SOUTH ASIA
BIOSAFETY PROGRAM

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NEWSLETTER

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www.cera-gmc.org

SABP

The South Asia Biosafety Program (SABP) is an international developmental program initiated with support from the United States Agency for International Development (USAID). The program is implemented in India and Bangladesh and aims to work with national governmental agencies to facilitate the implementation of transparent, efficient and responsive regulatory frameworks for products of modern biotechnology that meet national goals as regards the safety of novel foods and feeds and environmental protection.

SABP is working with its in-country partners to:

- Identify and respond to technical training needs for food, feed and environmental safety assessment.
- Develop a sustainable network of trained, authoritative local experts to communicate both the benefits and the concerns associated with new agricultural biotechnologies to farmers and other stakeholder groups.
- Raise the profile of biotechnology and biosafety on the policy agenda within India and Bangladesh and address policy issues within the overall context of economic development, international trade, environmental safety and sustainability.

E-LEARNING COURSE ON "COMPLIANCE MANAGEMENT OF CONFINED FIELD TRIAL"

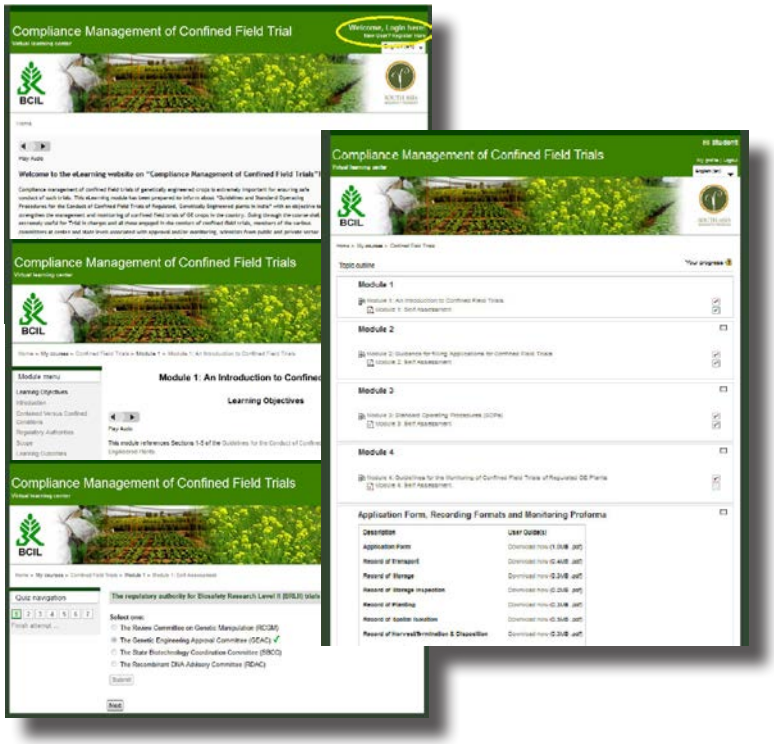
An e-learning course on "Guidelines & Standard Operating Procedures (SOPs) for Confined Field Trials of Regulated, Genetically Engineered (GE) Plants" has been prepared by Biotech Consortium India Ltd. (BCIL) and the South Asia Biosafety Programme (SABP). This course has been developed with the objective of strengthening the management and monitoring of confined field trials of GE crops.

This e-learning course is expected to be a useful tool for Trial-in-Charges and all those engaged in the conduct of confined field trials, members of the various committees at central and state levels associated with the approval and/or monitoring of confined field trials, scientists from the public and private sectors engaged in research on GM crops, and other interested stakeholders including students.

THE COURSE CAN BE ACCESSED AT http://cft.biotech.co.in.

The course contains four modules.

MODULE 1: An Introduction to Confined Field Trials
MODULE 2: Guidance for Filling Applications for Confined Field Trials
MODULE 3: Standard Operating Procedures (SOPs)
MODULE 4: Guidelines for the Monitoring of Confined Field Trials of Regulated GE Plants



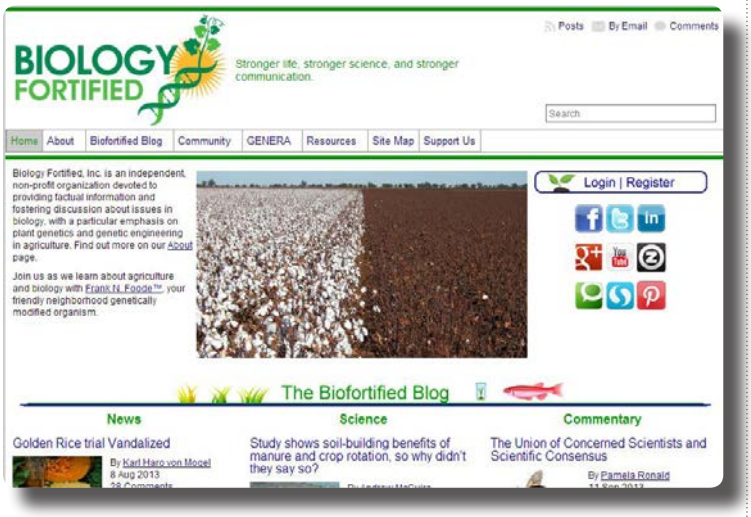
The features of the e-learning course are as follows:

1. The "Getting Started Help Guide" has been prepared to help users to become familiar with the programme.
2. It provides audio facility in English.
3. It keeps track of the modules already covered.
4. The first page of each module provides the "Learning Objectives" for the module, which are a brief outline of the course material that the users are expected to understand once the module has been completed.
5. Each module page consists of a "Navigation Menu" and "Module Menu" to navigate through the module.
6. Self-assessments following each module provide feedback to the learner and also provide the opportunity to demonstrate understanding of the material.
7. In order to proceed to the self-assessment, users must first complete the module.
8. At the end of each module a "Summary of Previous Attempts" is provided for self-assessment and an opportunity to re-attempt the quiz.
9. A course glossary is available for all course modules; the glossary link displays as a gray underlined link.

Spotlight on the Worldwide Web

www.biofortified.org

Biology Fortified, Inc. (BFI) is an independent educational non-profit organization incorporated in Wisconsin. Its mission is to strengthen the public discussion of issues in biology, with particular emphasis on genetics and genetic engineering in agriculture.



BFI focuses on four major areas:

- Educating and engaging members of the public both through online content and in-person events.
- Reaching out to people who hold differing points of view to promote inclusive discussion. It is committed to transparency and ethical conduct, while promoting the importance of these values.
- Promoting two-way communication between the scientific community and the public.
- Providing expert scientific analyses to support the public good and the scientific community. Generates public resources to promote accessibility and comprehension of the scientific literature.

The website also features a helpful list of resources including:

- Blogroll
- List of genetic engineering companies
- List of biotech traits
- Images for media
- GENERA (GENetic Engineering Risk Atlas)
- Guide to GENERA
- Studies for GENERA (their running list of risk-related research)
- Studies with independent funding (the above list, but only the independent ones)
- Bookstore

BSTI STANDARDS FOR THE SAFETY ASSESSMENT OF FOODS DERIVED FROM GENETICALLY ENGINEERED PLANTS

Dr. Syed Humayun Kabir, Director (Standards), Bangladesh Standards and Testing Institutions (BSTI)

Modern biotechnology involving the use of recombinant-DNA (r-DNA) technologies, also known as genetic engineering, has emerged as a powerful tool with many potential applications in agriculture and healthcare. New plant varieties developed using r-DNA techniques, commonly referred to as genetically modified (GM), genetically engineered (GE) or transgenic plants, have been and are being developed with the aim of enhancing productivity; decreasing dependence on the use of agricultural chemicals; modifying the inherent properties of crops; and improving the nutritional value of foods and livestock feeds. As more GE plants are released and the resultant food products become commercially available and subsequently traded across various countries, concerns have been expressed about their safety to human and animal health and the environment.

To address the human health safety of foods derived from GE plants, there is a need to adopt a systematic and structured approach to their risk analysis. In Bangladesh, the manufacture, import, use, research and release of genetically modified organisms (GMOs), as well as products made from using such organisms, are governed by the Biosafety Guidelines of Bangladesh, gazetted in 2008. However, the Biosafety Guidelines mainly address the environmental impacts of living modified organisms (LMO) and there is a need for comprehensive guidance for the safety assessment of foods derived from GE plants, particularly with respect to the impact on human health.

The Bangladesh Agricultural Research Council (BARC), in collaboration with the Bangladesh Standards and Testing Institution (BSTI), the Department of Environment (DoE), the Institute of Public Health (IPH), the Directorate General of Food, and other relevant stakeholders, took the initiative to develop guidelines to establish the safety assessment procedures for foods derived from GE plants. As the apex body for the National Agricultural Research System, BARC has much of the expertise necessary for both the development and safety assessment of agricultural products of biotechnology.

Initially a drafting committee was formed with relevant experts and the guidelines were finalized through several stakeholders consultation meetings. After finalization, the guidelines were submitted to the Ministry of Environment and Forests for their endorsement. The guidelines were thoroughly discussed in the meetings of Biosafety Core Committee (BCC) and finally endorsed by the National Committee on Biosafety (NCB). NCB also took the decision to request that BSTI adopt the guidelines as the BSTI standards for assessing the safety of foods derived from GE plants.

Bangladesh Standards and Testing Institution has a set procedure for developing a standard, which is a document approved through consensus by a recognized standardization body that provides, for repeated and common use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory. A standard describes the features of the product, process, service, interface or material. Standards are indispensable for the international marketing of a product as they convey consistent and understandable information to the buyer, thus helping to prevent, reduce or settle disputes over specifications and the quality of goods imported

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or exported.

Standards development process in Bangladesh:

In Bangladesh, the BSTI is the lone national standards body. It was established under BSTI Ordinance, 1985. The principal activity of BSTI is to develop national standards on products, process and services. BSTI Council is the highest body to govern all its affairs and functions. BSTI maintains liaisons with all international standards-setting organizations. BSTI has been a full member of ISO since 1974. It is also the national Codex Contact Point of the Codex Alimentarius Commission.

The development of standards mainly needs to follow five stages. The first step in the process is to form technical committees for different areas constituted by representative experts from local industry, business, research organizations, academia, government, consumers and interested parties from non-governmental organizations. Under BSTI 73, technical committees are involved in developing standards in different fields. Six divisional committees, as higher bodies, also work for final approval of the standards. These divisional committees are constituted by the governing body of BSTI, the BSTI Council.

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The Reading List

. . . new and notable articles

GENETICALLY ENGINEERED TREES FOR PLANTATION FORESTS: KEY CONSIDERATIONS FOR ENVIRONMENTAL RISK ASSESSMENT

Häggman H, Raybould A, Borem A, Fox T, Handley L, Hertzberg M, Lu MZ, Macdonald P, Oguchi T, Pasquali G, Pearson L, Peter G, Quemada H, Séguin A, Tattersall K, Ulian E, Walter C, McLean M.

Forests are vital to the world's ecological, social, cultural and economic well-being yet sustainable provision of goods and services from forests is increasingly challenged by pressures such as growing demand for wood and other forest products, land conversion and degradation, and climate change. Intensively managed, highly productive forestry incorporating the most advanced methods for tree breeding, including the application of genetic engineering (GE), has tremendous potential for producing more wood on less land. However, the deployment of GE trees in plantation forests is a controversial topic and concerns have been particularly expressed about potential harms to the environment. This paper, prepared by an international group of experts in silviculture, forest tree breeding, forest biotechnology and environmental risk assessment (ERA) that met in April 2012, examines how the ERA paradigm used for GE crop plants may be applied to GE trees for use in plantation forests. It emphasizes the importance of differentiating between ERA for confined field trials of GE trees, and ERA for unconfined or commercial-scale releases. In the case of the latter, particular attention is paid to characteristics of forest trees that distinguish them from shorter-lived plant species, the temporal and spatial scale of forests, and the biodiversity of the plantation forest as a receiving environment.

PLANT BIOTECHNOLOGY JOURNAL. (2013). AUG 5. DOI: 10.1111/PBI.12100. [EPUB AHEAD OF PRINT]. DOWNLOAD THE PDF FROM HTTP://ONLINELIBRARY.WILEY.COM/DOI/10.1111/PBI.12100/PDF

EFSA'S SCIENTIFIC ACTIVITIES AND ACHIEVEMENTS ON THE RISK ASSESSMENT OF GENETICALLY MODIFIED ORGANISMS (GMOS) DURING ITS FIRST DECADE OF EXISTENCE: LOOKING BACK AND AHEAD

Devos Y, Aguilera J, Diveki Z, Gomes A, Liu Y, Paoletti C, du Jardin P, Herman L, Perry JN, Waigmann E.

Genetically modified organisms (GMOs) and derived food and feed products are subject to a risk analysis and regulatory approval before they can enter the market in the European Union (EU). In this risk analysis process, the role of the European Food Safety Authority (EFSA), which was created in 2002 in response to multiple food crises, is to independently assess and provide scientific advice to risk managers on any possible risks that the use of GMOs may pose to human and animal health and the environment. EFSA's scientific advice is elaborated by its GMO Panel with the scientific support of several working groups and EFSA's GMO Unit. This review presents EFSA's scientific activities and highlights its achievements on the risk assessment of GMOs for the first 10 years of its existence. Since 2002, EFSA has issued 69 scientific opinions on genetically modified (GM) plant market registration applications, of which 62 for import and processing for food and feed uses, six for cultivation and one for the use of pollen (as or in food), and 19 scientific opinions on applications for marketing products made with GM microorganisms. Several guidelines for the risk assessment of GM plants, GM microorganisms and GM animals, as well as on specific issues such as post-market environmental monitoring (PMEM) were elaborated. EFSA also provided scientific advice upon request of the European Commission on safeguard clause and emergency measures invoked by EU Member States, annual PMEM reports, the potential risks of new biotechnology-based plant breeding techniques, evaluations of previously assessed GMOs in the light of new scientific publications, and the use of antibiotic resistance marker genes in GM plants. Future challenges relevant to the risk assessment of GMOs are discussed. EFSA's risk assessments of GMO applications ensure that data are analysed and presented in a way that facilitates scientifically sound decisions that protect human and animal health and the environment.

TRANSGENIC RESEARCH. (2013) AUG 21. [EPUB AHEAD OF PRINT] SEE HTTP://LINK.SPRINGER.COM/ARTICLE/10.1007%2FS11248-013-9741-4

CALENDAR OF EVENTS

Event	Organized by	Date and Venue	Website
INDIA			
Scientific Workshop on Biotech Safety Assessment	International Life Sciences Institute (ILSI-INDIA), ILSI International Food Biotechnology Committee (IFBiC) and Department of Biotechnology(DBT)	September 23 - 24, 2013 New Delhi	http://www.ilsi-india.org
Seed Industry Program: Traits – Market – Growth – Leadership	Cornell University and Sathguru Management Consultants	October 7 - 10, 2013 Hyderabad	http://www.sathguru.com/seeds/
International Conference on Biotechnology (IICB-2013)	University School of Biotechnology, Guru Gobind Singh Indraprastha University	October 22 - 25, 2013 New Delhi	
National Seminar on Technology for Development and Production of Rainfed Cotton and Farmers' Day	Navsari Agricultural University	October 24 - 26, 2013, Bharuch, Gujarat	http://www.nau.in/announce.php?id=11897
Bangalore India Bio	MM Activ Sci Tech Communications Pvt. Ltd.	February 10 - 14, 2014 Bangalore	http://www.bangaloreindiabio.in/Index_New.php
INTERNATIONAL			
2013 International Conference on Food and Agricultural Sciences (ICFAS 2013)	International Proceedings of Chemical, Biological and Environmental Engineering, Singapore (IPCBEE)	October 5 - 6, 2013, Melaka, Malaysia	http://www.icfas.org/index.htm
3rd ABSANZ Biosafety Conference	International Federation of Biosafety Associations	October 29 - November 1, 2013 Auckland, New Zealand	http://www.absanz.org.au/Conference%202013.html
Risk Assessment: The Role of Science in GMO Decision-making	International Centre for Genetic Engineering and Biotechnology, Biosafety Unit, Trieste, Italy	June 30 – July 4, 2014 Trieste, Italy	http://www.icgeb.org/tl_files/Meetings/2014/ICGEB%20TS%20Biosafety%202014_prel_WEB.pdf

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1ST STAGE: The items are selected by considering the industrial need and relevance. The requests come from different stakeholders, such as industry, government and/or consumers.

2ND STAGE: The list of the items is submitted to the divisional committee's meeting for approval.

3RD STAGE: The initial draft is prepared by the BSTI secretariat if a reference standard is available. The ideal is the international standard. If the international standard is available, it is adopted identically or with minimum modification. Occasionally, a sub-committee is formed by technical committee to develop an initial draft.

4TH STAGE: The initial draft is prepared and submitted to the technical committee meeting. The committee discusses the draft thoroughly and accords initial approval, with amendments, if necessary.

5TH STAGE: The draft standard is circulated to stakeholders for comments allowing 60 days for feedback. The comments are taken into account and submitted to the technical committee for further discussion. The committee discusses the draft and finalizes the draft standard. Since the guidelines were developed with an extensive consultation process involving appropriate experts and stakeholders, this step was omitted in the case of the guidelines for the safety assessment of foods derived from GE crops.

FINAL STAGE: The finalized draft standard is submitted to the divisional committee. The divisional committee discusses the draft thoroughly and accords final approval, with amendments, if necessary. Sometimes the draft standard is referred back to the technical committee.

ENDORSEMENT: The standard approved by the divisional committee is endorsed by the Director General of BSTI and published as the national standard.

As mentioned above, inthe case of the guidelines for the safety assessment of foods derived from GE crops, all the steps were followed during the adoption of these guidelines as BSTI standards.

In general, the standards are revised every five years. In some cases, by necessity or by requests from the manufacturers, the standard is revised or amended without waiting five years. During the revision the same procedure is followed.

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Center for Environmental Risk Assessment

IFPRI

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