LEGISLATION FOR SEED LAWS IN INDIA.

¹Amruta Desai and ²B.M Aher. ¹Department of Agricultural Biotechnology, Anand Agricultural University, Anand. ²College of Agriculture, Anand Agricultural University, Jabugam

Abstract: Seed is the primary determinant for a flourishing agriculture. It is therefore highly essential to impose regulations to maintain the purity and quality of seeds through various stages of seed production i.e. Breeder, foundation, registered and certified seed. Different legislations are framed by the Government of India to protect the quality of seeds and planting materials and also provide adequate safeguards for quality assurance in the seed multiplication chain to maintain the purity of variety as it flows from the breeders to the farmers. This review deals with the different stages through which seed inspection goes through and measures taken to assure the purity and quality of the seed.

"As you sow, so you reap!"

Recent government advertisement in Indian newspapers telling consumers ("Grahak") to wake up ("Jago") to the importance of branded seeds

Introduction

Seed is the fundamental and vital determinant for a successful agricultural production and productivity in different agroclimatic regions. Therefore it is highly essential to maintain its purity and quality through various stages of seed production i.e. Breeder, foundation, registered and certified seed. Seed quality attains higher importance in view of emerging biotic and abiotic stresses, issues related to quality, phytosanitary measures and competition in domestic and international markets and emerging food needs. Different legislations are framed by the Government of India to protect the quality of seeds and planting materials and also provide adequate safeguards for quality assurance in the seed multiplication chain to maintain the purity of variety as it flows from the breeders to the farmers.

Measures of seed legislation with respect to quantity and quality were initiated in the country by establishment of National Seed Corporation during 1963 under Ministry of Agriculture. Indian seed programme includes the participation of Central and State governments, Indian Council of Agricultural (ICAR), State Agricultural Universities (SAU) system, Public sector, cooperative sector and private sector institutions. Seed sector in India consists of two national level corporations i.e. National Seeds Corporation (NSC) and State Farms Corporation of India (SFCI), 15 State Seed Corporations (SSCs) and about 100 major seed companies.

The NSC was the Central Body to produce seeds of superior dwarf varieties in rice, wheat and, superior hybrids in maize, pearl millet and sorghum. It was also charged with the responsibility of promoting seed industry development from production through processing, storage and marketing, and establishing a system of quality control. For quality control and certification, there are 22 State Seed Certification Agencies (SSCAs) and 104 state Seed Testing Laboratories (SSTLs).

The involvement of Public sector in the seed industry began at the advent of the "green revolution" with the establishment of the National Seed Corporation (NSC) in 1963. The Indian seed industry was initially dominated by public sector seed companies. But owing to the easing of government regulations and the implementation of a new seed policy in 1988, the private sector has started to play a pivotal role in the production and distribution of seeds. However, the organized seed sector particularly for food crops cereals continues to be dominated by the public sector.

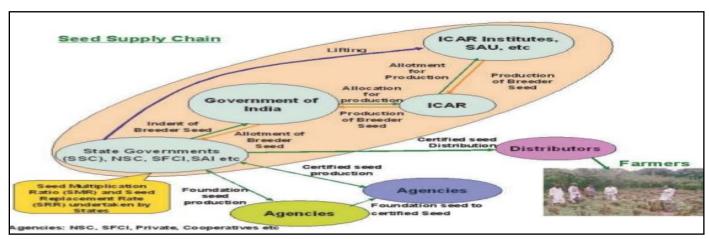
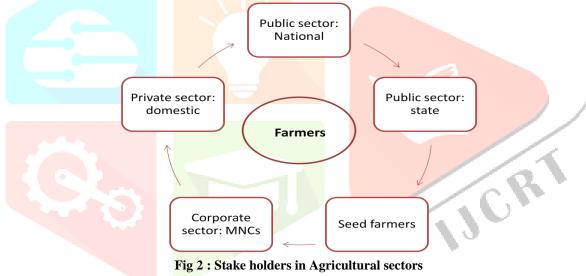


Fig1: The seed supply chain

Recently, the private seed industry is undergoing a transition owing to Governments' decision to embrace biotechnology as a source of achieving food security has made seed quality an important aspect in R & D and business sector in India. Intensifying international competition, increasing R&D costs, and the complexity of biotechnology have lead to increased consolidation of the Indian seed industry with several of the large and medium companies merging or being taken over by multinational seed companies.



Several leading multinational seed companies (Monsanto, Bayer CropScience, Syngenta, Advanta, Hicks-Muse-Tate, Emergent Genetics, Dow Agro, Bioseed Genetics International Inc., Tokita Seed Co, and Nunhems Zaden BV) have entered the seed market and currently the composition of the seed industry by volume of turnover, is reportedly 60:40 between the private and public sectors (Govindan, 2003).

The Indian Government has framed certain rules to govern the production and distribution of quality seeds to the farming community since most of the farming community is either illiterate or semi- literate. To designate seed quality parameters the Seed Act was formed in 1966 followed by Seed Rules in 1968. Both the acts were adopted during 1969 for the whole region of India except Sikkim and Kashmir. The Seeds Act provided a legislative framework for regulation of quality control of seeds sold in the country. Certain amendments were made subsequently for the Seeds Act during the years 1972, 1973, 1974 & 1981. The Central Seed Committee (CSC) and the Central Seed Certification Board (CSCB) were set up under the Act to deal with all matters relating to administration of the Act and quality control of seeds. Essential Commodity Act, 1955 was formed which insisted on compulsory licensing of the dealer as newer varieties were emerging.

To help Multinational Corporation in utilizing the manpower and knowledge base of our country, the Plants, Varieties and Fruits Order was passed during 1989 and amended subsequently during 1998, 2000 and 2001. Finally the order was revised by another order, Plant Quarantine (Regulation of import into India) Order in 2003. Signing of WTO in 1995 paved the way for private research and development of varieties. In order to regulate such varieties, the protection of Plant Varieties and Farmers' Right Act was passed in 2001 which was followed by National Seed Policy, 2002 and Seeds Bill, 2004.

SEED LEGISLATIONS BY GOVERNMENT OF INDIA.

Seed and Sowing- The Indian Seed Act (1966)

It was enacted in 1966 and has been in force since Oct. 2, 1969 in all over states of India. This act aims at regulating the quality of seed sold for agricultural purpose and provides the basic regulatory structure to ensure seed quality control through compulsory labeling and voluntary certification. The Act specifies the function of various regulatory bodies associated with the industry as well as chalks certain rules for notification of new varieties, specifications of minimum limits of germination and purity, regulation of sale of seeds, certification, labeling, etc. Under compulsory labeling, any one selling the seed of a notified kind or variety, in the region for which it has been notified, should ensure that:

- 1. The seed confirms to the percentage of germination purity.
- 2. The seed container is labeled in the prescribed manner for easy identification and validation,
- 3. The label truly represents the true quality of seed in the container.

For voluntary certification, certified seeds can be produced by applying to the seed certification agency for the grant of certificate. The agency grants the certificate and certification tags after satisfying itself that the seed has been after satisfying itself that the seed has been produced according to the prescribed standards and procedures.

There are mainly two regulatory bodies' viz., the central seed committee and the central seed certification board, which advises the central and the state governments in the matters related to the general administration of the seeds act and of seed certification, respectively.

The full text of the Seed Act is available at: http://agricoop.nic.in/seedsact.htm

Seed Rules, 1968

The Seed Rules framed under The Indian Seed Act (1966) and was notified in 1968 to implement various legislations given under Seed Act, 1966 and contain 11sections.

I. Preliminary

This section provides definitions of various terms that are used under the seed rule.

II. Central Seed committee

This section provides information regarding daily allowances and travelling expenditure along with different functions allotted to the seed committee such as recommendation for Seed Testing fee, advice on the suitability of seed testing laboratory, recommendation for the procedure and standards for seed certification and testing.

III. Central Seed Laboratory

This section provides information regarding specific functions allotted to the Central Seed Laboratory such as coordinating with State Seed Laboratories for uniformity in test results, collecting data on quality of seeds available in the market and any other function assigned to it by the Central Government.

IV. Seed Certification Agency

This section describes the specific functions of Certification Agency such as outlining the procedure for submission of applications, growing, harvesting and processing and storage of seeds indented for certification, maintaining a list of recognized nucleus seed breeders, inspections of seed production fields, seed processing plant and seed stores, grant of certificates.

V. Marketing or Labeling

Several rules for marketing are noted in this section. It is important to mention the name, and address of the person or agency that produced the seed on the label. Along with that germination and purity level of the seed, net weight of the seed, date of seed testing and a statement if the seed is treated should also be mentioned. It is the person/agency's responsibility for the accuracy of information given in the unopened original container. Any transparent cover used solely for the purpose of packing during transport or delivery need not be marked or labeled.

VI. Requirements for Certification

Certification of seeds into three sections viz. Foundation seed, Registered seed and Certified seed on the basis of the standards of each class.

VII. Certification of seeds

The detailed procedure of seed certification starting from applying for certification till the grant of certificate has been provided in this section. Application has been outlined by the certification agency containing the name and details of the applicant, the name of the seed to be certified, class & source of the seed, germination and purity and mark or label. A fee of Rs. 25 is levied for certification. Once certified, the certification tag containing information such as name and address of the certification agency, name of variety, lot number, name and address of the producer, date of issue of its certificate and its validity, an appropriate sign, to designate certified seed. The color of the tag shall be white for foundation, purple for registered and blue for certified seed. The holder of certificate shall allow any seed inspector to enter and inspect the seeds kept for sale, registers or other documents.

VIII. Appeal

Provision for appeal has been provided by submitting a memorandum accompanied by a treasury receipt for Rs. 100. The appellate authority shall exercise all the powers which a court has, while deciding appeal under the code of civil procedure, 1908.

IX. Seed Analyst and Seed Inspectors

This section describes specific qualifications and authorities allotted to seed analyst and seed inspectors. Seed analyst and seed inspectors should possess a Master Degree in Agriculture/ Agronomy/ Botany/ Horticulture from a recognized University with at least one year experience in Seed Technology or possess a Bachelors degree in Agriculture/Botany from a recognized university with a minimum of three years experience in Seed Technology for this purpose. Analysis of seed by seed analyst will be conducted according to the provisions of the Act.

X. Sealing, Dispatch and Analysis of Samples

The details of sampling, labeling, manner of packing and sealing the samples as well as its dispatch to the seed analyst has been provided.

XI. Miscellaneous

The need to maintain stock record of seeds and record of the sale of seed have been provided in this section.

The full text of the Seed Rules is available at: http://agricoop.nic.in/seedsrules.htm

Amendments to the Seed Act / Seed Rules the Seeds (amendment) Rules, 1972

Inclusion of "jute seeds" into the Seeds Act, Establishment of a Seed Certification Board, and empowerment of the Board to fix minimum standards

The primary objective of the certification board was to establish Central Seed Certification Board to advise Government on all matters relating to the certification and co- ordinate the functioning of certification agencies. The rule says that the seed should meet a prescribed standard provided that the standard is not lower than the minimum limits of germination and purity specified for the seed. Clause for "Power to fix standards for which seeds should confirm" was added under the power to make rules in the Seeds Act, 1966.

It also provides information of the Board members to be included with a Chairman and employees nominated by the Central Government, Directors of Agriculture and Directors of Research.

The Seeds (amendment) Rules, 1973

Powers and duty of seed analyst have been modified. Reference of seed analyst is necessary for the testing manual published by ICAR. The seed analyst shall analyze samples in accordance with the procedures laid down in the Seed Testing Manual published by the ICAR in specific time period (maximum 30 days after receipt of the sample). The Judicial powers of authority provided in Seed Rules under Appeal, has been omitted. Amendment by empowering the State Government to assign any duty to Seed Inspector has also been made.

The Seeds (amendment) Rules, 1974

More powers were conferred on seed inspector in the situation of crop failure. The amendment says that the inspector shall investigate causes of failure by sending seed samples for detailed analysis and shall also submit the report to the competent authority in case of crop failure.

It also modified the seed rules by adding an extra clause which insisted on action taken by the seed inspector to take proceedings against supplier if the inspector comes to conclusion that failure of performance is due to low quality seed not meeting the minimum standards notified by the Central government.

The Seeds (amendment) Rules, 1981

A new rule added under the seed certification and has mentioned Indian Minimum Seed Certification Standards published by the Central Seed Committee to be referred for certification

The amendment says certification agency shall ensure that the seed standards confirm to the minimum seed certification standards laid down in the manual known as Indian Minimum Seed Certification Standards published by the Central Seed Committee which is commonly called as Blue Book.

Seed (Control) Order, 1983

A Seeds (Control) Order was issued in 1983 under the Essential Commodities Act of 1955. The Essential Commodity Act, 1955 gives powers to State governments to regulate various aspects of trading in essential commodities under the supervision of Central Government. The act again passed with amendments in the year 1980 clearly states that detaining of persons whose activities are unethical in the supply of essential commodities. This help in prevention of black marketing of the supplies.

Seed (Control) Order, 1983 required the seed dealers to obtain a license valid for three years in order to operate, grants the Controller powers to regulate the sale and distribution of seed and provide additional power to the seed inspectors as to appoint a licensing authority, inspectors and mode of action for supply regulation. The time period for completion of seed analysis in case of any doubt about quality is 60 days as compared to 30 days under Seed Rules. The seed dealer has to essentially display the stock position (opening and closing) on daily basis along with a list indicating prices or rates of different seeds. A cash or credit memorandum has to be compulsorily given by the dealer to purchaser of seeds.

The National Seed Project undertook various measures and had set up huge processing plants in order to provide processing of certified seeds of self pollinated food crops to farmers. However it did not result in complete fulfillment of the mission since private sectors were able to take forward their quality seeds in both self and cross pollinated crops of varieties/ hybrids respectively. In the year, 1971, National Commission on Agriculture recommended breaking of Public sector hold and entry of private sector into the Indian Seed market. Subsequently, the National Seed Policy in 1988 was formulated to help privatize the Indian seed industry at that

New Policy on Seed Development, 1988

time the import of seeds were restricted.

This policy was issued for the purpose to regulate the import of agricultural items into India. This policy permits the import of high quality seeds (oilseed crops, pulses, coarse grains, vegetables, flowers, ornamental plants, tubers, bulbs, cuttings and saplings of flowers) under the monitoring of Open General License (OGL), to increase productivity thereby farm income. Private seed producing firms should compulsorily register with NSC before importing the seeds. The import of horticultural crops including flowers needs recommendation from Directors of Horticulture, import of crop seeds require permission from ICAR. Multi-locational trials in various agro-climatic conditions at least for one season will be conducted by ICAR. Evaluation of important traits such as yield, pest resistance etc. needs to be done within 3 months of harvest after which importer shall apply to the DAC for permit. Within a month, DAC will process it and thereafter controller of Imports and Exports will issue a license.

Plants, Fruits and Seeds Order (Regulation of Import into India order) 1989

The full text of the Order is available at: http://agricoop.nic.in/seedsconord.htm

The order was made to regulation of Import of Plants, Fruits and Seeds Order only through specified customs stations into India 1984 based on post entry quarantine. Facilities for post entry quarantine shall be established which shall be permitted to be released by Designated Inspection Authority. Import of any form of seed for consumption or sowing should carry a permit issued by the competent authority, and the import should be inspected by the Plant Protection Advisor. With the liberalized trade in agriculture, further amendments have currently been made for the above order during 1998, 2000 and 2001. In year 2003, Plant Quarantine (Regulation of import into India) Order has been issued which has now replaced the Plants, Fruits and Seeds order, 1989

Protection of Plant Varieties and Farmers Right Act, 2001

- The agenda of this act is that the variety being claimed for protection needs to be notified. Constitution of Plant Variety
 Protection Appellate Tribunal to exercise jurisdiction and powers consisting of Judicial as well as Technical members. The
 act is unique in the world with inclusion of rights of farmers, breeders, researchers and equity concerns. The Act covers all
 categories of plants except microorganisms.
- First priority is given to the food crops including major cereals, pulses, oilseeds, vegetables and fruit crops while second priority is given to Crops important for India in the world trade, species of Indian origin, crops where India could benefit from introduction of new germplasm.
- The Central Government shall establish a PPV & FR Authority with a Chairman and 15 Members are included to implement the various functions of the Act. The detailed contents to be provided in the application form for registration has been given. Complete passport data of the variety, clear pedigree and source of origin of the variety, statement declaring no terminator gene is present, specification on novel and distinct character of the variety etc. are some of the major features in the form.
- The DDS test guidelines have been laid for the registration for many crops for protection.
- Such a variety can be registered for protection if it satisfies the criteria of Novelty, Distinctness, Uniformity and Stability (NDUS) criteria.
- Novel variety means the variety not sold or disposed by the breeder for commercial exploitation in India earlier than one year or outside India, earlier than four years before the date of filing of application for registration. A Distinct variety would be defined as the variety is clearly distinguishable by at least one essential characteristic from any other variety whose existence is known in any country at the time of filing of application While Uniformity means the variety is sufficiently uniform for essential characteristics other than the variation that may be expected within the variety due to its mode of reproduction Stability means the variety remain unchanged for its essential characteristics even after repeated Propagation
- Period of protection is six years in case of crops and may be renewed on condition that the total period of validity does not exceed 15 years.
- Breeder has to pay an annual fee based on the royalty gained by the variety for retention of registration of the same. A
 National Gene Fund has been constituted which will be utilized for payment as rewards to farmers who has preserved a
 variety and which has been used as donor of genes in development of a new variety by any breeder.
- The gene fund also provides compensation to farmers if the variety does not perform to the expected performance of the variety. The expected performance of a protected variety under specific condition needs to be compulsorily provided to the farmers during sale. Along with that under situations of unavailability of seeds of protected varieties, the authority can grant reasonable price, provided the expiry period of 3 years of registration of variety is completed.
- The National Gene fund is credited with the benefit sharing from the breeder, the annual fees payable by the breeder through royalties and contribution from any national and international organization and other sources.
- Farmers have the right to save, re-sow, exchange, share and sell farm produce of any protected variety. He is only exempted for the commercial marketing with brand name

• Registration certificate issued to a breeder allow him/her exclusive right to produce, sell, market, distribute, import or export the variety. The breeder of essentially derived varieties so developed using the protected varieties shall have the same rights as the breeder of other new varieties

New Seed Legislation, 2002

The GOI is in the process of formulating a new seed legislation aiming at regulating the quality of seeds for sale, imports, and exports. National Seed Policy was formulated in 2002 to raise the Indian share in the global seed trade by facilitating advanced scientific aspects such as biotechnology to farmers and in March 2002, first transgenic Bt cotton was approved for commercial cultivation in India. Various stakeholders are currently reviewing the draft bill.

The main objectives of the National Seeds Policy, therefore, are

- To provide an appropriate climate for the seed industry,
- To utilize available and prospective opportunities,
- Safeguarding of the interests of Indian farmers and
- The conservation of agro-biodiversity.
- While unnecessary regulation needs to be dismantled, it must be ensured that gullible farmers are not exploited by unscrupulous elements.
- A regulatory system of a new genre is, therefore, needed, which will encompass quality assurance mechanisms coupled with facilitation of a vibrant and responsible seed industry.

The salient features of the proposed legislation are:

- The policy encourages private sector participation in research and development of new plant varieties.
- Establishment of a National Seed Board in place of Central Seed Committee and Central Seed Certification Board to
 undertake seed certification and advising Government on all matters related to seed planning and development. NSB will
 serve as the apex body in the seed sector
- Compulsory registration of all varieties being offered for sale by National Seed Board (NSB), to be constituted by the government. This registration is valid up to 15 years for annual and biennial crops and 18 years for long duration perennial crops
- The rights empowered to various bodies for regulating the quality of seeds produced, distributed and for providing variety protection as per the Seeds Act, 1966 and PPV & FR Act, 2001 have been retained in the policy. Major rights are maintenance of a National Register on seeds of varieties, establishing a national gene fund, disclosure of the variety's expected performance and provision for farmer to claim compensation in case of crop failure. Further, aims of National Seed Policy such as development of infrastructure, ensuring supply of good quality seeds and facilitating the International seed trade are sought to be addressed through the proposed Seeds Bill, 2004.
- Setting up of National Seed Research and Training Centre to impart training in seed technology
- Development of a National Seed Grid to provide information on availability of different varieties of seeds with production details. Both public and private sector will be encouraged to join the grid for a clear assessment of demand and supply of seeds
- Registration of genetically engineered crops subject to clearance under the Environmental (Protection) Act, 1986 i.e. Selling, bartering, importing/exporting of seed of any transgenic kind/variety subject to declaration to this effect

1JCR

- Registration of all seed producers and seed processing. Registration of existing varieties on the basis of three years of
 agronomic performance data to be submitted by the applicant and Registration of new/exotic varieties only provisionally
 for two years
- · Declaration of information on adaptability and expected agronomic performance by the breeder
- The seed standards is decided by, to appoint private/public seed certification agencies and to formulate rules for compensation to farmers in the event of a crop failure due to defective seeds
- Establishment of seed banks for ensuring supply in times of calamity and storage facility at village level
- Promotion of seed village scheme to increase the production and make available the seeds in time as well as upgrading the quality of farmers' saved seeds and also exemption of farmers' seed from the Seed Act and allowing them to save their own seeds and market it without branding.

Phytosanitary Regulations

The Destructive Insects and Pests Act, 1914 & Plants, Fruits and Seeds (Regulation of Import in India) Order, 1989

This Act and Order regulates the import into India of agricultural products including plants and seeds. Some of the salient features are:

- Prohibit import of seeds for sowing and planting materials without a valid permit Clearance of consignments subject to inspection, fumigation, disinfection, and disinfestations as the case may be under official supervision
- Imports not permitted unless accompanied by an official Phytosanitary Certificate.

The full text of the Act, Order and Amendments are available at:

http://agricoop.nic.in/dtpact.htm

http://agricoop.nic.in/pfs.htm

http://agricoop.nic.in/pfsorder.htm

Intellectual Property Rights Plant Variety Protection and Farmers' Rights Act, 2001 & Rules

The GOI enacted legislation in August 2001 named, "Plant Variety Protection and Farmers Rights Act, 2001" to address concerns about the lack of effective intellectual property rights in the seed industry. This legislation provides for the establishment of a "Protection of Plant Varieties and Farmers' Right Authority" to implement the Act. Under the new legislation, farmers will continue to enjoy their traditional rights to save, use, exchange, share, and sell the produce of the protected variety with the only restriction that the farmer will not be able to sell branded seed of the protected variety for commercial purpose. The legislation contains several of the contentious issues such as the compulsory acquisition of parental material of a variety and granting production license to a third party to produce proprietary variety when there is a shortage of such seeds.

The GOI recently published the rules under this legislation, which are available at:

http://agricoop.nic.in/seeds/farmersact2001.htm

Biodiversity Act, 2002

Being a signatory to the United Nations' Convention on Biological Diversity, India enacted a Biodiversity Act in 2002. The Act provides for the establishment of a National Biodiversity Authority (NBA) and State Authorities. The full text of the Act is available at:

http://envfor.nic.in:80/divisions/biodiv/act/bio div act.htm

The provisions of the Act, which will have a bearing on seed trade, are:

- Person(s) who do not belong to India would be required to take permission of NBA before obtaining any biological resource occurring in India. Foreign companies, and even Indian companies having foreign equity are included in the list of such persons.
- Prohibits transfer of material or research occurring in India or obtained from India unless the research is collaborative and there are agreements to this effect before the Act was commenced
- Does not allow application for IPRs without permission of NBA in case the biological resource from India has been used for development of such a product
- Provides for imposition of charges by way of royalty subject to terms and Conditions

Environment (Protection) Act, 1986 monitors manufacture, use, import, export, and storage of hazardous microorganisms genetically engineered organisms or cells under the All genetically engineered crops/varieties will be tested for environment and bio-safety and their commercial release.

Department of Biotechnology (DBT) formulates Bio-safety guidelines and regulations in exercise of powers conferred to it through "Rules for the manufacture, use, import, export, and storage of hazardous microorganisms genetically engineered organisms or cells" formulated under the Environment (Protection) Act, 1986 and issued by the Ministry of Environment and Forests in JCR

Imports and exports of bio-engineered products are also governed by these rules.

The fulltext of the Rules is available at:

http://envfor.nic.in/legis/hsm/hsm3.html

National Seed Policy, 2002

The National Seed Policy, 2002, is expected to lay will entail significant changes to the existing legislative framework in order to stimulate varietal development in line with market trends and to introduce advanced scientific knowledge (including biotechnology) to meet farmers' needs.

The full text of the National Seed Policy, 2002 is available at:

http://agricoop.nic.in/seedpolicy.htm

Biotechnology is globally recognized as a rapidly emerging and far-reaching technology. It is aptly described as the "technology of hope" for its promising of food, health and environmental sustainability. The recent and continuing advances in life sciences clearly unfold a scenario energized and driven by the latest tools of biotechnology. There are a large number of therapeutic biotech drugs and vaccines that are currently being marketed, accounting for a US\$40 billion market and benefiting over a hundred million people worldwide. Hundreds more are in clinical development. In addition to these there are a large number of agri-biotech and industrial biotech products that have enormously helped mankind in many ways. Biotechnology is hence predicted to play a vital role in the development of the agriculture sector. This technology can be used not only to develop new crops/varieties, which are tolerant to disease, pests and abiotic stresses, but also to improve productivity and nutritional quality of food.

As it is important to recognize the potential of Genetic Engineering and its relevance to India, Ministry of Science and Technology gave sufficient impetus for research and monitoring of transgenic seed development.

The measures of transgenic regulation fall under the Environment and Protection Act, 1986 and EPA rules, 1989.

- Establishment of Department of Biotechnology in 1986 exclusively to utilize biotechnological approaches in agriculture and human health.
- Establishment of Review Committee on Genetic Manipulation (RCGM) in 1989 for effective monitoring and assessment which lay guide lines for assessment of GM crops
- Establishment of Institute Bio-safety Committee at the organization level, to evaluation r-DNA technology work
- Establishment of Special Monitoring cum Evaluation Committee under RCGM to monitor the positive and negative effect of transgenic plants on the environment with following members:
- Establishment of Genetic Engineering Approval Committee which will recommend for an approval of a transgenic variety for commercial cultivation to the government.

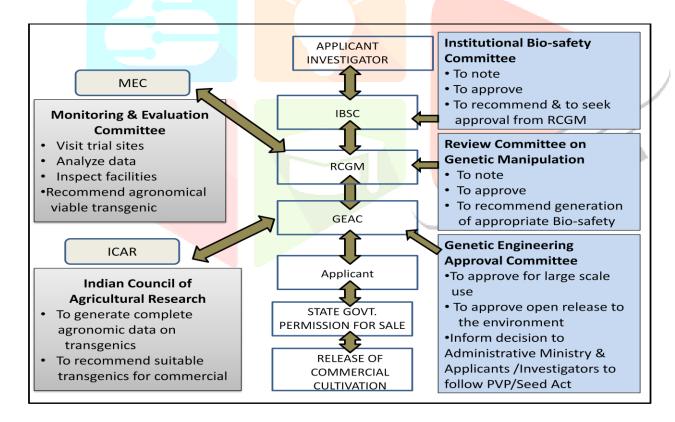


Fig 3: Procedures Involved in the Commercialization of Indigenously Developed Transgenic Crops

Procedures Involved in the Commercialization of Indigenously Developed Transgenic Crops

- All genetically engineered crops/varieties will be tested for environment and biosafety before their commercial release, as per the regulations and guidelines of the Environment Protection Act (EPA), 1986.
- The EPA, 1986, read with the Rules, 1989 would adequately address the safety aspects of transgenic seeds/planting
 materials. A list will be generated from Indian experience of transgenic cultivars that could be rated as environmentally
 safe.
- Seeds of transgenic plant varieties for research purposes will be imported only through the National Bureau of Plant Genetic Resources (NBPGR) as per the EPA, 1986.
- Transgenic crops/varieties will be tested to determine their agronomic value for at least two seasons under the All India Coordinated Project Trials of ICAR, in coordination with the tests for environment and bio-safety clearance as per the EPA before any variety is commercially released in the market.
- After the transgenic plant variety is commercially released, its seed will be registered and marketed in the country as per the provisions of the Seeds Act.
- After commercial release of a transgenic plant variety, its performance in the field, will be monitored for at least 3 to 5 years by the Ministry of Agriculture and State Departments of Agriculture.
- Transgenic varieties can be protected under the PVP legislation in the same manner as non-transgenic varieties after their release for commercial cultivation.
- All seeds imported into the country will be required to be accompanied by a certificate from the Competent Authority of
 the exporting country regarding their transgenic character or otherwise.
- If the seed or planting material is a product of transgenic manipulation, it will be allowed to be imported only with the approval of the Genetic Engineering Approval Committee (GEAC), set up under the EPA, 1986.
- Packages containing transgenic seeds/planting materials, if and when placed on sale, will carry a label indicating their transgenic nature. The specific characteristics including the agronomic/yield benefits, names of the transgenes and any relevant information shall also be indicated on the label.
- Emphasis will be placed on the development of infrastructure for the testing, identification and evaluation of transgenic planting materials in the country.

Seed Bill (2004) The Seed Bill is proposed to replace the Seed Act, 1966

In 1998, a Seed Policy Review Group in India recommended a long-awaited shake-up and reform to the Indian seed laws; a new seed law that would replace the current 1966 Seeds Act. In 2004, a new Seed Bill2 was announced. The major objectives of Seed Bill (2004) were:

- Making the registration of varieties obligatory (previously voluntary)
- Creating a National Register of Seeds
- Regulating (make easier) the importing and exporting of seeds
- Accommodating new regulations on GM crops
- Improving market conditions for private seed companies

Highlights of the bill.

The Seeds Bill, 2004 aims to regulate the quality of seeds sold, and replaces the Seeds Act, 1966.

- All varieties of seeds for sale have to be registered. The seeds are required to meet certain prescribed minimum standards.
- The Bill does not restrict the farmer's right to use or sell his farm seeds and planting material, provided he does not sell them under a brand name. All seeds and planting material sold by farmers will have to conform to the minimum standards applicable to registered seeds.
- If a registered variety of seed fails to perform to expected standards, the farmer can claim compensation from the producer or dealer under the Consumer Protection Act, 1986.
- The Bill permits self certification of seeds by accredited agencies and allows the central government to recognize certification by foreign seed certification agencies.
- Every seed producer and dealer, and horticulture nursery has to be registered with the state government.
- Compulsory registration of seeds that are to be offered for sale has to pass through test for Value for Cultivation and Use (VCU) which would be conducted by multi-locational trials over three seasons. Samples of materials for registration will also be sent to NBPGR for retention in the National Gene Bank
- Voluntary Seed certification
- Enable two years provisional registration based on the information filed by the applicant relating to trials over one season to tide over the stipulation of testing over three seasons before the grant of registration.
- The control of the seed committee and State Government is subjected to any organization or individual or any seed producing organization
- Registration of seed processing units will be required.
- Periodic registration of varieties already in the market at the onset of policy implementation required.
- Disclosure on the expected performance of a variety sold to a farmer is Compulsory. During failure the farmer may claim compensation under the Consumer Protection Act, 1986
- Minimum limits of germination, purity and seed health should be met by all registered seeds and the seed lots on sale should be compulsorily labeled. In transgenic varieties, the label should carry the name of transgene. Central Seed Committee in line with National Seed Board provided in the Seed Policy, 2002 will be the apex body to fix or set the minimum standards for the seeds and decide which seeds are harmful or dangerous to the environment and public health
- Compulsory registration of seed producer or any seed production organization, horticultural nurseries engaged in business
 is required. If the dealer intends, any registered varieties offered for sale can also be certified by the State Certification
 Agency
- Seed testing labs will be established in conformity with ISTA to meet the quality requirements of seeds during export and will also serve as referral lab in case of disputes.
- The import of transgenic seeds to be done only through NBPGR after approval from GEAC as per the EPA, 1986

- Compulsory testing of transgenic crop varieties conducted under AICCIP to determine their agronomic value in coordinance with the tests for its positive or negative effect on environment as per the EPA before its commercial release.
 Strengthening of testing and certification facility conducted with international standards
- Post release monitoring of transgenic for performance for 3 5 years by the Ministry of Agriculture and State Departments of Agriculture
- Provision of protection of transgenic as per PPV & FR provisions required. Appointing Seed inspectors with more powers unlike that mentioned in Seed Act, 1966. No warrant or procedural safeguards shall be applicable
- Plant quarantine procedure need to be strictly followed during import of seed material with a permit from Plant Protection Adviser to the G.O.I. keeping a record of availability of seeds of different crops to assess the impact of exports on domestic availability of seeds by Creating data base.
- Encouraging seed production in non-traditional areas and subsidy to take up seed production in marginal lands Revocation of certificate under misrepresentation
- Recognition of Seed Certification Agencies in foreign countries
- Provision of appeals and establishment of an appellate authority A public opinion has emerged on the fact that Seed Bill provisions are contradictory to the PPV & FR legislations and that the Seed Bill has been drafted to suppress the merits of PPV & FR Act, 2001.

Biotechnology Regulatory Authority of India (BRAI) BILL, 2013

The BRAI Bill is being introduced by Department of Biotechnology (DBT), Ministry of Science & Technology. DBT with has the mandate of promoting biotechnology research and product development and therefore, cannot be the regulator.

• BRAI shall be an independent, autonomous, statutory agency to regulate the research, transport, import, manufacture and use of organisms and products of biotechnology.

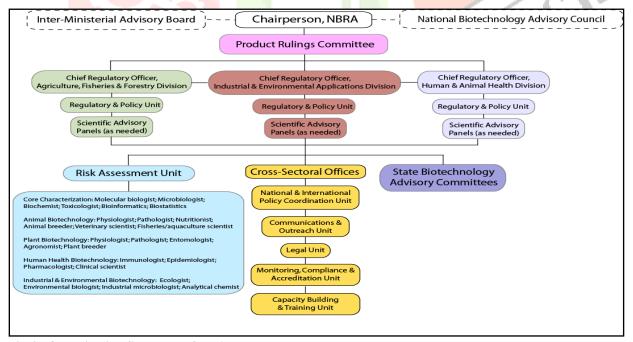


Fig 4 : Organization Structure of BRAI

- •The proposed statutory independent regulator that is the Biotechnology Regulatory Authority of India (BRAI) would be a nodal agency of the Government of India to ensure comprehensive safety assessment of organisms and products of modern biotechnology.
- •Commercialization of biotechnology products in agriculture and healthcare would be subject to all other laws whether central or State, for the time being in force and rules and regulations made there under.

PROPOSED MANAGEMENT STRUCTURE FOR BRAI

• Agriculture, Forest and Fisheries Branch (AFFB) to regulate GM plants, animals and micro-organisms used in agriculture, forestry or fisheries, including aquaculture.

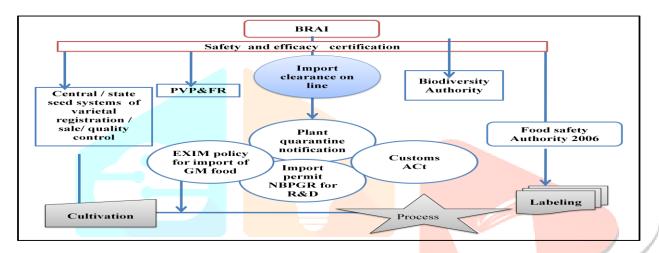


Fig 5: Harmonization with other acts/policies/systems/authorities

- Human and Animal Health Branch (HAHB) to regulate genetically modified organisms with applications in human and veterinary health, such as assessing the potential environmental risks and benefits associated with the application of GMOs in pharmaceutical development or recombinant livestock vaccine production.
- <u>Industrial and Environmental Applications Branch (IEAB)</u> to regulate GMOs used in industrial manufacturing and in environmental applications, such as the use of GMOs for bioremediation of contaminated sites or oil spills. (Other branches as per need in future)

Conclusion

Agriculture production is completely dependent on seed as it is the primary and highly critical input. Indian seed programme largely adheres to the limited generation system for seed multiplication. Until the purity, quality and seed standards are maintained, agricultural production programme cannot be successful. Legislation serve the purpose o maintain these quality standards, legislations, they also take part in monitoring the these legislations of the quality of the seeds at production, processing, marketing and labeling and marketing levels to ensure the farmer gets the best quality seed. Therefore Government of India had taken steps in framing Seed Act, Seed Rules, Seed (control) order, National Seed Policy, Plant quarantine order, PPV & FR Act to not only to protect breeders, researchers but also a common farmer. This information might enhance the agricultural productivity of India which is primarily considered as "an **Agricultural Land**"

Reference

- 1. Altieri, M.A. and P. Koohafkan (2008). Enduring farms: Climate change, small holders and traditional farming communities. TWN Environment 8 development series No. 6. Third world network, Penang.
- 2. Fontes, EMG. (2003). Legal and regulatory concerns about transgenic plants in Brazil. Journal of invertebrate pathology 83: 273-313.
- 3. Leisinger, K.M. (1996). Ethical and Ecological Aspects of Industrial Proprty rights in the context of genetic engineering and Biotechnology. Basel, Switzerland: Novartis Foundation for sustainable Develoment http://www.foundation.novartis.com/genetic engineering biotechnology htm
- 4. Losey JE, Rayor LS, Carter ME (1999) Transgenic pollen harms monarch larvae. Nature 399:214.
- 5. Lucca, P. et al. (2001). Genetic engineering approaches to improve the bioavailability and the level of iron in rice grains. *Theor. Appl. Genet.* 102: 392-397
- 6. Sagar, A., Daemmrich, A. and Ashiya, M. (2000). The tragedy of the commoners: Biotechnology and its publics. Nature Biotechn. 18: 2-4.
- 7. Sears MK, Hellmich RL, Stanley-Horn DE, Oberhauser KS, Pleasants JM, Mattila HR, Siegfried BD, Dively GP (2001) Impact of Bt corn pollen on monarch butterfly populations: a risk assessment. Proc Natl Acad Sci USA 98:11937–1194.
- 8. Simmons, N,W., Smart, J., Millam, S. and Spoor, W. (1999). Principles of Crop Improvement, 2nd edition. Oxford, UK: Blackwell publication.
- 9. Wachbroit, R (1991). Describing risk, risk assessment in genetic engineering. Environmental release of organisms. New York, NY: McGraw-Hill, pp. 368-377.

