



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.

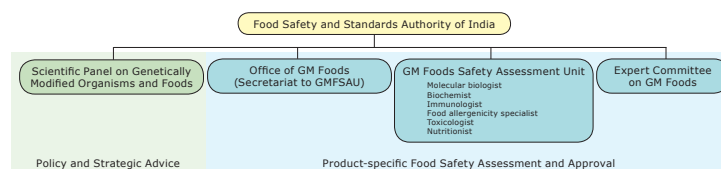
OPERATIONALIZING THE REGULATION OF GM FOODS IN INDIA

The Food Safety and Standards Act (FSSA), 2006 established the Food Safety and Standards Authority of India (FSSAI) as the statutory body for "laying down science based standards for articles of food and regulating manufacturing, processing, distribution, sale and import of food so as to ensure safe and wholesome food for human consumption". The Act, 2006 has a significant impact on the regulation of genetically modified (GM) foods in India as it provides the FSSAI with the authority to regulate GM foods through the inclusion of "genetically modified or engineered food or food containing such ingredients" within the definition of food.

To meet its regulatory obligations, the FSSAI has proposed a "Draft on Operationalizing the Regulation of Genetically Modified Foods in India" for implementing a safety assessment and approval process for GM foods that leverages existing regulatory capacity within the Government of India, notably within the Department of Biotechnology (DBT), the Ministry of Environment and Forests (MoEF) and the Indian Council of Medical Research (ICMR). FSSAI will assess GM foods at the level of an "event" and approvals will apply to foods derived from the event, its progeny and any foodstuffs that contain ingredients derived from the approved event and its progeny.

It has been proposed to set up a new secretariat within the FSSAI, namely, the Office of GM Foods and the GM Food Safety Assessment Unit. Initially staffed with two scientific officers, the Office of GM Foods will be responsible for:

- coordinating the receipt of GM food safety applications;
- conducting administrative reviews of applications;
- verifying submitted documents;
- managing communication and correspondence with applicants;
- managing the tracking of applications;
- providing a secretariat function for the GMFSAU and expert committee on GM foods; and
- managing communications and outreach with stakeholders and the public (e.g., ensuring that information about GM food regulation, policy and decisions are made promptly available on the FSSAI website).



Organizational relationships within the FSSAI for the regulation of GM foods in India.

The GMFSAU will comprise a multi-disciplinary team of scientists trained in GM food safety assessment and will include each of the following (at a minimum):

- molecular biologist;
- biochemist;
- immunologist;
- food allergenicity specialist;
- toxicologist; and
- nutritionist.

The GMFSAU will be situated at the National Institute of Nutrition (NIN), Hyderabad. NIN has experience in GM food safety assessment and already provides scientific advice to regulatory agencies in this regard. Further, the scientists at GMFSAU will have access to the library and other facilities at NIN for the latest literature on the subject. The GMFSAU will report administratively to the director, NIN, and operationally to the FSSAI. The FSSAI and NIN will be committed to ensuring that the member scientists of the GMFSAU have the appropriate combination of subject-matter expertise, are free from conflicts of interest, and are provided with opportunities to maintain and enhance their scientific knowledge and safety assessment experience.

The FSSAI will also establish an expert committee on GM Foods, which will:

- oversee a public consultation process;
- consider and respond to comments received during public consultations; and

CALENDAR OF EVENTS

Event	Organized by	Date and Venue	Website
INDIA			
A practical training course on "Techniques in Plant Tissue Culture, Genetic Engineering and Molecular Biology"	CCS Haryana Agricultural University	June 17 – July 28, 2010 Hisar	http://hau.ernet.in/
A practical training course on "Genomics, Transformation and Molecular Marker Tools for Crop Improvement"	CCS Haryana Agricultural University	June 17 – July 7, 2010 Hisar	http://hau.ernet.in/
A practical training course on "Theory and Practices in Agricultural Biotechnology"	CCS Haryana Agricultural University	June 17 – June 23, 2010 Hisar	http://hau.ernet.in/
TERI-ITEC Courses 2010-11 - Applications of Biotechnology and its Regulation	The Energy and Resources Institute (TERI)	August 2 - 22, 2010 Gurgaon	http://www.teriin.org/index.php?option=com_events&task=details&sid=307
BIO JOHOR 2010: The Second International Biotechnology and Biodiversity Conference	Johore Biotechnology and Biodiversity Corporation (J-Biotech)	July 6 - 8, 2010 Johor, Malaysia	http://www.biojohor.my/biojohor.html
ABIC 2010: Bridging Biology and Business	Agricultural Biotechnology International Conference	September 12 - 15, 2010 Saskatoon, Canada	http://www.abic.ca/abic2010/
IBS 2010 – 14th International Biotechnology Symposium and Exhibition	Alma Mater Studiorum – University of Bologna, ADRIA CONGREX and Elsevier	September 14 - 18, 2010 Rimini, Italy	http://www.ibs2010.org/index.asp
An Introduction to the Risk Analysis of Current Genetically Modified Organisms (GMOs) and their Products, and to Possible Issues Raised by Novel GMOs in the Future	Biosafety Unit, International Centre for Genetic Engineering and Biotechnology (ICGEB)	September 27 – October 1, 2010 Trieste, Italy	http://www.icgeb.org/meetings-and-courses.html
11th International Symposium on the Biosafety of Genetically Modified Organisms (ISBGMO)	International Society for Biosafety Research	November 15 - 20, 2010 Buenos, Argentina	http://www.isbgmo.info/
BIT's 4th Annual World Congress of GENE-2010: Gene Technology, Environment and Economic Growth	BIT Life Sciences, Inc.	December 1 - 4, 2010 Sanshui, Foshan, China	http://www.bitlifesciences.com/wcg2010/fullprogram.asp

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- recommend any conditions to be stipulated for product approvals keeping in view the safety assessment report by GMFSAU.

The expert committee on GM foods will comprise following members:

- Chief Executive Officer (CEO), FSSAI (acting as chair of the expert committee on GM foods);
- Principal scientific officer, FSSAI;
- Chair, scientific panel on GM organisms and foods;
- Director, National Institution of Nutrition; and
- Advisor, Department of Biotechnology.

The FSSAI is seeking comments from stakeholders regarding the above "Draft on Operationalizing the Regulation of Genetically Modified Foods in India" by July 14, 2010. The copy of the draft can be accessed at <http://www.fssai.gov.in/>.

CONSULTATION WORKSHOP ON BIOSAFETY RULES OF BANGLADESH

On April 29, 2010 Bangladesh Department of Environment (DOE), Ministry of Environment and Forests (MOEF), in collaboration with the South Asia Biosafety Program (SABP), held a one-day consultation workshop to finalize the Biosafety Rules of Bangladesh.

Mr. M. Solaiman Haider, Deputy Director, DOE and Member Secretary, National Committee on Biosafety (NCB) welcomed the invited guest, Dr. Robert Potter, a consultant to AGBIOS



Guests seated on the dias (from left):
Dr. R.H. Potter, Mr. M.A. Sobhan,
Dr. M.K. Majumder, Dr. W. Kabir.

Canada; government dignitaries including Mr. Md. Abdus Sobhan, DOE; Dr. Mihir Kanti Majumder, MOEF; and Dr. Wais Kabir, Executive Chairman, Bangladesh Agricultural Research Council (BARC); and the 46 participants who came from government ministries, NARS institutes, public universities, non-governmental organizations and the private sector. He outlined the salient features of the draft rules mentioning they had been formulated through a series of expert consultations. He asked the workshop participants to provide comments on the draft rules to ensure a final version without gaps.

Dr. Potter provided an overview of the draft rules and described how other developing countries had developed and were using biosafety rules. He also related his recent experience with biotechnology and biosafety activities being undertaken in some African countries.

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The Reading List

... new and notable articles

GENETICALLY ENGINEERED CROPS BENEFIT MANY FARMERS, BUT THE TECHNOLOGY NEEDS PROPER MANAGEMENT TO REMAIN EFFECTIVE

Source: U.S. National Academy of Science

Many U.S. farmers who grow genetically engineered (GE) crops are realizing substantial economic and environmental benefits -- such as lower production costs, fewer pest problems, reduced use of pesticides, and better yields -- compared with conventional crops, says a new report from the National Research Council. However, GE crops resistant to the herbicide glyphosate -- a main component in Roundup and other commercial weed killers -- could develop more weed problems as weeds evolve their own resistance to glyphosate. GE crops could lose their effectiveness unless farmers also use other proven weed and insect management practices.

The report provides the first comprehensive assessment of how GE crops are affecting all U.S. farmers, including those who grow conventional or organic crops. The new report follows several previous Research Council reports that examined the potential human health and environmental effects of GE crops.

"Many American farmers are enjoying higher profits due to the widespread use of certain genetically engineered crops and are reducing environmental impacts on and off the farm," said David Ervin, professor of environmental management and economics, Portland State University, Portland, Ore., and chair of the committee that wrote the report. "However, these benefits are not universal for all farmers. And as more GE traits are developed and incorporated into a larger variety of crops, it's increasingly essential that we gain a better understanding of how genetic engineering technology will affect U.S. agriculture and the environment now and in the future. Such gaps in our knowledge are preventing a full assessment of the environmental, economic, and other impacts of GE crops on farm sustainability."

First introduced in 1996, genetically engineered crops now constitute more than 80 percent of soybeans, corn, and cotton grown in the United States. GE soybeans, corn, and cotton are designed to be resistant to the herbicide glyphosate, which has fewer adverse environmental effects compared with most other herbicides used to control weeds. In addition to glyphosate resistance, GE corn and cotton plants also are designed to produce *Bacillus thuringiensis* (Bt), a bacterium that is deadly when ingested by susceptible insect pests.

Farmers need to adopt better management practices to ensure that beneficial environmental effects of GE crops continue, the report says. In particular, farmers who grow

GE herbicide-resistant crops should not rely exclusively on glyphosate and need to incorporate a range of weed management practices, including using other herbicide mixes. To date, at least nine species of weeds in the United States have evolved resistance to glyphosate since GE crops were introduced, largely because of repeated exposure. Federal and state government agencies, technology developers, universities, and other stakeholders should collaborate to document weed resistance problems and develop cost-effective ways to control weeds in current GE crops and new types of GE herbicide-resistant plants now under development.

Environmental Benefits

Improvements in water quality could prove to be the largest single benefit of GE crops, the report says. Insecticide use has declined since GE crops were introduced, and farmers who grow GE crops use fewer insecticides and herbicides that linger in soil and waterways. In addition, farmers who grow herbicide-resistant crops till less often to control weeds and are more likely to practice conservation tillage, which improves soil quality and water filtration and reduces erosion.

However, no infrastructure exists to track and analyze the effects that GE crops may have on water quality. The U.S. Geological Survey, along with other federal and state environmental agencies, should be provided with financial resources to document effects of GE crops on U.S. watersheds.

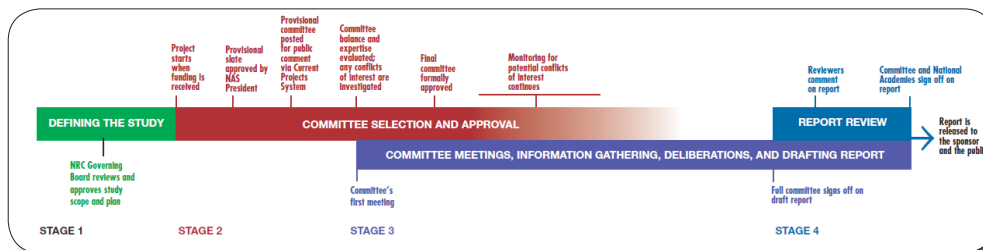
The report notes that although two types of insects have developed resistance to Bt, there have been few economic or agronomic consequences from resistance. Practices to prevent insects from developing resistance should continue, such as an EPA-mandated strategy that requires farmers to plant a certain amount of conventional plants alongside Bt plants in "refuge" areas.

Economic and Social Effects

In many cases, farmers who have adopted the use of GE crops have either lower production costs or higher yields, or sometimes both, due to more cost-effective weed and insect control and fewer losses from insect damage, the report says. Although these farmers have gained such economic benefits, more research is needed on the extent to which these advantages will change as pests adapt to GE crops, other countries adopt genetic engineering technology, and more GE traits are incorporated into existing and new crops.

The higher costs associated with GE seeds are not always offset financially by lower production costs or higher yields, the report notes. For example, farmers in areas with fewer weed and pest problems may not have as much improvement in terms of reducing crop losses. Even so, studies show that

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During the introductory speeches Dr. Kabir expressed his appreciation to the MOEF, DOE and SABP for taking the initiative to prepare the biosafety rules. He pointed out that Bangladesh's present ability to grow adequate food grain to feed its people was being undermined by the annual one per cent loss of cultivable land to river erosion, infrastructure development and other factors. He said that although the Green Revolution had contributed greatly to overcoming the global food crisis the need to grow more foods to feed an increasing population still existed and, in this context, agricultural biotechnology could be useful for the development of biotic and abiotic stress tolerant crop plants but it needed a sound and transparent biosafety regulatory system in place.

Dr. Majumder expressed his satisfaction at the wide range of participants in attendance at the day-long workshop. He said his ministry had been taking steps to develop regulatory systems so products developed through biotechnology could be handled safely. He urged participants and organizers to look at the developments of some of Bangladesh's neighbours like India, Pakistan, Malaysia, and the Philippines to see how they had been working through biosafety related issues. He suggested sharing experiences.

Mr. Sobhan concluded the opening session by thanking the members of the Review Committee who drafted the biosafety rules. He then urged cooperation by the workshop participants to expedite finalization of the document.

Following the opening session, the Rules were presented in outline and discussed in detail by the participants. Notes from these discussions and follow up submissions from the participants will be used to develop the final draft of the Rules for submission to the MOEF. The Rules will give a more formal legislative basis to the current Biosafety Guidelines of Bangladesh and provide enforcement powers under the Environment Conservation Act of 1995.

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farmers value the greater flexibility in pesticide spraying that GE crops provide and the increased safety for workers from less exposure to harmful pesticides.

The economic effects of GE crops on farmers who grow organic and conventional crops also need further study, the report says. For instance, organic farmers are profiting by marketing their crops as free of GE traits, but their crops' value could be jeopardized if genes from GE crops flow to non-GE varieties through cross-pollination or seed mingling.

Farmers have not been adversely affected by the proprietary terms involved in patent-protected GE seeds, the report says. However, some farmers have expressed concern that consolidation of the U.S. seed market will make it harder to purchase conventional seeds or those that have only specific GE traits. With the exception of the issue of seed industry consolidation, the effects of GE crops on other social factors of farming -- such as labor dynamics, farm structure, or community viability -- have largely been overlooked, the report says. More research is needed on the range of effects GE crops have on all farmers, including those who don't grow GE crops or farmers with less access to credit. Studies also should examine impacts on industries that rely on GE products, such as the livestock industry.

Research institutions should receive government support to develop GE traits that could deliver valuable public benefits but provide little market incentive for the private sector to develop. Examples include plants that decrease the likelihood of off-farm water pollution or plants that are resilient to

changing climate conditions. Intellectual property that has been patented in developing major crops should be made available for these purposes whenever possible.

The study was funded by the National Research Council. The National Academy of Sciences, National Academy of Engineering, Institute of Medicine, and National Research Council make up the National Academies. They are independent, nonprofit institutions that provide science, technology, and health policy advice under an 1863 congressional charter. Committee members, who serve pro bono as volunteers, are chosen by the Academies for each study based on their expertise and experience and must satisfy the Academies' conflict-of-interest standards. The resulting consensus reports undergo external peer review before completion. For more information, visit <http://national-academies.org/studycommitteeprocess.pdf>.

Copies of The Impact of Genetically Engineered Crops on Farm Sustainability in the United States are available from the National Academies or on the internet at <http://www.nap.edu>.

IMPROVED TOLERANCE TOWARD FUNGAL DISEASES IN TRANSGENIC CAVENDISH BANANA (*MUSA SPP. AAA GROUP*) CV. GRAND NAIN.

J. Vishnevetsky, T.L. White Jr., A.J. Palmateer, M. Flaishman, Y. Cohen, Y. Elad, M. Velcheva, U. Hanania, N. Sahar, O. Dgani O and A. Perl

The most devastating disease currently threatening to destroy the banana industry worldwide is undoubtedly Sigatoka Leaf spot disease caused by *Mycosphaerella fijiensis*. In this study, we developed a transformation system for banana and expressed the endochitinase gene ThEn-42 from *Trichoderma harzianum* together with the grape stilbene synthase (StSy) gene in transgenic banana plants under the control of the 35S promoter and the inducible PR-10 promoter, respectively. The superoxide dismutase gene Cu,Zn-SOD from tomato, under control of the ubiquitin promoter, was added to this cassette to improve scavenging of free radicals generated during fungal attack. A 4-year field trial demonstrated several transgenic banana lines with improved tolerance to Sigatoka. As the genes conferring Sigatoka tolerance may have a wide range of anti-fungal activities we also inoculated the regenerated banana plants with *Botrytis cinerea*. The best transgenic lines exhibiting Sigatoka tolerance were also found to have tolerance to *B. cinerea* in laboratory assays.

Transgenic Res. (2010) Apr 16. [Epub ahead of print]

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