Stakeholders Dialogue on

Enabling Policies for Harnessing the Potential of Genome Editing in Crop Improvement

Proceedings and Recommendations

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Acronyms and Abbreviations

BCIL	Biotech Consortium of India Ltd
BIRAC	Biotechnology Industry Research Assistance Council
CCMB	Centre for Cellular and Molecular Biology
CGIAR	Consultative Group of International Agricultural Research
CIMMYT	International Maize and Wheat Improvement Center
CoE	Centre of Excellence
COVID	Corona Virus Disease
CRISPR	Clustered Regularly Interspaced Short Palindromic Repeat
CSIR	Council of Scientific and Industrial Research
CSOs	Civil Society Organisations
DARE	Department of Agricultural Research and Education
DBT	Department of Biotechnology
DNA	Deoxyribo Nucleic Acid
DRDO	Defence Research and Development Organisation
EMBRAPA	Brazilian Agricultural Research Corporation – Embrapa
EPA	Environmental Protection Agency
ERS	ERS Genomics Limited, Dublin
FSII	Federation of Seed Industry of India
GABA	Gamma-amino Butyric Acid
GAP	Good Agricultural Practices
GDP	Gross Domestic Product
GE	Genetically engineered
GEAC	Genetic Engineering Appraisal Committee
GM	Genetically modified
GMOs	Genetically modified organisms
GoI	Government of India
gRNA	Guide Ribonucleic Acid

HOLL	High Oleic Low Linolenic
HT-BT	Herbicide Tolerant BT/ Holistic Technology based BT
IARI	Indian Agricultural Research Institute
IBSC	Institutional Biosafety Committee
ICAR	Indian Council of Agricultural Research
ICRISAT	International Crop Research Institute for Semi Arid Tropics
IIOR	Indian Institute of Oilseeds Research
IP	Intellectual Property
IPM	Integrated Pest Management
IPR	Intellectual Property Rights
MIT	Massachusetts Institute of Technology
MoEF&CC	Ministry of Environment, Forest and Climate Change
NAAS	National Academy of Agricultural Sciences
NABI	National Agri-Food Biotechnology Institute
NARS	National Agricultural Research System
NGOs	Non Governmental Organisations
NIAP	National Institute of Agricultural Economics and Policy Research
NIPB	National Institute of Plant Biotechnology
PPP	Public-Private Partnership
PPVFRA	Protection of Plant Varieties and Farmers' Rights Act
R&D	Research and Development
RCGM	Regulatory Committee on Genetic Manipulation
SAUs	State Agricultural Universities
SDG	Sustainable Development Goals
SDN	Site Directed Nuclease
TAAS	Trust for Advancement in Agricultural Sciences
TALEN	Transcription Activator-Like Effector Nuclease
T-DNA	Transfer Deoxyribo Nucleic Acid
TIGS	Tata Institute for Genetics and Society
UC Berkeley	University of California Berkeley

Stakeholders Dialogue on
Enabling Policies for Harnessing the Potential of Genome Editing in Crop Improvement

CONTEXT

Looking at the Sustainable Development Goals 2030 and beyond, the challenge to feed India's growing population is going to be a major task. India will be the world's most populous country by 2027, surpassing China. In order to meet growing food demand, we would need around 355 mt (FICCI, 2019) of foodgrains by 2030 against the current production of 305 mt, i.e. around 50 mt more or additional 5 mt per annum. In fact, continuing to remain food self-sufficient is going to be a major challenge especially in view of declining availability and quality of our natural resources such as - land, water, and air, besides rising temperature and increasing frequency of floods and droughts due to climate change.

Major breakthroughs in agricultural production in mid-sixties were achieved mainly through breeding of dwarf high yielding varieties of wheat and rice, coupled with good agronomic practices and integrated pest management. Appropriate government policies, intensive research and development (R&D), and innovative extension did facilitate the development and availability of new technologies in order to extend the benefits to farmers and the general public. Continuing with this approach, currently the government is emphasizing on the need for increased productivity and production efficiency. While classical plant breeding ushered in the green revolution, during the past 20 years, molecular breeding has brought further incremental as well as transformational production gains highlighting the need to adopt new innovations to address emerging challenges to agricultural growth and sustainability. In order to ensure this, science-led disruptive innovations have to be scaled faster through right investments, good institutions and enabling policy environment.

Genome editing is one such new tool that enables both precise and efficient modification of an organism's genome. Recently, the two women scientists, Dr Emmanuelle Charpentier of France and Dr Jennifer Doudna of USA, the developers

of CRISPR/Cas9 genome editing technology, received Nobel Prize in Chemistry (2020). CRISPR/Cas9 and other genome editing techniques are currently being used extensively by scientists all over the world to incorporate desirable traits in different crops, including cereals, pulses, oilseeds, fruits and vegetables. These include varieties requiring low inputs like fertilizers, water, insecticides, fungicides and varieties with better nutritional qualities.

Successful examples of improved crops being developed through genome editing are citrus resistant to greening and banana resistant to panama disease; climate-resilient wheat and rice that can grow well under high temperatures as well as submergence and saline soils; tomatoes and ground cherries suited for efficient farming systems indoors and in the field; cassava, rice, wheat, millets, mustard with improved nutrition or low anti-nutritional traits; high oleic low linolenic (HOLL) soybean; non-browning mushroom; blight resistant rice, and gamma-amino butyric acid (GABA) tomato.

Recognizing the potential of gene editing in plants, the Indian Council of Agricultural Research (ICAR), and the Department of Biotechnology (DBT) have initiated programs to harness the desired benefits. DBT is proposing to establish a Centre of Excellence (CoE) and develop a Mission Program on Improved Crop Varieties through Gene Editing. DBT's National Agri-Food Biotechnology Institute (NABI), Mohali (Punjab), is among the first in India to use CRISPR/Cas9 to carry out a change in the phytoene desaturase (fruit ripening) gene of banana cv *Rasthali*. Several ICAR institutes are currently involved in application of CRISPR/Cas9 technology for enhancing stress tolerance and nutritional quality in a number of crops.

Regulation of Genome Editing Technology

In line with the continuous technological advancement and development of genome edited plants, regulatory requirements for such products are also being defined by various countries. Argentina, Australia, Israel, Japan and USA have already notified regulatory procedures to genome editing in plants. In India, activities involving genetic engineering and new gene technologies are regulated under "Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms/ Genetically Engineered Organisms or Cells, 1989 (Rules, 1989)" under the Environment (Protection) Act, 1986. These rules are implemented by the Department of Biotechnology (DBT) and Ministry of Environment, Forest and Climate Change (MoEF&CC). Taking note of the developments in genome editing, DBT prepared a draft regulatory framework and risk-assessment guidelines for genome-edited organisms, which were placed for public comments in January, 2020. Amongst various stakeholders, the National Academy of Agricultural

Sciences (NAAS) provided comments to DBT based on high level consultation and also prepared a detailed Policy Brief "Regulatory Framework for Genome Edited Plants". Key recommendations by NAAS include: i) separate guidelines need to be developed for genome edited plants disaggregating them from those of other organisms, ii) categorization of genome edited plants should be made into internationally acceptable SDN1, SDN2 and SDN3 categories, and iii) SDN1 and SDN2 product categories, being free from foreign DNA and indistinguishable from those developed through conventional breeding, should be exempt from regulation and risk assessment.

The guidelines are presently being reviewed by Genetic Engineering Appraisal Committee (GEAC) in the MoEF&CC. Once approved, research and adoption of genome edited plants is expected to be taken up at rapid pace, which in turn will provide enormous benefits particularly for smallholder farmers. The regulatory system will also align with a large number of countries who have taken a similar position on genome editing and make international seed trade seamless, while also enabling Indian government to make India a global seed hub. Without approval of the guidelines by the GEAC and the Ministry, the public will remain deprived of the benefits of the improved crop varieties developed through genome editing.

Public-Private Partnership

The rapid developments in gene editing technologies and their commercial potential have spurred extensive research and development efforts by both industry and academic institutions. While this trend has given boost to technological developments, it has also necessitated negotiations for use of protected technologies for commercialization of gene editing plants. The International Crops Research Institute for the Semi-Arid Tropics (ICRISAT) has signed a Master Alliance Agreement with Corteva Agriscience to provide access to CRISPR-related resources for genetic improvement to the ICRISAT mandate crops. Corteva Agriscience holds the licence for Massachusetts Institute of Technology (MIT) and Harvard CRISPR technologies. Similar partnerships for acquisition of other genome editing technologies need to be built by other Indian public and private sector organisations engaged in crop improvement either individually or through an umbrella agreement by organizations such as DBT and ICAR.

THE STAKEHOLDERS DIALOGUE

In view of the enormous potential of genome editing technology to enhance productivity and nutritional quality of food and other crops, and the need to develop an appropriate regulatory and partnership environment in the country, the

Trust for Advancement in Agricultural Sciences (TAAS), a neutral 'Think Tank' in collaboration with Indian Council of Agricultural Research (ICAR), National Academy of Agricultural Sciences (NAAS), Biotech Consortium India Limited (BCIL), Tata Institute for Genetics and Society (TIGS), National Agri-Food Biotechnology Institute (NABI) and Biotechnology Industry Research Assistance Council (BIRAC) organized a `Stakeholders Dialogue (virtual mode) on "Enabling Policies for Harnessing the Potential of Genome Editing in Crop Improvement" on 17 March, 2021 with the objective to: i) develop consensus on regulation of genome edited plants and catalyze approval of the regulatory policies; ii) deliberate on the mechanism of access to genome editing technologies for development and commercialization of genome edited crops by public and private sector enterprises; and iii) discuss policy directions for promoting application of genome editing technology for sustainable agriculture. The Dialogue brought together diverse stakeholders from the National Agricultural Research System (NARS), DBT, MoEF&CC, CGIAR centres, other public and private sector organizations engaged in R&D and IP management of biotechnologies. The webinar was attended by over 70 participants representing a cross section of stakeholders including scientists, policymakers, regulators and industry representatives.

Inaugural Session and Setting the Stage

The Stakeholder Dialogue was chaired by Padma Bhushan Dr. R. S. Paroda, Chairman, TAAS, Former Secretary, DARE and DG, ICAR. The deliberations comprised opening session, thematic presentations and a panel discussion by eminent national experts in the field followed by concluding session.

In his opening remarks, Dr. Paroda spoke about the urgent need for innovative technologies in agriculture to meet the challenges of achieving SDGs, particularly to end poverty in all its forms everywhere (SDG1) and to end hunger (SDG2), ensure good health and well-being through improved nutrition (SDG3). He indicated that several programs on plant breeding have helped in crop improvement, and achieving self-sufficiency in food and nutrition. However, there is a need for using innovative technologies to deal with current challenges particularly with respect to climate change, urbanization and need for diversification for meeting nutritional requirements. He spoke about development of CRISPR/Cas technology and its rapid adoption at the global level as a tool to deal with above challenges. He appreciated the initiatives by the DBT, ICAR and NAAS in preparing draft guidelines for genome editing in plants and stressed the need for their early adoption and implementation. He indicated that in addition to streamlining the regulatory requirements for gene editing, issues relating to intellectual property rights (IPR) of the CRISPR/Cas technology also need to be deliberated. He also stressed on the

need for exploring public private partnerships (PPP) for enhancing application of gene editing technology for the benefit of the farmers.

Dr. Rakesh Mishra, Director, CSIR-Centre for Cellular and Molecular Biology (CSIR-CCMB) and Chairman, Review Committee on Genetic Manipulation (RCGM) spoke about how developments in genome sequencing and availability of large information sets are helping in targeted research and development. He opined that regulatory system must be responsive to the advances in technology and innovation and cited the example of COVID vaccine wherein the regulatory system ensured timely approvals for expediting the availability of vaccine for the masses. He further stressed that similar importance needs to be given to expediting regulatory processes in agriculture in order to meet the growing food demand and suggested that regulatory requirements should be commensurate to the technology requirements.

Dr. Renu Swarup, Secretary, DBT addressed the participants through a video message and stressed the need for an enabling ecosystem to take forward applications of gene editing. Elaborating on the key components of such an ecosystem, she stressed the need for required capacity building for both human and infrastructure, skill enhancement through exchange of knowledge at national and international level and streamlining the regulatory system. Dr. Swarup indicated that there is a need for institutions to work in a network mode and also in public private partnerships so as to create trained manpower, enhance capacities and develop new technologies. She informed that DBT has prepared draft guidelines for regulation of gene editing technology and the same are under consideration by GEAC. Efforts are also being made to expedite the adoption of the guidelines.

Dr. T. Mohapatra, Secretary, DARE and DG, ICAR emphasized that the regulatory framework for gene editing needs to be approved at the earliest so that the technology developers in public and private sector have the required clarity. He cautioned that most GM crops have not been able to reach the public in view of complex regulatory process of the country. It is extremely important that the regulatory aspects for gene editing should be dealt with product-oriented approach and the guidelines be approved at the earliest. Expressing concerns over the IPR issues related to genome edited plants, he emphasized on the need for strengthening collaborations and partnerships. He opined that beyond the scientific advancements, there is an urgent need to create awareness among administrators and policymakers about the technology. In addition, initiating national programs, network of public private partnerships and dedicated funding can help in development of products relevant to the country's need in a timely manner.

TECHNICAL SESSION - THEMATIC PRESENTATIONS

The following three thematic presentations were made during the technical session:

- Genome Editing in Crops: Opportunities and Future Strategies by Dr. C. Vishwanathan, Head, Division of Plant Physiology, ICAR-IARI, New Delhi
- Regulatory Guidelines for Genome Editing by Dr. K. V. Prabhu, Chairperson, PPV&FRA, GoI, New Delhi
- IP Protection and Sharing CRISPR/Cas Technology by Dr. Amitabh Mohanty, Corteva Agriscience

Dr. C. Viswanathan spoke about three categories of genome editing in plants, viz., SDN1, SDN2 and SDN3. He gave examples of genome edited plants which have been deregulated in various countries, viz., soybean with high oleic acid, non-browning mushrooms, tomato with prolonged shelf life, waxy corn and also some promising initiatives such as bacterial blight resistant rice from Germany. He informed about research initiatives underway in Indian institutions with support from DBT and ICAR. He indicated that expertise in crop transformation and genome editing is available, but needs to be enhanced. There is also a need for prioritization and initiating mega programs and crop specific centres of excellence. Scientists also need clarity in IP/patent issues and scientifically appropriate regulations.

Dr. K.V. Prabhu informed about the key features of the regulatory guidelines for genome edited plants prepared by a committee under his chairmanship. He indicated that the guidelines provide for separate regulatory requirements for three categories of genome edited plants, viz., SDN1, SDN2 and SDN3. Exemption of SDN1 and SDN2 plants from Rules, 1989 has been recommended, whereas SDN3 plants will be subjected to the same regulatory requirements as for genetically engineered (GE) plants. The proposed data requirements for SDN1 and SDN2 genome edited plants include: i) plant species and its relatives, purpose of the experiment including the targeted genomic region for mutation with expected trait variant, ii) transformation/transient expression method and nucleases used, iii) characteristics and molecular mechanisms of editing used and their mode of action, type of breaks (single or double strand), iv) proof of claim that edited plant is SDN1 or SDN2 type, v) molecular characterization of changed region at the target site, and vi) comparative expression profile of target gene and/or product before and after editing. The application and products of SDN3 gene editing technology are proposed to be subject to regulation under the Rules, 1989, in the same manner as GE plants. He further pointed out the challenges in registration of such plants under PPV&FRA.

Dr. Amitabh Mohanty informed that under their open innovation policy, Corteva Agriscience and the Broad Institute of MIT and Harvard have joined hands to provide non-exclusive licenses to CRISPR-Cas9 technology for use in agricultural applications. The IP coverage includes Foundational patent families from the Broad Institute, DuPont Pioneer/Corteva, Vilnius University, UC Berkeley, University of Vienna and ERS Genomics. He further explained that the license terms are flexible and royalties are adapted to the activities chosen and the size of the licensees with preferential terms for Not-For-Profit/Public research organizations. Further licensees maintain the ability to seek independent licenses from the Broad Institute, from Corteva or from third parties. He informed that there are stewardship requirements i.e. no work in tobacco, gene drive, terminator technology, herbicide tolerance not preferred etc. He further informed that open innovation collaboration has already been signed with various public sector institutions such as CIMMYT, ICRISAT, Danforth Center, EMBRAPA, etc.

PANEL DISCUSSION

The panel discussion on 'Future Road Map' on policies for harnessing the potential of genome editing in crop improvement was moderated by Dr. T. R. Sharma, Deputy Director General (Crop Sciences), ICAR and involved eleven discussants, namely, Dr. Deepak Pental, DU-Centre for Genetic Manipulation of Crop Plants, New Delhi; Dr. Ram Kaundinya, Federation of Seed Industry of India, New Delhi; Dr. C. D. Mayee, South Asia Biotechnology Centre, New Delhi; Dr. A. K. Singh, ICAR-IARI New Delhi; Dr. Rajeev Varshney, ICRISAT Patancheru; Dr. Bharat Char, Mahyco; Dr. Ashwani Pareek, NABI, Mohali; Dr. K. C. Bansal, NAAS, New Delhi; Dr. Vibha Ahuja, BCIL, New Delhi; Dr. S. K. Dasgupta, TIGS, Hyderabad and Dr. Sanjay Saxena, BIRAC, New Delhi.

Dr. Deepak Pental opined that there is an urgent need for enhancing competence in the country for application of advanced genome technologies. He pointed out that:

- Genome editing is a new generation technology which should flow through the system, strategies should be implemented in such a way that brings forwardness for open research.
- Recommendations by NAAS should be adopted at the earliest. To expedite their implementation, NAAS may draft another resolution reminding the Government of the need of the new technologies.
- International terminology SDN1, SDN2 and SDN3 should be adopted. SDN1 and SDN2 should be handled as recombinant DNA work with Institutional Biosafety Committee (IBSC) making sure the material is grown under confinement till

T-DNA is removed by segregation. In case only protein and gRNA has been used, the material can be grown in open.

- Gene editing projects cleared by IBSC should be reported to the RCGM to develop a national database on what work is going on and where in the country, and the funding source. IBSC should meet once every 3 months. Their performance should be monitored by the RCGM.
- Patents cannot be granted on products developed with the gene editing enzymes. Only the enzymes can be covered like restriction enzymes, DNA polymerase, etc. Technologies like *Agrobacterium* based transformation protocols and method to produce cotton transgenics were not provided patent protection in India. Similarly, human cDNAs were not given protection by the US Supreme Court.
- There is a need for building capacities and good laboratories to attain competencies in this area starting from basics such as good genetic transformation protocols.

Dr. Ram Kaundinya highlighted the urgent need to finalize regulatory guidelines for genome edited crops and make the regulatory framework clear. Prolonged uncertainty prevents private sector investments in new technologies. He informed that Federation of Seed Industry of India (FSII) is of the opinion that "Plant varieties developed through the latest breeding methods should not be differentially regulated if they are similar or indistinguishable from varieties that could have been produced through earlier methods." A consistency can be established by not regulating products of gene edited plant phenotypes that have been, or can be achieved using conventional plant breeding techniques (which includes mutagenesis techniques). He opined that:

- The regulation should not be prohibitive and constrain the product development using innovative technologies. Too much regulation only helps big companies and is restrictive for public sector and small companies. Timelines must be introduced for regulatory approvals.
- SDN1 and SDN2 should not be regulated/controlled in regulation as these are equivalent to conventional breeding system.
- Guidelines for gene editing must be consistent with the approach being adopted in other countries. Regulatory authorities must recognise credibility and consistency of private industry and research-based companies for investment and promotion.
- There must be alignment between state and centre on regulatory guidelines and policy. Lack of political projection of the technology must be avoided for

confusion free solution and decisions to promote smooth sailing of the upcoming technologies.

- A public outreach program is required on safety and benefits before introduction of gene editing and approval of products, not just for farmer groups but also for consumers and general public.
- PPP model for accessing the technology should be developed to work jointly and facilitate usage.
- Stand-alone research labs as outsourcing agency or contract research institutes may be established jointly with/funded by public and private institutions.

In his remarks, **Dr. C. D. Mayee** said that genome editing research is considered a revolutionary step forward in biological sciences and therefore it has special significance in agriculture. Genome editing technologies have been projected as a game-changer as these can improve yield, increase food diversity, nutrition, develop disease-pest resistance, control food waste, mitigate the effects of climate change and thus support sustainable agriculture. When India is still in "Debate- Caveat" mode in deciding the commercial applications of GM technologies such as Bt brinjal, GM-mustard, HT-BT cotton, golden rice, the genome editing technologies has hit the doors of researchers with a big bang. Indian scientists have shown the capabilities in GM research and certainly are well prepared for the use of the current genome editing tools for crop improvement. However, there is overall apprehension as to what will happen to the end product derived out of this technology. He pointed out that: i) the experience with GM crops has clearly indicated that if a technology is of benefit for farmers, then the farmers will adopt it and may not wait for approvals e.g., HTBT cotton grown in Maharashtra and Telangana states, despite not approved so far; and ii) in view of benefits of genome editing technology, products need to be promoted. At the same time regulatory framework should be simple so that smallest of institutions/companies could promote their products and bring to the market.

Dr. A. K. Singh, Director, ICAR-IARI New Delhi was of the opinion that: i) in view of extensive potential of the technology, particularly for public good, the licensing of gene editing technology must be considered on priority; ii) SDN1/SDN2 vs. SDN3 are typically following different application pathways as per proposed guidelines; situations like when the gene is not present in plant and obtained from same gene pool or sources should also be discussed; and iii) prime editing and base editing is equivalent to SDN1 and the same is not mentioned in the earlier recommendations by NAAS. It should be included at GEAC level.

Dr. Rajeev Varshney opined that there is need to work in both landscapes of gene editing i.e. research and regulatory aspects and stressed on the following points:

- In the research areas, there is a need to have efficient transformation systems across the crop species and identify the "casual" genes for various traits. This is possible now due to availably of large-scale sequencing data, advances in high-throughput- precision phenotyping and possibility of undertaking multi-omics and systems biology approaches. A success story is of gene editing of SWEET genes for development of broadly resistant lines for bacterial wilt by IRRI, Heinrich Heine University, Germany and University of Missouri USA, wherein genomes of different isolates of *Xanthomonas* and 3,000 rice genomes were surveyed extensively that helped to identify the target sites in SWEET genes. India should also undertake such studies. More attention should be paid on the SDN1 technologies with a focus on base editing and prime editing.
- Possibilities of identifying the deleterious alleles and editing may also be explored for minimizing the impact of such alleles and enhancing agronomic performance.
- India needs to come up with clear policies so that research community and all stakeholders will be well informed to develop the products and take them through regulatory process.
- Outreach and communication are very important to ensure dissemination of factual information and develop public trust about the technology and acceptance of the gene editing products.

Dr. Bharat Char from Mahyco pointed out that Innovation in plant breeding is essential and equally important is the speed at which we can bring these innovations to the farm. He highlighted the following important points:

- Regulation of new breeding techniques should be necessary only if there is a significant change, so we should have product-based regulation. GoI/Regulator should take a product-based and globally harmonised approach in order to mitigate trade-based issues.
- In order to achieve expected use of the technology commercially, freedom to operate is a must. Industry is not prepared to invest unless a predictable path forward is visible. GoI should have proactive role both in engaging with IP holding entities, as well as in facilitating an enabling regulatory environment around the technology. This could be taken up in a public-private partnership (PPP) mode or have a subscription based or royalty-based model.

Dr. Ashwani Pareek, NABI Mohali said that precise editing of genes and genomes, especially using CRISPR/Cas, has allowed tremendous advancement in crop improvement. In addition to major crops, this technology can be very useful for

polyploids, as well as species with long cycle duration, which requires extensive back-crosses. Dr Pareek emphasised on the following major points:

- It is critical to develop centres dedicated to genome editing preferably at institutes where basic infrastructure and prior expertise for crop editing exist, with facilities for plant tissue culture and transformation, growth chambers, greenhouse and nethouses (with facilities for speed breeding). Bioinformatics and wet lab capabilities for vector development should also be provided in these selected centres. Workshops and comprehensive training programs within the country and short-term training in India and abroad need be managed to generate world-class human resource.
- DBT may negotiate with the developers of the original CRISPR/Cas technology for freedom-to-operate facility for commercial applications within the country. This will be a unique 'One Nation One Licence' experiment similar to 'One Nation One Subscription' being advocated for the journals in the new Science and Technology Policy (STP).
- Priorities can be given to crops whose reference/draft genome sequences have been reported, as it will allow precise designing of targets and the downstream efficient molecular analysis.
- A centralized repository for newly developed vectors and reagents need be created in the country. This will help laboratories that are newly practising the genome-editing field.
- Special funding provision needs to be made for the development of novel genome editing tools. It includes isolating novel endonucleases with higher specificity and better activity, codon optimizing the novel endonucleases for use in specific crops, novel vectors including those with promoters for somatic embryogenic-stage and apical meristem specific expression of Cas9, novel gene delivery mechanisms like using growth-promoting factors for non-tissue-culture and non-transgenic approaches, reference genomes of crops of interest, protoplast-based regeneration and editing to generate transgene-free edited stable lines, use of DNA-free genome editing tools, software and algorithms for designing guide RNAs and detection of edited lines.
- Over the next five years, dedicated research programs need to be supported to overcome delivery mechanisms, vector designing, transgene-free and knock-in gene editing with economically important traits as well as improving the efficiency of complex edits such as SDN2 and SDN3 type.
- Make a mission mode program to develop genome-edited crops with economically important traits. Ten such lines (each line is one crop/one trait) will be available in five years for field testing as per regulatory norms.

In his remarks, **Dr. K. C. Bansal,** NAAS suggested the following priority actions:

- A national level mission mode program on genome editing should be developed cutting across crops, livestock and micro-organisms for sustainable agriculture with direct funding from Government of India with the following two objectives: i) carry out basic research to promote innovation and new discoveries, and ii) product development for commercialization.
- Capacity building and human resource development should be strengthened to take advantage of genome editing technology.
- Science-based regulatory system need to be adopted that is predictable, transparent, dynamic and interactive.
- IP-free access should be provided for all reagents, ingredients and processes for enhanced use of the technology in basic research as well as for product development.

Dr. Vibha Ahuja, BCIL, New Delhi pointed out that the basis of regulatory approach proposed to be adopted for genome editing in plants need to be communicated extensively to the concerned stakeholders, particularly policymakers, politicians and general public. A separate document, preferably a 'White Paper' must be prepared and circulated to highlight the rationale for suggested regulatory approach, particularly exemption for SDN1 and SDN2 categories. Further, a communication plan should be in place for reaching out to all concerned for ensuring acceptance of the suggested approach. Consistency with the approaches being adopted in other countries, particularly trading partners is extremely important to ensure harmonization. Asynchronous approval will not only be a major hindrance for trade and enforcement of regulations, but will also put local developers to disadvantage. The data requirements for seeking approvals/ exemptions should also be consistent with other countries, so that it is a level playing field for both local developers and importers. In addition to licensing of the technology, possibility of developing an open-source platform should also be initiated through the public sector institutions.

Dr. S. K. Dasgupta, TIGS, Hyderabad remarked that, i) scientific and technology information exchange is extremely important for adoption of innovative technologies, ii) community outreach program is essential for successful deployment of the technology. It is important to be open and recognise concerns of the stakeholders, and iii) digital modes of information should be explored for wider outreach.

Dr. Sanjay Saxena, BIRAC, New Delhi gave the following suggestions:

- In agriculture sector, it is difficult to engage small companies particularly start-ups in view of IP and regulatory aspects. Taking into account various challenges such as technical complexities, long gestation, higher cost, etc, and not so well-defined regulatory policy and IPR regime for commercializing of final product, it would be difficult for any private company to take this technology forward on its own. This is more so for small 'start-ups'/ companies who have very limited resources (both technical and financial) at their disposal. Therefore, it would be prudent for the academic/research institutions to take lead in researching in this important upcoming area of plant biotechnology.
- Realizing the fact that involvement of industry is a must for commercialization of final product, PPP would be very crucial. However, to ensure wider participation of the industry, policies should be so formulated that facilitate wider participation of the industry particularly start-ups. Exchange of scientific knowledge by industry and academia is also quite important and needs to be given priority attention.
- There are several species where there is a need to apply this technology, but efficient *in vitro* regeneration protocols are not available for them. Therefore, while prioritizing the crops and the traits, it would be desirable to ensure that *in vitro* procedures for regeneration for those crops are in place.
- Since this technology involves multiple skill sets of high standards which may not be available with a single institution, a consortia-based approach for maximum output in minimum time duration could be adopted.
- In the genome editing network projects, it is important to assign work with specific objectives to various institutions like tissue culture, molecular characterization, etc. since all institutions cannot cover every aspect of research.

GENERAL DISCUSSION

Dr. N. K. Singh, National Professor (Dr. BP Pal Chair), ICAR-NIPB, New Delhi opined that the proposals with GEAC for approval of the guidelines should include freeing SDN1 and SDN2 type gene edited plant products from regulation since it is not possible to regulate these due to absence of trans genes.

Dr. S. R. Bhat, Former Principal Scientist, ICAR-NIPB, New Delhi suggested; i) genome editing should be taken mainly as a translation project to improve crops while basic research on genome editing and its feeder systems (functional genomics,

pangenomics, etc.) could be pursued under standard competitive grant programs. Translational projects should be taken up in mission mode; ii) Government (DBT/ ICAR & other stakeholders) should come out with priority crops and traits so that both public and private players could come forward with their individual or joint programs. In particular, developing genome edited crops for fertilizer and water use efficiency could lead to enormous direct and indirect benefits (environment/health) and this could be the basis for demanding a special fund for this initiative. There should be consensus on crops and traits for genome editing to avoid problems in trade and commerce; iii) IPR issues are going to be critical considering the fact that genes governing most of the traits that are targets for editing are under patent. So, a strong support to researchers to navigate through the IPR web before they embark on genome editing is essential to ensure that they do not face handicap after developing a product; iv) tissue culture is still a major stumbling block in most crops. In particular, genome editing is the most relevant to clonally propagated, perennial crops where even conventional plant breeding cannot be efficiently applied. There is a serious deficiency of expertise in this area and a special drive to identify new qualified people to develop protocols for important crops is needed; v) efficient nationwide testing systems for genome edited crops are needed. Field scale trials should be allowed along with conventional varieties once the researchers show that events are free from non-target effects based on genome sequence information.

Dr. K. S. Varaprasad, Former Director, ICAR-IIOR, Hyderabad opined that the reason behind failure of bringing GM Crops to the farmer level was due to: i) limited budget from the ICAR, and other funding agencies and thin fund distribution across the NARS (more than 100 laboratories) without long-term focus on tangible products; ii) NGOs/ CSOs role in societal acceptance was undermined by the investors both in public and private sectors; iii) select groups of scientific community partly contributed to negative opinion on genetically modified (GM) crops, instead of highlighting countries that harvested the benefit of GM Crops, that led to public confusion and added strength to NGOs/ CSOs that were against GMs; and lastly iv) political parties were generally more influenced by NGOs/CSOs, while even good scientists and scientist leaders alienated themselves from politicians and were only spectators to negativity on GM crops. First GM crops should have been released by the public sector exclusively or jointly with the private sector. Trust in public sector research in agriculture is even today very high compared to the private sector. Importance and role of IBSCs without any budgetary support needs attention at least from ICAR.

Dr Kiran Sharma, ICRISAT emphasised the need for more such events to sensitise various stakeholders, and ensure that this technology is not boxed like

the GM technology. In fact, going forward, gene editing should be considered as a routine intervention in plant breeding like any other enabling technology.

Dr J. L. Karihaloo emphasized that: i) research on gene editing should be initiated in a mission-mode with appropriate fund allocation, ii) list of crops and traits must be prioritized for undertaking work on genome editing, and iii) outreach programs are required for policymakers as well as farmer groups and associations.

Dr Bhag Mal highlighted the need for: i) bringing out a 'White Paper' or high-level policy paper in order to create awareness about the benefits and usefulness of this innovative technology, and ii) a well-organized capacity building program and strengthening of institutional infra-structure must be taken-up by ICAR to facilitate technology development and dissemination at all levels and in all related areas of genome editing.

Dr Umesh Srivastava emphasised that genome editing is relevant to clonally propagated crops where application of conventional crop breeding is slow and cumbersome, also regeneration by tissue culture in such crops is difficult or very limited and thus, it may be beneficial to design methodologies that do not require regeneration. Also, there is a need to take into account government regulations and consumer acceptance around the use of these new gene-editing technologies.

CONCLUDING SESSION

In his concluding remarks, **Dr. T.R. Sharma,** DDG (Crop Sciences), ICAR thanked all the panellists and discussants for sharing their views. He indicated that the product development approach should be trait driven. The regulatory procedure should be simple and clearly understandable. Capacity development program must be strengthened with involvement of relevant institutions, centres and platforms. Dr. Paroda, in his concluding remarks, mentioned that it is the right time to act rather than only talking. He emphasized on the need for a mission-mode inter-institutional platform for genome editing with adequate funding provision. He also expressed the urgency for the clearance of genome editing guidelines by the GEAC on priority and if necessary, an Inter-Ministerial Committee be constituted to push forward the clearance of guidelines. He also thanked all the participants and highlighted the need to bring out a "Policy Brief" giving salient recommendations made during the dialogue which will be communicated to the policymakers and other concerned authorities for expeditious action. The dialogue ended with a vote of thanks by Dr JL Karihaloo to the distinguished invitees, Co-Chairs, Chair, Moderator, Speakers, Panelists and Participants.

SALIENT RECOMMENDATIONS

Based on in-depth discussion during the Stakeholders Dialogue, it was strongly felt that to harness the potential of genome editing in crop improvement and ensure food and nutritional security, there is an urgency to have in place an action plan on research and developmental (R&D), and policy related issues. The key recommendations that emerged from the Dialogue are placed below:

I. Research and Development

1. Greater national effort to apply genome editing technology for targeted crop improvement by all concerned organisations/institutions such as DBT, ICAR, CSIR, DST, DRDO and State Agricultural Universities (SAUs), through a national flagship program/platform is strongly recommended for which initial funding of Rs 1,000 crore be provided as a special grant. This could be a Mission Mode program with defined targets and outcomes in next 5 years monitored jointly by DBT and ICAR.
2. Sustained success in the application of genome editing for crop improvement requires good competence in the editing technology as well as other related technologies including tissue culture and gene sequencing. Thus, there is a need to develop protocols for identifying "causal" genes for various traits through large-scale sequencing, high throughput precision phenotyping and multi-omics and systems biology approaches. The target genes for editing should not only be the ones that confer superior traits but also those that have deleterious agronomic or nutritional impacts. Similarly, sequence information on wild species can provide clues to homologues of resistance genes in susceptible cultivated species that could be candidates for genome editing.
3. Tissue culture and transformation protocols are still major stumbling blocks in many crops. Genome editing is also relevant to clonally propagated and perennial crops where application of conventional crop breeding is slow and cumbersome. There is also a serious deficit of expertise in this area and special drives to identify experts to develop tissue culture protocols for important crops are needed.
4. A mission-mode inter-institutional platform comprising centres of excellence on genome editing for specified crops be established on priority having mandate to: i) develop novel and more efficient genome editing tools, and have a national repository for newly developed vectors and reagents, ii) develop genome edited crop varieties with desired traits for commercialization, and iii) build required human resource to effectively use genome editing in crop improvement.

5. A strong support to researchers to negotiate through the IPR web before embarking on genome editing projects is essential. Appropriate central government agency like DBT or ICAR should negotiate with developers of CRISPR/Cas9 and other genome editing technologies for freedom-to-operate national licenses to commercialize the products within the country. At the same time, research should be pursued actively to develop new open-source platforms for gene editing through collaborations with national and international institutions.
6. Outreach and effective communication strategy for much-needed positive public perception is critical to reap the benefits of genome edited products. This would demand well-organized public awareness campaigns to ensure acceptance both by consumers and farmers. The role of NGOs/CSOs in creating the right perception needs to be appreciated and their involvement encouraged. Many organizations, namely, DBT, ICAR, NAAS, BIRAC, BCIL, TIGS, ICRISAT, CGIAR have been doing phenomenal work in disseminating information about gene editing to various stakeholders which needs to be accelerated further. In addition, a Status Paper on benefits of genome editing will help in creating needed awareness and ownership of this new technology.
7. Public-private participation (PPP) needs to be strengthened through incentives and enabling policy support by the government. Also, an effective coordination between the state and central government is needed to harmonise decisions relating to use of genome editing and commercialisation of end products. Collaborative network projects with targeted crops and traits may be initiated and infrastructure shared between public and private organizations for this purpose. Laboratories need to be set-up in PPP mode which provide outsourcing opportunities for small companies to undertake genome editing work on crops of their choice. This will help in creating a level playing field for all companies involved in the business.

II. Regulations and Enabling Policies

8. Draft regulatory guidelines on genome editing as recommended by the DBT, using a consultative process involving NAAS and reviewed by RCGM, be cleared without delay by the GEAC. This will ensure quick government approvals for scaling the technology in the national interest.
9. The products of genome editing that are shown to contain no foreign genetic material (SDN1) or whose altered genetic material is indistinguishable from natural gene pool, or is sourced from primary or secondary gene pool (SDN2), be exempted from biosafety testing as otherwise prescribed under the existing

"Rules for the Manufacture, Use/Import/Export and Storage of Hazardous Micro Organisms/ Genetically Engineered Organisms or Cells (Rules, 1989)". Hence, the genome edited plants exploiting available genetic variability within the same genus (cis) be simply treated as products of normal breeding method, such as mutation, and be allowed for cultivation like normal varieties/ hybrids.

10. Regulation should be consistent with the evolving regulatory and policy landscape in various countries. Disproportionate regulatory requirements and delays will lead to stagnation in research and development. It will specifically hamper the product pipeline of smaller companies which can't afford higher regulatory costs and delays as it happened with the GM crops. If highly regulated, the technology will be concentrated among few big companies who can afford to invest significantly higher amount of funds. On the other hand, if there are practical regulations or exemptions, then it would stimulate product development and investment by smaller companies. This will also lead to newer products in crops especially vegetables where the new varieties have shorter market life cycle.
11. International terminology on categorization of GE products, SDN1, SDN2 and SDN3 should be followed. As all the three involve rDNA work, reporting to IBSC/RCGM should be a requirement. In case of SDN1 and SDN2 products, IBSC should make sure that the material does not contain T-DNA or is grown under confinement till T-DNA is removed by segregation. Thereafter, the material can be grown in open and should not need any environmental regulation.
12. IBSCs need to be strengthened and funded well to undertake its responsibilities more effectively. IBSC should meet every three months and its work monitored by the RCGM. Genome editing projects cleared by IBSC should be reported to the RCGM to develop a national database on the subject.
13. Research community and all stakeholders need to be well informed about the regulatory process for genome edited product development.
14. Gene edited foods should not be subjected to additional food safety approvals as long as they have similar composition to their counterparts from conventionally bred crops.
15. As a policy matter, there should be a central authority to develop agriculture policy which may include adoption on modern breeding techniques. There should be alignment between Centre and States and among different political parties on the safety and benefits of this technology so that it will ensure smooth regulatory approvals and commercialization. We should avoid the mistakes we made with GM crops on this front.

Annexure I

Technical Program

17 MARCH 2021 (14.00-18.00 HRS)

14.00-15.05	**OPENING SESSION** ***Co-Chairs:*** **T Mohapatra,** Secretary DARE & DG ICAR **Renu Swarup,** Secretary DBT	
14.00-14.20	**Welcome & Setting the Context**	**RS Paroda,** Chairman, TAAS
14.20-14.35	Special Remarks	**Rakesh Mishra,** Director, CCMB & Chairman, RCGM
14.35-15.05	Co-Chairs' Remarks	**Renu Swarup,** Secretary, DBT **T Mohapatra,** Secretary, DARE & DG, ICAR
15.05-16.05	**Technical Session: Research, Development and IP Management** ***Chair:*** **RS Paroda,** Chairman,TAAS	
15.05-15.25	Genome Editing in Crop Plants: Opportunities and Future Strategy	**C Viswanathan,** Head, Div of Plant Physiology, IARI
15.25-15.45	Regulatory Guidelines for Genome Editing – Way Forward	**KV Prabhu,** Chairperson, PPV&FRA
15.45-16.05	IP Protection and Sharing CRISPR/ CAS Technology	**Amitabh Mohanty,** Corteva Agriscience
16.05-17.05	**Panel Discussion on Future Road Map** ***Moderator:*** **TR Sharma,** DDG (CS), ICAR *Panelists (5 Min. each)*	
	Deepak Pental, CGMCP **Ram Kaundinya,** FSII	

	CD Mayee, SABC **AK Singh,** IARI **Rajeev Varshney,** ICRISAT **KC Bansal,** NAAS **Bharat Char,** Mahyco **Ashwani Pareek,** NABI **Vibha Ahuja,** BCIL **SK Dasgupta,** TIGS **Sanjay Saxena,** BIRAC	
17.05-17.55	**General Discussion & Concluding Remarks**	**TR Sharma,** DDG (CS), ICAR **RS Paroda,** Chairman, TAAS
17.55-18.00	**Vote of Thanks**	**JL Karihaloo,** Trustee, TAAS

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9. A Road Map on Policy Framework for Increasing Private Sector Investments in Agriculture and Enhancing the Global Competitiveness of Indian Farmers, December, 2019.
10. Crop Biotechnology for Ensuring Food and Nutritional Security – Strategy Paper by Dr J.L. Karihaloo and Dr R.S. Paroda, December, 2019.
11. National Dialogue on Land Use for Integrated Livestock Development –Proceedings and Recommendations, 1-2 November, 2019.
12. Horticulture for Food and Nutritional Security - Strategy Paper by Dr K.L. Chadha and Dr V.B. Patel, October, 2019.
13. Urgency for Scaling Agricultural Innovations to Meet Sustainable Development Goals (SDGs) – Strategy Paper by Dr R.S. Paroda, April, 2019.
14. Tenth Foundation Day lecture on "Can India Achieve SDG 2 – Eliminate Hunger and Malnutrition by 2030" by Dr Prabhu Pingali, Professor in the Charles H. Dyson School of Applied Economics and Management at Cornell University, January 24, 2019.
15. Motivating and Attracting Youth in Agriculture - Strategy paper by Dr R.S. Paroda, November, 2018.
16. Road Map on Motivating and Attracting Youth in Agriculture (MAYA), November, 2018.
17. Regional Conference on Motivating and Attracting Youth in Agriculture (MAYA) - Proceedings and Recommendations, August 30-31, 2018.
18. Brainstorming Meeting on Harnessing Intellectual Property to Stimulate Agricultural Growth – Proceedings and Recommendations, July 27, 2018.
19. Women Empowerment for Agricultural Development - Strategy Paper by Dr R.S. Paroda, May, 2018.
20. Policy Brief on Agricultural Policies and Investment Priorities for Managing Natural Resources, Climate Change and Air Pollution - April, 2018.
21. Strategy for Doubling Farmers' Income - Strategy Paper by Dr R.S. Paroda, February, 2018.
22. Livestock Development in India - Strategy Paper by Dr A.K. Srivastava, Member, ASRB & Trustee, TAAS, February, 2018.
23. Policy Brief on Scaling Conservation Agriculture in South Asia, December 2017.
24. Indian Agriculture for Achieving Sustainable Development Goals -Strategy Paper by Dr R.S. Paroda, October, 2017.

25. Retrospect and Prospect of Doubling Maize Production and Farmers' Income – Strategy Paper by Dr N.N. Singh, September 10, 2017.
26. Regional Policy Dialogue on Scaling Conservation Agriculture for Sustainable Intensification, Dhaka, Bangladesh, September 8-9, 2017.
27. Policy Brief on Efficient Potassium Management in Indian Agriculture,August 28-29, 2017.
28. National Conference on Sustainable Development Goals: India's Preparedness and Role of Agriculture, May 11-12, 2017.
29. Delhi Declaration on Agrobiodiversity Management – Outcome of International Agrobiodiversity Congress 2016, November 6-9, 2016.
30. Awareness-cum-Brainstorming Meeting on Access and Benefit Sharing –Striking the Right Balance – Proceedings, October 22, 2016.
31. Round Table Discussion on Promoting Biotech Innovations in Agriculture and Related Issues - Proceedings & Recommendations, August 4, 2016.
32. National Dialogue on Innovative Extension Systems for Farmers' Empowerment and Welfare - Road Map for an Innovative Agricultural Extension System, December 17-19, 2015.
33. Regional Consultation on Agroforestry: The Way Forward - New Delhi Action Plan on Agroforestry, October 8-10, 2015.
34. National Dialogue on Efficient Management for Improving Soil Health -Soil Health Declaration, September 28-29, 2015.
35. The Ninth Foundation Day Lecture on "21st Century Challenges and Research Opportunity for Sustainable Maize and Wheat Production" by Dr Thomas A. Lumpkin, Former DG, CIMMYT, September 28, 2015.
36. Recommendations of Brainstorming Workshop on "Up-scaling Quality Protein Maize (QPM) for Nutrition Security", May 20-21, 2015.
37. Strategy Paper on "Need for Linking Research with Extension for Accelerated Agricultural Growth in Asia" by Dr. R.S. Paroda. September 25, 2014.
38. The Eighth Foundation Day Lecture on "Sustainable Agricultural Development – IFAD's Experiences" by Kanayo F. Nwanze, President, IFAD, August 5, 2014.
39. Recommendations of Brainstorming Workshop on "Soybean for Household Food and Nutrition Security", March 21-22, 2014.
40. Proceedings of Brainstorming Workshop on "Strategy for Conservation and Productivity Enhancement of Farm Animal Genetic Resources", January 10, 2014
41. Proceedings and Recommendations of National Workshop on "Outscaling Farm Innovation", September 3-5, 2013.
42. Strategy Paper on "The Indian Oilseed Scenario: Challenges and Opportunities" by Dr. R.S. Paroda. August 24, 2013.
43. Proceedings and Recommendations of Brainstorming on "Achieving Inclusive Growth by linking Farmers to Markets, June 24, 2013.
44. A Brief report of Dr. M.S. Swaminathan Award function, June 24, 2013.
45. Strategy Paper on "Managing our Water Resource for Increased Efficiency" by Dr. R.S. Paroda, May 28, 2013.
46. Proceedings and recommendations of "Foresight and Future Pathways of Agricultural Research through Youth", March 1-2, 2013.


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