

## Concept Note

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

Date: October 10-11, 2019

Venue: International Crop Research Institute for Semi-Arid Tropics, Patancheru,  
Hyderabad, India

#### Background

Globally, most of the poor and undernourished people live in rural areas of developing countries, where they depend on mainly agriculture as a source of food, income, and employment. International data show a clear association between low agricultural productivity and high rates of undernourishment<sup>1</sup>. Global studies have also shown that rapid reduction of extreme poverty is only possible when the incomes of smallholder farmers are increased. Therefore, sustained improvement in agricultural productivity is central to socioeconomic development.

Plant breeding has been improving crops to meet the needs of agricultural value chain in an incremental manner by developing varieties in response to plant pests, diseases and environmental stresses. 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. Today's innovative plant breeding draws on years of knowledge and scientific advances that have enabled the development of precise methods like gene editing to safely improve the efficiency of breeding, and increase genetic diversity for breeding programs. These technologies are also known as new plant breeding techniques (NPBTs) and also gene editing.

Raising livestock is a vital source of income in developing countries. But lack of sophisticated breeding programs in these countries has deprived farmers to enhance their income through dairying. Gene-edited livestock could be a boon to farmers in developing countries<sup>2</sup>. 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 nucleotide changes in the genome of an organism, be it insertion, deletion, modifications or replacement of sequences. Gene editing is done using engineered endonucleases, of which CRISPR-Cas9 (Clustered regularly interspaced short palindromic repeats) since the first report has been the most favored system, though others like Cpf1 and Cas12 are also being used for editing. The site directed editing can cause small insertions/deletions (indels) or use complementary sequence to repair. These edits do not lead to insertion of foreign DNA. Site-specific insertion of DNA from same or different species can also be achieved by this system. Recent advances in gene editing allow the alteration of endogenous genes to improve traits in crops without transferring transgenes across species boundaries. In particular, CRISPR-Cas9 has emerged as one of the foremost

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<sup>1</sup> FAO (2018) *State of Food Security and Nutrition in the World. Food and Agriculture Organization of the United, Rome*

<sup>2</sup> Carlsen (2019) *Science*, doi:10.1126/science.aax1548

systems for editing crop and livestock genome, with rapidly increasing agricultural applications in major cereals such as rice, wheat, and maize and other food security crops such as banana and cassava<sup>3,4</sup>.

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) in crops. Similarly, resistance to disease and more productive livestock will also benefit the farmers.

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 competitive advantage to conventionally bred products. When considering the criteria for the scope of regulatory oversight, plant varieties developed through the latest 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.

Gene editing could be a renewed opportunity to harness the potentials of modern biotechnology for ensuring food security.

### **Rationale**

Gene editing typically does not introduce any foreign DNA, instead it can be used to modify existing genes in a precise manner, hence, edited plants maybe similar or indistinguishable from conventionally bred plants and need regulations and governance that optimizes the promotion of the technology with its safe and sustainable use. The genetic variation in the final plant product may not be covered under the scope of existing biotechnology regulations from biosafety point of view if:

- a) There is no novel combination of genetic material,
- b) The gene-edited product contains genetic material from sexually compatible plant species,
- c) The genetic variation is the result of spontaneous or induced mutagenesis.

World-wide regulatory agencies and governments are currently in the process of formulating policy and guidelines for gene edited products. US and Canada do not regulate new plant varieties or animal breeds developed through gene editing when they are indistinguishable from those developed through traditional breeding methods. Edits involving small deletions and insertions have been exempted from regulation by Australia. Similarly, Japan also may not require safety screening, provided there are no foreign genes or parts of genes in the target organism. There is a growing demand to incorporate social, economic and ethical considerations into biotechnology governance. And urgency is to discuss and understand the ethics and politics of care in governance of new biotechnological innovations.

South American nations like Argentina, Brazil and Chile have policies in place that regulate edited organisms on case by case basis and exempt organisms with no sequence insertion. In Chile and Argentina edited products are already being evaluated. However, Court of Justice of the European Union on the other hand ruled that organisms with edits using CRISPR/Cas9 and other gene editing methodologies, should be considered GMOs. This view has been sharply criticized by The European Commission's top scientific advisory panel.

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<sup>3</sup> Zaidi et al (2019) *Science*, 363 (6434), 1390

<sup>4</sup> Bull et al (2018) *Science Advances* 4, eaat6086

India too is in the process of formalizing regulatory policies for gene edited organisms and their products. Gene editing technology offers an opportunity to provide the latest technology to the Indian farmers that will empower the smallholder farmers towards sustainable growth. The technology can be employed to address the issue of climate change and enable socio-economic growth, typical of the region but only with prudent regulatory mechanisms, its potential can be harnessed for global food security. Many other south Asian and southeast Asian, and the Pacific countries also have no regulation to deal with gene edited products in respective countries.

## **Objectives**

The objectives of the Expert Consultation are to:

1. Highlight the innovations through gene editing and their impact on 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.

## **Expected outcomes**

The Expert Consultation will enable:

1. Record opinions and inputs from public and private sector regarding the regulatory framework in relation to gene edited products.
2. A white paper on recommendations for science-based, consistent, predictable regulatory policies.
3. Recommend the best regulatory path forward for India, considering its unique status and influence in the region, and other countries of Asia-Pacific region.

## **Participation**

Participants will include researchers, representatives of various public institutions and private sector; policy makers and scientists from member countries of Asia-Pacific Association of Agricultural Research Institutions (APAARI); CGIAR centres; government departments and bodies including Department of Biotechnology, Ministry of Agriculture & Farmers' Welfare, Ministry of Health and Family Welfare, Ministry of Environment, Forest and Climate Change. Recognized diverse set of experts will be invited to make presentations and participate in panel discussion.