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Sushmita
Department of Seed Science and Technology, Bihar Agricultural College, B.A.U Sabour, Bhagalpur, Bihar, India

Bal Manohar
Department of Agronomy, Bihar Agricultural College, B.A.U Sabour, Bhagalpur, Bihar, India

Correspondence
Sushmita
Department of Seed Science and Technology, Bihar Agricultural College, B.A.U Sabour, Bhagalpur, Bihar, India

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Testing and biosafety concerns regarding genetically modified seeds

Sushmita and Bal Manohar

Abstract
'Transgenics' or GMOs are the organism having genetic construct of interest that has been introduced by molecular or recombinant DNA techniques. Only a few of GM plants have been approved for commercial cultivation in specific countries. This pose a challenge in terms of ensuring that the non-approved GM seeds/grains are not imported into country. It is thus necessary to be able to distinguish the GM seed from non GM seed. An organic farmer needs to provide evidence that the seed being sold to him or the grain he is producing is not genetically engineered. A breeder needs to verify that a seed contains the intended genetic modification that will result in value added product. The assessment of GM content in samples can be done in three different levels: - detection, identification and quantification. In general, three GMO detection methods are commonly used are: - Phenotypic Bioassay, Protein-based Methods and DNA-based Methods. Since no technology is risk free, a logical assessment of risk-free, a logical assessment of risk involved and scientific evaluation of the identified risks would be a prudent way to harness the new technology. It is mandatory for transgenic to be evaluated for biosafety. In India the Department of Biotechnology of Ministry of Science and Technology is entrusted with responsibility of ensuring biosafety. A three-tier system involving Institute Biosafety Committee, Review committee on genetic manipulation, under DBT and Genetic engineering Approval Committee is formulated to address the biosafety issue of transgenic.

Keywords: Testing and biosaftey, GM seeds/grains

Introduction
Agricultural biotechnology which includes the areas of DNA fingerprinting, molecular marker assisted breeding, transgenic technology, genomics and diagnostics, could help us to achieve improvements in both crop quality and quantity in a sustainable manner. The transgenics or genetically modified organisms (GMO) are at the centre of attention, sparking off intensive debates worldwide while the trasngenic approach cannot certainly solve all the problems associated with agricultural production, it has the potential to effectively address specific problems. It offers the possibility of not only bringing in desirable characteristics from other varieties of the plant, but also adding important characteristics from unrelated species.

Transgenics or GMOs are defined as those organisms with a gene or genetic construct of interest that has been introduced by molecular or recombinant DNA techniques. The GMO, thus carries transgene(s) which when integrated and expressed stably and properly, confer either a new trait to the organism, which was hitherto not present (for instance, insect resistance).or enhance an already existing trait (for instance, nutritional quality) (*Rai And Prasanna,* 2000).

Transgenic research and development is progressing at a rapid pace, with focus largely on traits such as insect pest resistance, herbicide resistance, disease resistance, improved nutritional quality. The first transgenic crops entered the market on a commercial scale in 1986 (in china, transgenic tobacco with viral resistance.) in 2006, 22 countries grew biotech crops - 11 developing countries and 11 industrial countries, in order of hectares are USA, Argentina, brazil, Canada, India, china, Paraguay, south Africa, Uruguay, Philippines, Australia, Romania, Mexico, Spain, Colombia, France, Iran, Honduras, Czech republic, Portugal,

Germany and Slovakia (*James,* 2016). Insect –resistant (Bt) cotton was the first transgenic crop to be commercialized in India.

Testing For the Presence of Gm Seeds

A range of transgenic plants are already approved or under approval internationally. However, only a few of the GM plants have been approved for commercial cultivation in specific countries. It is necessary to distinguish the GM seed/plant from the non-GM seed/plants and to determine whether a specific GM line/event is approved.

An organic farmer needs to provide evidence that the seed being sold to him or the grain that he is producing and marketing has not been genetically engineered. A breeder needs to verify that a seed contains the intended genetic modification(S) that will result in a value-added product. A seed company needs to ensure that it is producing and marketing pure inbred or hybrid seed. However, it is important to differentiate that assessment of GM content in samples can be made at three different levels:

Detection

Purpose of detection is to be determine whether a sample contains GM seed. The screening method are usually based on the polymerase chain reaction (PCR)

Identification

A positive detection of a GM line, further analysis is required to discover which GM line it is and whether this is approved. Identification of each GMO variety are method based on the PCR.

Quantification

F a product has been shown to contain GMO, the next step is compliance with the specific threshold level determined by a country by the determination of the exact amount of each of the GM seed present in the sample. GMO can be identified by the detecting either the inserted genetic material at DNA level. The analytical tests on raw materials (e.g. seeds) are genetically carried out with the PCR method detecting the inserted DNA, immunological assays detecting the resulting protein (e.g. the enzyme-linked immunoassay (ELISA). And lateral flow sticks), or using bioassays to detect the resultant phenotype (e.g.herbicide bioassays). Herbicide bioassays and immunoassays can be regarded as low- technology method because they can be set up in most laboratories while PCR and microassays are regarded as high-technology method. In general, PCR based method have a threshold detection of 0.01%. Even though 0.01% is the limit of detection using PCR, quantitative analysis is not possible in this concentration range. Most of the laboratories set the limit of quantification ten-fold higher at 0.1% to avoid the problems with precision that occur near the limit of detection. To reliably quantify at the 0.1%level through statistics require that at least 10,000 seed should be homogenized and thoroughly mixed, and duplicate sample of this homogeneous powder subjected to DNA analysis (Prasanna and Arunkumar, 2016).

There are three GMO detection method are commonly used:-

Phenotypic bioassays

It is also known as herbicide bioassays. It is used most of the laboratory as it does not need any high class training and equipments. Only test for traits such as resistance/ tolerance to herbicide are available, termed as herbicide bioassays. Phenotypic characterization allows detection of the presence or absence of a specific traits. The detection is dependent on germination of the seed, and the germination methods should ensure that all viable seeds of a given sample should germinate. At present herbicide bioassays are available for roundup ready soybean, maize etc.

Protein-based method

Immunoassay is the current method for detection and quantification of new (foreign) protein introduced through genetic modification of crop plants. A successful immunoassay depends on certain characteristics of the antigen used for development of the antibody i.e., size, hydrophobicity and the tertiary structure of antigen. ELISA is a faster and less expensive technique than PCR.

DNA- based method

DNA-based test use the PCR to detect specific DNA sequences. PCR test can be designed to detect any of the inserted genetic material such as promoter, structural gene, and stop signal or marker gene.

Biosafety Concerns

No technology is a risk- free, a logical assessment of risks involved and scientific evaluation of the identified risks would be a prudent way to harness the new technology. Genetic engineering provides an opportunity for mobilizing genes across the biological world. The major bio-safety concerns associated with transgenicsare:-

- Possibility of them becoming weed.
- Generation of super weed
- Evolution of new and virulent forms of pests and pathogens
- Toxicity and allergic to humans and animals
- Damage to biodiversity
- Harm to non- targeted organisms
- Long-term environmental consequences (Frankoberspach and *keller*, 1997; *Bhatia* and *Mitra*, 1998; *Rai* and *Prasanna*, 2000; Ellstraand and Hegde, 2002) [3, 1].

There are also other scientific concerns, such as resistance management, transgenic silencing etc., besides socio-economic issues related to commercialization of GM crops and their access to resources-poor farmer (Rai and Prasanna, 2000). Today, government of most of the countries planning to use transgenic have brought out legislation for bio-safety regulations. It is mandatory for transgenics to be evaluated for biosafety. The research organization carries out field testing or field trials. Following appropriate regulatory guidelines:-

- Possible risks associated with the transgenic, when grown under field conditions
- Suitability of the transgenic in the farm situation
- Assessment of the net benefit offered by the transgenic.

In India,the department of biotechnology (DBT) of the ministry of science and technology is entrusted with the responsibility of ensuring biosafety of r-DNA related research and experiments, while the ministry of environment and forest (MoEF) is authorized to approve transgenic crops for commercial release. A three-tier system involving institute biosafety committee (IBSC), review committee on genetic manipulation (RCGM),under DBT and genetic engineering approval committee (GEAC), an inter-ministerial committee under MoEF, is formulated to address the bio-safety issue of transgenics and to facilitate commercialization of biotech products (Ghosh,1997; Rai and Prasanna, 2000).

Concluding Remarks

Biotechnology provides us tool to respond to the demand of society in general. Translating the potential of a transgenic line into a successful variety depends on effort of biotechnologist and other plant scientist. The world opinion on bio-safety of transgenic plant has got distinctly polarized either in support or against the use of GM plants. The public and the media would like to get convinced about safety of such plants before their commercialization. What we need is the balanced and judicious view of the technology.

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