

In India, the Ministry of Environment, Forest and Climate Change (MoEFCC) promulgated the rules and procedures for the manufacture, import, use, research and release of GMOs as well as products made from such organisms in December, 1989 under the provisions of the Environment (Protection) Act, 1986. This umbrella legislation governing the GMO regulation is implemented through a series of biosafety guidelines and sectoral policies notified from time to time.

This brochure provides a comprehensive overview of the biosafety regulatory framework for GE plants in India with a view to facilitate easy understanding of the key provisions of various Acts, Rules, Guidelines and Sectoral Policies among various stakeholders.

This brochure is a part of the **Biosafety Resource Kit** prepared under the UNEP-GEF Phase II Capacity Building Project on Biosafety being implemented by the MoEFCC.

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ACCESSING INFORMATION DATABASES: USEFUL RESOURCES FOR SAFETY ASSESSMENT OF GMOs

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Phase-II Capacity Building Project on Biosafety



Ministry of Environment Forest
and Climate Change

**Ministry of Environment
Forest and Climate Change
Government of India**

In association with



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INFORMATION RESOURCES/DATABASES

Safety assessments of genetically modified organisms (GMOs)/living modified organisms (LMOs) are based on information from a wide variety of sources such as scientific data, published literature and regulatory decision documents. Making available scientific data is primarily the responsibility of the technology developers. In addition to the scientific data generated through experiments, the same is supplemented by information through peer reviewed scientific literature, general technical information, regulatory agencies, international bodies and other interested parties. Regulatory authorities also need to access data on safety assessment for evaluation of the applications.

Much of this information can be accessed through the internet. Using internet resources reduces the cost and time of planning safety assessment and undertaking the review. Access to reliable sources of information and adds transparency to the regulatory decision making process.

There have been several initiatives at the international level to provide biosafety information in a comprehensive manner. Key features of the following internationally accepted and extremely useful resources and databases are explained in this brochure.

- Biosafety Clearing-House (BCH)**
- OECD BioTrack Product Database**
- FAO GM Foods Platform (linked to BioTrack product database)**
- Risk Assessment Search Mechanism (RASM)**

Evaluating Sources of information on the Internet

In addition to the above resources, extensive information is available on the internet. However, it is extremely important to check the authenticity of the information before relying on such data, particularly regarding safety of GMOs. Some of the factors to be kept in mind are as follows:

- Is the publisher clearly identified?
- Organization vs. private person's page
- Have you heard of the organization?
- Is the purpose of the website stated clearly?
- Does the site have advertisements?
- Is the information substantiated by citations to peer reviewed literature and official government documents?
- Does the site use sensational language, disturbing graphics, and lots of exclamation points?
- Are there links to other resources on the topic.



BIOSAFETY CLEARING HOUSE (BCH):

A repository of up-to-date information on LMOs and biosafety

The Biosafety Clearing House is a mechanism set up under the Cartagena Protocol on Biosafety to facilitate the exchange of information on LMOs and assist countries that are Parties to the Protocol to comply with their obligations.

The BCH provides open and easy access to a variety of scientific, technical, environmental, legal and capacity building information provided in all 6 languages of the UN.

The BCH contains the information that must be provided by Parties to the Protocol, such as decisions on release or import of LMOs, risk assessments, competent national authorities, and national laws. Governments that are not Parties to the Protocol are also encouraged to contribute information to the BCH, and in fact a large number of the decisions regarding LMOs have been registered in the BCH by non-Party governments.



E-learning module on BCH

As part of capacity building project for effective participation in the BCH, UNEP has developed interactive e-learning modules on "Cartagena Protocol on Biosafety" and "Biosafety Clearing-House". The interactive module on BCH addresses the purpose and functioning of the Biosafety Clearing-House; the various categories of information available on the BCH, and what

information Parties are required to post, and when they are required to make this information available on the BCH. The module can be downloaded from <http://bch.cbd.int>.



Information Available on BCH

National Records	Reference Records
National Contacts i. National Focal Points ii. Competent National Authorities iii. National Biosafety Websites and Databases	LMOs, Genetic elements or Organisms i. The LMO-UID Registry ii. Gene Registry iii. Organism Registry
Laws and Regulations i. National Laws, Regulations ii. Guidelines and Bilateral, Regional and Multilateral Agreements	Capacity-Building i. Biosafety Capacity Building Projects ii. Capacity-Building Opportunities iii. Compendium of Academically-Accredited Biosafety Courses iv. Capacity-Building Needs and Priorities
National Reports National reports and analysis	Directory of International Organizations involved in Biosafety Activities International organisations involved in activities relevant to implementation of the Biosafety Protocol with summaries of their activities and contact information.
Country's Decisions and other Communications i. Decisions on LMOs under Advance Informed Agreement ii. Decisions on LMOs for food, for feed or for processing under Article 11 iii. Other decisions & declaration (iv) Risk Assessment Reports	The BCH Virtual Library i. Biosafety Information Resource Centre (BCH-BIRC) ii. Scientific Bibliographic Database on Biosafety (Bibliosafety). iii. Access to Research4Life, a collective name for four public-private partnerships to provide the developing world with free or low cost online access to academic and professional peer-reviewed content.
Roster of Experts Access a database of experts in biosafety, searchable using various fields.	

For each category of information on BCH, search mechanisms have been provided for retrieval of information in a user friendly manner. The records of decisions, risk assessments, LMOs, donor and recipient organisms, and DNA sequences are cross-referenced in a way that facilitates data retrieval.

The BCH also contains other relevant information and resources, including information on national contacts, capacity-building, a roster of government-nominated biosafety experts and links to other websites, publications and databases through the Biosafety Information Resource Centre (BIRC).

LMO Quick-links are small image files, which can be easily copied and pasted, that identify an LMO through its unique identifier, trade name and a link to the BCH where information on the LMO is available (e.g. LMO characteristics, countries' decisions, risk assessments, etc.). Through the LMO Quick-links the BCH page can be easily accessed by either scanning the barcode or by typing the URL in a web browser.



Biosafety Information Resource Centre

The Biosafety Information Resource Centre (BIRC), a sub-section of BCH contains electronic catalogues of biosafety-related publications and information resources for policymakers, educators, researchers, and the general public. BIRC records may be registered by all BCH account-holders. The BIRC contains news services, e-mail list servers, online databases and search engines; reports and case studies; journals, newsletters and teaching materials (manuals, toolkits and presentations). Its objective is to increase the accessibility and utilization of available biosafety information and resources for policymakers, educators, researchers, and the general public.



Information from BIRC can be retrieved using various search options by clicking on the "Search the Biosafety Information Resource Centre (BIRC)". Several search criteria boxes available on BIRC are:

1. Publication year: Selection lists to narrow search results by year of publication. The first selection list specifies whether resources published earlier or later than the date specified in the second box are to be considered. If any of



the two selection lists is left empty, then this field will not narrow the search results.

- 2. Thematic area:** Selection list to narrow the search results to resources regarding the specified subjects.
 - 3. Type of record:** Selection list to specify the types of resources to be included in the search results.
 - 4. Language:** Selection list to narrow the search results to resources in the specified languages.
 - 5. Date of record:** Date field for narrowing the search results to a time interval
 - 6. Keyword search:** Keyword field for narrowing the results by keyword
- Using the search pages helps to learn about types of fields and their operation.

Biodiversity E-learning Platform

The Biodiversity E-Learning Platform provides a one-stop access to e-modules and courses relating to the Convention on Biological Diversity, the Cartagena Protocol on Biosafety and the Nagoya Protocol on Access and Benefit-sharing. The courses available on Biosafety are as follows:

1. Course on the Cartagena Protocol on Biosafety for Customs/Border Officials, has been developed jointly by the Secretariat of the Convention on Biological Diversity (CBD), the United Nations Environment Programme (UNEP) and the World Customs Organization (WCO). It comprises five modules, which provide the

necessary foundation for Customs Officers to understand and enforce the requirements of the Cartagena Protocol on Biosafety regarding the safe transfer, handling and use of living modified organisms.

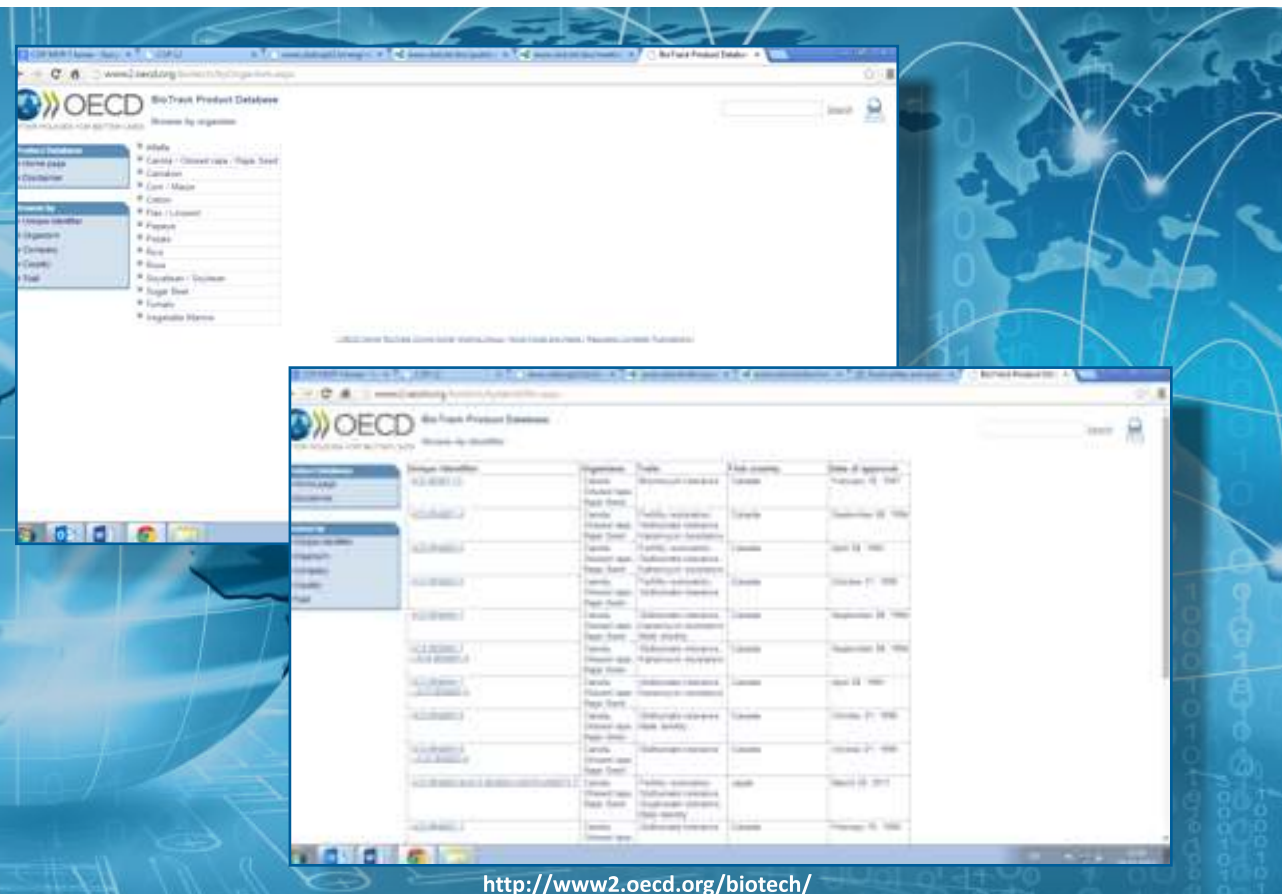
The course can take about 3 hours to complete.

- 2. Course on Public Awareness, Education and Participation,** has two modules on public access to biosafety information and public participation in decision making processes concerning LMOs
- 3. Course on Mainstreaming Biosafety,** has toolkit and a module on mainstreaming biosafety

OECD BioTrack Online Website

The OECD has created "BioTrack Online" website to provide information on environmental, food and feed safety issues relating to modern biotechnology. In addition to information related to major legislative developments and documents, the website has online databases of modern biotechnology products, as well as field trials.

BioTrack (Biotech) Product Database: It provides information regarding products derived using modern biotechnology, e.g. transgenic plants which have been approved for commercial applications, as well as some plants with novel traits produced by conventional breeding and mutagenesis. A Unique Identifier is assigned to the approved product on the basis of the OECD Guidance as a key to each product in the database.

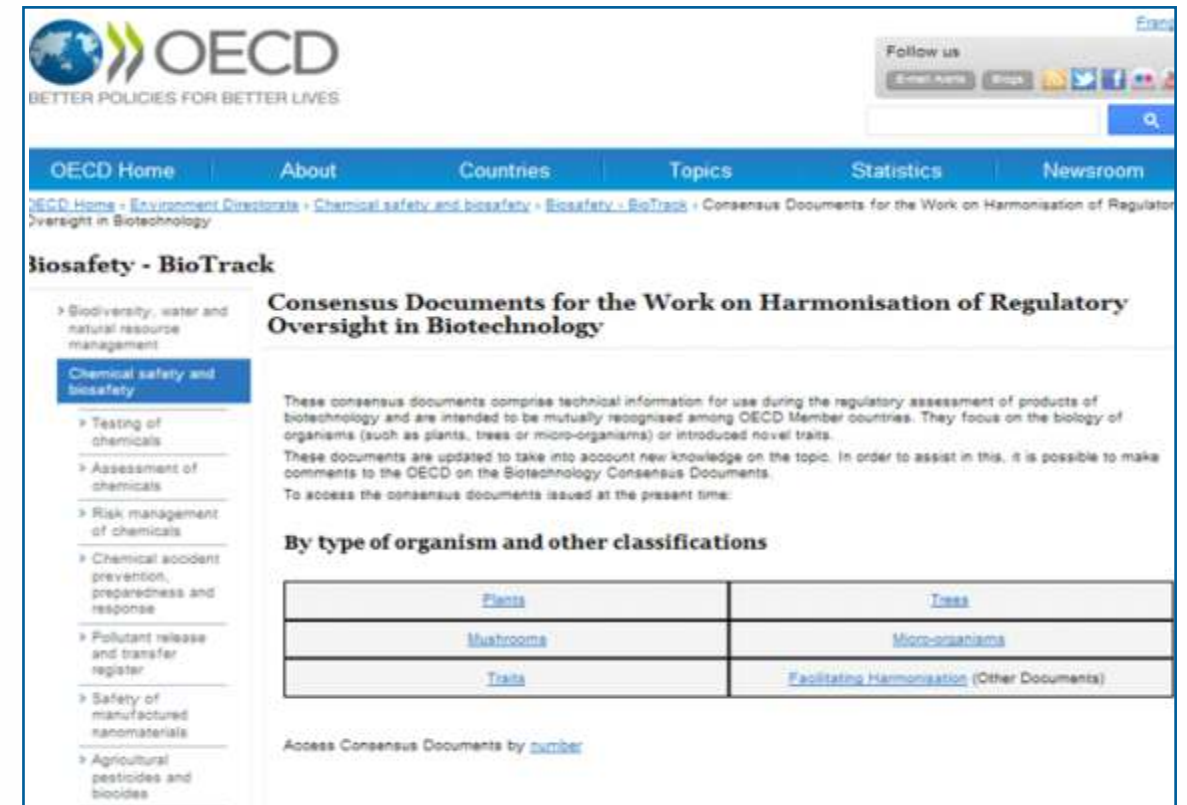


<http://www2.oecd.org/biotech/>



OECD website also provides a series of consensus documents comprising of science based information for use during the safety assessment of GMOs. The consensus documents for use in environmental risk/safety assessment contain information on the biology of the host species, characteristics of the introduced traits, considerations on possible environmental impacts, and other aspects for facilitating harmonisation.

In addition, consensus documents have already been prepared in the area of food and feed safety. These consensus documents contain information nutrients, anti-nutrients or toxicants, product's use as a food/feed and other relevant information.



Safety Assessment of Transgenic Organisms (Biosafety Cons. Docs Compendium, Vol. I to IV, 1996-2010)

Consensus documents on Biology for Environmental safety

Consensus documents for the Safety of Novel Foods and Feeds

FAO GM Foods Platform

The FAO GM Foods Platform is a simple online platform to share information on safety assessment of foods derived from recombinant-DNA 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).

The details of approval, the summary of the safety assessment and detection methods protocols etc. can be accessed by browsing through the database. The "Resources" section provides access to the

official Codex documents as well as to a range of other relevant resources.

This Platform also facilitates the effective utilization of food safety assessment in situations of Low Level Presence (LLP) of r-DNA plant materials in food.

This database is a part of the International Portal on Food Safety, Animal and Plant Health, a single access point developed by FAO for authorized official international and national information across the sectors of food safety, animal and plant health.



http://www.fao.org_GoBack_GoBack/food/food-safety-quality/gm-foods-platform/en/



Biosafety Databases by ICGEB

The International Centre for Genetic Engineering and Biotechnology (ICGEB) provides information on biosafety and risk assessment for the environmental release of GMOs through dedicated section on "Biosafety" (<http://www.icgeb.org/~bsafesrv/index.html>). The key resources include three databases i.e. a Biosafety Bibliographic database (Bibliosafety), the Risk Assessment Search Mechanism (RASM) and the BiosafeRes database of past and current projects in GMO biosafety research.

- Bibliosafety is an open access searchable collection of scientific studies (full reference + abstract) on biosafety and risk assessment in biotechnology published since 1990. It is updated monthly and the new records are immediately distributed by e-mail to freely subscribed users. The database is also interoperable with the central portal of the Biosafety Clearing-House (BCH), hosted by the Convention on Biological Diversity.
- RASM is an open access collection of Risk Assessment documents related to official government decisions concerning the commercial release of GMOs worldwide. The selection criteria include taxonomical classification; OECD identifier or Company identifier; trait; gene; year (assessment date); country and type of authorised use.
- The BiosafeRes database is a public-access database of past and current research projects in GMO Biosafety. Scientists engaged in biosafety research can directly enter their projects into the database.



<http://rasm.icgeb.org/>





Indian Biosafety Regulatory Websites

The website <http://geacindia.gov.in> provides information about the Genetic Engineering Appraisal Committee, the apex regulatory body in India. This website has been established by the Ministry of Environment, Forest and Climate Change, the lead Ministry responsible for implementing biosafety regulatory framework in India.

The website of Department of Biotechnology (DBT), Ministry of Science & Technology has a section on

policy and guidelines on biosafety <http://www.dbtindia.nic.in/regulations/>

Indian Council of Agricultural Research (ICAR) has set up a biosafety portal

<https://biosafety.icar.gov.in/> that serves as a resource to strengthen compliance with the Government of India's biosafety regulatory framework so as to effectively facilitate research and development of agricultural biotechnology



<http://geacindia.gov.in/>



<http://www.dbtindia.nic.in/regulations/>



<https://biosafety.icar.gov.in/>

Newsletters on Biosafety Information

Newsletters provide a quick update on activities of particular programmes, projects, agenda etc. A brief overview of some of the newsletters providing information on biosafety related topics and activities are as provided. These newsletters are available electronically and can also be subscribed through email.

Biosafety Newsletter: The Ministry of Environment, Forest and Climate Change (MoEF & CC), Govt. of India circulates a quarterly newsletter to give an update on national international activities/ developments relevant to biosafety issues in India. The newsletter can be subscribed by contacting MoEFCC at biosafety-mef@nic.in

Biosafety Protocol News: Biosafety Protocol News (BPN) is prepared by the Secretariat to the Convention on Biological Diversity (SCBD) as part of its awareness and out reach efforts under its outreach strategy for the Cartagena Protocol on Biosafety and the Global Initiative on Communication, Education and Public Awareness of the CBD. The purpose of this newsletter is to provide Parties, other Governments, relevant agencies and other stake holders with a medium to exchange information and news regarding their efforts to implement and promote awareness of the Protocol. The newsletter can be accessed at http://bch.cbd.int/protocol/cpb_newsletter.shtml.

OECD Biotechnology Newsletter Updates: The purpose of the OECD Biotechnology Update is to provide up-to-date information on the diverse activities at OECD related to biotechnology. The newsletter, issued twice a year, though mainly

intended for delegates to OECD meetings who are familiar with OECD's work, is a useful resource for the wider biotech community

Food and Agriculture Organization (FAO) Biotech-News: The FAO publishes a quarterly newsletter covering news that are relevant to applications of biotechnology in food and agriculture in developing countries. Its main focus is on the activities of FAO, of other United Nations agencies/bodies and of the Consultative Group on International Agricultural Research (CGIAR) research centers. It can be subscribed by a request to FAO-Biotech News@fao.org along with the subscriber's e-mail address.

South Asia Biosafety Programme (SABP) Newsletter: The SABP is a capacity building project being implemented in India and Bangladesh. The SABP published a monthly newsletter which includes invited editorials, information about biosafety regulation and policy developments and capacity building activities in the region, and related science or news stories. The newsletter can be subscribed through an e-mail request at vibhaahuja.bcil@nic.in or downloaded from <http://geacindia.gov.in>

