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HANDBOOK FOR FOOD SAFETY OFFICIALS

Genetically Modified Foods
Safety Assessment and Regulations

Prepared under

gef UNEP

Phase-II Capacity Building Project on Biosafety

Ministry of Environment
Forests and Climate Change

Ministry of Environment
Forests and Climate Change
Government of India

In association with

BCIL
Biotech Consortium India Limited
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Genetically Modified Foods: Safety Assessment and Regulations

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Biotech Consortium India Limited, New Delhi
under the UNEP/GEF supported Phase II Capacity Building Project on Biosafety

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Introduction

Most of the foods we eat today come from plants and animals that have been grown and bred by humans for thousands of years. Traditionally, plants or animals with the most desirable characteristics were chosen for food and then subjected to improvement through breeding the next generation, leading to genetic changes over time. Modern biotechnology involving genetic engineering techniques has provided new ways to allow selected individual genes to be transferred from one organism into another, also between non related species. The resulting organisms are referred to as genetically modified organisms (GMOs) i.e. organisms (plants, animals or microorganisms) in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination. GMOs are also referred to as genetically engineered (GE) organisms, living modified organisms (LMOs) or transgenics. Foods produced from or using GMOs are often referred to as genetically modified (GM) foods. Examples include GE plants that are sold as food commodities (such as GM potato, GM maize, GM papaya) and/or are further processed into food ingredients (such as GM canola for modified oil composition).

GM foods presently being marketed, come from GE plants that have been genetically modified to improve their growing characteristics. For example, to protect the crop from pests or to make it tolerant to herbicides. GE plants have also been developed for disease resistance, modified nutritional properties, increased yield etc. As of 2017, 16 GE plants have been cultivated in 24 countries. Additional 43 countries have approved these plants for food and feed use.

The introduction of GM foods into food supply has stimulated much discussions about the nature of these foods and their safety. Accordingly, safety assessment methodologies have been developed and biosafety regulations put in place by various countries.

In India, all GMOs including GE plants are regulated by the Ministry of Environment, Forest and Climate Change (MoEFCC) as per rules notified under the Environment (Protection) Act, 1986. Guidelines and protocols are in place for safety assessment of GM foods. GM foods are also subjected to regulations by the Food Safety and Standards Authority of India (FSSAI) under the Food Safety and Standards Act, 2006.

MoEFCC and other concerned ministries have undertaken various capacity building initiatives from time to time for creating awareness among stakeholders about GE plants and regulatory aspects.

MoEFCC being the nodal ministry for biosafety regulatins has implemented the Phase II Capacity Building Project on Biosafety with support from Global Environment Facility (GEF) through the United Nations Environment Program (UNEP), to strengthen the biosafety management in India. 'Enhancing Public Awareness' is one of the key thrust areas of the project and is essential for better understanding of the biosafety regulatory framework. Accordingly, several knowledge products have been developed as part of the project and significant efforts have been made to ensure outreach through multiple tools viz. workshops, printed material, short film etc. In continuing with the same, MoEFCC in association with Biotech Consortium India Ltd. (BCIL), the project coordination unit has prepared booklets for specific categories of stakeholders focusing on their information requirements.

This handbook has been prepared to inform food safety officials and other concerned stakeholders about the basics of GM foods, safety assessment, regulations, detection methods and useful information resources. It has the following five sections:

1. Basics of GM foods
2. Safety assessment of GM foods
3. Regulations of GM foods in India
4. Detection of GMOs and GM foods
5. Useful Information Resources

Section 1: Basics of GM Foods

Genetic modification, involving the copying and transfer of genes from one organism to another is possible because the genetic code is universal i.e. the DNA[1] of all organisms is made up of the same building blocks and is encoded in exactly the same way. A copy of DNA sequence or gene[2] encoding a particular characteristics can be therefore transferred into the cell of a different organism. Genes contain the instructions needed by the cell to produce proteins, that have a variety of roles in the cell.

Once the gene is incorporated into the genome of a plant recipient, the resulting plant is considered to be genetically engineered and the new characteristics coded by that gene are inherited by subsequent generations. As characteristics of interest do not always exists in related species, GE plants are developed to bring together useful genes from a wide range of living sources for development of superior plant varieties.

Development of a GE plant is a stepwise process as indicated below:

- **Identification of a gene:** The first step is the identification of a gene(s) responsible for a desired trait in an organism (plant, animal or microorganism) followed by isolation and copying the gene of interest by use of molecular biology techniques.
- **Designing genes for insertion:** Once isolated and cloned, the gene of interest has to be modified with additional components (referred to as gene construct) before it can be effectively inserted into the host plant. These may include addition of a promoter and termination sequences to signal the initiation and completion of the sequence of gene of interest and marker gene for identification of GE cells/tissues during experimental process.

[1]DNA: Deoxyribonucleic acid, more commonly known as DNA, is a complex molecule that contains all of the information responsible for the inheritance of traits such as size, shape, color, build and other physical attributes of microorganisms, plants, animals and humans. DNA exists in the nucleus of each cell.

[2]Gene: A gene is basically a discrete segment of DNA encoding for set of instructions in the cell and contains all information concerning the form and functions of all living cells that give characteristics to an organism.

- **Transformation:** The gene construct is then transferred to the host plant through the process of transformation using a Gene Gun method or the Agrobacterium method. Transformation is a heritable change in a cell or organism brought about by the uptake and establishment of introduced gene in the host plant.
- **Selection:** Following the gene insertion process, plant tissues are transferred to a selective medium (such as containing an antibiotic or herbicide), depending on the type of selectable marker used. Only plants expressing the selectable marker gene will survive indicating that they possess the transgene of interest. The whole plants are generated using tissue culture methods for further evaluation in laboratories and green houses. The evaluation includes activity of the introduced genes, stable inheritance of the genes and any unintended effects on plant growth, yield quality etc.
- **Field Trials and Safety Assessment:** The next step in the process is multi-location and multi-year evaluation trials in greenhouse and field environment to test the effects of the transgene and its overall performance. This phase also includes evaluation of environmental effects and food safety.

  All data/ information generated through above experimental trials and studies are evaluated by regulatory authorities before granting permission for environmental release or commercialization.

As per the available reports, 16 GM crops have been cultivated in 24 countries in 2017 (Table 1). A total of 67 countries have issued regulatory approvals to GM crops in 2017, including 24 countries for planting/cultivation and 43 countries that are non-planting for importing GM crops for use as food, feed and processing.

From 1992 to 2017, a total of 40 countries (including European Union as one) have issued regulatory approvals to GM crops for consumption either as food and/or feed as well as for environmental release. From these countries, 3,768 approvals have been issued by regulatory authorities for 29 GM crops (not including those for carnation, rose and petunia) and 498 GM events. Of these approvals, 1,995 are for food use (direct use or for processing), 1,338 are for feed use (direct use or for processing) and 800 are for environmental release or cultivation.

Table 1: Status of cultivation of GE plants in various countries in 2017

S.No.	GE Plants	Traits/Uses	Countries where approved
1	Alfalfa	Herbicide tolerance	USA
2	Apple	Anti-bruising and anti-browning	USA
3	Beet pepper	Virus Resistance	China
4	Canola	Herbicide tolerance and improved protection against weeds	Canada, USA, Australia, Chile
5	Carnation	Modified flower colour and herbicide tolerance	Australia, Columbia
6	Cotton	Improved insect protection, herbicide tolerance and improved protection against weeds	Australia, USA, China, Mexico, South Africa, China, Argentina, India, Columbia. Burkino Faso, Sudan, Pakistan, Brazil, Myanmar, Paraguay, Costa Rica
7	Egg Plant (Brinjal)	Insect resistance	Bangladesh
8	Maize	Improved insect protection and herbicide tolerance for efficient weed management.	Canada, USA, Argentina, Brazil, South Africa, Uruguay, Philippines, Chile, Columbia, Honduras, Spain, Portugal, Paraguay, Cuba, Czech Republic, Romania, Slovakia
9	Papaya	Virus resistance	USA, China
10	Petunia	Modified flower color	China
11	Poplar	Insect resistance	China
12	Potato	Improved quality, anti-bruising and anti-browning	USA
13	Soybean	Improved insect protection and herbicide tolerance for efficient weed management.	USA, Argentina, Canada, Paraguay, Mexico, Bolivia, Brazil, Chile, South Africa, Romania, Uruguay, Costa Rica
14	Squash	Resistance against watermelon mosaic virus and zucchini yellow mosaic virus	USA
15	Sugar beet	Herbicide tolerance	USA and Canada
16	Tomato	Delayed Ripening, Virus resistance	China

Source: ISAAA Global Status of Commercialized Biotech/GM crops, 2017

In addition, beans, sugarcane and cowpeas have been approved by Brazil, Indonesia and Nigeria and are expected to be planted in the near future. Brazil has also approved GE Eucalyptus, an important pulp and paper producing tree. GE salmon is the only animal approved for food use in USA and Canada.

Section 2: Safety Assessment of GM Foods

Traditionally, the foods are considered safe based on their history of safe use. In practice, very few of the foods we eat today have been subject to any toxicological studies and yet they are generally accepted as safe. Whenever new plant or animal varieties are developed using the conventional breeding methods, some of the characteristics may be altered either in a positive or negative way. However, they are not generally subjected to any safety assessment process. On the other hand, GM food obtained from a particular type of GMO requires a separate safety assessment. All GMOs undergo rigorous evaluation to ensure safety to human health and the environment.

GM foods cannot be assessed as a single class because the safety concerns will vary, depending on the type of food and the type of genetic modification. For example, if two types of maize were modified to have different characteristics, or were modified in different ways to achieve the same characteristic, separate safety assessments would be needed for the different GM maize varieties. Similarly, if the GM maize were modified further, they would require another safety assessment.

Once foods derived from a GMO have been assessed as safe, they may be used as ingredients in other foods. For example, oil, flour etc. obtained from GM soybeans or GM maize can be used in foods such as breads and snack foods if the GM soybeans or GM maize have already been assessed as safe. The various such products produced from them are not required to be assessed individually.

Evaluating the safety of a GMO is a comprehensive process that involves several steps. Systematic safety assessment methodologies are in place that have been agreed on years of consultations under the aegis of international organizations and agreements viz. Food and Agriculture Organization (FAO), World Health Organization (WHO), Codex Alimentarius

Commission, Organisation for Economic Co-operation and Development (OECD) and Cartagena Protocol on Biosafety.

The potential changes introduced using genetic engineering are assessed using comparative risk assessment approach. The underline assumption of this comparative approach is that traditionally grown organism has a history of safe use and thus serves as the comparator. As a consequence, safety assessment process gives conclusion on whether or not the GMO is as safe as its conventional non-GM counterpart.

Fig 1: Components of Safety Assessment of GE plants

Safety assessment studies required for commercial release of a GE plant comprise of food and feed safety assessment and the environmental risk assessment coupled with information through the molecular characterization of the GE plant and characterization of the expressed transgenic proteins, as shown in Figure 1.

Impact on human health is studied by analyzing the modified organism for the risks of toxicity, allergenicity, nutritional analysis etc. as relevant to the particular situation of targeted genetic modification. The toxicity and allergenicity assessment takes into account the chemical nature and functions of the newly expressed substance, the concentration of the substance in the edible plant parts and likely dietary exposure. Appropriate oral toxicity studies in laboratory animals are also carried out on a case by case basis. For allergenicity assesment, data is generated on amino acid homology for expressed proteins with known allergens from bioinformatics database, heat stability, pepsin digestibility etc in an integrated, step-wise manner. Nutritional equivalence is established through detailed compositional analysis by comparing concentration of key components in GE plants with a conventional counterpart that is grown and harvested under the same agro-climate and growing conditions. Livestock feeding studies may also be carried out in specific cases. Environmental risk assessment of GE plants is undertaken on a case to case basis and there is no single method or model to follow in view of diverse biological properties of crops. Familiarity i.e. knowledge and experience of unmodified plant is the basis

for comparative risk assessment of a GE plant. Baseline information as documented in biology documents is used as basis for this comparison. Potential changes that are compared include weediness/ invasiveness, gene flow pattern of the introduced trait, impact on non-target beneficial organisms etc. Broad information requirements for safety assessment of GE Plants are placed in Box 1

Box 1: Broad Information Requirements for Safety Assessment of GE Plants

Effect of Genetic Modification and Protein Characterization

- Description of the GM crops
- Description of the biology of the non-modified host plant
- Description of the donor organism
- Description of the genetic modification
- Inheritance and stability of inserted gene(s)
- Molecular characterization
- Function/ specificity/ mode-of-action of expressed protein
- Protein expression levels
- History of safe use and consumption

Food and Feed Safety

- Toxicity assessment by animal toxicity studies such as acute and sub-chronic studies
- Assessment of allergenicity by comparing amino acid sequence homology of the newly expressed protein.
- Heat stability and susceptibility of the expressed protein to pepsin digestion
- Compositional analysis by comparing changes in the level of key nutrients, natural toxicants or anti- nutrients, secondary metabolites, physiologically active (bioactive) substance etc
- Livestock feeding studies
- Effect of processing

Environmental Safety

- Confirmation of expression level of new proteins: Quantify the expression level of the gene product associated with each introduced trait
- Field trial locations and experimental designs
- Description of the phenotype of the transformed plant
- Plant growth and specific observations recorded during the field trials
- Changes in weediness and aggressiveness potential
- Susceptibility to diseases and pests.
- Impact on non-target and beneficial organisms like predators, soil micro flora etc
- Changes in gene flow pattern through pollen flow studies and crossability studies with sexually compatible relatives

Government of India is following a case by case safety assessment of GE plants. The information requirement and analysis by regulatory authorities depends on the development stage of a particular product. Data requirement may also vary depending on the crop specific trait and intended use.

Section 3: Regulations of GM foods in India

In India, the regulation of all activities related to GMOs and products thereof are regulated as per **"Rules for the Manufacture/Use/Import/Export and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or Cells, 1989"** (commonly referred to as Rules, 1989) under the provisions of the Environment (Protection) Act, 1986. The Rules, 1989 are very broad in scope, essentially covering entire spectrum of activities involving GMOs and products thereof including sale, storage, exportation, importation, production, manufacturing, packaging, etc. These rules are implemented by the MoEFCC, the Department of Biotechnology (DBT), Ministry of Science & Technology, Government of India and State Governments. Six competent authorities, their composition and roles have been notified under the Rules, 1989. The function of these six competent authorities is given in Table 2.

Table 2: Competent Authorities as per Rules, 1989

Statutory Committee	Function	Housed at
rDNA Advisory Committee (RDAC)	Review developments in biotechnology and recommend appropriate safety regulations for recombinant DNA research, use and applications	Department of Biotechnology, Ministry of Science and Technology
Institutional Biosafety Committee (IBSC)	Responsible for ensuring adherence to safety guidelines for experimentation at designated location	All organizations engaged in activities involving GMOs
Review Committee on Genetic Manipulation (RCGM)	Review all ongoing rDNA projects and approve experiments falling in risk category III and above; also responsible for bringing out manuals of guidelines for conduct of GMO research and use	Department of Biotechnology, Ministry of Science and Technology
Genetic Engineering Appraisal Committee (GEAC)	Authorized to review, monitor and approve all activities including import, export, transport, manufacture, use or sale of GMOs and products thereof from environment angle	Ministry of Environment, Forest and Climate Change
State Biotechnology Coordination committee (SBCC)	Monitoring and supervision at state level	Concerned State Governments
District Level Committee (DLC)	Supervision and compliance at district level	

Various sub-committees and expert committees are set up by Review Committee on Genetic Manipulation (RCGM) and Genetic Engineering Appraisal Committee (GEAC) on a case by case basis and comprise of experts from various disciplines drawn from public sector institutions to prepare and review various guidelines and biosafety data. Central Compliance Committees (CCC) are also set up for monitoring of confined field trials of regulated GE Plants on case by case basis. The procedure for seeking approval for confiend field trails and release of GE plants is placed at Figure 2.

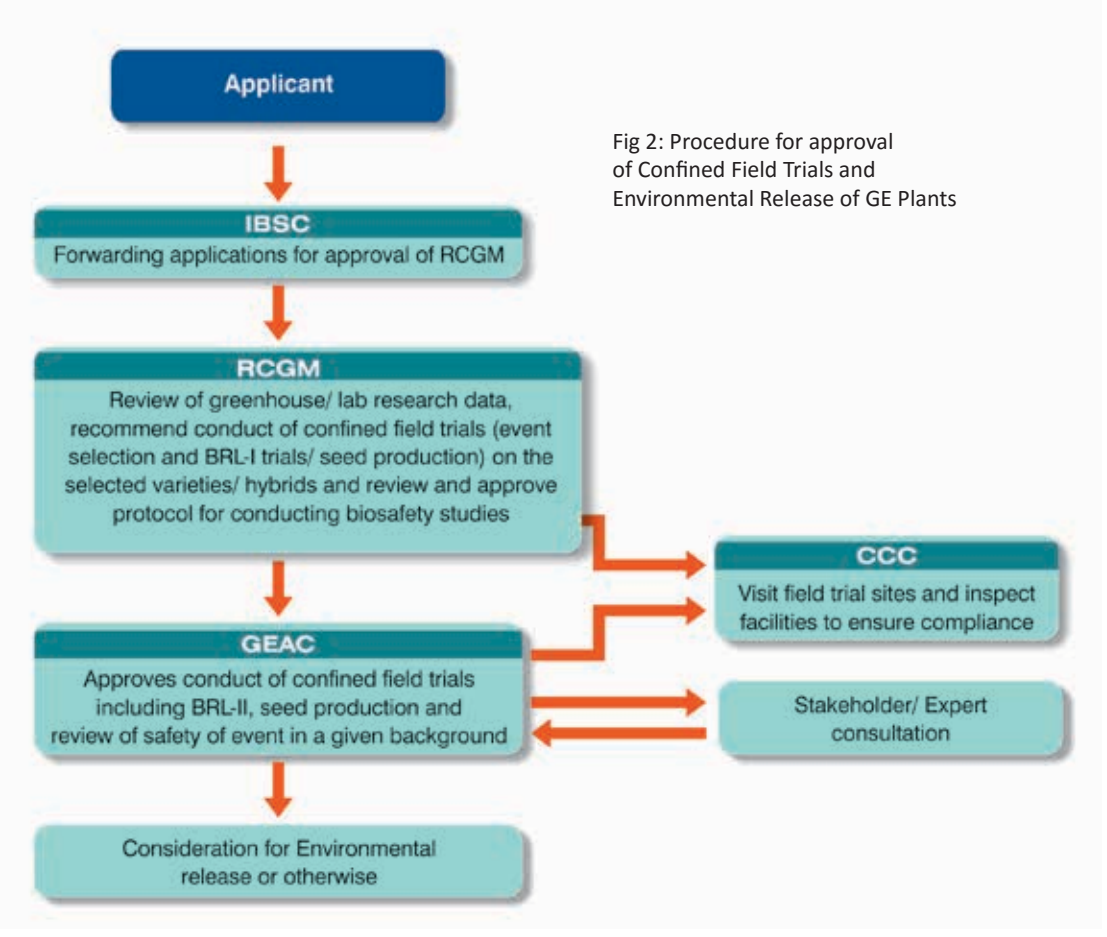


Fig 2: Procedure for approval of Confined Field Trials and Environmental Release of GE Plants

The Rules, 1989 included reference to foods derived from biotechnology in Rule 11, Permission and Approval for Food Stuffs which states:

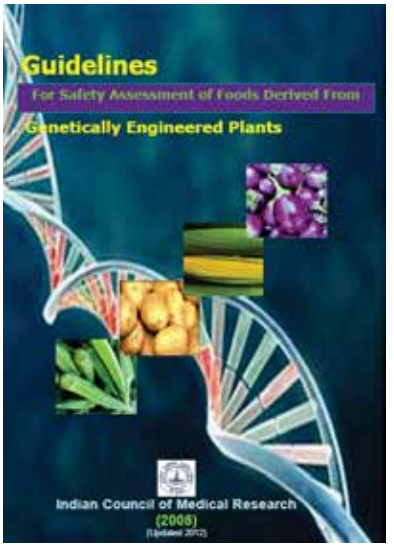
> *Food stuffs, ingredients in food stuffs and additives including processing aids containing or consisting of genetically engineered organisms or cells, shall not be produced, sold, imported or used except with the approval of the GEAC.*

Until 2006, this meant that GEAC was the competent authority to approve or disapprove the release of GM foods in the marketplace. However, this changed with the enactment of the **Food Safety and Standards Act (FSSA), 2006** which includes GM foods within the definition of food.

Specific to the regulation of GM foods the FSSA, 2006 states:

> *22. Save as otherwise provided under this Act and regulations made thereunder, no person shall manufacture, distribute, sell or import any novel food, genetically modified articles of food, irradiated food, organic foods, foods for special dietary uses, functional foods, neutraceuticals, health supplements, proprietary foods and such other articles of food which the Central Government may notify in this behalf.*
>
> *and*
>
> *(2) "genetically engineered or modified food" means food and food ingredients composed of or containing genetically modified or engineered organisms obtained through modern biotechnology, or food and food ingredients produced from but not containing genetically modified or engineered organisms obtained through modern biotechnology;*

Accordingly, Food Safety and Standards Authority of India (FSSAI) is the competent authority to regulate GM foods through the inclusion of "genetically modified or engineered food or food containing such ingredients" within the definition of food. As per the provisions of the FSSA, 2006, the FSSAI has a separate scientific panel to deal with GMOs and foods.



The Indian Council of Medical Research (ICMR) has also prepared **"Guidelines for Safety Assessment of Foods derived from GE Plants, 2008",** which have been further updated in 2012. These guidelines have been adopted by the GEAC. The guidelines are based on principles and guidance issued by Codex Alimentarius Commission and elaborate on the steps for safety assessment of foods derived from GE plants. A comprehensive summary of information and data requirements that must be provided to regulatory authorities to demonstrate human health safety of foods derived from GE plants are also included.

The guidelines include three appendices on:

a. Dossier preparation checklist
b. Codex Alimentarius Principles for the risk analysis of foods derived from modern biotechnology
c. Annexes II & III to the Codex Alimentarius guidelines on safety assessment of foods derived from GE plants modified for nutritional or health benefits and food safety assessment in situations of low level presence of GE plant material in food.

A series of "Protocols for Food and Feed Safety of GE plants", prepared by the DBT in 2008 are also in place to specifically address key elements of the safety assessment of foods and/or livestock feed that may be derived from GE plants. The protocols have been prepared based on international best practices and include the following:

a. Acute oral safety limit study in rats and mice
b. Sub-chronic feeding study in rodents
c. Protein thermal stability
d. Pepsin digestibility assay
e. Livestock feeding study

Section 4: Detection of GMOs and GM Foods

Generally, GMOs are indistinguishable from non-GMOs to the naked eye. It is more difficult to detect the novel genes in the processed GMOs or GM foods. However, GMOs and GM foods need to be tested for variety of reasons such as screening of samples for presence of unapproved GMOs in the country, or quantity of GM ingredients. Highly sensitive and specific testing methods are required that can look for the genes (DNA) engineered into the particular organism or the proteins produced in the organism by the introduced DNA.

The objective of this section is to introduce the methods used to detect the presence of GMOs, to identify which GMOs are present and to calculate the quantity of GMOs in a sample. It may be recalled that a GMO is created by inserting a gene from one organism into the DNA of another organism and this new gene usually leads the organism to produce a protein that gives the organism a desired characteristics.

In view of the above, there are two basic approaches to test the GMOs :

1. Protein based methods
2. DNA based testing

1. Protein based methods include testing for the proteins produced by the gene that has been inserted into the GMO**.** These methods can be used for screening (yes/no) and quantification of expressed protein in a GMO using strip test and ELISA based test respectively.

- **Strip tests** are simplest of all the detection methods. Strip test kits produced by different companies, include specially coated paper strips that are designed to detect specific proteins produced by different GMOs. Typically a small sample is first ground into a powder. A liquid extraction buffer, included in the kit is added to a tube along with the powder. The tube is then shaken to allow the maximum amount of protein to be released into the buffer. A small amount of this mixture (referred to as extract) is transferred into vial. The coated paper

strip is then placed in the vial. The result monitored as the colour of the strip changes indicating whether or not it is a GMO. Unskilled personnel in the field can easily carry out strip based tests (Figure 3).

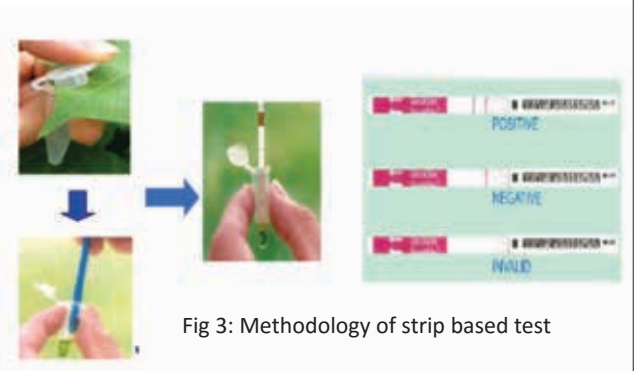


Fig 3: Methodology of strip based test

- **Enzyme-linked immune sorbent assay (ELISA) based test:** This test uses antibody (polyclonal or monoclonal) raised against a specific protein encoded by the transgene. These antibodies are colour coated to enable them to be easily detected and quantified. The kits for ELISA test are also produced by companies that specialize in GMO testing. ELISA kits include plastic plates with number of wells, which are pre-treated so that the protein of interest in the sample will stick to the well.

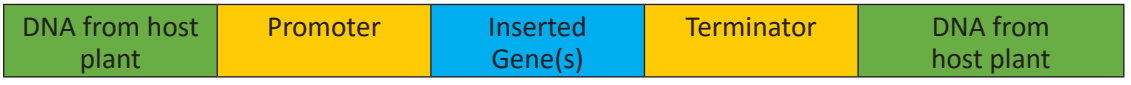
Methodology for ELISA test

For the ELISA test, an extract is prepared by grinding the sample into a powder and adding an extraction buffer (similar to the process with strip tests). The extract is then added to the wells in a plate. If the extract contains the protein of interest then this protein will stick to the bottom and sides of the well.

Whether the protein has stuck to the well is not visible to the human eye so additional steps are needed to determine the results of the test. A reagent (a chemical used for analysis and reactions, also provided in the kit) is then added to the wells and it attaches to the protein of interest that is stuck to the well. Finally, the results of the test are visualized with a colour development step. In this step, another chemical is added to the wells, which causes a reaction that changes the colour of the contents in the well. The darker the colour, the higher the concentration of the protein of interest. The intensity of colour is measurred using an ‘‘ELISA Reader’’.

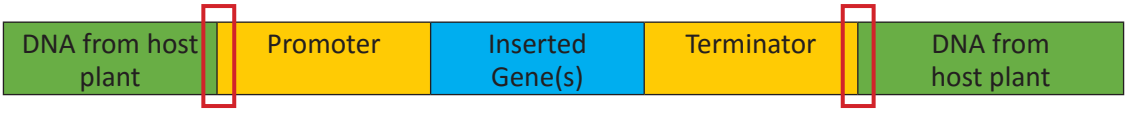
While protein testing is considered reasonably simple to apply, it is limited by the development and availability of protein antibodies for all type of available transgenes in the form of commercial kits. Protein based methods can be used on raw and semi-processed samples, as long as the protein is not denatured or destroyed by processing.

2. DNA based testing include testing for the introduced gene itself. The DNA that is introduced into an organisms to create a GM crop consists of several components and is known as a gene construct. Components of a gene construct are generally as follows:



It is possible to test for any one of the components of a gene construct in order to detect a GMO. A number of components, however, have been inserted into more than one GMO. For example, the 35S promoter isolated from the cauliflower mosaic virus (and thus known as the CaMV 35S promoter) is one of the most widely used promoters in GE plants. It is used, for example, in both Liberty Link maize (product of Bayer Crop Science) and Roundup Ready cotton (product of Monsanto). Using DNA-based testing to detect the CaMV 35S promoter will tell if the sample contains GMOs but it will not allow you to specifically identify which GMO has been detected. If a country has approved Liberty Link maize but has not approved Roundup Ready cotton then detecting the CaMV promoter that is common to both will not help in taking appropriate decisions.

A more specific test for detecting and identifying a particular GMO is to test for the combination of the host organism's DNA and either the promoter or the terminator from the gene construct. This is called 'event-specific detection'. Event-specific detection allows identification of the specific GMO in a sample.



Using again the example of the CaMV 35S promoter, event-specific detection can distinguish between Liberty Link maize and Roundup Ready cotton. While these two GMOs may both contain the CaMV 35S promoter, the combination of the promoter and the host organism DNA (either maize or cotton) will be unique.

DNA based testing involves multiplying/amplifying a specific DNA through polymerase chain reaction (PCR) technique. The PCR based techniques are used to detect the specific transgene in the GMOs or specific elements associated with the transgene by targeting and amplifying the same (Figure 4). The amplified DNA can be then seen using a technique known a gel electrophoresis. A positive result is indicated by a band on the gel and a negative result by no band.

Fig 4: PCR Machine

PCR based methods can be used on raw and processed products as long as DNA can be extracted from the sample. The selection of target sequence for PCR depends on the level of specificity required for GMO detection namely, GMO screening, transgene-specific, construct-specific and event specific detection. These methods are highly sensitive and can test for multiple GM varieties simultaneously. However, these require highly skilled personnel, laboratory infrastructure and are more expensive.

For both the protein and DNA based detection methods there are several general considerations that include sampling, food matrix effects on protein/DNA extraction, reference materials, method validation, harmonization of standards and access to information database.

In India, several public and private sector organizations have capabilities for detection of LMOs. There are also companies supplying various types of test kits. Four laboratories, strengthened under Phase II Capacity Building Project on Biosafety have been designated as National Referral Laboratories to detect for the presence or absence of GM Crops/GMOs under the Seeds Act, 1966.

The laboratories strengthened for detection of GM crops /GMOs include:

1. DNA Fingerprinting and Transgenic Crop Monitoring Lab (DFTCML), Department of Agriculture, Government of Andhra Pradesh, Guntur, Andhra Pradesh
2. ICAR-National Bureau of Plant Genetic Resources (NBPGR), New Delhi
3. Export Inspection Agency (EIA), Kochi Laboratory, Kochi, Kerala
4. Punjab Biotechnology Incubator (PBTI) Mohali, Punjab

More information about detection of GM crops can be seen at http://gmolabs.nbpgr.ernet.in:9090/ maintained by ICAR-NBPGR.

भारत का राजपत्र
The Gazette of India

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कृषि और किसान कल्याण मंत्रालय

(कृषि, सहकारिता एवं किसान कल्याण विभाग)

अधिसूचना

नई दिल्ली, 15 नवम्बर, 2017

का.आ. 3604(अ).—केंद्रीय सरकार बीज नियम, 1968 के नियम 5 के खंड (ग) के साथ पठित बीज अधिनियम, 1966 (1966 का 54) की धारा 4 की उप-धारा (1) द्वारा प्रदत्त शक्तियों का प्रयोग करते हुए, संपूर्ण भारत के लिए इसके प्रकाशन की तारीख से उक्त अधिनियम के अधीन जीवित परिवर्तित जीवों और आनुवंशिक रूप से परिवर्तित जीवों की उपस्थिति का अनुसंधिति की जांच का पता लगाने हेतु निम्नलिखित प्रयोगशालाओं को राष्ट्रीय संदर्भ प्रयोगशाला घोषित करती है, अर्थात्—

(i) डीएनए फिंगर प्रिंटिंग और ट्रांसजेनिक फसल निगरानी प्रयोगशाला (डीएफटीसीएलएल), गुंटूर (आंध्र प्रदेश);

(ii) आईसीएआर-राष्ट्रीय पौध आनुवांशिक संसाधन ब्यूरो (एनबीपीजीआर), पूसा परिसर, नई दिल्ली;

(iii) निर्यात निरीक्षण एजेंसी (ईआईए), कोच्ची प्रयोगशाला (केरल);

(iv) पंजाब बैव प्रौद्योगिकी इनक्यूबेटर (पीबीटीआई), मोहाली (पंजाब)।

[फा. सं. 13-127/2017-बीज-IV]

बी. राजेन्द्र, संयुक्त सचिव

2 THE GAZETTE OF INDIA : EXTRAORDINARY [PART II—SEC. 3(ii)]

MINISTRY OF AGRICULTURE AND FARMERS WELFARE

(Department of Agriculture, Cooperation and Farmers Welfare)

NOTIFICATION

New Delhi, the 15th November, 2017

S.O. 3604(E).—In exercise of the powers conferred by sub-section (1) of Section 4 of the Seeds Act, 1966 (54 of 1966), read with clause (c) of Rule 5 of the Seeds Rules, 1968, the Central Government hereby declares the following laboratories as the National Referral Laboratories to detect the presence or absence of Living Modified Organisms and Genetically Modified Organisms under the said Act with effect from the date of publication, for the whole of India, namely:—

(i) DNA Fingerprinting and Transgenic Crop Monitoring Lab (DFTCML), Guntur (Andhra Pradesh);

(ii) ICAR-National Bureau of Plant Genetic Resources (NBPGR), Pusa Campus, New Delhi;

(iii) Export Inspection Agency (EIA), Kochi Laboratory (Kerala);

(iv) Punjab Biotechnology Incubator (PBTI), Mohali (Punjab).

[F. No. 13-127/2017-SD-IV]

Section 5: Useful Information Resources

Several online databases are available for further information on GM foods. Some of the useful websites that can be used by food safety officials and other stakeholders are as follows:

i) **FAO GM Foods Platform** is a simple online platform to share information on safety assessment of foods derived from recombinant-DNA (GE) plants authorized in accordance with the Codex "Guideline for the conduct of food safety assessment of foods derived from recombinant DNA plants (CAC/GL 45-2003, annex III adopted in 2008). It provides information about the details of approval, the summary of the safety assessment and detection methods, protocols etc.

It is accessible at http://www.fao.org/food/food-safety-quality/gm-foods-platform/en/

ii) **Biosafety Clearing House (BCH)** is a website set up as per provisions of the Cartagena Protocol on Biosafety (CPB) to facilitate exchange of information on GMOs/LMOs by Parties. It is a repository of up-to-date information on GMOs and biosafety including information about the National laws, regulations, guidelines, competent national authorities and final decisions taken by countries that are parties to the CPB.

Information available on BCH is organized into ''National Records'' that are submitted by Parties and ''Reference Records'' that are submitted by general BCH users.

To facilitate easier understanding about results of queries involving decisions on LMOs, different icons have been used in the BCH as indicated in table 3.

It is accessible at http://bch.cbd.int

Icon	Approval of LMO for
	Intentional introduction into the environment
	Direct use as food
	Direct use as feed
	Processing
	Confined Use
	Pharmaceuticals
	Transit

Table 3: Icons used for conveying information about decisions

iii) GEAC Website provides information about Indian biosafety regulations and approval of GMOs. The website has been established by MoEFCC, the lead Ministry responsible for implementing biosafety regulatory framework in India.

It is accessible at http://geacindia.gov.in

NOTES

KEY CONTACTS

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Dr. Murali Krishna Chimata
Joint Director, MoEFCC & Member Secretary, GEAC

Ministry of Environment Forest and Climate Change

Ministry of Environment, Forest and Climate Change
Government of India
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