CRP-GLDC), ICRISAT, India and Council of Agriculture (COA), Taiwan. Dr Renu Swarup, Secretary, Department of Biotechnology, Government of India was the Chief Guest and delivered the inaugural address on the emerging needs of agriculture in India and how gene editing technology can be a game changer while addressing some of the intractable traits. Remarks were also presented by Drs Peter S Carberry, Director General, ICRISAT; Kiran K Sharma, Deputy Director General (Research), ICRISAT; Mr Ram Kaundinya, Director General, FSII; and Dr Rajeev K Varshney, RP Director, Genetic Gains, ICRISAT. Dr Rishi K Tyagi, Coordinator, APCoAB, discussed about the rationale and expectations from the Expert Consultation.

The objectives of the Expert Consultation were to: (i) highlight the innovations through gene editing and their impact in the agricultural sector; (ii) review the status of regulatory policies around gene editing across the globe particularly in countries of Asia-Pacific region; (iii) provide a platform to promote adoption of science-based predictable policies for regulating gene edited crops and breeds; (iv) provide a platform to discuss the impact of regulatory hurdles, delays and associated high cost on technology adoption; and (v) discuss on communication strategies, enabling policies for plant and animal breeding innovations.

About 110 experts from academia, agriculture industry, government and regulatory agencies from 12 different countries of the Asia-Pacific region participated in this consultation. The experts discussed that gene editing methods allow for making precise changes in the plant genomes and can be effectively used for improving the efficiency of breeding of plants and animals, and their productivity and quality. This includes the creation of plants with valuable nutrition and quality traits and with traits that confer tolerance to various biotic and abiotic stresses. Although the traits produced using gene editing, particularly oligo-directed mutagenesis (ODM), and site directed nuclease (SDN) 1 and SDN 2 approaches can also be produced through conventional breeding, these gene editing tools allow the generation of these traits with much more efficiency, precision and speed.

Key recommendations that emerged from the 2-day deliberations and the discussions are as follows:

1. Many governments are seeking to ensure that the regulation of genome-edited plants is commensurate with the potential risks of these plants to the environment, human or

livestock safety. To this end, some governments have already taken the position that gene edited plants with phenotypes that have been, or can be achieved using conventional plant breeding techniques (which includes mutagenesis techniques) should be subject only to those same regulations as their conventionally-bred counterparts e.g., phytosanitary regulations, variety registration etc. Any regulatory oversight should be based on the final product rather than the process involved.

Therefore, it was recommended that consistency can be achieved by not regulating products of plant varieties developed through the latest breeding methods if they are similar or indistinguishable from varieties produced through earlier breeding methods.

The genetic variation in the final product would not be regulated when:

(a) It does not contain a novel combination of genetic material*;

(b) The final plant product contains genetic material from sexually compatible plant species;

(c) Or any form of mutagenesis is involved.

This will ensure that agricultural innovation can proceed unhindered for the benefit of the farmers and the society.

Developments in countries in the Asia-Pacific region include Australia and Japan both excluding certain categories of gene editing products from the scope of GM regulation: Australia has expressly excluded all applications of SDN1; and Japan has excluded SDN1 on the basis that it does not involve the use of "extracellularly processed nucleic acids". These exclusions are based on the basis of the technology being the natural cellular repair mechanism, non-homologous end joining.

In other regions, countries of Latin America (e.g. Argentina) have adopted approaches more aligned with the criteria listed above, and products developed using ODM, SDN1 and SDN2 have be exempted from GM regulatory requirements. Based on these criteria, of the different gene editing approaches, only those products developed using SDN 3 that contain foreign DNA introduced from sexually incompatible species should be subjected to safety assessment on a case-by-case basis.

2. As is abundantly clear from our experience with the regulation of GM (genetically modified) plants across the globe, ambiguity in regulatory requirements causes unpredictable delays in approvals, thereby increasing costs, deterring innovation and restricting product pipelines. These costs have also effectively eliminated small- and medium-sized enterprises (SMEs) from being able to compete in this space. This has severely constrained the development and deployment of GM crops important for food security or with traits that are relevant for smallholder agricultural systems. Science-based, predictable and proportionate regulations with clear timelines are urgently required to encourage innovations. It was recommended that countries should clarify the scope of their regulation for the products of gene editing at the earliest.
3. Should it be determined that a sub-set of gene-edited plants may warrant regulation as GM, then harmonization of approaches within the Asia-Pacific region is important for collaboration in research, capacity development, regulation and trade. Efforts towards common ground should be facilitated by organizing interactive meetings among the researchers and the regulatory agencies in the region and should also be informed through appropriate stakeholder engagement and/or consultations.

*Novel combination of genetic material means the stable insertion in the plant genome of one or more genes that are part of a designed genetic construct.

4. Significant efforts are needed from all stakeholders to improve and prioritize communication and information exchange about gene editing, particularly focusing on how it is an extension of conventional plant breeding. Focused programs for communicating science-based information in easy to understand language should be initiated by academics, industry and experts from both public and private sectors.
5. Besides, capacity and competency building in research and development, deployment and delivery of the products of gene editing should be enhanced at the regional level. Partnerships – public–public and public-private should be encouraged. Better mechanisms for sharing knowledge/technology need to be in place to enable such partnerships. Public-private partnerships should be encouraged to work in the areas of relevance to the Asia-Pacific. Regional organizations like APAARI should lead the development of network projects involving national partners in the interest of smallholder farmers and consumers of the region.
6. Crops as well as areas of improvement need to be prioritized for an efficient deployment of gene editing technology. The first applications of gene editing in the country can set precedents, and hence proactively establish effective policies. The innovative institutional arrangements, networks and collaboration will contribute substantially to development of the human capital needed to ensure the judicious application of these advanced tools and technologies in the region. Similarly, the regional collaborations and networks can also contribute to capacity building, communication strategies, policy development and advocacy.

# Background and Objectives

Agriculture is at cross roads globally with multiple vicissitudes being faced by the agriculturists during cultivation. The fatigued soil, aberrant climatic changes and evolving pests all pose a challenge to the farmer, who is further burdened by fluctuating crop demand and prices, higher input costs leading to lower productivity and profitability. These challenges most impact the small holding farmers in the developing world where agriculture is the main source of food, employment and income. International data shows a clear association between low agricultural productivity and high rates of undernourishment[1]. Global studies have also shown that rapid reduction of extreme poverty is only possible when the smallholder farmers have assured and increased incomes. Therefore, sustained improvement in agricultural productivity is central to socioeconomic development.

Plant breeding has been employed to enhance productivity, address issues of pests and disease, with the knowledge gained over the years, ameliorating our efficiency of crop improvement. The current yield losses due to harsh temperatures, shifting rainfalls, drought, deteriorating soils, pest infestations and disease, need to be proactively addressed by efficient selection, breeding and employing advanced technologies for enhanced results. Therefore, innovative plant breeding draws on years of knowledge along with technological advances that have enabled the development of efficient and precise methods like marker assisted breeding and gene editing to improve crops and increase genetic diversity for breeding programs. Of these technologies, gene editing is one of the promising techniques which is also known and categorized as new plant breeding techniques (NPBTs).

Similar challenges are also managed by farmers raising livestock, which forms a significant source of income in the developing countries. Lack of infrastructure and technology deprive the farmers to adopt sophisticated breeding programs to enhance their income through dairying. Gene-edited livestock could be a boon to farmers in developing countries[2]. Various gene-editing projects are ongoing across the globe, with much of the work focusing on editing for traits that will benefit animal health and welfare.

Gene editing refers to making specific targeted changes in the genome of an organism, be it insertion, deletion, modifications or replacement of sequences. In case of insertion and replacement, the sequence/fragment can be from the same(cis) or different (trans) species. Gene editing is done using engineered endonucleases that mainly belong to four categories; Meganucleases, Zinc finger nucleases, Transcription activator-like effector-based nucleases (TALEN) and Clustered regularly interspaced short palindromic repeats (CRISPR/Cas9) system. The CRISPR-Cas, system since the first report in 2012 has been the most favoured system for gene editing and was selected by *Science* as 2015 Breakthrough of the Year.

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[1]FAO (2018) State of Food Security and Nutrition in the World. Food and Agriculture Organization of the United, Rome
[2]Carlsen (2019) Science, doi:10.1126/science.aax1548

The site directed nucleases (SDN) take advantage of the natural cellular repair machinery for making the edits. The edits are categorized as SDN1- spontaneous repair of the double stranded break that leads to small insertions/deletions (indels); SDN2- double-stranded break is repaired using a small nucleotide template that is complementary to sequence around the break; SDN3- target region is repaired utilizing a template sequence, resulting in the introduction of new genetic material. SDN-1 and SDN-2 usually do not lead to insertion of foreign DNA. SDN3, on the other hand, can have DNA from same or different species inserted at the target site, making it similar to transgenics with the advantage of site-specific insertion. Unlike conventional plant breeding and random mutagenesis, plant breeding innovation makes process of breeding rapid, precise and with no extra undesirable characteristics that need to be bred out.

The immense sequence data that has been generated for multiple crops and species can be utilized to specifically edit genes to enhance or correct their function for crop improvement. The gene editing based improvements can benefit farmers (yield, disease resistance, herbicide tolerance, abiotic stress tolerance, flowering and fruit ripening), enable commercial improvements (biomass enhancement, processing traits and sterility for hybrid production) and enhance consumer traits (increased nutrition, reduced toxins and allergens).

The first edited plant to be commercialized is soybean that has been edited to produce lower saturated fats and zero trans fats, this will be followed by many more edited food-crops that are expected to hit the market in the near future. These include, waxy corn, stress tolerant rice, disease resistant wheat, rapid flowering compact tomatoes, herbicide resistant rice and cassava, enhanced processing traits in potato and low gluten wheat. These examples and the ongoing research clearly show that gene editing is a tool of choice to overcome hurdles in the process of plant breeding by utilizing the diversity of the germplasm in an efficient manner. Gene editing can also provide viable options for biodiversity conservation.

Gene editing (SDN1 and 2) does not introduce any foreign DNA, instead modifies existing genes in a precise manner, in contrast to large and random genetic changes caused by chemical mutagenesis. Therefore, they are indistinguishable from conventionally bred plants and need regulations and governance that optimizes the promotion of the technology with its safe and sustainable use.

In spite of the benefits of the technology, the regulatory policies for gene editing will greatly impact its application and extent of adoption. A science-based, consistent, predictable regulatory policy will support the development and application of innovative breeding technologies by both public and private sectors in the developing countries. This can be done at minimum costs, with a competitive advantage over conventionally bred products. When considering the criteria for the scope of regulatory oversight, plant varieties developed through the new plant breeding methods should not be differentially regulated if they are similar or indistinguishable from varieties that could have been produced through earlier plant breeding methods.

Regulatory bodies and governments world-wide are currently at different stages in the process of formulating policy and guidelines for gene edited products. US and Canada do not regulate new plant varieties developed with genome editing when they are indistinguishable from those developed through conventional breeding methods. Similarly, SDN1 like changes involving small deletions and insertions are exempt from regulation by Australia. Japan also does not require safety screening, provided there are no foreign genes or parts of genes in the edited organism. The Japanese advisory panel recommendations leave open the possibility of requiring safety evaluations if there are insufficient details on the editing technique. South American nations like Argentina, Brazil and Chile have policies in place for gene edited organisms, that are regulated

on case by case basis and exempt organisms with no sequence insertion. In Chile and Argentina edited products are already being evaluated.

European Union, on the other hand, has ruled that organisms derived from the new techniques of directed mutagenesis, such as CRISPR/Cas9 and other gene editing methodologies, should be considered as genetically modified organisms (GMOs) within the meaning of the GMO Directive and subject to the same requirements. This regressive view has been sharply criticized by The European Commission's top scientific advisory panel. Also, European scientists from 93 leading plant and life science research centres have united around an urgent call urging European policy makers to safeguard gene editing and other innovations in plant science and agriculture.

Nations in Asia-Pacific are also in the process of formalizing regulatory policies for gene edited organisms and their products. Given the low cost and basic infrastructure requirements for gene editing, it is ideal for improving niche crops with small acreage that will benefit the small hold farmers in these nations. The rapid application of the technology can be employed to answer the issue of climate change and high socio-economic growth, typical of the region.

The world needs nutrient-rich, environmentally friendly food production. Employing gene editing for crop/breed improvement is the need of the hour, but only with prudent regulatory mechanisms its potential can be harnessed to address the issue of global food security.

Keeping in view the above facts, a Regional Expert Consultation on Gene Editing and its Regulation (here afterward referred to as Expert Consultation) was held on October 10-11, 2019 at the International Crop Research Institute for the Semi-Arid Tropics (ICRISAT), Hyderabad, India. The Expert Consultation was organized by Asia-Pacific Association of Agricultural Research Institutions (APAARI), under a program on Asia-Pacific Consortium on Agricultural Biotechnology and Bioresources (APCoAB), Thailand in collaboration with ICRISAT, India; Federation of Seed Industry of India (FSII), Alliance for Agri Innovation (AAI), India with support from the CGIAR Research Program on Grain Legumes and Dryland Cereals (CRP-GLDC), ICRISAT, India and Council of Agriculture (COA), Taiwan. The objectives of the Expert Consultation were to:

1. Highlight the innovations through gene editing and their impact in the agricultural sector.
2. Review the status of regulatory policies around gene editing across the globe particularly in countries of Asia-Pacific region.
3. Provide a platform to promote adoption of science-based predictable policies for regulating gene edited crops and breeds.
4. Provide a platform to discuss the impact of regulatory hurdles, delays and associated high cost on technology adoption.
5. Discuss on communication strategies, enabling policies for plant and animal breeding innovations.

# Inaugural Session

The session commenced after registration of participants with an introductory remark by **Dr Rajeev Varshney** (Research Program Director - Genetic Gains, ICRISAT). He elucidated the incremental impact of plant breeding on agricultural value chain. That had been achieved by increasing yield, breeding resistance to plant pests and diseases as well as tolerance to water limitation and climate change and improve crops over a period of time. Scientists and breeders have used and have had at their disposal multiple advanced technologies including gene editing that could improve the efficiency and precision of breeding. Although gene editing had potential to benefit farmers and enhance both commercial and consumer traits, regulatory policies for gene editing would be critical for taking forward the technology and harnessing its potential to the fullest. Globally governments and agencies were in the process of formulating policies and guidelines for regulating gene edited crops and products. Countries like US and Canada did not regulate edited crops, small insertion and deletions are exempted from regulation in Australia and Japan too would not be regulating crops with no foreign gene insertions.

The consultation would review the scientific advances in the technology, global regulatory status of gene edited crops particularly in Asia-Pacific region (APR), evaluate the impact of regulatory hurdles on economics, trade and adoption of technology. It would also serve as a platform for discussions around adoption of science-based predictable policy for regulating gene editing and a communication strategy for enabling the same. **Dr Varshney**, introduced the panel on the dais that included **Dr Peter S Carberry** (Director General, ICRISAT), **Mr Ram Kaundinya** (Director General- FSII), **Dr Kiran K Sharma** (Deputy Director General -Research and Director, CRP GLDC, ICRISAT) and **Dr Rishi Tyagi** (Coordinator, APCoAB, APAARI). The introduction and a formal welcome of the panel was followed by welcome remarks by **Dr Carberry**.

**Dr Peter Carberry** began his address by sharing the challenge to inspire the experts, while welcoming them in various events at ICRISAT. ICRISAT had a mandate to contribute to food globally with 6 semi-arid crops. ICRISAT uses breeding programs and collaborations with member nations to increase productivity by both public and private partnerships. The impact of these programs included biofortified sorghum and pearl millet varieties and hybrids released in India and high oil yielding groundnut and improved chickpea in Africa. Beyond these, there were issues like resistance to *Striga*, aflatoxin and rancidity that needed urgent attention, even though work had been ongoing to address these issues for multiple years. The dire need for a step change to improve the crops and address multiple new issues was most pressing in view of the growing population, consumer demand and climate change. The advanced technologies like gene editing were required to be considered as an equivalent of accelerated mutations for the understanding of the civic society. Moving forward the narrative around agriculture needed to be taken positively instead of being burdened by issues like climate change and green house gas (GHG) etc. A positive narrative would include the scientific achievements that

enabled global food security, poverty alleviation and the use of new technologies to continue solving multiple issues. The message needed to be reinforced and technologies like editing would contribute towards such a goal.

**Mr Ram Kaundinya** thanked the organizers for the well-timed Consultation as India is at cross-roads in agriculture. He introduced FSII as a federation led by research-based companies. The 40 member companies were committed to research investment, contributing 70% of research investment and held 65% of the market share in the seed sector. The Federation members believed in research and innovation using science and technology to improve farmers profitability, improve land use, make efficient use of available resources and make agriculture sustainable. In that context, gene editing offered a potential avenue that could support the above-mentioned goals. He was of the opinion that many technologies could co-exist, especially in a country like India, where contradictions and different level of technology had always co-existed. FSII rejected the option of a single silver bullet for all issues and presented that neither GMO nor gene editing could solve all issues. He insisted that access to a technology tool box would be critical for solving agricultural problems. Therefore, GMO, gene editing and ZBNF could co-exist with the final choice being with the farmers. Though, the responsibility of researchers to bring all options out and regulators to bring them to market was insisted upon. He said that GM technology had not been utilized to its full potential and made available to help farmers and the scientific community needed to avoid a similar fate for gene editing. He further proposed that the experts needed to address three points associated with gene editing before formulating regulations; first being whether gene editing as a technology delivered on its potential and was safe. The above-mentioned issue needed a scientific assessment and expert consultations. Secondly, identification of areas where it could be applied to harness its full potential along with prioritization of traits and crops, needed to be a policy decision. Thirdly, the nation needed to deliberate regarding the industrial policies associated with the technology.

Referring to the 1930s economist, Mr Kaundinya reminded the gathering of the cycle for any new technology; with new innovations bringing in a period of monopolies till other players in the field could catch up as the entire potential of new technology was unleashed. Since such technologies led to re-structuring of the system and posed a challenge to *status quo*, they were usually accompanied with phase of monopolies. FSII appealed to the government to bring out gene editing regulations soon, as industry needed clarity, predictability and would prefer to have science-based policy. He hoped that the consultation would lead to recommendations that were beneficial to farmers and smaller companies and that the outcome of this consultation may be use to Government of India.

**Dr Rishi Tyagi** talked about the Asia-Pacific Association of Agricultural Research Institutions (APAARI), which was established in 1990 by the Food and Agriculture Organization of the United Nations (FAO) and Governments of APR, it had 83 members from 33 nations, with a mandate to promote agricultural technology and innovation for safe agri-food research and innovation systems. APR is inhabited with 60% of global population, hence was a critical region to address global food security challenges. It also had the potential to solve global food security issues. APCoAB was also formed by FAO in 2003 with a mandate to promote and enhance the benefits of biotechnologies for the sustainable agricultural development in the APR, through greater stakeholder partnerships, improved dialogues with policy makers, capacity building and greater public awareness. APAARI worked for and with partners to address various issues in the region related to agricultural biotech for research prioritization, technology development, policy and advocacy. APAARI does not differentiate between available technologies, including plant tissue culture, genetic modification or gene editing, rather supported all for the ultimate

goal of farmer's welfare and food security. Gene editing had immense potential and could scientifically improve the age-old process of plant breeding. The public needed to delineate biotechnology from genetic modification as biotechnology is a vast field that could serve the farmer and consumers alike and genetic modification formed a component of biotechnology. Regarding the venue for the Expert Consultation, he mentioned that Hyderabad was chosen as a venue as India is a leader in agricultural biotechnology in the region. Also, ICRISAT is a valuable and strategic member of APAARI, with multiple ongoing collaborations and programs with APAARI.

Dr Tyagi mentioned that many countries in APR *e.g.* Vietnam, Thailand and Philippines, have taken up public-private partnerships in a big way for the benefit of smallholder farmers and the same has been an ongoing topic of discussion in ICAR, India. He opined that private sector was a major contributor and needed to be included in agricultural policy decisions. In countries like India, private sector is needed to meet the seed demands of the farmers along with public sector organizations. The meeting is the first of its kind in the region, seeking attention of the policy makers to look into the technology. The Expert Consultation would discuss the technology policy, its potential and benefits to smallholder farmers, with technology developers and policy makers. The group would get to hear from nations who have policies in place for gene editing like Australia, Japan, *etc.* and hopefully would learn from them and adopt the recommendations for developing the regulatory policy in India for gene editing. The platform would also help in networking between nations and initiating future collaborations. The organizers are looking forward for useful recommendations from the Expert Consultation to promote the gene editing technology in APR.

**Dr Renu Swarup**, Secretary, Department of Biotechnology (DBT), Government of India, was the Chief Guest of the Expert Consultation. She delivered an Inaugural Address on 'Gene Editing in India' during Technical Session I. However, for the sake of continuity of the proceedings of inaugural session, the main highlights of her inaugural address are presented below:

**Dr Swarup**, in her address, mentioned that the Expert Consultation is very critical as the nation is looking at new emerging technology, which would be the way forward and it was important to have all stakeholders on board, not only in the country but also amongst regional players. She mentioned that research could use the opportunities offered by exponential technology (not disruptive technology). Therefore, it was important that the technology's value is realised before they were fully employed. Indian expertise and national and international collaborations had given the nation confidence to go forward with newer technologies but an important consideration remained, to keep pace with the advancements in the technology and be prepared for adopting and applying these technologies. The present meeting is focused on gene editing and its potential for agricultural technology, as observed through the work done by scientists in the last decade, had enormous potential for agriculture, animals, human and microbes. Besides the potential, the responsible use of the technology was also an essential requirement. The researchers worked with new tools but should also to take up the responsibility for bringing out practices or guidelines for the safe use of new technology. Researchers worked on research problems in a responsible manner with all standard operating procedures (SOPs) for useful application of the technology and its evaluation. Post research, the next natural step was regulation of technology, regulations were important for safe and responsible use of the technology and should not be considered as hinderances for the technology. In India, gene editing is being taken up in a big way with multiple institutes and agricultural universities doing research to bring out the potential and value in the field of crop improvement, nutritional enhancement, climate change and productivity increase. Such research is being well-supported by DBT, ICAR and other funding agencies.

DBT had also set up a task force for evaluating India's preparedness for the gene editing technology. The foremost task in the preparedness is to have the critical mass of the human expertise for taking the technology forward, followed by capacity building with infrastructure and these had been well supported by the various government agencies. In Post-preparedness phase, research on the priority crops and critical areas for the country would be the way forward for the application of technology.

She brought out the importance of Expert Consultations even when restricted to the field of research, as a lot of proprietary knowledge was involved in gene editing technology. Therefore, it is important to address issues around research sharing and the IPR play at the initiation of a project. Especially, when research was planned to lead to a product, so as not to be at a disadvantage when the product was ready for commercialization. She brought forward the important issue of information and knowledge sharing amongst scientists, so as to avoid repetitive research which would lead to loss of valuable resources and time. The Expert Consultation forum would provide a platform for collaboration to develop a non-competitive space, where researchers would come together and share knowledge and expertise.

Dr Swarup acknowledged that policies within the government to enable such an open/sharing ecosystem are key and critical. In case of gene editing many other nations have come out with their policy stand which are quite divergent. In her opinion, guidelines for research should have fundamental underlying principle of safe and responsible use of technology. When the technology was not regulated, the onus of the safe, responsible use is on the scientist/technology developer, hence, the principle remained constant in all kinds of policies/ regulations. Scientists would remain at the forefront to direct the safe and responsible use of technology, even with clear policy and guidelines for research as well as the application and use of the technology on scale. Government of India, especially DBT, has been most proactive in engaging with private sector in the field of plants, animal or human research, ensuring the move of technology from knowledge to research to product, *e.g.* Biotechnology Industry Research Assistance Council (BIRAC) worked with start-ups and DBT encouraged collaborations/partnerships with international institutes.

Dr Swarup mentioned that an expert working group has been set up for guiding the government with development of clear policy for gene editing and its use as a technology, the plan was to have a clear regulatory pathway for research and its adoption for plants, animals and humans. The first round of discussions had been completed with the field-specific experts and internal discussions were ongoing on the first draft of guidelines. The draft would be brought out for public consultation soon before its finalization.

Government of India already has a clear regulatory system and policy, therefore, it was important to evaluate the aspects of gene editing that could be managed within the current policy and those that may fall out of the current system. Most of the stakeholders had already been consulted on these aspects. DBT had come out with its Gene Therapy policy recently, that was put out for public consultation. World Health Organization (WHO) has set up a Task Force for evaluating gene therapy for humans and it was a matter of pride for India for being invited to be part of the Task Force.

While emphasizing the role of scientists, Dr Swarup mentioned that scientists would play an important role in guiding the regulatory path as well as in communication on the science behind the technology. Policy was guided by the enormous scientific data generated by the scientists but clear communication regarding the associated risks, their management and safeguards for any new technology, were equally momentous. As such a communication would make policies and regulations much more inclusive and participatory. Gene editing policy is being

guided by research, as the policy needs to be science-based. Dr Swarup urged the group to come up with clear, understanding of science and guidance on application and science data for guiding national policy. She reiterated the importance of the consultation and put forth her expectation of key recommendations, with clear scientific parameters to drive the policy and also enable the establishment of 1-2 regional network programs to look collectively into common practices and priorities. She proposed that international collaborations are the best way to bring out the science and make the policies robust and well-accepted.

The plan of Government of India for communicating regarding the safety, use and policy for gene editing in agriculture, health, *etc.* was discussed. Dr Swarup mentioned that Government of India was planning to constitute a group of science communicators, who could talk about science as well as benefits of the technology. Government could be an enabler and facilitator for such endeavours and looked towards its scientists to be the flag-bearers for the task. With regard to communication, Dr Swarup insisted on the importance of publishing good work so as to bring out its impact. There was space before competition, which she referred to as the pre-competitive space, where collectively the value of the new technology could be brought out by scientists. It was important to bring the pros and cons and suggest safeguards for new technologies. She congratulated the organizers particularly APAARI for taking initiatives to organize the Expert Consultation on Gene Editing and wished all success for the meeting. Dr Rishi Tyagi, APAARI felicitated Dr Swarup and thanked her for encouragement by her benign presence and delivering an Inaugural Address.

**Dr Kiran Sharma**, while making closing remarks for the introductory session, brought out the ICRISAT-APAARI collaborations on multiple programs involving meetings and workshops. He said the meeting would provide opportunities for networking with experts like Dr Ian Godwin, Prof. Arjula Reddy and also experts from other Asia-Pacific countries. In the context of India's exigency of increased agricultural productivity, he emphasized on the accessibility of a comprehensive tool box to improve crops, besides the requisite to empower all stakeholders, as was mentioned by previous speakers. He said that, precise editing had revolutionized the ability to mutate genes and would have major implications for food security, as it has great promise due to its specificity and ease of adoption. The technology would facilitate understanding of biological processes that could help in crop improvement. Gene editing could also help in increasing genetic gains for crops. It was important that the triggers that might shape the policy were discussed at the onset of scientific journey of technology adoption. In absence of such deliberations, policy makers might fall back on the old policies to tackle the new technologies. He said that, policy considerations for gene editing were unique since some of the improvements could not be differentiated from the conventional varieties. India required to decide, when regulation is required on a case by case basis for gene edited products. Several nations had already decided not to differentiate edited crops from conventional crops, therefore, differentiation between gene edited and conventionally-bred products could not be arbitrary in other countries too. He mentioned the need for addressing non-science barriers for the adoption of technology and appreciated the design of Expert Consultation that addressed all such issues. Since most CGIAR centres were already using or intending to use the gene editing technology, the information would help to forge new linkages between various stakeholders, including public and private sector. He announced that APAARI will also organized a 2-week Hands-on Training for Gene Editing Technology at ICRISAT after the Expert Consultation, starting from October 14, 2019 for early career researchers as part of its outreach. Dr Sharma opined that the consultation would not only offer platform for deliberations on science, crop improvement but will also forge collaborations among the scientists of participating countries of APR. Finally, he thanked all the dignitaries and the participants.

## Technical Session I: Status and Advances in Gene Editing

*Co-Chairs* : **Peter Carberry**, ICRISAT, India
**Swapan Datta**, Calcutta University, India

*Rapporteurs* : **Rajeev Gupta**, ICRISAT, India
**Sneh Lata Singla-Pareek**, ICGEB, India

**Dr Swapna Datta** formally welcomed Dr Swarup, Secretary, Department of Biotechnology (DBT). Dr Swarup delivered Inaugural Address. The highlights of her address are mentioned on preceding pages.

The proceedings of the Technical session I are mentioned as below:

**Dr Ian Godwin**, QAFFI, Australia, presented his work on sorghum. Sorghum was considered a poor man's grain but lately farmers were going back to sorghum due to health benefits as well as climate change driven water scarcity. In Australia, many wheat growers were shifting to sorghum due to water scarcity. University of Queensland had programs targeting starch, lignin, cellulose, lipid and sugars metabolism in sorghum. The first improvements were made using genetic modifications but recently gene editing is being used. Genomics with all the sequence data had enabled us to select and prioritize our target genes for crop improvement. Besides genomics, the knowledge of crop physiology, genetics and crop protection all had increased the positive impact of agricultural research. The genetic modification approaches to improve protein content included, targeting proteins to protein bodies, over-expression and knockout of G protein-gamma subunits as well as over expression of their truncated versions. RNAi silencing led to 70% down regulation of the gene and increased seed size and number. The negative correlation between grain number and size could be overcome in the study. Similarly, foldase knockout lines were generated to increase protein content. The knockout lines had 15-17% higher in peripheral endosperm which was more digestible too. The protein bodies were like rice protein bodies and the grains were bigger and heavier.

There were multiple examples of mutants with distinct advantages over wild-type plants being successful crops, these include - Brandywine tomatoes, Fuji apples, wine grapes, aromatic rice etc. All these were natural mutations, selected for their quality and consumer preference. Mutations underpin most of the crop improvements and the process of gene editing could generate similar mutations in an endonuclease directed specific genetic change.

As of October 8, 2019, SDN1 was not to be regulated in Australia, because the edits were indistinguishable from natural mutations. The sorghum edited for high grain number and larger

grain had more protein per grain. There were lines with 32%-40% more grain, 12%-18% larger grain and potential to produce 25% more protein per hectare. Such sorghum could be a beneficial alternate in poultry feed. A large amount of cereal (60%) was used for feed and with ever increasing demand for feed grain, alternates for feed were important for the food supply. Other traits that would be targeted using editing included- brown mid rib sorghum, evaluation of rice and sorghum promoters, staygreen phenotype, increasing flavanol and lower flavonoids. Gene editing was also being taken up in barley and wheat improvement programs. Efforts were being made to combine gene editing with the technique of speed breeding to improve efficiency of breeding. The knowledge of genomics and physiology as a back ground for genetic modification or gene editing would lead to better genetic gain and improved crop yields.

In Australia, the interest in the technology and its adoption has increased tremendously after the policy for exempting SDN1 from regulation, clearly demonstrating that clarity in policy helps in encouraging the adoption of technology.

**Dr Szabolcs Ruthner**, ISF, Switzerland, presented the seed industry's perspective and gave an update on the global status of gene editing regulations. He introduced International Seed Federation (ISF) as the voice of global seed industry, with 58 national seed associations and outreach in 75 countries. Via associations 7500+ companies that had breeding programs in place and were not only seed suppliers were part of ISF. He said that plant breeders had been responding to global challenges and needs, though they needed access to all different tools to achieve their goals. Regarding the regulatory status of gene edited products, he put forward 2 factors before the participants, firstly, the history of plant breeding that has acquired and accumulated knowledge which was being used for new technologies like gene editing. Therefore, breeding objective remained the same but process had become more efficient. Secondly, the need to consider the global nature of the seed flow, with production in one region, processing and packaging in another and use in the third region. Hence, regulatory decisions in one region would impact the global seed supply.

The region, thus, needed clear, science-based consistent policies across economies and countries, that could facilitate innovation. ISF had brought out a position paper that postulated that when the product was indistinguishable from natural product, it needs not to be regulated. ISF was against creating a third class of products and insisted on an agreement on criteria for regulatory oversight as well as implementation of agreed criteria across geographies. There was a lot of diversity, when the policies across the globe were considered. Europe and New Zealand had restrictive policy for gene editing, while SDN1 was not regulated in US, South and Central America (Brazil, Argentina, Chile Columbia, Honduras, Guatemala), Russia and Australia. In Canada, the regulations were product-based and discussions were ongoing for improvements. Japan had excluded certain products from regulations. Japan had come out with a developer's guide with clarity on required information for regulation. Israel, too had a guidance that certain techniques were outside genetic modification scope. They were still working on the requirements for regulation. There was a strong demand from scientific community in European Union too, for re-visiting the restrictive regulations.

South America was a very good example of collective policy adoption by regional collaboration. Comparison of regulations in the region showed them to be very consistent and aligned. Multiple dossiers had already been submitted under the new regulations in Argentina in last 2 years (around 13 products), clearly demonstrating the positive impact of predictable regulations on innovation and new product development. It was important to point out that the technology developers in South America were local and smaller companies. If regulations had been similar to GMOs, it would have only benefit global companies, who could afford the

cost of de-regulation and consequently would also require higher return on their investment. Whereas, with no or simpler regulations, the smaller companies and institutes could also bring out products and contribute towards seed and commodity import/export. In the discussions following the presentation, the import/export of gene edited products was considered and since only one edited product has been commercialized so far, no example of import/export could be cited. But it was accepted that the ISF's position of alignment between countries would help in movement of products of gene editing. Since there was no global forum yet, regional discussions between governments would be the way forward in building such trade networks.

It was pointed out that, intellectual property rights for the technology should not be considered a deterrent as it was freely available for research and restrictions would come in play only for commercialization. However, IPR play would be there both for mutated variety and GM crop, as both products needed to be protected.

**Dr Swapan Datta**, Co-Chair, in his closing remarks, urged scientists to move forward with good science. Plant breeding, he said, was aimed at improvement of the particular genome, therefore, scientists should continue with good science to harness the tremendous potential and scope of the gene editing technology. A good product from the technology would be accepted by the farmers and consumers alike. Both public and private sectors should aim for the best products, that would make the regulation and acceptance easier.

## Technical Session II: Regulatory Status of Gene Editing in Asia-Pacific Region

*Co-Chairs* : **Ian Godwin**, QAFFI, Australia
**Arjula Reddy**, University of Hyderabad, India

*Rapporteurs* : **A Ashok Kumar**, ICRISAT, India
**Tanushri Kaul**, ICGEB, India

**Dr Takeshi Urao**, JIRCAS, Japan, gave an overview of Japanese regulatory policy for gene editing. The Japanese regulatory framework included evaluation of the product for biodiversity impact as per Cartagena Protocol and could be used for evaluations, within lab or in open confined trials. After evaluations, there were food and feed safety assessments for commercialization. The Japanese Ministry of Environment in their policy for gene editing regulation, established the conditions as to when gene editing would be exempted from regulation. The policy clearly defined that an organism would not be considered as GMO, when no foreign DNA was inserted in its genome. Though, the developer needed to provide details of the product to the government agency. The information regarding the edited plant/organism that had to be provided with: 1. Data to show that there was no foreign DNA integration, 2. Taxonomical species details, 3. Purpose of its use, 4. Method of gene editing including the nuclease that was used, 4. The function of the gene being modified, 5. Type of mutation, insertion or deletion needed to be detailed, 6. Off-target changes and 7. The expected impact of change on biodiversity. The developer also needed to provide toxicity and allergenicity data.

Similarly, if it was demonstrated that there was no remnant of foreign DNA in the plant, it would be considered as a non-GMO product. In case, bombardment and microinjection were

the methodologies for creating indels then the product would not be considered as GMO. Whereas a stable integration of foreign DNA in the genome would be considered as GMO, but in case the integrated gene was crossed out then the product would be non-GMO. In case the food contained foreign DNA, it would be considered as GM food and would have to undergo food safety assessment, no safety assessment would be required when product would have no foreign DNA insertion, further it was not mandatory to mention its origin on the packaging. Fundamental to Japanese regulatory policy was the insertion of foreign DNA, though currently there was not enough clarity regarding insertion of DNA from sexually compatible species.

**Dr Saturnina C Halos**, Biotechnology Coalition, Philippines, presented the regulatory status of gene editing in Philippines. The regulations for gene editing were under development. The Department of Agriculture by Administrative Order No. 8, 2002 had allowed for the import of seeds and commodities derived from genetically engineered plants and the commercial production of Bt/RR corn. The Executive Order No. 514, 2006 established the National Biosafety Framework, that prescribed the guidelines for implementation of regulatory framework, reorganized the National Committee on Biosafety of the Philippines (NCBP) and defined the roles of various agencies in implementing biosafety protocols as per Cartagena Protocol on Biosafety. Only living modified organisms (LMOs) are to be regulated. In December 2015 Supreme Court called Order 8, 2002 null and void, though this ruling was reversed in 2016 and JDC1 was recognized as the agency for formulation of policy to include new breeding technologies (NBTs). NBTs included Site-Directed Nucleases (genome/gene editing), cisgenesis and intragenesis, RNA-directed DNA methylation, reverse breeding, Synthetic genomics, Agro-infiltration/agro-inoculation, grafting with GM material and cell fusion.

An expert review of NBTs and its global regulation was taken up by Department of Agriculture, Biotechnology Program in 2018 and the review and recommendations were endorsed by the NCBP in 2019. NCBP had formed technical committee to draft guidelines on NBTs-derived products regulation, compliant with JDC1 regulations. A symposium on risk assessment of NBT was held in October 2019, where it was proposed that gene editing will not be regulated as LMO, they will be regulated under variety regulation regime and registration. The committee was expected to release the first draft of regulatory guidelines in the near future.

**Dr Ramakrishnan**, NARI, Papua New Guinea, spoke on 'Regulatory Status of Gene Editing in the Pacific SIDS". PNG had the third largest rainforest and held 7% of the global biodiversity. Most of the crops in the region were vegetatively propagated, *e.g.* banana, cassava, taro, sago palm, Irish potato, sweet potato, yams and plantains. The PNG cash crops included coconut, oil palm, rubber, spices, sugarcane, betel nut, coffee, cocoa, with agri-export of coffee to United States and cocoa to New Zealand and European Union. PNG governances on biotechnology relied heavily on principles and concepts established in Cartagena Protocol on Biosafety (CPB), ensuring safe handling, transport and use of GMOs/LMOs. PNG was in the process of developing biosecurity ("Effective minimization, mitigation and, wherever feasible, prevention of risks and consequences associated with the emergence, introduction, establishment and spread of pests and diseases harmful to animals, plants, humans, biodiversity, the economy and the environment of PNG and other nations ". One Health- WHO) policy and had no specific policy on GMOs.

Public perceptions regarding transgenics and genome editing elicits considerable public misunderstanding, mistrust and was the greatest hurdle for bringing out new plant breeding technologies including genome editing. The implementation of national biosafety laws was also encumbered. PNG needed to focus on capacity building and would seek help for managing the bio security for managing pest and diseases. He postulated that collaborations and joint

projects were important for development in the region. Open data sources would also help the nations in the region and organizations like APAARI could be of great help in enabling collaborations. Oceania were unique and needed to be considered separately and scoped out for strategies and networks for long-term benefits. The way forward for regulatory policy for PNG included governance of technology calls for cooperation in responding to rapidly advancing technologies in biosciences and Asia-Pacific taking a lead position on genomics-based agri-biotechnology through formation of working groups and inter-agency collaborations, similar to the approach taken up by OECD.

**Dr Chwan-yang Hong**, NTU, Taiwan, presented the view of the government, where it was committed to transformation of agricultural industry, with the small holder farmers together comprising an enterprise architecture and establishing professional areas for agricultural products. Since 1999 vast investments had been made to promote innovation in agricultural biotechnology especially for ornamental fishes, animal-based vaccines and diagnostic kits. In 2016 a program on developing bio-economy industries was launched with focus both on technology and environment. Work was ongoing in fisheries, rice, pigs, poultry, vegetables and ornamentals.

The regulatory amendments status in other countries would influence the research and industrial development internationally. Communication to clarify genetic modification and gene editing technologies and their benefits needed to be done for better public awareness and acceptance.

**Dr Piyarat Thammakijjawat**, DOA, Thailand presented the regulatory status of genome editing technology in Thailand. Dr Piyarat mentioned that the Ministry of Natural Resources and Environment manages the regulations in Thailand, though currently there were no regulations in place for gene editing. The regulations for LMO and plant quarantine laws were being used to manage the gene editing work. The GM micro-organism were managed by the Ministry of Public Health for ensuring safety of operators, community and environment. Thailand regulates both biotechnology and synthetic biology. The regulations of Synthetic Biology recognized importance of NBTs, though existing laws did not define LMO, modern biotech and synthetic biology very well. The Technical Biosafety Committee (TBC) had organized a meeting with researchers and inspectors to discuss and brainstorm on preparation of synthetic biology data on April 2, 2018 and January 7, 2019. Similarly, Department of Agriculture (DOA) had organized seminar on Synthetic Biology, Modern Biotechnology for Plant Breeding and Guideline for regulations during July 2017 and February 2019.

**Dr Ta Hong Linh**, VAAS, Vietnam gave an overview of regulatory status of genome editing in Vietnam. While giving the background regarding the economic and social importance of agriculture in Vietnam. In Vietnam agricultural production activities were key source of livelihood for 65% of the rural population *i.e.* of the 95.5 million population more than 80 million were living in rural area. Agriculture contributed 15.35% to national GDP. Main crops were rice, maize, cassava and vegetables with tea, coffee, black pepper and cashew being the major cash crops of the nation. The nation had achieved food security, policy reform for land ownership and fast and sustainable agriculture in spite of multiple challenges. The challenges included – under developed agro-processing industry, high input costs, low quality and low competitiveness, huge losses due to diseases, environmental pollution and impact of climate change. Gene editing work in Vietnam was focussed on yield and biotic stress tolerance bacterial leaf blight (BLB) for rice; herbicide tolerance and higher flowering for cassava and stress tolerance in soybean. Gene editing or Plant Breeding Innovation (PBI) was categorized as a form of biotechnology, though there were no specific policies in place

in Vietnam. Biotechnology was promoted in the Prime Minister's Decision No. 11/2006 on National Target Program on Development and Application of Biotechnology in Agriculture 2020. The program was intended to get extend up to 2030 with a possible inclusion of PBI/genome editing techniques. Academicians have planned to share material for reference in policy making for Vietnam. Vietnam Academy of Agricultural sciences (VAAS) planned to organize several workshops targeting different stakeholders involved in the seed industry, including plant scientists, policy makers, traders, *etc.* in order to introduce PBI/genome editing. Regulations for PBI were important and would help Vietnam to use the technology for crop improvement.

## Session III: Status of Gene Editing in CG centres and Perception of Gene Editing by Different Stakeholders

*Co-Chairs* : **KK Sharma**, ICRISAT, India
**T Radhakrishnan**, DGR, India

*Rapporteurs* : **P Sudhakar Reddy**, ICRISAT, India
**K Visharda**, IIMR, India

During this session a presentation was made on Status of Gene Editing Technologies in CG Centres and perspectives about the gene editing were presented by various stakeholders from academicians, researchers, research managers, public sector and private sector (industry). The major points of the presentations/discussions are given below:

**Dr Pooja Bhatnagar-Mathur**, ICRISAT, India, gave an overview of the ongoing gene editing research in the various CGIAR institutes. The talk on 'Gene editing for accelerated breeding' included contributions from CGIAR centres *i.e.* IRRI-Philippines, IITA-Nigeria, CIMMYT-Mexico, ICARDA-Egypt, CIP-Peru, and ICRISAT-India. She had put forward the breeder's challenge of getting back to the elite recurrent parent germplasm post crossing with the donor, which was not only time consuming but laborious, with enormous effort required for selection, data collection and analysis. Gene editing could squeeze that time frame to 2-3 years instead of a decade, besides being precise and specific for the target sequence. CGIAR institutes were focussing on input, output and nutritional traits using gene editing. For input traits, the focus was on disease resistance for fungal, bacterial and viral pathogens for rice, maize, wheat, potato and banana. Weed (Striga) resistance was also being worked on for sorghum and pearl millet using gene editing. The output traits being worked on by CGIAR institute included, enhanced iron and zinc content in rice, higher rice grain weight, enhanced pro-Vitamin A and iron and zinc in maize and reduction in rancidity to improve shelf-life of pearl millet. Abiotic stress tolerance was another trait that was being addressed by gene editing in rice and chickpea for drought tolerance. Gene editing had also been used to efficiently develop double haploids, that could be used in breeding programs.

She opined that the choice of technology for crop enhancement would depend on the trait, ease of generating the product as well as the economics of the process. Regulatory ambiguity had led to decrease in innovation and had restricted the product pipeline. The inherent characteristics of genome editing supported an oversight similar to conventional breeding (variety registration *etc.*) than the overly-regulated GMOs. Therefore, it was not appropriate to make

arbitrary and unjustifiable distinctions between gene edited products and mutation breeding products. The uniqueness of the edited products needed to be considered for its regulatory policy. She said that the first applications of genome editing in country would set precedents and hence the existing legislations needed to be looked into with fresh perspective, rather than assuming a GMO like applicability. CGIAR institutes could contribute to encourage the gene editing technology by proactively working with various nations to ensure judicious use of the technology, collaborations to enhance the knowledge and skills around gene editing.

**Dr MK Reddy**, ICGEB, India, mentioned about the ability of gene editing to pyramid the various alleles from wild landraces into elite germplasm, which would be otherwise difficult to achieve. Four elite rice lines had been edited at ICGEB to increase yield by increasing tiller number, branching of rachis, grain number or grain weight. Four non-functional alleles from *Japonica* germplasm had been introduced into *Indica* lines. The grain quality trait for rice was also being worked on at ICGEB. The protocol for non-integrative enhancement of template based SDN2 editing had been established to improve efficiency of gene editing.

**Dr Ramanathan Vairamani**, Metahelix Lifesciences, India, presented the hierarchy of decisions in business enterprises. He mentioned that a technology that could enable scientists to achieve their goal efficiently and in an economical way, would be preferred over the traditional ones. Gene editing was one such technology and there were ample publications to prove that, but the adoption of the technology would be based on how the regulatory scenario panned out. He proposed that gene editing should be subject to reasonable amount of regulation. There were certain traits that could only be managed by transgenic approaches; hence the importance of genetic modifications could not be undermined. Genetic modification was also safe, though its de-regulation was expensive. It was therefore, important that gene editing does not follow the path of GMOs. Metahelix had conducted proof-of-concept studies for gene editing in cotton and established its competency. There were multiple new players who were using the technology for crop improvement thereby, increasing the volume of innovation. With manageable regulations, the technology could go far in enabling crop improvement.

**Dr Amita Joshi**, BIRAC, DBT, India, brought out the importance of regulations for the direction/ decisions taken by the start-ups and small players. She was of the opinion that post genetic modification, the government would be open to feedback and accept scientifically backed guidelines for gene editing. When BIRAC mapped their technology-wise growth and funding, it clearly showed the change in direction taken by the companies due to restrictive regulations. There was no blanket regulation in place for the gene editing technology, though most nations had their checks and balances in place for regulating the technology. Another phenomenon which was unique to gene editing was the importance being given to stakeholder inputs and public opinion regarding the technology.

She explicitly said that the Environmental Act, 1986 of Ministry of Environment and Climate Change would apply to gene editing in the country. Though the characteristics of the edited organisms and extent of genetic change would determine the level of scrutiny required for the gene editing. In case of India, the trigger for regulation was both process and product. The tiered approach for risk assessment would be the focal point with level of risk being determined by the complexity of the modifications. Detailed guidelines and procedures regarding the gene editing regulations were being formulated and would be shared soon. Dr Joshi reiterated that evaluation of regulations was a continuous process, which required regular inputs and updates.

**Dr TR Sharma**, IIAB, India, presented that the institute has focus on capacity building to take up gene editing work in the future. The advantages offered by gene editing were well established

and India could not afford to lose the benefits offered by gene editing, the way it had failed to take advantage of genetic modification technology. The region needed to develop Centers of Excellence for providing training and sharing knowledge and expertise to both public and private sectors.

**Dr Vibha Ahuja**, BCIL, India, presented that there was no single definition of gene editing or a definitive list of the varied techniques included under the technology. Most definitions incorporate the idea of making targeted changes at a known location. Gene editing tools allowed the generation of these traits much more efficiently. Gene editing did not necessarily allow for making changes that were not possible conventionally, though it did make the said changes easier and precise. Some methods of gene editing required a genetic transformation step, but it was transient *i.e.* no transgenes remained in the final product. She said that most of the ongoing debate around the regulation of gene-edited plants focussed on the possible capture/inclusion of gene editing in the scope/broad definitions of existing laws/regulations for GM plants. Many governments were actively looking to avoid regulating certain categories of gene-edited plants where they were indistinguishable from products of conventional breeding (which includes accelerated mutagenesis). Scientists needed to ensure that innovation proceed smoothly, unlike the hinderances under the regulatory paradigm that many governments applied to GM plants.

The existing risk/safety assessment paradigm could be used to assess the environmental or food safety assessment of gene edited plants, but the questions remained regarding the best path forward. Gene-edited products should be evaluated on case by case basis. Enforcement of any regulation would be exceedingly difficult as it was difficult to prove that a genomic change was the result of gene editing by examining the plant (phenotype), which effectively led to voluntary compliance. Gene-editing had been discussed under the Cartagena Protocol as a potential 'issue' requiring further risk assessment guidance but [bracketed]. Free global trade required internationally harmonized regulations; therefore, different regulation and authorization requirements would hinder international exchange especially when products would be indistinguishable from conventional ones. Therefore, there was an urgent need to streamline and increase collaboration amongst regulatory authorities to achieve some level of harmonization at international/regional policy. Another important factor was the necessary freedom to operate (FTO) for the technology to grow and be adopted successfully.

**Dr T Radhakrishnan**, DGR, India, presented that his institute had done a lot of work in the field of transgenics for oilseeds and soon will embark on using gene editing for oilseed improvement. He expressed hope that the regulations for gene editing would be clear, simple and realistic to encourage better and wider adoption of the technique. He mentioned that no genetically modified food crop had been approved in India but Bt cotton seed oil was being used as vegetable oil. He said that clarity was important and unnecessary regulatory burden should be avoided for utilizing the potential benefits of the technology.

## Special Session I: Thematic Presentation on Gene Editing

*Co-Chairs* : **Ram Kaundinya**, FSII, India
**Jan Debaene**, ICRISAT, India

*Rapporteurs* : **Harish Gandhi**, ICRISAT, India
**Bhagirath Chaudhary**, SABC, India

**Dr Carl Ramage**, La Trobe University, Australia, made his presentation through Skype on Gene Editing: Research Prioritisation, Capacity and Policy Development in Asia Pacific. He began his talk, with reference to the 23 years of proven biological safety record of transgenic crops along with benefits of food security, environmental and socio-economic benefits. There had been than more than 1,260 food safety decisions across 24 economies on biotech crops without any difference of opinion. Australian regulations (Gene Technology Act 2000) dealt with risk management to protect people health, safety and environment. Though, new technologies, had brought new challenges, especially with the emergence of consumer-focused products. Australian regulatory process was quite mature and had taken up case by case evaluations, in alignment with Codex and OECD. The process involved coordination between multiple agencies, cooperation with Health Canada within the predictable timing set in the legislation. The challenges to the system included the different definitions of a GMO (OGTR/FSANZ), wide scope of the Gene Technology Act (process-based) and lack of public awareness.

As per schedule 1 of the Act, a mutant organism in which the mutational event did not involve insertion of foreign DNA was not considered as GMOs though gene editing was not explicitly listed or defined. With the proposed changes to the gene Technology act, SDN-1 (NHEJ) would not be considered as GMOs. He appreciated South America for leading the way for gene editing regulations. The South American nations had agreed not to regulate plants with no novel genetic combinations as well as those wherein the final product was free of transgenes. Stewardship of products was pivotal in protecting markets and trade, particularly post approval/import/export. He postulated that a balance between managing risk and innovation was important.

**Dr Rajeev Varshney**, ICRISAT, India, made presentation on 'Gene Editing for Good Times'. In his presentation, he mentioned that technology could take us towards ample nutritious food for growing population and make farming a profitable business. Plant breeding journey has had multiple technology inputs with marker assisted breeding, Genome-wide association study (GWAS), *etc.* and gene editing was another such technology input and genomics could inform transgenics and gene editing studies for better results. The technology was available but absence of enabling policies are restricting the deployment of technology. Technological advances and automation have enabled us to generate accurate data quickly. Multiple crops critical for multiple developing nations had been sequenced and the information had been used for making better crosses. Genomics information could not only help in product development but also to accelerate breeding. Many enhanced products had been released in India and in Africa using advanced technologies across the disciplines. The combined comprehensive information generated would enable us to address multiple issues of phenotyping and diagnostics; purging genetic load from elite gene-pool and bringing back useful alleles from wild accessions - reverse domestication. With multiple uses and to harness the benefits of the available technologies, clarity in regulatory policy is imperative.

**Dr Shivendra Bajaj**, FSII, India, made presentation on 'Plant Breeding Innovation: Industry Perspectives' and he presented the seed industry's view on behalf of FSII – a 40-member association of research-based companies that had committed research investment and respect the intellectual property rights. Multiple options of crop improvements that gene editing are being pursued by Indian seed industry for multiple crops. Arbitrary regulations would generate financial burden and favour bigger players, which in the long run would hamper innovation and technology adoption for smaller niche crops. Also, lack of policy harmony would hinder seed movement and trade regionally and internationally. The scientific community and industry could propose a shift from product-based regulation instead of process-based regulations that were currently being applied in the country. Along with the clarity on regulations, predictable

time bound decisions needed to be made. During the discussion, it was opined that since most countries had process-based regulation, it would be difficult to amend it to product-based, getting exemptions for some processes would be easier to achieve rather than change to product-based regulation.

**Dr Valasubramanian Ramaiah**, Corteva Agriscience, India, made presentation on 'Open Innovation in Gene Editing' and discussed the intellectual property scenario for gene editing. He introduced the open innovation platform of Corteva. He said that challenges and opportunities co-existed and scientists and technologists were addressing multiple issues faced by agriculture using the most advanced tools available to them. Innovation could definitely benefit from collaborations, partnerships and data sharing. Corteva had the IPR for the CRISPR-Cas9 and was open for collaborations and partnerships. The company is also open to helping its partners in capacity building and skill development. Open Innovation Platform offered the technology freely for research purposes, though stewardship was an important component of the collaboration. Corteva already had ongoing collaborations with ICRISAT and Danforth Center.

## Technical Session IV: Panel Discussion to Prioritise Research Areas, Capacity and Infrastructure Development, Regulatory Policy Development & Public Awareness, and Possible Partnerships to Achieve SDGs

*Moderators* : **KK Sharma**, ICRISAT, India
**Amitabh Mohanty**, NIPGR, India

*Rapporteurs* : **C Vishwanathan**, IARI, India
**Siddhartha Tiwari**, NABI, India

The panel discussion comprised the eminent panellists from Asia-Pacific countries to discuss about the prioritization of research, capacity and infrastructure development, regulatory policy development, public awareness, and possible partnerships to promote the gene editing technologies.

**Dr Amitabh Mohanty**, NGGF, NIPGR, India, presented the advantage of precision that was part of the gene editing process. The SDN1 editing involved non homologous end joining which was not a high-fidelity process, generating multiple changes, thereby generating multiple alleles of the gene which were a treasure trove for plant breeding. While addressing the topic of off-target effects, he mentioned that a good design and good knowledge of the target sequence would reduce/eliminate the off-targets. Off-target changes were not a major concern as plants with off targets could be easily selected out, post an in-depth molecular analysis. Plant breeding presently involved pyramiding of multiple traits, which could be a time consuming and laborious work, whereas editing could enable allelic changes for multiple targets, to achieve similar trait combinations within 2-3 years. It offered opportunities for polyploid crops and crops with limited genetic diversity to be improved as per our knowledge of wild landraces. There were multiple reports, where the power of the technology had been thus demonstrated. The economical cost associated with the gene editing (USD 10-15M) would enable smaller players and academic institutions to bring forward products, unlike GMOs which cost around USD 130M for de-regulation. Capacity and competency development were very important and DBT was enabling the same by giving grants and supporting training programs. The gene

editing technology could bring out good products but it would be the associated regulation that would decide the commercialization path for the products.

**Ms Masami Takeuchi**, FAO-RAP, Thailand, made presentation *via* Skype and focussed on the safety of foods derived from newer technologies including genetic modifications, gene editing, *etc.* FAO worked for food security and aimed to have zero hunger in the world. Food security was defined in 1996 as, when all the people all the time have access to safe, sufficient and nutritious food. SDG2 (zero hunger) and SDG3 (good health and well-being) have the most relevant association with gene editing technology. Beyond the potential of technology, research priorities and associated regulations, impact on socio-economic balance was also very important. It was required for scientists to deliver the right message using substantial data, so that the technology could contribute for food security. Data and information sharing between various agencies was also critical, so that similar messages could be delivered and confusion was avoided. FAO also tracked and took regular stock of country-wise regulation, applications in the food sector, risk assessment, risk management approaches and good practices. Codex needed to receive multiple requests from members to develop the safety standards for the gene editing technology, making it a time-consuming process. FAO, meanwhile, would be using risk analysis paradigm for other technologies to evaluate the gene editing technology on case by case basis, though an expert consultation was planned during 2020.

**Dr Takeshi Urao**, JIRCAS, Japan, while talking on consumer acceptance of the gene editing technology said, that it was better to begin communication early in the project or process, so that questions regarding the technology could be reasonably answered to the satisfaction of the regulators or public. Communication could be part of the research planning also *e.g.* the selection of target could be based on attaining food security, sustainability for the agri-industry as well as safety. Scientists needed to craft the communications to suit the audience. All available options to communicate consistently, including media, social media should be utilized. He emphasized that technology, policy and regulation as well as social licence all connect and contribute towards development and acceptance of new innovations.

**Dr Sonny Tababa**, CLA, Singapore, made presentation on considerations around regulatory policies for gene editing technologies. Plant breeding innovations included marker assisted breeding, transgenic, editing and any other futuristic technique that improved the process of plant breeding. For any technology to be accepted, technological benefits, associated regulations and social impact all contribute and cross-talk to shape the technology's future. Seeds and grains were traded globally and differences in regulatory policies would hamper the movement of seed/grains and their products. The era of genetic modification had also begun with tremendous interest on part of companies, institutions and governments but finally very few companies went to the market with selected number of traits. Considering the potential of gene editing technology, it was hoped that multiple player could enable multiple traits and products to benefit the farmers and consumers alike. CropLife Asia supported the ISF position that plant varieties indistinguishable from conventional ones, should not be regulated, similar stand had been taken by WTO also. She presented that regulatory framework should also be consistent amongst agencies, time-bound and with predictable process for clarity.

Scientists needed expert support for navigating the IPR space for gene editing technology. It has been observed in the past that once the research is near to commercialization the voices of dissent increased. Therefore, for social acceptance it was required that the message was moulded to address specific audiences, so that the safe and responsible use of the technology could be clearly conveyed.

**Dr Subeer Majumdar**, NIAB, India, mentioned about the dichotomy of public acceptance when biotechnology is used in animals than in crops. Human diseases can be simulated well in animals, especially mice, hence, they were routinely used to study as well as design cures. The earliest example of such a social licence was xenotransplantation of pig's liver into humans. Transgenesis too for addressing human diseases have been more acceptable than genetically modified food. Livestock could be improved to address food security i.e. more meat or milk producing animals or more egg producing chicken. These were more acceptable as the final product *i.e.* milk or eggs were not perceived as transgenic. A lot of human infections happen *via* animals, hence, there was a lot of interest in engineering animals that could be made non-carriers of diseases. In his opinion, the scientific community should partner with media to influence the public perception. He reiterated that the responsible use of technology was of prime importance, hence, some degree of regulation should exist for gene editing, as it would enhance the technology use and acceptance.

**Dr Chwan-Yang Hong**, NTU, Taiwan, while talking on research priorities, he eluded to the potential of the technology. Gene editing had the potential to address biotic, abiotic stresses as well as enable sustainable agriculture. Besides addressing food security, the technology could be used to reduce input costs and manage climate change. It could also be a tool of choice for biofortification, especially in under-utilized potential indigenous crops.

**Dr Kanokwan (May) Chodchoey**, APSA, Thailand presented her views on public awareness/ societal acceptance. She referred to a paper published in Transgenic Research 2019 (Lassoued *et al*., 28: 247–256). The survey in the publication suggested that experts agreed on the enhanced agronomic performance and product quality of genome-edited crops over alternatives. The surveys also indicated that the regulations for health and safety played a major role in determining where and how gene editing would be developed and used in agriculture. She also mentioned that communication with public and consumers should be in parallel to technology development and regulation. Consumers now-a-days are not only concerned with safety but also sustainability and environmental impact of a technology or product, therefore consistent, positive, science-based messaging would be essential for public awareness and acceptance as public had access to multiple information sources may be not all of them are authentic.

**Dr Sanjeev Kalia**, BASF, India, submitted that regulations should be product-based, science-based and proportionate to the risk associated with the product. They should be consistently applied, clear and predictable with time-bound clearances. He insisted that the industry was not opposed to regulation, but the burden needed to be commensurate with the risk. Products of genome editing should not be regulated as GMOs when they could also occur/ be obtained through conventional methods of classical breeding or classical microbial strain improvement.

Additionally, having globally harmonized regulations would enhance collaborations and trade as presently different concepts of regulations were being applied by nations. Process-based exclusions, *e.g.* in Japan and Australia; Product-based case-by-case assessment and exclusion from GMO regulatory scope, *e.g.* in USA, Argentina. Moving forward, the community needed to appreciate the uniqueness of gene editing and communicate it as being different from genetic modification.

Active audience participation in deliberations and discussion brought out certain other important points as mentioned below:

(i) There should be a strong call for encouraging public-public and public-private partnerships and there was a need for more flexible programs, promoted by DBT and BIRAC to achieve these targets.

(ii) A better mechanism for sharing knowledge/technology was needed to evolve to foster all partnerships.

(iii) Capacity and competency development were emphasized on, especially the inclusion of smaller institutions and universities.

(iv) To allow better access to technology, it was proposed that government should obtain CRISPR license and provide it to public and private sectors for product development in the country.

(v) The Expert Consultation group agreed that science-based, predictable regulations with clear timelines would encourage innovation and whereas arbitrary regulatory burden needed to be avoided.

(vi) Clarity in the definitions used in the regulations was also considered important.

(vii) It was proposed that APAARI and APSA could coordinate and enable discussions around harmonized regulations in the region for better technology flow.

(viii) It was agreed that the initiative on communication regarding the technology should be taken up at multiple levels and academicians, industry and experts should contribute to educational and awareness programs.

# Plenary Session

*Co-Chairs* : **Peter Carberry**, ICRISAT, India
**Kuldeep Singh**, NBPGR, India

*Rapporteurs* : **P Santisree**, ICRISAT, India
**Basavaprabhu L Patil**, IIHR, India

During the Plenary Session, the summary of discussion and major recommendations emerged out from the deliberations made in various technical sessions and Panel Discussion were presented.

The Co-Chairs appreciated the efforts of the organizers in bringing together regional experts on such a crucial topic of scientific interest. The 2-day deliberations were summarized in the plenary session and the recurrent themes were highlighted. The Co-Chairs requested for the group to come forward with any points of contentions mentioned in the summary presentation. While discussing the recurrent points, **Dr Vibha Ahuja**, BCIL, highlighted the following point as priority for gene editing related regulations i.e. exemption for SDN1 edits similar to US, Australia and Japan; development of a communication strategy; importance of capacity building especially regulatory capacity building in the region.

Some of the points that were discussed included that the usage of the abbreviations GM (genetically modified) and GE (gene edited) should be avoided, also comparisons between genetically modified and gene editing needed to be avoided. **Dr Amitabh Mohanty**, NIPGR, said that specifying the amount of change might not be the best way forward for SDN1 kind of edits. **Dr Pooja Bhatnagar Mathur**, ICRISAT, responded to Dr Mohanty's view that specifying change would enable getting exemptions for some SDN2 edits too. The forum was of the view that instead of using SDN-1 or 2 as criteria, the products that were indistinguishable from the products of conventional breeding should be exempted from regulations. Similarly crops/products with no replacement of sequence or replacements of sequence from a sexually compatible species should undergo minimal (middle path) regulatory procedures. **Dr Bhagirath Choudhary**, SABC, did not want the guidelines and regulations to be regularly reviewed and updated.

**Saturina Halos**, Philippines, was of the opinion that if LMO definition was improved and well accepted, the regulations would be better. On similar lines **Dr Bhagirath Choudhary** mentioned that biosafety definition needed to be well defined.

Other points that the participants agreed were:

(i) Strengthening of regional collaborations to have country guidelines in place. This would further bring harmonization in global regulatory procedures. APPARI and APSA might organize a regulatory conclave in the due course of time.

(ii) Regarding gene editing technology it was suggested to communicate in simple language instead of more scientific terms e.g. the changes are derived from the same species is more acceptable explanation than terms like 'Cisgenics'.

(iii) The concern was expressed by **Dr Sonny Tababa**, CLA, regarding the recommendations being too specific, which would be limiting for future technologies, therefore, it was required to make the recommendations future proof.

**Dr Rishi Tyagi**, APAARI, requested the the Co-Chairs for constituting a task group to deliberate and come up with the key recommendations on the basis of deliberations and summary presented during Plenary Session to propose before the appropriate government authorities. It was decided that representatives from organizers *i.e.* Dr Rishi Tyagi from APAARI, Dr Rajeev Varshney and Dr Pooja Bhatnagar Mathur from ICRISAT, Dr Shivendra Bajaj from FSII will jointly develop the Proceedings and Recommendations. Dr Kiran Sharma, ICRISAT will overview the proceedings and recommendations. Dr Vibha Ahuja, BCIL, voluntarily offered her services to draft the key recommendations.

The themes selected for further discussion by the task group to come up with final recommendations were the following:

(1) Science based, predictable regulations with clear timelines will encourage innovation.

(2) Arbitrary regulatory burden needs to be avoided. Events with no insertion or replacement from same species *i.e.* if a product is indistinguishable from natural product, it should not be regulated.

(3) Plan for regional collaborations for harmonization of regulation globally as well as in the region for unhindered movement of seeds and commodity trade.

(4) Capacity and competence building is a critical factor for taking forward the technology

(5) The initiative on communication regarding the technology should be taken up at multiple levels and academicians, industry and experts should contribute to it.

Co-Chairs presented the closing remarks. **Dr Kuldeep Singh**, NBPGR, commented that governments have considerations beyond science. The kind of first products offered by the technology would also shape the government's opinion regarding the technology. He suggested nutritionally enhanced crops or crops with reduced anti-nutritional properties as one such example. While congratulating the organizers for organizing excellent discussion by inviting the experts from Asia-Pacific, **Dr Peter Carberry**, ICRISAT, offered the support of ICRISAT as well as CGIAR to take the discussion and recommendations forward for the benefit of the society.

At the end, a vote of thank was given by **Dr Shivendra Bajaj**. He profusely thanked **Dr Renu Swarup**, Secretary, DBT, Government of India, for accepting the invitation of being Chief Guest, delivering Inaugural Address and underlining the expectations from the Expert Consultation. He also offered his appreciation for Dr Tyagi from APAARI for connecting with **Dr Swarup**. He also thanked **Dr Peter S Carberry**, Director General, ICRISAT and **Dr KK Sharma**, Deputy Director General-Reserach, ICRISAT, for their permission and encouragement and immense support for organization of the Expert Consultation at ICRISAT and offering their perspectives and interacting with the participants.

**Dr Bajaj** thanked **Dr Rajeev Varshney**, RP Director, Genetic Gains, ICRISAT and **Dr Pooja Bhatnagar-Mathur**, Theme Leader – Cell, Molecular Biology and Genetic Engineering, ICRISAT as member of co-organizing team for taking the lead for all the technical and logistic support for the Expert Consultation. He also thanked and expressed his sincere gratitude to

APAARI especially Dr Rishi Tyagi, Coordinator, APCoAB, APAARI, who made efforts to invite the Secretary, DBT, Government of India as Chief Guest and various experts from the Asia-Pacific region for the Expert Consultation. Dr Bajaj mentioned that this was the first step in the journey and hoped that APAARI would continue to organize stakeholder consultation meetings as well as capacity building programs to enable technologies like gene editing and other advanced breeding methodologies.

He expressed his delight in connecting with all participants from academia, industry, and government officials from all over the globe and thanked them for accepting the invitation and taking time out to be a part of the Expert Consultation and sharing their perspectives on the regulation of the technology. He thanked all the session Co-Chairs and Panellists for their proactive engagement that contributed to the deliberations. He was equally thankful to all Rapporteurs for their efforts in recording the key points of the deliberations during their respective sessions. Financial support for organization the Expert Consultation provided by CRP-GLDC and FSII was also gratefully acknowledged. Dr Bajaj ended this vote by thanking all the volunteers who worked day and night to make the event a success.

Key recommendations that emerged from the 2-day deliberations and the discussions are as follows:

(1) Many governments are seeking to ensure that the regulation of genome-edited plants is commensurate with the potential risks of these plants to the environment, human or livestock safety. To this end, some governments have already taken the position that gene edited plants with phenotypes that have been, or can be achieved using conventional plant breeding techniques (which includes mutagenesis techniques) should be subject only to those same regulations as their conventionally-bred counterparts e.g., phytosanitary regulations, variety registration etc. Any regulatory oversight should be based on the final product rather than the process involved.

Therefore, it was recommended that consistency can be achieved by not regulating products of plant varieties developed through the latest breeding methods if they are similar or indistinguishable from varieties produced through earlier breeding methods.

The genetic variation in the final product would not be regulated when:

(a) It does not contain a novel combination of genetic material*;

(b) The final plant product contains genetic material from sexually compatible plant species;

(c) Or any form of mutagenesis is involved.

This will ensure that agricultural innovation can proceed unhindered for the benefit of the farmers and the society.

Developments in countries in the Asia-Pacific region include Australia and Japan both excluding certain categories of gene editing products from the scope of GM regulation: Australia has expressly excluded all applications of SDN1; and Japan has excluded SDN1 on the basis that it does not involve the use of "extracellularly processed nucleic acids". These exclusions are based on the basis of the technology being the natural cellular repair mechanism, non-homologous end joining.

In other regions, countries of Latin America (e.g. Argentina) have adopted approaches more aligned with the criteria listed above, and products developed using ODM, SDN1 and SDN2

*Novel combination of genetic material means the stable insertion in the plant genome of one or more genes that are part of a designed genetic construct.

have be exempted from GM regulatory requirements. Based on these criteria, of the different gene editing approaches, only those products developed using SDN 3 that contain foreign DNA introduced from sexually incompatible species should be subjected to safety assessment on a case-by-case basis.

2. As is abundantly clear from our experience with the regulation of GM (genetically modified) plants across the globe, ambiguity in regulatory requirements causes unpredictable delays in approvals, thereby increasing costs, deterring innovation and restricting product pipelines. These costs have also effectively eliminated small- and medium-sized enterprises (SMEs) from being able to compete in this space. This has severely constrained the development and deployment of GM crops important for food security or with traits that are relevant for smallholder agricultural systems. Science-based, predictable and proportionate regulations with clear timelines are urgently required to encourage innovations. It was recommended that countries should clarify the scope of their regulation for the products of gene editing at the earliest.
3. Should it be determined that a sub-set of gene-edited plants may warrant regulation as GM, then harmonization of approaches within the Asia-Pacific region is important for collaboration in research, capacity development, regulation and trade. Efforts towards common ground should be facilitated by organizing interactive meetings among the researchers and the regulatory agencies in the region and should also be informed through appropriate stakeholder engagement and/or consultations.
4. Significant efforts are needed from all stakeholders to improve and prioritize communication and information exchange about gene editing, particularly focusing on how it is an extension of conventional plant breeding. Focused programs for communicating science-based information in easy to understand language should be initiated by academics, industry and experts from both public and private sectors.
5. Besides, capacity and competency building in research and development, deployment and delivery of the products of gene editing should be enhanced at the regional level. Partnerships – public–private and public-private should be encouraged. Better mechanisms for sharing knowledge/technology need to be in place to enable such partnerships. Public-private partnerships should be encouraged to work in the areas of relevance to the Asia-Pacific. Regional organizations like APAARI should lead the development of network projects involving national partners in the interest of smallholder farmers and consumers of the region.
6. Crops as well as areas of improvement need to be prioritized for an efficient deployment of gene editing technology. The first applications of gene editing in the country can set precedents, and hence proactively establish effective policies. The innovative institutional arrangements, networks and collaboration will contribute substantially to development of the human capital needed to ensure the judicious application of these advanced tools and technologies in the region. Similarly, the regional collaborations and networks can also contribute to capacity building, communication strategies, policy development and advocacy.

# List of Participants*

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**About 110 participants attended the Expert Consultation; some names are not included in above list due to non-availability of their detail addresses*

# Technical Program

## *Regional Expert Consultation on Gene Editing in Agriculture and its Regulation*

**Date: October 10-11, 2019**

Venue: Ralph Cummings Auditorium, International Crop Research Institute for the Semi-Arid Tropics, Patancheru, Hyderabad, India

### Day 1: Thursday; October 10, 2019

| | | |
|---|---|---|
| 08:00-09:00 | **Registration** | |
| 09:00-09:10 | Introduction | **Rajeev Varshney**, RP Director, Genetic Gains, ICRISAT, India |
| 09:10-09:20 | Welcome Remarks | **Peter Carberry**, Director General, ICRISAT, India |
| 09:20-09:30 | Remarks by FSII | **Ram Kaundinya**, Director General, FSII, India |
| 09:30-09:40 | Remarks by APAARI | **Rishi Tyagi**, Coordinator, APAARI, Thailand |
| 09:40-09:55 | Presentation of Souvenirs by APAARI | |
| 09:55-10:05 | Closing Remarks | **Kiran K Sharma**, Deputy Director General - Research, ICRISAT, India |
| 10:05-10:30 | ***Tea/Coffee Break*** | |

## Technical Session I: Status and Advances in Gene Editing

*Co-Chairs* : **Peter Carberry**, ICRISAT, India
**Swapan Datta**, Calcutta University, India

*Rapporteurs* : **Rajeev Gupta**, ICRISAT, India
**Sneh Lata Singla-Pareek**, ICGEB, India

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|---|---|---|
| 10:30-11:00 | ***Chief Guest Lecture* – Gene Editing in India** | **Renu Swarup**, Secretary, DBT, India |
| 11:00-11:15 | **Souvenir Presentation to Chief Guest and Group Photograph** | |
| 11.15-11.45 | **Recent Advances in Gene Editing Technology** – **Ian Godwin**, QAAFI, Australia | |
| 11:45-12:15 | **Global Regulatory Status of Gene editing products** – **Szabolcs Ruthner**, ISF, Switzerland | |
| 12:15-12:45 | Discussion and Concluding Remarks by the Co-Chairs | |
| 12:45-14:00 | ***Lunch*** | |

## Technical Session II: Regulatory Status of Gene Editing in Asia-Pacific Region

***Venue: PTCC Conference Hall, ICRISAT***

*Co-Chairs* : **Ian Godwin**, QAFFI, Australia
**Arjula Reddy**, Univ. of Hyderabad, India

*Rapporteurs* : **A Ashok Kumar**, ICRISAT, India
**Tanushri Kaul**, ICGEB, India

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|---|---|
| 14:00-15:30 | **Regulatory Status of Gene Editing in Asia-Pacific Region** (15 min each)<br>– **Takeshi Urao**, JIRCAS, Japan<br>– **Saturnina Halos**, Biotechnology Coalition, Philippines<br>– **A Ramakrishna**, NARI, PNG<br>– **Chwan-yang Hong**, NTU, Taiwan<br>– **Piyarat Thammakijjawat**, DOA, Thailand<br>– **Ta Hong Linh**, VAAS, Vietnam |
| 15:30-15:45 | Discussion and Concluding Remarks by the Co-Chairs |
| 15:45-16:15 | ***Tea/Coffee Break*** |

## Technical Session III: Status of Gene Editing in CG centres and Perception of Gene Editing by Different Stakeholders

*Co-Chairs* : **KK Sharma**, ICRISAT, India
**T Radhakrishnan**, DGR, India

*Rapporteurs* : **P Sudhakar Reddy**, ICRISAT, India
**K Visharda**, IIMR, India

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|---|---|---|
| 16:15- 16:40 | **Status of Gene Editing Technologies in CG centres** | **Pooja Bhatnagar-Mathur**, ICRISAT |
| 16:40-17:40 | **Perception for Gene Editing by Different Stakeholders** (8-10 min each speaker)<br>– **MK Reddy**, ICGEB (Academia)<br>– **Ramanathan Vairamani**, FSII (Industry)<br>– **Amita Joshi**, DBT (Policy)<br>– **TR Sharma**, IIAB, (Research Manager)<br>– **Vibha Ahuja**, BCIL (Public Ltd. Company)<br>– **T Radhakrishnan**, DGR, India (Research Manager) | |
| 17:40-18:00 | Discussion and Concluding Remarks by the Co-Chairs | |
| 18:30 | ***Social Dinner at IMOR Plaza (Hosted by DG, ICRISAT)*** | |

**Day 2: Friday; October 11, 2019**

## Special Session I: Thematic Presentation on Gene Editing

*Co-Chairs* : **Ram Kaundinya**, FSII, India
**Jan Debaene**, ICRISAT, India

*Rapporteurs* : **Harish Gandhi**, ICRISAT, India
**Bhagirath Chaudhary**, SABC, India

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|---|---|
| 09:00-09:20 | **Gene Editing: Research Prioritization, Capacity and Policy Development in Asia-Pacific**<br>– **Carl Ramage**, La Trobe University, Australia (via Skype) |
| 09:20-09:40 | **Gene Editing for Good Times**<br>– **Rajeev Varshney**, ICRISAT, India |
| 09:40-10:00 | **Plant Breeding Innovation: Industry Perspectives**<br>– **Shivendra Bajaj**, FSII, India |
| 10:00-10:20 | **Open Innovation in Gene Editing**<br>– **Valasubramanian Ramaiah**, Corteva Agriscience, India |
| 10:20-10:45 | ***Tea/Coffee Break*** |

## Technical Session III: Status of Gene Editing in CG centres and Perception of Gene Editing by Different Stakeholders

*Moderators* : **KK Sharma**, ICRISAT, India
**Amitabh Mohanty**, NIPGR, India

*Rapporteurs* : **C Vishwanathan**, IARI, India
**Siddhartha Tiwari**, NABI, India

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|---|---|
| 10:45-12:15 | **Perception of Panellists** (10 min each speaker)<br>– **Takeshi Urao**, JIRCAS, Japan (Public Acceptance and Research Priorities)<br>– **Rakesh K Mishra**, CCMB, India (Regulatory Policies)<br>– **Masami Takeuchi**, FAO-RAP, Thailand (Sustainable Development Goals)<br>– **Sonny Tababa**, CLA, Singapore (Regulatory Policies)<br>– **Subir Majumdar**, NIAB (DBT), India (Research Priorities in Animal)<br>– **Chwan-Yang Hong**, NTU, Taiwan, (Research Priorities)<br>– **Kanokwan (May) Chodchoey**, APSA, Thailand (Public Awareness/ Societal Acceptance)<br>– **Sanjeev Kalia**, FSII, India (Regulatory Policies) |
| 12:15-12:45 | Discussion and Concluding Remarks by the Moderators |
| 12:45-14:00 | ***Lunch*** |

## Plenary Session

*Co-Chairs* : **Peter Carberry**, ICRISAT, India
**Kuldeep Singh**, NBPGR, India

*Rapporteurs* : **P Santisree**, ICRISAT, India
**Basavaprabhu L Patil**, IIHR, India

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|---|---|---|
| 10:30-11:00 | Presentation of Draft Recommendations of Technical Sessions/Panel Discussion | **Rishi Tyagi**, APAARI, Thailand |
| 14:30-14:45 | *Closing Remarks by the Co-Chairs* | **Co-Chairs** |
| 14:45-14:55 | ***Vote of Thanks*** | **Pooja Bhatnagar-Mathur**, ICRISAT, India |
| 15:00-15:30 | ***Tea/Coffee Break*** | |
| 15:30-17:00 | Visit to ICRISAT Facilities by Interested Participants | |
| 18:30 | Thanks Giving Dinner at 204 Banquet Hall (Hosted by APAARI) | |

Departure

# Photo Gallery

## Inaugural Session


*Introductory remarks by Dr Rajeev Varshney*


*Inaugural session panel*

*View of audience*

## Felicitation of Dignitaries

*Dr Peter Carberry*

*Mr Ram Kaundinya*

*Dr KK Sharma*

*Dr RK Tyagi*

*Dr Rajeev Varshney*


*Dr Peter Carberry*


*Mr Ram Kaundinya*


*Dr RK Tyagi*


*Dr KK Sharma*

# Felicitation of Dignitaries by APAARI

*Dr Peter Carberry*

*Mr Ram Kaundinya*

*Dr KK Sharma*


*Dr Rajeev Varshney*



*Dr Renu Swarup*

*Dr Renu Swarup, Secretary, DBT, Government of India, Felicitated post her address*

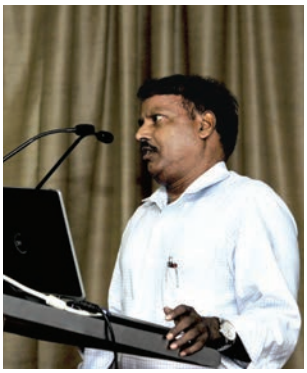
*Closing remarks by Dr Swapan Datta*

*Dr Renu Swarup, Secretary, DBT, Government of India, interacting with the audience*

## Technical Session III

# Status of Gene Editing in GC Centres and Perception of Gene Editing by Different Stakeholders

*Dr Pooja Bhatnagar Mathur*



*Dr MK Reddy*

*Dr Vairamani*


*Dr Anita Joshi*

*Dr TR Sharma*

*Dr Vibha Ahuja*

## Special Session I

## Thematic Presentation on Gene Editing


*Session Co-Chairs and Rapporteurs*

*Dr Rajeev Varshney*

*Dr Shivendra Bajaj*

*Dr Valasubramanian Ramaiah*

## Technical Session IV

# Panel Discussion to Prioritise Research Areas, Capacity and Infrastructure Development, Regulatory Policy Development & Public Awareness, and Possible Partnerships to Achieve SDGs


*Session Co-Chairs and Rapporteurs*


*Dr Amitabh Mohanty*

*Dr Masami Takeuchi*

*Dr Takeshi Urao*

*Dr Sonny Tababa*

*Dr Kanokwan (May) Chodchoey*

*Dr Sanjeev Kalia*

*Dr Subir Majumdar*

*Dr Chwan-Yang Hong*

# Participant Interactions and Discussions


# Participants at the Expert Consultation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