Regulatory Framework For GM Crops

BCIL
Biotech Consortium India Limited
New Delhi

सत्यमेव जयते
Department of Agriculture & Cooperation
Ministry of Agriculture
Govt. of India

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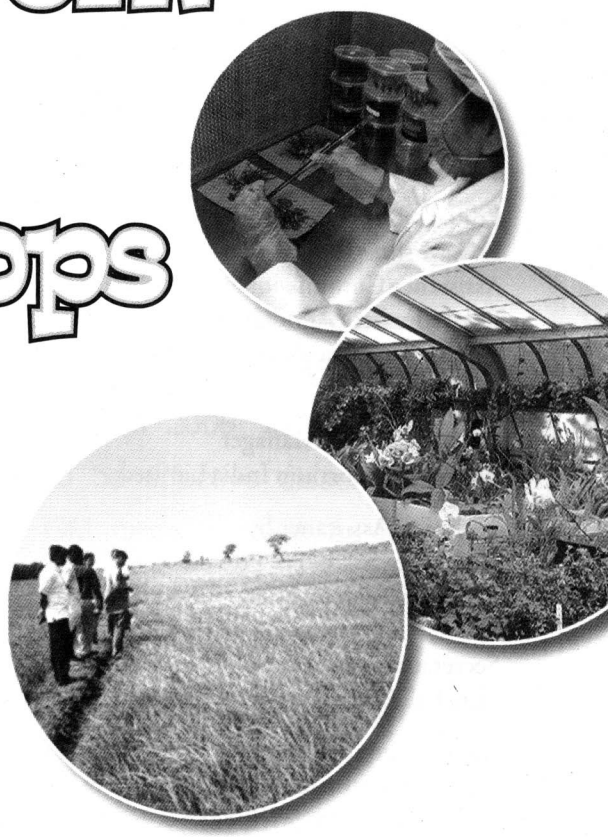

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Edited by
D.S. Mishra
Assistance Commissioner (Seeds)
Department of Agriculture & Cooperation,
Ministry of Agriculture, Government of India

Dr. Vibha Ahuja
Deputy General Manager
Biotech Consortium India Limited

Technical Assistance by
Jeetendera Solanki & Priti Semwal
Project Executive, BCIL

Secretarial assistance by
Hira Lal, BCIL

All correspondence may be addressed to
Biotech Consortium India Limited (BCIL)
Anuvrat Bhawan, 5th Floor
210, Deen Dayal Upadhyaya Marg
New Delhi - 110 002
Tel. No. ++91-11-23219064-67
Fax No. ++91-11-23219063
Email: biotechdelhi@vsnl.com
bcildelhi@vsnl.com
Website: www.biotech.co.in

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We thankfully acknowledge the contribution of :

- Dr. O.P. Govila
  Former Head,
  Department of Genetics,
  Indian Agricultural Research
  Institute, New Delhi.
- Dr. K.K. Tripathi
  Member-Secretary,
  (Review Committee on
  Genetics Manipulation) &
  Advisor, Department of Biotechnology,
  Ministry of Science & Technology
  Government of India.
- Dr. Ranjini Warrier
  Member-Secretary,
  (Genetic Engineering Approval
  Committee) & Director, Ministry of
  Environment and Forests,
  Government of India

S. L. BHAT
संयुक्त सचिव
भारत सरकार
कृषि मंत्रालय
(कृषि एवं सहकारिता विभाग)
कृषि भवन, नई दिल्ली–**110001**

सत्यमेव जयते

Joint secretary
Government of India
Ministry of Agriculture
Department of Agriculture
& Cooperation)
Krishi Bhawan, New Delhi-110001

e-mail: sl.bhat@nic.in
Telefax: 91-11-2338 9348

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FOREWORD

India is one of the major countries which have released Genetically Modified cotton for commercial cultivation. The area under the cultivation of Bt. cotton has increased rapidly to reach the figure of 3.8 million hectares in 2006. In the context of developments, it is necessary that there should be effective dissemination of information and awareness about benefits of GM crops as well as risks and constraints, in a transparent manner. This programme will help the farmers to have right perspective about the GM crops.

I am glad that the BCIL has taken up the execution of the programme in right earnest. The training programmes are being conducted at District and Tehsil levels in association with State Agriculture Department. I would like to compliment the BCIL for bringing out useful and comprehensive material for the benefit of the trainees in their vernacular languages.

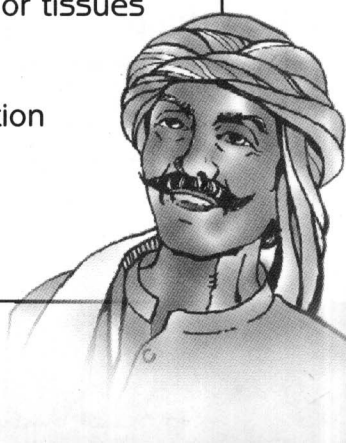
(S. L. Bhat)

REGULATORY FRAMEWORK FOR GM CROPS

INTRODUCTION

Genetically modified organisms (GMOs) and products thereof including GM crops are regulated products in India under the Environment Protection Act, 1986. Under this Act, Rules for the manufacture, use/import/export and storage of hazardous micro organisms/ genetically engineered organisms or cells have been notified by Ministry of Environment and Forests through their Notification No. 621 in Official Gazette of Govt. of India on December 5, 1989. These Rules commonly referred as Rules 1989 cover areas of research as well as large scale applications of GMOs and its products and apply to:

- Manufacture, import and storage of microorganisms and gene technological products
- Genetically engineered organisms/microorganisms and cells and correspondingly to any substance and products and food stuffs, etc., of which such cells, organisms or tissues form part
- New gene technologies in addition to cell hybridization and genetic engineering



IMPLEMENTING AGENCIES

These rules and regulations are implemented by:

- Ministry of Environment and Forests
- Department of Biotechnology
- State Governments

Six Competent Authorities and their composition have been notified under these Rules, which are as follows:

i. Recombinant DNA Advisory Committee (RDAC)

ii. Institutional Biosafety Committees (IBSC)

iii. Review Committee on Genetic Manipulation (RCGM)

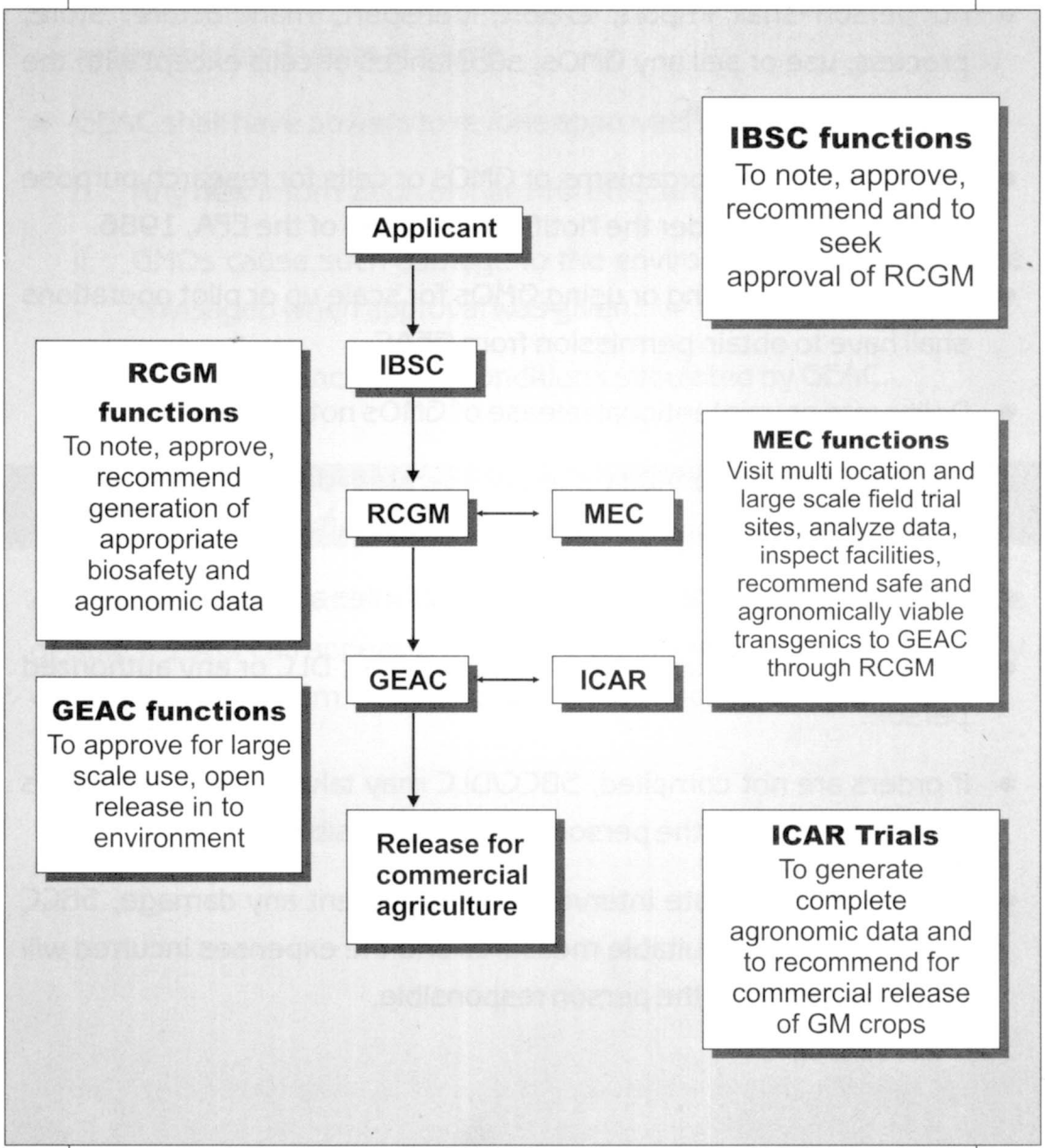
iv. Genetic Engineering Approval Committee (GEAC)

v. State Biosafety Coordination Committees (SBCC)

vi. District Level Committees (DLC).

While the RDAC is of advisory in function, the IBSC, RCGM, and GEAC are of regulatory function. SBCC and DLC are for monitoring purposes. The composition of each committee is defined in the Rules, 1989. In addition to the above, a Monitoring cum Evaluating committee (MEC) has been set up by the RCGM to monitor the field performance of GM crops.

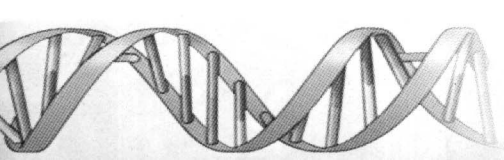
PROCEDURE FOR APPROVAL OF GM CROPS



Source: Department of Biotechnology

APPROVALS AND PROHIBITIONS UNDER RULES 1989

- No person shall import, export, transport, manufacture, store, process, use or sell any GMOs, substances or cells except with the approval of the GEAC.
- Use of pathogenic organisms or GMOs or cells for research purpose shall be allowed under the Notification, 1989 of the EPA, 1986.
- Any person operating or using GMOs for scale up or pilot operations shall have to obtain permission from GEAC.
- Deliberate or unintentional release of GMOs not allowed.
- Production in which GMOs are generated or used shall not be commenced except with the approval of GEAC.
- GEAC supervises the implementation of rules and guidelines.
- GEAC carries out supervision through SBCC, DLC or any authorized person.
- If orders are not complied, SBCC/DLC may take suitable measures at the expenses of the person who is responsible.
- In case of immediate interventions to prevent any damage, SBCC and DLC can take suitable measures and the expenses incurred will be recovered from the person responsible.



- All approvals shall be for a period of 4 years at first instance and renewable for 2 years at a time.
- GEAC shall have powers to revoke approvals in case of:
  - i. Any new information on harmful effects of GMOs.
  - ii. GMOs cause such damage to the environment as could not be envisaged when approval was given.
  - iii. Non-compliance of any conditions stipulated by GEAC.

APPEAL MECHANISM

Any person aggrieved by a decision made by GEAC/SBCC in pursuance of Rules, 1989 can appeal to National Environment Appellate Authority within thirty days from the date of communication of decision.

GUIDELINES

Recombinant DNA Guidelines

Recombinant DNA Guidelines have been issued by Department of Biotechnology in 1990 which were further revised in 1994. These guidelines include guidelines for R&D activities on GMOs, transgenic crops, large-scale production and deliberate release of GMOs, plants, animals and products into the environment, shipment and importation of GMOs for laboratory research.

The research activities have been classified into three categories based on the level of the associated risk. Appropriate practices, equipment and facilities necessary for safeguards in handling organisms, plants and animals in various risk groups have been recommended. The guidelines require the interested party to evaluate GMOs for potential risk prior to application in agriculture and environment i.e properties of the organism, possible interaction with other disease causing agents and the infected wild plant species. An independent review of potential risks should be conducted on a case-to-case basis.

Revised Guidelines for Research in Transgenic Plants

DBT has also formulated "Revised Guidelines for Research in Transgenic Plants" in 1998. These also include the guidelines for toxicity and allergenicity testing of transgenic seeds, plants and plant parts. These guidelines cover areas of recombinant DNA research on plants including the development of transgenic plants and their growth in soil for molecular and field evaluation. The guidelines also deal with import and shipment of genetically modified plants of research use.

The guidelines include complete design of a contained green house suitable for conducting research with transgenic plants. Besides, it provides the basis for generating food safety information on transgenic plants and plant parts

SEED POLICY, 2002

Seed Policy, 2002, has a separate section (No. 6) on transgenic plant varieties which states that all genetically engineered crops/varieties will be tested for environment and biosafety before their commercial release as per the regulations and guidelines under the EPA, 1986. 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. Once 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. The Ministry of Agriculture and State Departments of Agriculture will monitor the performance of the commercially released variety in the field for at least 3 to 5 years.

It has also been mentioned that transgenic varieties can be protected under the Plant Varieties & Farmers Rights Protection (PVP) legislation in the same manner as non-transgenic varieties after their release for commercial cultivation.

QUALITY CONTROL OF GM CROPS

Various notifications have been issued by Ministry of Environment and forests and Ministry of agriculture to ensure the seed quality of GM crops particularly Bt cotton as detailed below:

A. POWERS TO SEED LAW ENFORCEMENT AGENCIES UNDER EPA

As the Seeds Act, 1966 does not cover transgenic seeds, there were difficulties faced by State departments of Agriculture in the enforcement of the Bt cotton seeds quality. The Department of Agriculture and Cooperation, Ministry of Agriculture, therefore, had requested the Ministry of Environment and Forests to notify the Seed Inspectors under Section 13 of the Seeds Act and Section 12 of the Seeds (Control) Order to draw the seed samples of transgenic seeds as mentioned under Section 10 of the Environment (Protection) Act, 1986 Ministry of Environment & Forests in consultation with Ministry of Law & Justice has issues six Gazette Notifications (G.S.R.584 (E) to 589(E) dated September 1, 2006) wherein Seed Inspectors have been given adequate power to draw seed samples of transgenic seeds for the purpose of quality control and to get it tested in the notified seed testing laboratories and prosecute in case of spurious Bt cotton seeds. With the promulgation of the said notifications, the seed law enforcement agencies are empowered to take necessary punitive action against the offenders.

B. REFERAL LABORATORY FOR Bt COTTON

Ministry of Agriculture has issued a Notification on November 12, 2003 nominating Central Institute of Cotton Research (CICR) to act as a referral laboratory for ascertaining the presence or absence of cry1Ac gene in cotton seeds for the whole of India

C. PURITY OF COTTON SEEDS

In addition to the above, Seeds Division has issued minimum limits of purity in respect of Bt cotton seeds as 90% (Bt. Protein-toxin) under Section 6 of the Seeds Act, 1966 in the Gazette Notification issued vide SO No. 1567 (E) dated 5th November, 2005.

ROLE OF STATE AGENCIES IN MONITORING OF GM CROPS

State Agriculture Departments and State Agricultural Universities have an important role to play in the enforcement and monitoring of regulations regarding GM crops to harness their maximum benefit in a sustainable manner.

As per Rules, 1989 notified by Ministry of Environment & Forests, the responsibility of monitoring the activities related to GMOs is vested with State Biotechnology Coordination Committee (SBCC) and District Level Committee (DLC). The SBCC in the states shall have powers to inspect, investigate and take punitive action in case of violation of statutory provisions through the nodal department and the State Pollution Control Board/Directorate of Health/Medical Services. The DLC is to be set up in the districts wherever necessary under the District Collectors to monitor the safety regulations. The composition of SBCC and DLC is as follows:

Composition of SBCC and DLC

SBCC

(i) Chief Secretary - Chairman
(ii) Secretary, Department of Environment Member Secretary
(iii) Secretary, Department of Health - Member
(iv) Secretary, Department of Agriculture - Member
(v) Secretary, Department of Industries and Commerce - Member
(vi) Secretary, Department of Forests - Member
(vii) Secretary, Department of Public works/Chief Engineer, Department of Public Health Engineering - Member
(viii) State microbiologists and Pathologists - Member
(ix) Chairman of State Pollution Control Board

DLC

i) District Collector - Chairman
ii) Factory Inspector Member
iii) A representative of the Pollution Control Board - Member
iv) Chief Medical Officer (District Health Officer) Member (Convenor)
v) District Agricultural Officer Member
vi) A representative of the Public Health Engineering Department Member
vii) District Microbiologists Pathologist (Technical expert) - Member
viii) Commissioner Municipal Corporation - Member

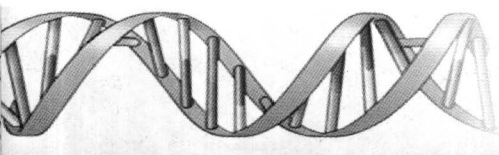
Secretary, Department of Agriculture in the State is a member of SBCC and District Agriculture Officer is a member of DLC and therefore is responsible for monitoring of GM Crops at State and District level. State Agriculture Department has a major responsibility towards monitoring compliance of conditions stipulated by GEAC for commercial release, field trials and seed production of GM Crops.

Further, the functionaries from State Agriculture Department implementing the Seed Act including seed laboratories and analyst have been empowered to take punitive action and the sampling procedures have been notified to ensure uniform action by the field staff. The State Agriculture Departments are also notified about the field trials by GEAC with copies of communications addressed to Secretary, Agriculture and Commissioner, Agriculture, simultaneously.

In addition to the above, the State Agricultural Universities (SAUs) are also being actively involved in pre release and post release monitoring of Bt cotton. The same has been recommended by Sub Committee on Bt cotton and related issues set up by the Ministry of Environment & Forests to look into streamlining the current regulatory framework for transgenic crops as both SAUs and State Agriculture Departments have elaborate establishment in place to monitor the performance of agricultural crops in their jurisdiction. A brief of alternate monitoring mechanisms for pre release and post release monitoring are as follows:

Pre release monitoring

Responsibility of monitoring Multi-location field trials (MLT) and Large Scale field trials (LST) has been entrusted to the State Agriculture Universities



(SAU) under the direct supervision of Director of Research of each SAU. The monitoring team shall visit the fields for minimum of two times during the cotton crop season matching boll development and other important stages of the cotton crop. All the replicated field trials conducted by the applicants in its SAU jurisdiction and at least 25% of large scale field trials in its jurisdiction would be monitored as per the conditions given in the experimental trial permits issued by DBT/MoEF. Monitoring teams are required to submit report on the large-scale field trials to MEC/GEAC and replicated multi-location field trials to RCGM/ MEC within 15 days from conclusion of the last visit.

Post release monitoring

Responsibility of post release monitoring has been entrusted to the State Agriculture Universities (SAU) under the direct supervision of Director of Agriculture Extension of each SAU.

The monitoring team shall visit the fields for a minimum of two times during the cotton crop season matching boll development and other important stages of the cotton crop. The recorded observations will consist of date of sowing, seed rate, method of planting, spacing, fertilizer application, micro-nutrient application, irrigation if any, control of pest/disease measures undertaken, IPM practices followed, method of harvesting, performance of the hybrid, economic benefits, views of public acceptability / other comments, compliance of GEAC conditions and any other parameter of relevance. The monitoring team may also be the focal point for providing feed back on the representations received by the GEAC/RCGM through an on the spot verification.

The composition of Pre and Post release monitoring team is given below:

Pre release monitoring Team

1) Director of Research, SAU, Nodal person - Team Leader
2) Plant Breeder (concerned crop), SAU - Member
3) Entomologist- Head of the Department - Member or Nominee State Agriculture University
4) Agronomist- Head of the Department- Member or Nominee State Agriculture University
5) Pathologist- Head of the Department - Member or Nominee State Agriculture University
6) Subject matter specialist - Member Relevant to the transgene (Biotechnologist).
7) Joint Director/Deputy Director,State Member Agriculture Department
8) Agriculture Officer of the concerned district/ State Agriculture Department - Member
9) Nominee of RCGM - Member
10) Nominee of GEAC -Member

Post release monitoring Team

1) Director of Extension, SAU, Nodal person - Team Leader
2) Plant Breeder (concerned crop), SAU - Member
3) Entomologist- Head of the Department Member or Nominee State Agriculture University
4) Agronomist- Head of the Department Member or Nominee State Agriculture University
5) Pathologist- Head of the Department Member or Nominee State Agriculture University
6) Subject matter specialist relevant to - Member transgene (Biotechnologist)
7) Biostatistician - Member

The detailed terms and conditions of the monitoring teams including financial support are available at http://www.envfor.nic.in.

CARTAGENA PROTOCOL ON BIOSAFETY

In addition to national biosafety legislations to ensure the safe use of Genetically modified organisms (GMOs) and products thereof, agriculture biotechnology being a global industry and GM crops traded across borders, international rules are needed as well.

Cartagena Protocol on Biosafety is an attempt to produce a globally harmonized regime for biosafety under the Convention of Biological Diversity (CBD). Named after the Colombian city where the final round of talks was launched, the Cartagena Protocol on Biosafety sets out a comprehensive regulatory system for ensuring the safe transfer, handling and use of Living modified organisms (LMOs) subject to transboundary movement. In every day usage LMOs are considered to be same as GMOs although definitions and interpretations vary widely.

The Protocol entered into force from September 11, 2003. As of December, 2006, 138 countries have ratified the protocol. India ratified the Protocol in January 2003. The Ministry of Environment & Forests (MoEF) is the nodal ministry for implementation of Cartagena Protocol.

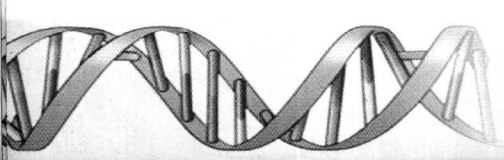
The Protocol deals primarily with LMOs that are to be intentionally introduced into the environment (such as seeds, trees or fish) and with genetically modified farm commodities (such as corn and grain used for food, animal feed or processing). It does not cover pharmaceuticals for humans addressed by other international agreements and organizations or products derived from LMOs, such as cooking oil from genetically modified corn.

The Protocol features a set of procedures including one for LMOs that are to be intentionally introduced into the environment (advance informed agreement procedure), and one for LMOs that are intended to be used directly as food or feed or for processing. Decisions by importing countries on whether or not to import these LMO-FFPs are taken under its domestic regulatory framework.

The Protocol empowers governments to make its decisions in accordance with scientifically sound risk assessments. The Protocol requires each country to manage and control any risks that may be identified by a risk assessment. Key elements of effective risk management include monitoring systems, research programmes, technical training and improved domestic coordination amongst government agencies and services. The Protocol provides for practical requirements that are deemed to contribute to the safe movement of LMOs. Parties are required to take measures for the safe handling, packaging and transportation of LMOs that are subject to transboundary movement..

The Protocol established a Biosafety Clearing-House (BCH) as part of the clearing-house mechanism of the Convention, in order to facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms; and to assist Parties to implement the Protocol. The Biosafety Clearing-House has been developed as an Internet-based system and can be found at http://bch.biodiv.org.

The Protocol calls for cooperation on promoting public awareness of the safe



transfer, handling and use of GMOs. It specifically highlights the need for education, which will increasingly have to address GMOs as biotechnology becomes more and more a part of our lives.The full text of the protocol may be seen at http://www.biodiv.org/biosafety/protocol.asp.

By becoming Party to the Protocol, a country is benefited in terms of harmonized rules, procedures and practices in managing the transboundary movement of LMOs and improved access/exchange of information and expertise.

NOTES




2007

January

1- Id-ul-Zuha, 13- Lohri
23- Basant Pancami,
26- Republic Day, 30- Moharram

Sun	Mon	Tue	Wed	Thu	Fri	Sat
	1	2	3	4	5	6
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28	29	30	31			

February

16- Maha Shivratri

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March

3- Holi, 4- Dhulendi, 27- Ram Navami
31- Mahaveer Jayanti

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April

1- Id-Ul-Milad, 6- Good Friday
14- Baisakhi, 14- Ambedkar Jayanti

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May

2- Budh Purnima

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August

15- Independence Day
28- Raksha Bandhan

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September

4- Janmashtmi, 15- Ganesh
Chaturthi, 25- Anant Chaudas

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October

2- Gandhi Jayanti
14- Id-Ul-Fitar, 21- Dushera

Sun	Mon	Tue	Wed	Thu	Fri	Sat
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November

9- Diwali, 11- Bhaiya Dooj
24- Gurunanak Birthday

Sun	Mon	Tue	Wed	Thu	Fri	Sat
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December

21- Id-Ul-Zuha
25- Christmas Day

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