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

CONCEPT NOTE

Background

India has achieved major breakthroughs in agricultural productivity largely through proactive adoption of new crop breeding, cultivation and protection technologies. Appropriate R&D, regulatory and other policies have greatly facilitated the development and availability of such technologies and delivery of the resultant benefits to farmers and the general public. Continuing with this approach, the current government's Strategy for New India @ 75[1] clearly emphasizes the need for modernizing agriculture to increase productivity and production efficiency. While classical plant breeding ushered in the green revolution, and molecular breeding brought further incremental as well as transformational genetic gains in the past 20 years, there is an urgent need to adopt more innovative tools for providing solutions to the new and emerging challenges, particularly climate change and nutritional security[2]. The use of frontier disruptive technologies and situation-specific innovations is thus required to build diversified, secondary and specialty agriculture and tackle the rising concerns of post-harvest losses, nutritional quality and safety of food in the face of climate change and declining profits and above all the adverse impact on food systems due to COVID-19 pandemic.

Genome editing is a new tool on the horizon that enables both precise and efficient targeted modification of an organism's genome. 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[3].These include varieties requiring low inputs like fertilisers, water, insecticides, fungicides or those that have better nutritional qualities. Some examples are pest-resistant crops (resistant to citrus greening and panama disease of banana), climate-resilient crops that can grow well under higher temperatures, submergence and saline soils (wheat and rice), plants with architecture suited for efficient farming systems indoors or in the field (tomatoes and ground cherries) and crops with improved nutrition or lower anti-nutritional traits (cassava, rice, wheat, millets, mustard). The first genome edited crops approved for use globally included improved soybean oil and non-browning mushrooms. Recently, blight resistant rice has been permitted for use in USA and Colombia.

Recognizing the enormous potential of genome editing applications in plant improvement, the Department of Biotechnology (DBT) is proposing to establish a Centre of Excellence and

[1] https://niti.gov.in/sites/default/files/2019-01/Strategy_for_New_India_2.pdf

[2] Discussion Paper: Science, Technology and Innovation at National Dialogue - Indian Agriculture Towards 2030: Pathways for Enhancing Farmers' Income, Nutritional Security and Sustainable Food Systems(https://niti.gov.in/sites/default/files/2021-01/5-Abstract-Final-STI-Policy-English.pdf)

[3] Financial Express, November 16, 2020, CRISPR-Cas9: Applying gene editing in agriculture by Dr. R.S. Paroda (https://www.financialexpress.com/opinion/crispr-cas9-applying-gene-editing-in-agriculture/2129069/)

develop a Mission Programme on Improved Crop Varieties through Gene Editing[4]. 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 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 applications of genome editing, regulatory requirements for such products are also being defined by various countries. Argentina, Australia, Israel, Japan and USA have already notified regulatory approaches to genome editing in plants. For example, in USA[5], products developed through genome editing under most conditions have been exempted from regulatory obligations imposed on GM crops. In Canada, no new regulatory approach is required, as it follows product specific regulations. In European Union, on the other hand, genome editing is to be considered in the same way as GMOs, a decision based on court ruling. Preparation of draft guidelines are at advanced stages of discussion in other countries e.g., Kenya and the Philippines.

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 (MoEFCC). 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, 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:

- Separate guidelines need to be developed for genome edited plants disaggregating them from those of other organisms.
- Categorization of genome edited plants should be made into internationally acceptable SDN1, SDN2 and SDN3[6] categories.
- SDN1and SDN2product categories, being free of 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)[7].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. However, once approved, genome editing technology adoption will accelerate the process of plant breeding and provide enormous benefits to smallholder farmers as well as the nation. It will also align with a large number of countries who have taken a position on gene-editing and make international seed trade seamless, while also enabling Indian government to make India a global seed hub[3].

[4]DBT National Biotechnology Development Strategy 2020-2025 (Draft)

[5]The Sustainable, Ecological, Consistent, Uniform, Responsible, Efficient(SECURE) rulehttps://www.aphis.usda.gov/brs/fedregister/BRS_2020518.pdf

[6]Three categories of products based on the joining type of double-strand breaks created by site-directed nucleases (SDN) gene editing

[7]http://geacindia.gov.in/decisions-of-GEAC-meetings.aspx

Public-private partnership

The rapid developments in gene editing technologies and their commercial potential have spurred bioenterprise development in 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 derived products. The ICRISAT (India) 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 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 ICRISAT.

Issues for discussion

While classical plant breeding is the most widely used approach in crop improvement, it is labor intensive and usually takes several years to progress from the early stages of screening phenotypes and genotypes to the first crosses and finally into commercial varieties. The use of GM technology, though highly promising, has been restricted to small number of cultivated crops and countries, due to biosafety issues and high costs of regulatory compliance. Further, there have been delays in decision making due to prevailing policy direction. Contrary to this, genome editing in plants, as a promising new tool, has significant potential for crop improvement in terms of speed, adaptation, resilience, and end-use. In fact, several novel breakthroughs are now possible through genomeediting. Further, being cost effective, the technology is expected to be of great use to public sector research institutions and also private R&D organizations. Hence, there is an urgency for defined policy direction to harness the unique opportunity of genome editing in crop plants.

The Dialogue

In view of above, 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 of India Ltd. (BCIL), Tata Institute for Genetics and Society (TIGS), National Agri-Food Biotechnology Institute (NABI) and Biotechnology Industry Research Assistance Council (BIRAC) will be organizing a Stakeholders Dialogue on "Enabling Policies for Harnessing the Potential of Genome Editing in Crop Improvement" on 17 March, 2021. The Dialogue will bring together diverse stakeholders from the National Agricultural Research System, Department of Biotechnology, Ministry of Environment, Forests and Climate Change, CGIAR centres, other public and private sector organizations engaged in R&D and IP management of biotechnologies.

Objectives

- To develop consensus on regulation of genome edited plants and catalyze approval of the regulatory policies
- To deliberate on the mechanism of access to genome editing technologies for development and commercialization of genome edited crops by public and private sector enterprises.
- To discuss policy directions for promoting application of genome editing technology for sustainable agriculture

Expected outputs

- A roadmap suggested for approval of regulatory guidelines for genome edited crop improvement and environmental release.
- The Infrastructure and human capacity needs for implementation of the guidelines identified.
- Modalities for utilizing genome editing in crop improvement and technology transfer mechanisms developed

Organizers

- Trust for Advancement of Agricultural Sciences (TAAS)
- Indian Council of Agricultural Research (ICAR)
- National Academy of Agricultural Sciences (NAAS)
- Biotech Consortium of India Ltd. (BCIL)
- Tata Institute for Genetics and Society (TIGS)[8]
- National Agri-Food Biotechnology Institute (NABI)
- Biotechnology Industry Research Assistance Council (BIRAC)

Participants

About 50 participants from the National Agricultural Research System, Department of Biotechnology, Ministry of Environment, Forests and Climate Change, CGIAR centres, other public and private sector organizations engaged in R&D and IP management of biotechnologies.

Venue and date

Webinar; 17 March, 2021

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[8]TIGS wishes to remain neutral with respect to any recommendations made by the speakers, whose views are being presented in this meeting as their own