Genome editing of crop plants: relaxation and realities

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Genome editing technologies are once again in the limelight after the issue of the office memorandum dated 30 March 2022 by the Ministry of Environment, Forest and Climate Change, Government of India (GoI), exempting transgene-free genome-edited plants falling under the categories of SDN1 and SDN2 from the provisions of the Rules 7-11 of GSR 1037 (E) dated 5 December 1989. The changes have been recommended by the Department of Biotechnology (DBT), the Ministry of Science and Technology, the Department of Agriculture Research and Education, and the Ministry of Agriculture and Farmer's Welfare, GoI.

Genome editing and conventional transgenic crops

Genome editing is the technique by which the genetic material of an organism is altered by adding, deleting or changing the bases present in the DNA, thereby altering the gene function. Genome editing currently utilizes programmable nucleases like CRISPR/Cas, TALENS and ZFN, which can precisely modify the target DNA. These nucleases make nicks/breaks in the DNA, which are further repaired by the innate repair mechanism of the cells, leading to mutations. The genome editing approach can lead to the development of transgene-free plants in 2–3 years. In the conventional transgenic approach, foreign/transgenic DNA is introduced into the plant system to obtain the desired trait and often transgenic DNA must be present in the plant system maintain the desired function. In genome editing, once the mutations are introduced into the DNA, they remain there forever. This makes genome editing more acceptable compared to conventional transgenic crops.

SDN1 and SDN2 categories?

Genome editing results into three categories of mutation, viz. SDN1, SDN2 and SDN3. In SDN1, when the natural mechanism of DNA repair is evoked in the cells after double-stranded breaks such as error-prone, non-homologous end-joining, random mutations are introduced, which can lead to either loss or modification of gene function or silencing of the affected gene. The type of mutations can be base insertions, deletions or substitutions. Such alterations are generally similar to those occurring naturally in an organism's gene pool, or introduced through conventional mutation breeding. The plant produced will be free from foreign DNA.

SDN2 mutations are template-guided double-repair mechanisms facilitated by an exogenously supplied donor DNA fragment. The donor DNA contains a few mutations, which are incorporated into the target site on the DNA based on the homology between the donor DNA and the DNA to be repaired. The modified DNA carries mutations similar to those in the donor DNA fragment, leading to altered gene function. Here the edited version can be considered similar to the allelic form of the gene, which is present naturally in the gene pool.

In the SDN3 category of mutations, the template or donor DNA used for altering the genome can be a long stretch of double-stranded DNA, an entire gene or longer with ends homologous to the double-stranded breaks facilitating the introduction of donor fragment at the target site. Hence, the edited plants contain novel, foreign genes at the target site. These are distinct from natural mutations and fall under the category of transgenics.

Impact on Indian agriculture sector

India has at present strict regulatory guidelines for the release of genetically modified crop release. Even though genetic engineering has huge potential for impacting the Indian agriculture sector, the fear and apprehensions regarding genetically modified organisms (GMOs) are impeding crop improvement programmes. Many of the varieties with improved traits developed through genetic engineering are still in dark boxes waiting for commercialization. This ultimately discourage scientists working hard for developing such improved varieties and affect their research temperament. However, the new rule relaxing the regulatory guidelines for genome-edited crops can give a huge push for crop improvement programmes using genome editing. The technology is rather simple and can enable the development of new crop varieties with improved traits in less time when compared to conventional breeding, which takes at least 8–10 years for a variety to release. In a developing country like India, translational research is of importance. There are huge crop losses and farmer suicides every year due to various factors affecting crop production like pests and diseases, abiotic stress and other natural calamities. The genome editing technology can tackle many of our crop production challenges.

The decision to exempt genome-edited plants from biosafety assessment in pursuance of Rule 20 of the 'Rules for the Manufacture, Use and Import, Export and Storage of Hazardous Microorganisms/Genetically Engineered Organisms or Cells', 1989 can evoke a mixed response among the scientific and farming communities.

Is it really going to gear up crop breeding?

The exemption of genome-edited plants falling under the categories of SDN1 and SDN2 in the provisions of Rules 1989 does not give complete freedom to the scientists for varietal release. Only provisions of Rules 7–11 are exempted here. For such plants, further development and evaluation will be according to the other applicable Rules/Acts. Research for the development for genome edited plants (both SDN1 and SDN2) with improved traits will be subjected to the existing regulations of rDNA research until they are transgene-free.

The initial application for research must be submitted to the Indian Biosafety Knowledge Portal (IBKP), which will be reviewed by the Institutional Biosafety Committee (IBSC) to confirm the proposed category according to the SDN definitions. This information will be passed on to the Review Committee on Genetic Manipulation (RCGM). All research work will be carried out in contained facilities (as per the Regulations and Guidelines for Recombinant DNA Research and Biocontainment, 2017, specifically Section 3.4.2.1 Plant Biosafety Level-1 for SDN1 plants and section 3.4.2.2 Plant Biosafety

Level-2 for SDN2 and SDN3 plants). Once the variety is free from exogenous/foreign material, including the vector segments, the scientists can communicate the same to IBSC, which will be reported to RCGM. Once the claim is confirmed, there will be no further regulations under Rules 1989.

The Genetic Engineering Appraisal Committee (GEAC) is the body that is responsible for approving the release of genetically engineered crops for commercial cultivation. The present office memorandum exempting the transgene-free genome-edited crops has taken the responsibility of releasing the SDN1 and SDN2 categories of transgene-free plants out of GEAC. Easing a major hurdle in the release of genome-edited crops can hasten the genetic improvement of crops at a pace never seen before. However, DBT has yet to release proper guidelines in this regard.

Global scenario of commercialization of GE crops

The genome-edited crops are being accepted as non-GMOs in many countries worldwide. The United States has shown the green flag to genome-edited crops, which will be regulated in a case-by-case manner. Many countries have adopted legislations or released guidelines supporting the research and commercialization of genome-edited crops. The National Institute of Agricultural Botany, UK, has encouraged the approval by both Houses of Parliament of a Statutory Instrument that will facilitate easier execution of field trials of genome-edited plants. Recently, on 24 January 2022, China's agriculture ministry released guidelines allowing the commercialization of genome-edited crops, which include wheat varieties resistant to the fungal disease, powdery mildew.

Gamma-aminobutyric acid tomato, high oleic acid canola and soybean, non-browning mushroom, etc. are some of the genome-edited crops in the global market. The US Food and Drug Administration has approved the low-risk determination for marketing products derived from genome-edited cattle. This is the first instance of low-risk determination for marketing products from intentional genomic alteration in an animal for food use.

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