

Accessing Information/ Databases:

Useful resources for Safety Assessment of Genetically Modified Organisms

Phase-II Capacity Building
Project on Biosafety



सत्यमेव जयते



Ministry of Environment, Forest and Climate Change

Government of India

In association with



BCIL

Biotech Consortium India Limited

New Delhi

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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 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)

CERA GM Crop database



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:

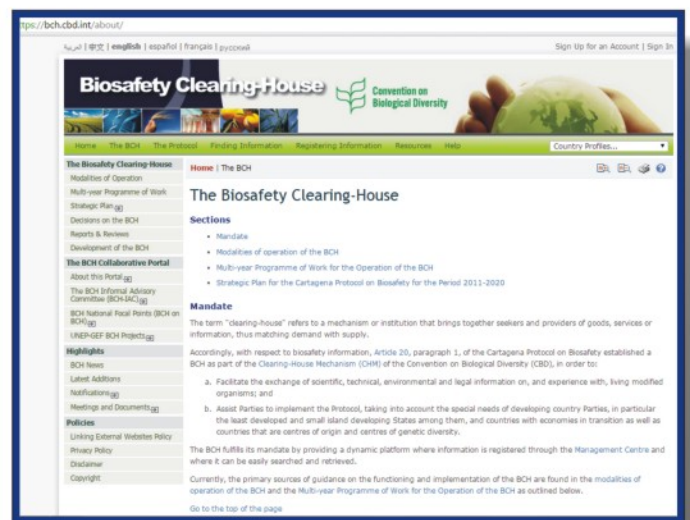
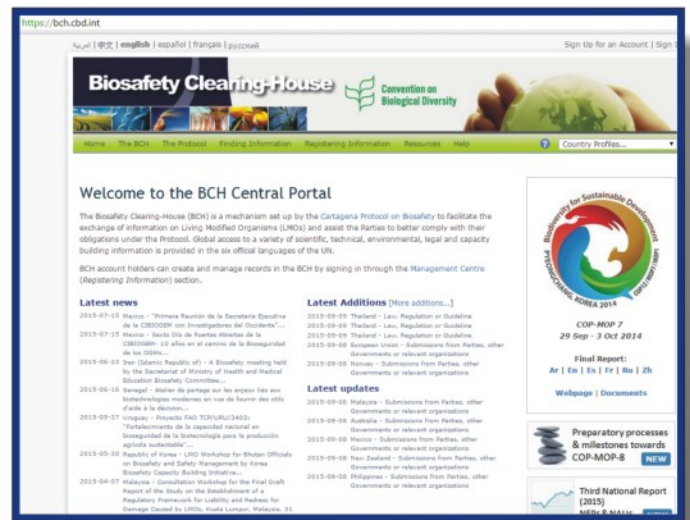
- Is the publisher clearly identified?
- Organization vs. private person's page.
- Have you heard of the organization?
- Is the purpose of the website stated clearly?
- Does the site have advertisements?
- Is the information substantiated by citations to peer-reviewed literature and official government 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

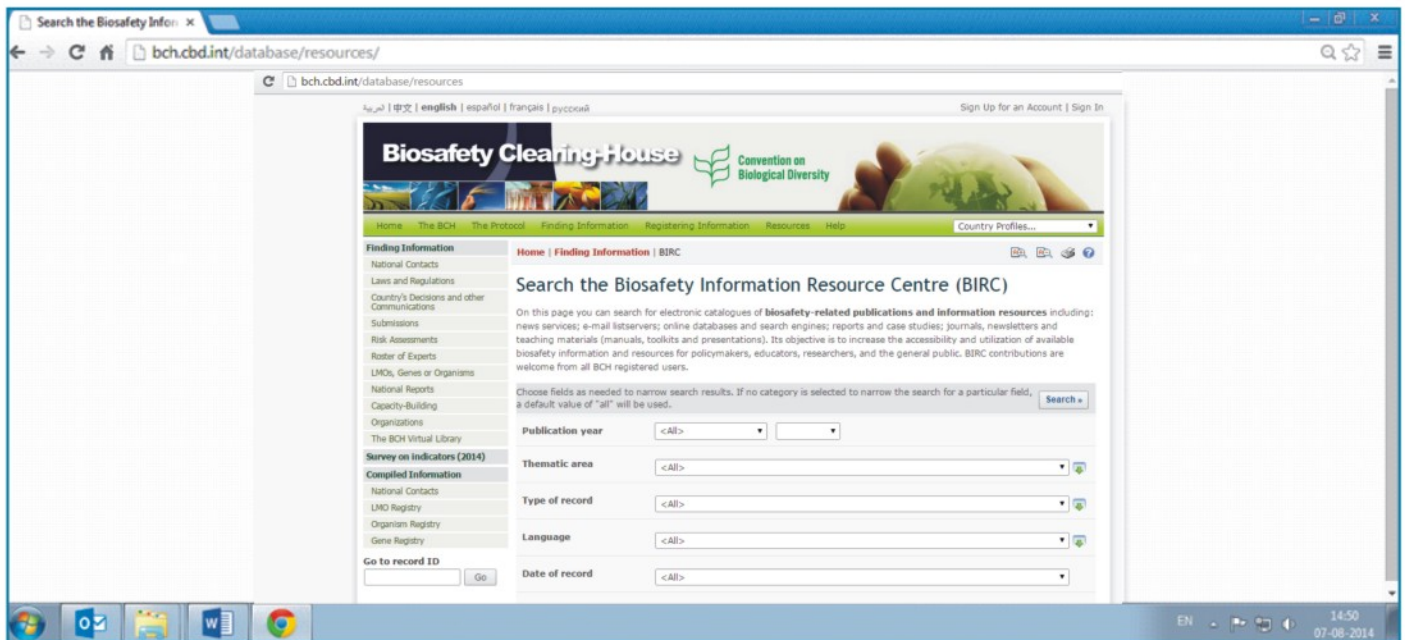
National Records	Reference Records
National Contacts <ul style="list-style-type: none"> i. National Focal Points ii. Competent National Authorities iii. National Biosafety Websites and Databases 	LMOs, Genetic elements or Organisms <ul style="list-style-type: none"> i. The LMO-UID Registry ii. Gene Registry iii. Organism Registry
Laws and Regulations <ul style="list-style-type: none"> i. National Laws, Regulations ii. Guidelines and Bilateral, Regional and Multilateral Agreements 	Capacity-Building <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> 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).

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.

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.



Unique Identifier	Organism	Traits	Field country	Date of approval
ACC-BIO001.0	Canola (Brassica napus)	Brassica napus	Canada	February 18, 1991
ACC-BIO001.1	Canola (Brassica napus)	Brassica napus	Canada	September 18, 1994
ACC-BIO001.2	Canola (Brassica napus)	Brassica napus	Canada	April 26, 1995
ACC-BIO001.3	Canola (Brassica napus)	Brassica napus	Canada	October 21, 1996
ACC-BIO001.4	Canola (Brassica napus)	Brassica napus	Canada	September 18, 1994
ACC-BIO001.5	Canola (Brassica napus)	Brassica napus	Canada	September 18, 1994
ACC-BIO001.6	Canola (Brassica napus)	Brassica napus	Canada	April 26, 1995
ACC-BIO001.7	Canola (Brassica napus)	Brassica napus	Canada	October 21, 1996
ACC-BIO001.8	Canola (Brassica napus)	Brassica napus	Canada	October 21, 1996
ACC-BIO001.9	Canola (Brassica napus)	Brassica napus	Canada	February 18, 1991

<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 on nutrients, anti-nutrients or toxicants, product's use as a food/feed and other relevant information.

www.oecd.org/env/ehs/biotrack/consensusdocumentsfortheworkonharmonisationofregulatoryoversightinbiotechnology.htm

OECD.org Data Publications More sites News Job vacancies

OECD
BETTER POLICIES FOR BETTER LIVES

OECD Home About Countries Topics

OECD Home > Environment Directorate > Chemical safety and biosafety > Biosafety - BioTrack > Consensus Documents for the Work on Harmonisation of Regulatory Oversight in Biotechnology

Consensus Documents for the Work on Harmonisation of Regulatory Oversight in Biotechnology

These consensus documents comprise technical information for use during the regulatory assessment of products of biotechnology and are intended to be mutually recognised among OECD Member countries. They focus on the biology of organisms (such as plants, trees or micro-organisms) or introduced novel traits. These documents are updated to take into account new knowledge on the topic. In order to assist in this, it is possible to make comments to the OECD on the Biotechnology Consensus Documents.

To access the consensus documents issued at the present time:

By type of organism and other classifications

Plants	Trees
Mushrooms	Micro-organisms
Traits	Facilitating Harmonisation (Other Documents)

Access Consensus Documents by [number](#)



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.

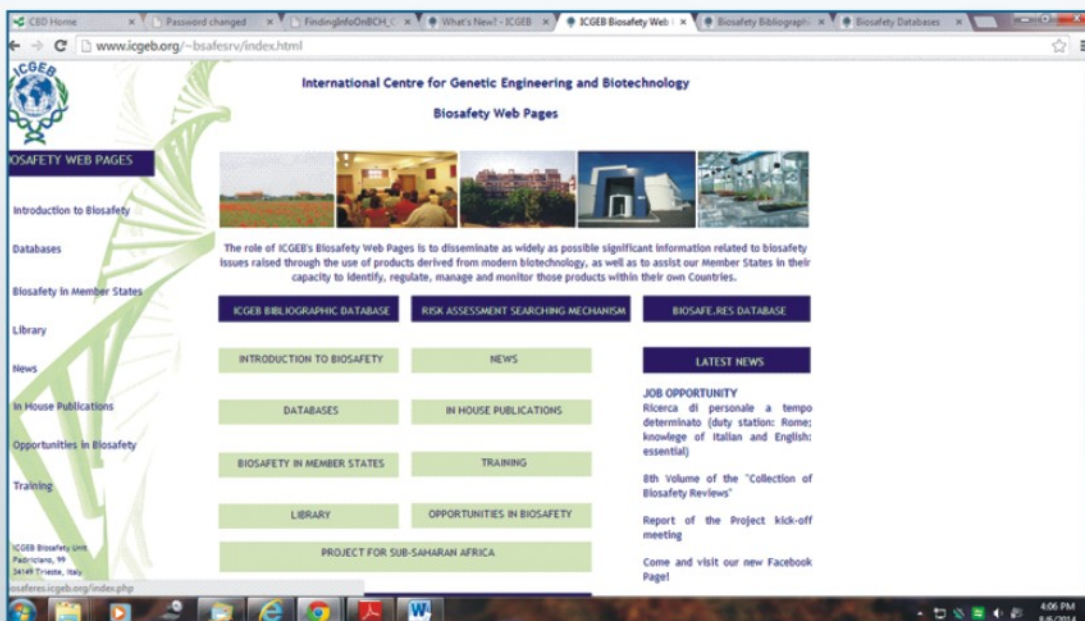


http://www.fao.org_GoBack_GoBack/food/food-safety-quality/gm-foods-platform/en/

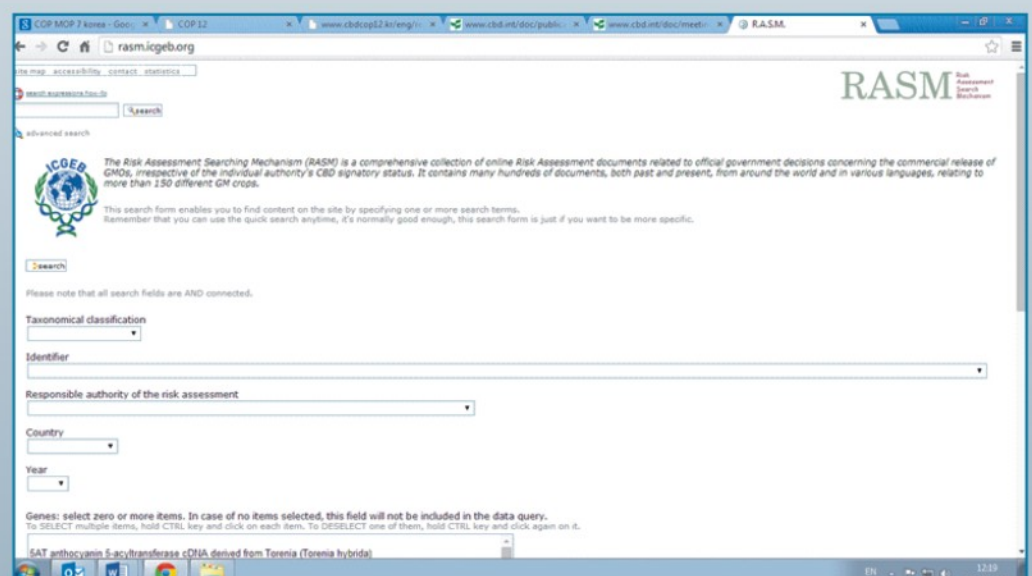
Biosafety Databases by ICGEB

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/>



GM Crop Database by CERA

Centre for Environmental Risk Assessment of ILSI Research Foundation (CERA-ILSI) maintains the GM CROP DATABASE, that provides safety-related information about regulatory evaluations and approvals of genetically modified plants. Searches can be performed on a number of criteria, including event names, crop plants, traits, inserted genes, types of approval, countries, original developers and the number of years approved. This database is used extensively by regulatory agencies,

the academic and product developer communities and other stakeholders.

CERA'S BIBLIOGRAPHY contains a comprehensive collection of over 4,000 citations from peer-reviewed literature, books and conference proceedings relevant to agricultural biotechnology. Users may customize their queries by searching the bibliography by keyword, author, date and source.

The image displays two screenshots of the CERA GM Crop Database website. The top screenshot shows the homepage with a welcome message and a list of recent news. The bottom screenshot shows the search interface with various filters like Event ID, Crop Plant, Trait, and Inserted Gene.

Center for Environmental Risk Assessment

GM Crop Database
CERA Meetings & Events
CERA Publications
S. Asia Biosafety Program
Partnership for Biosafety

Welcome to CERA

The Center for Environmental Risk Assessment (CERA) is dedicated to developing and applying sound science to the environmental risk assessment of agricultural biotechnologies so their contributions to the sustainable production of food, fuel and fiber may be safely realized. As part of the non-profit ILSI Research Foundation, CERA serves as a scientific resource for governments, academic and private sector organisations. Our research is supported by the ILSI Research Foundation.

Recent News

- New paper published on identifying GE crop plants that pose a low or negligible risk to the environment under conditions of low-level presence in seed
- View the August Edition of the

GM Crop Database

Query page

Event ID: -Any-
4, 11, 15, 16
19-51A
23-18-17, 23-198
35 1 N

Crop Plant: -Any-
Alfalfa
Argentine Canola
Carnation
Chicory

Trait: -Any-
Agronomic performance
Amino acid composition
Fatty acid composition
Fertility restoration

Inserted Gene: -Any-
5AT
aad
aad-12
ACC

Synopsis

Overview of all products in database

Query Options

New Database Query
Go to Event
Please select

Help

How To Use the GM Crop Database

http://cera-gmc.org/index.php?action=gm_crop_database

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 MoEF & CC at warrier@nic.in or 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, Bangladesh and Pakistan with support from USAID. 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@biotech.co.in or downloaded from http://ceragmc.org/index.php?action=sabp_newsletter



The access to and availability of relevant biosafety information and knowledge-sharing is extremely important for safety assessment of GE plants. It is particularly important that the factual, unbiased and reliable information on biosafety is made available for stakeholder participation and decision making. There have been several such initiatives by the international organizations including setting up of Biosafety Clearing House (BCH) under the Cartagena Protocol on Biosafety.

This brochure brings together the information about international online databases and information resources of particular relevance to the biosafety of GE plants, giving a brief description of their content and objective with a view to facilitate information sharing among various stakeholders.

This brochure is a part of **Biosafety Resource Kit** prepared under the Phase II Capacity Building Project on Biosafety being implemented by the Ministry of Environment, Forest and Climate Change.

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