SOUTH ASIA
BIOSAFETY PROGRAM

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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.

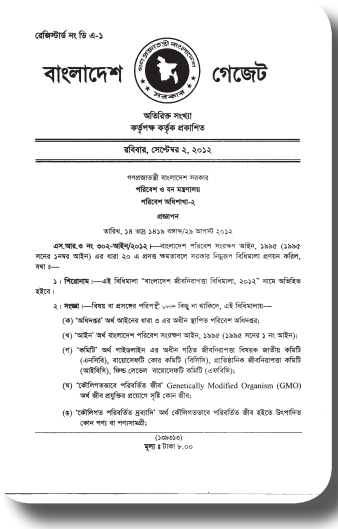
SABP is working with its in-country partners to:

- 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.

BANGLADESH BIOSAFETY RULES, 2012 — A SUMMARY

Mohammed Solaiman Haider, Deputy Director (Technical), Department of Environment, Bangladesh and Member Secretary, National Committee on Biosafety (NCB). Email: haider.doe@gmail.com

The Bangladesh Ministry of Environment and Forests enacted the "Bangladesh Biosafety Rules, 2012" (Rules) on August 29, 2012. These rules govern the introduction and use of genetically modified organisms in the environment in Bangladesh and, together with other documents and policies, including the Biosafety Guidelines of Bangladesh and the 2012 Bangladesh Biotechnology Policy, form an important part of the Government of Bangladesh's strategy for ensuring safe access to modern technologies. The following is an English-language summary of the 13 substantive rules.


রেজিস্টার্ড নং ডি এ-১

বাংলাদেশ গেজেট

অতিরিক্ত সংখ্যা
কর্তৃপক্ষ কর্তৃক প্রকাশিত

রবিবার, সেপ্টেম্বর ২, ২০১২

গণপ্রজাতন্ত্রী বাংলাদেশ সরকার
পরিবেশ ও বন মন্ত্রণালয়
পরিবেশ অধিশাখা-২
প্রজ্ঞাপন

তারিখ, ১৪ ভাদ্র ১৪১৯ বঙ্গাব্দ/২৯ আগস্ট ২০১২

এস.আর.ও নং ৩৩২-আইন/২০১২।—বাংলাদেশ পরিবেশ সংরক্ষণ আইন, ১৯৯৫ (১৯৯৫ সনের ১নং আইন) এর ধারা ২০ এ প্রদত্ত ক্ষমতাবলে সরকার নিম্নরূপ বিধিমালা প্রণয়ন করিল, যথা :—

১। শিরোনাম।—এই বিধিমালা "বাংলাদেশ জীবনিরাপত্তা বিধিমালা, ২০১২" নামে অভিহিত হইবে।

২। সংজ্ঞা।—বিষয় বা প্রসঙ্গের পরিপন্থী কোন কিছু না থাকিলে, এই বিধিমালায়—

(ক) 'অধিদপ্তর' অর্থ আইনের ধারা ৩ এর অধীন স্থাপিত পরিবেশ অধিদপ্তর;

(খ) 'আইন' অর্থ বাংলাদেশ পরিবেশ সংরক্ষণ আইন, ১৯৯৫ (১৯৯৫ সনের ১ নং আইন);

(গ) 'কমিটি' অর্থ গাইডলাইন এর অধীন গঠিত জীবনিরাপত্তা বিষয়ক জাতীয় কমিটি (এনসিবি), বায়োসেফটি কোর কমিটি (বিসিসি), প্রাতিষ্ঠানিক জীবনিরাপত্তা কমিটি (আইবিসি), ফিল্ড লেভেল বায়োসেফটি কমিটি (এফবিসি);

(ঘ) 'জৌলিপদ্ধতিতে পরিবর্তিত জীব' Genetically Modified Organism (GMO) অর্থ জীব প্রযুক্তির প্রয়োগে সৃষ্টি কোন জীব;

(ঙ) 'জৌলিপদ্ধতি পরিবর্তিত দ্রব্যাদি' অর্থ জৌলিপদ্ধতিতে পরিবর্তিত জীব হইতে উৎপাদিত কোন পণ্য বা পণ্যসামগ্রী;

(১৩৯৩৯)

মূল্য ঃ টাকা ৮.০০

Rule 2 provides definitions for the different terms in the document, namely, "Directorate", "Act", "Committee", "GMO", "Guidelines", Biotechnology", "Pollution", "Environment", "Director General", etc.

Rule 3 has three "**Sub-rules**" that describe various aspects of the **restrictions of import or export, etc., on genetically modified organisms and products.**

Sub-rule 1 says that no person or organization can import, export, buy, sell or commercially use any genetically modified organism or product without first obtaining permission from the Ministry of Environment and Forests. However, accepting, conducting and implementing projects on genetically modified organisms or products must follow the instructions described in the Biosafety Guidelines (Guidelines) and before the research results can be commercialized, permissions have to be obtained from the relevant ministries, directorates, if any, etc., upon getting approval from the Ministry of Environment and Forests.

Sub-rule 2 says that, subject to obtaining approval under Sub-rule 1, the notifier can apply to the Ministry of Commerce or related other authorities under existing import-export policy rules for import, export or other commercial uses of GMOs.

Sub-rule 3 reinforces, in case of approval under Sub-rule 2, that the Ministry of Environment and Forests must follow the Environment Conservation Act, 1995 and any of its applicable rules, the Guidelines, etc.

Rule 4 describes the **implementation of Guidelines** to control genetically modified organisms and products and their detrimental and adverse effects, etc., on the environment. It goes on to say that if there is any contradiction or inconsistency with any part of the Rules or Guidelines, the relevant Act will prevail.

Rule 5 says **labeling** is required on the container or cover used to carry genetically modified organisms or products. The provision of labeling under the Rules is additional to such requirement stated in any other rules.

Rule 6 describes the provision on receiving support from various organizations, etc., if the committee or Director General asks for the assistance and support from any ministry, organization, directorate for any emergency response or sometimes, facing the situation of any risk to environment, biodiversity, human health, or dangerous situation or environmental pollution or any kind of accident or probability of an accident caused by genetically modified organism or products therof. The Rules authorizes that relevant ministry, division, organization or directorate will be bound to come forward for the assistance as requested by the committee or Director General.

Rule 7 Describes provisions for **informing about accident, negligence in duty, administrative fines, etc.** The Rules say that if there is any risk to the environment, biodiversity, human health or dangerous situation or environmental pollution or any kind of accident caused by genetically modified organisms or products, the relevant person or organization must take measures to control it and a detailed report of such measures must be submitted to the Biosafety Core Committee (BCC) and National Committee on Biosafety (NCB) immediately.

(continued on page 2 - see Bangladesh)

Bangladesh - *continued from page 1*

It goes on to say that if any dangerous situation or accident arises due to the negligence of any person or organization then the person or organization will be held responsible for such situation. And, upon serving notice with appropriate cause, the NCB will be able to take any kind of legal measures including administrative fines rational to the gravity of the damage caused by the responsible person or organization.

Rule 8 describes the provisions of a **plan to address an emergency situation** and how the approved person or organization will have to prepare to deal with any possible accident at the field trial site or any possible accident or emergency situation away from the site and informing the Field Level Biosafety Committee (FBC) of its implementation and supervision.

Rule 9 described the provision for the **offence of environmental pollution or damaging neighbourhood management.** It outlines how, if such pollution or damage occurs then everyone, including producing organization, exporter, importer, store, supplier, retailer of the producing organism or products, will be liable unless they can prove that they have not had a direct relationship in that pollution.

Rule 10 describes provisions for **offence** and **penalty.** Specifically, if any person or organization breaches **Rules 3** or **5** or causes pollution as described in Section 9 it will be considered as an offence under the Rules. According to Subsection 2 of Section 15 of the Act, a penalty of two years imprisonment, a penalty of 10,000 Taka, or both, would be applicable for committing this kind of offence.

Rule 11 describes the provision for **appeal** if **Rule 7** has been violated. As per Section 14 of the Act and Rules 9, 10 and 11 of the Environmental Conservation Rules, 1997.

Rule 12 describes provisions for review if **Rule 3** has not been satisfied. Specifically, it says that if anyone is not satisfied by **Rule 3** then application can be made to the Ministry of Environment and Forests or to other appropriate authorities for review within 30 days of the order.

Rule 13 describes how the Director General or a committee formed by the Director General or under the Guidelines will submit a half-yearly report to the government about activities governed by the Rules that have been conducted.

A full copy of the Rules, in Bangla, is available at: http://www.doe-bd.org. An English version will be posted on the DOE website soon.

INTERACTIVE PANEL DISCUSSION ON "GENETICALLY MODIFIED CROPS AND FOOD SECURITY"

As part of National Science Day celebrations on February 28, 2013, the Indian National Science Academy (INSA) organized an interactive panel discussion on "Genetically Modified (GM) Crops and Food Security" at New Delhi.

Three eminent scientists, Prof. G. Padmanaban, former Director, Indian Institute of Science, Bangalore; Prof. Akhilesh Kumar Tyagi, Director, National Institute of Plant and Genomic Research (NIPGR), New Delhi; and Prof. N.K. Singh, National Professor, B.P. Pal Chair, National Research Centre on Plant Biotechnology, New Delhi were the discussion panelists. Prof. Krishan Lal, President, INSA, chaired the panel discussion and briefed the gathering about the current status of food security in India.

Prof. Lal informed, as per estimates, the global population is expected to reach about 9 billion by the end of 2050 and the need for adoption of some alternate means of meeting the demands of an increasing population for sufficient food both in terms of quantity and quality is necessary.

Photo: http://www.insaindia.org/

In his presentation, Prof. Tyagi mentioned, although agricultural production has increased fivefold in the last 50 years, per capita food availability has not changed significantly. He advised that many developing countries have adopted and benefited from GM technology. He said almost 120 million hectares of land are under GM crop cultivation globally with soybean, maize, cotton and canola the major crops. He also explained that the success of Bt cotton in India has lead to a 50 per cent yield increase and a reduction in insecticide use.

Prof. Tyagi spoke about GM crops under development in public sector research institutes in India and the various guiding principles and robust regulatory procedures in India that ensure the safety and efficacy of GM crops. He emphasized that GM technology is completely safe and is a complementary option in meeting increased global food demand.

Photo: http://www.insaindia.org/

Prof. Tyagi also stressed the need for a policy on multiplication, procurement and distribution of GM seeds and indicated that closer communication between policy makers, scientists, industry, farmers and consumers must be established along with post-release surveillance and risk aversion strategies.

The Reading List

. . . new and notable articles

RISK ASSESSMENT FOR *HELICOVERPA ZEA* (LEPIDOPTERA: NOCTUIDAE) RESISTANCE ON DUAL-GENE VERSUS SINGLE-GENE CORN

Edwards KT, Caprio MA, Allen KC, Musser FR

Recent Environmental Protection Agency (EPA) decisions regarding resistance management in Bt-cropping systems have prompted concern in some experts that dual-gene Bt-corn (CrylA.105 and Cry2Ab2 toxins) may result in more rapid selection for resistance in *Helicoverpa zea* (Boddie) than single-gene *Bacillus thuringiensis* (Bt)-corn (CrylAb toxin). The concern is that Bt-toxin longevity could be significantly reduced with recent adoption of a natural refuge for dual-gene Bt-cotton (CrylAc and Cry2Ab2 toxins) and concurrent reduction in dual-gene corn refuge from 50 to 20%. A population genetics framework that simulates complex landscapes was applied to risk assessment. Expert opinions on effectiveness of several transgenic corn and cotton varieties were captured and used to assign probabilities to different scenarios in the assessment. At least 350 replicate simulations with randomly drawn parameters were completed for each of four risk assessments. Resistance evolved within 30 yr in 22.5% of simulations with single-gene corn and cotton with no volunteer corn. When volunteer corn was added to this assessment, risk of resistance evolving within 30 yr declined to 13.8%. When dual-gene Bt-cotton planted with a natural refuge and single-gene corn planted with a 50% structured refuge was simulated, simultaneous resistance to both toxins never occurred within 30 yr, but in 38.5% of simulations, resistance evolved to toxin present in single-gene Bt-corn (CrylAb). When both corn and cotton were simulated as dual-gene products, cotton with a natural refuge and corn with a 20% refuge, 3% of simulations evolved resistance to both toxins simultaneously within 30 yr, while 10.4% of simulations evolved resistance to CrylAb/c toxin.

JOURNAL OF ECONOMIC ENTOMOLOGY (2013). 106(1):382-92.
SEE: HTTP://WWW.BIOONE.ORG/DOI/ABS/10.1603/EC12203

VIRUS-LIKE PARTICLES PRODUCED IN PLANTS AS POTENTIAL VACCINES

Scotti N, Rybicki EP

Virus-like particles (VLPs) have been produced as candidate vaccines in plants virtually since the introduction of biofarming. Even today, VLPs remain the best candidates for safe, immunogenic, efficacious and inexpensive vaccines. Well-characterized human animal viruses such as HBV, HCV, HIV and HPV, rotaviruses, norovirus, foot and mouth disease viruses and even influenza virus proteins have all been successfully investigated for VLP formation. Proteins have been produced in transgenic plants and via transient expression techniques; simple structures, structures depending on more than one protein, naked and enveloped particles have all been made. There have been multiple proofs of concept, more than a few proofs of efficacy, and several products moved into human trials. This review will cover the history of VLP production in plants, and will explore a few examples in detail to illustrate the potential of such a mode of production for human and animal medicine.

EXPERT REVIEW OF VACCINES. (2013).12(2):211-24. DOI: 10.1586/ERV.12.147.
SEE: HTTP://WWW.EXPERT-REVIEWS.COM/DOI/ABS/10.1586/ERV.12.147

IMPACT OF SIX TRANSGENIC *BACILLUS THURINGIENSIS* RICE LINES ON FOUR NONTARGET THRIPS SPECIES ATTACKING RICE PANICLES IN THE PADDY FIELD

Akhtar ZR, Tian JC, Chen Y, Fang Q, Hu C, Peng YF, Ye GY

As a key component of ecological risk assessments, nontarget effects of *Bacillus thuringiensis* (Bt) rice have been tested under laboratory and field conditions for various organisms. A 2-yr field experiment was conducted to observe the nontarget effects of six transgenic rice lines (expressing the Cry1Ab or fused protein of Cry1Ab and Cry1Ac) on four nontarget thrips species including *Frankliniella intonsa* (Trybom), *F. tenuicornis* (Uzel), *Haplothrips aculeatus* (F.), and *H. tritici* (Kurd), as compared with their rice parental control lines. Two sampling methods including the beat plate and plastic bag method were used to monitor the population densities of the four thrips species for 2 yr. The results showed that the seasonal average densities of four tested thrips species in Bt rice plots were significantly lower than or very similar to those in the non-Bt rice plots depending on rice genotypes, sampling methods, and years. Among all six tested Bt rice lines, transgenic B1 and KMD2 lines suppressed the population of these tested thrips species the most. Our results indicate that the tested Bt rice lines are unlikely to result in high population pressure of thrips species in comparison with non-Bt rice. In some cases, Bt rice lines could significantly suppress thrips populations in the rice ecosystem. In addition, compatibility of Bt rice, with rice host plant resistance to nontarget sucking pests is also discussed within an overall integrated pest management program for rice.

ENVIRONMENTAL ENTOMOLOGY. (2013). 42(1):173-80. DOI: 10.1603/EN12055.
SEE: HTTP://WWW.BIOONE.ORG/DOI/ABS/10.1603/EN12055

BACILLUS THURINGIENSIS CRY34Ab1/CRY35Ab1 INTERACTIONS WITH WESTERN CORN ROOTWORM MIDGUT MEMBRANE BINDING SITES.

Li H, Olson M, Lin G, Hey T, Tan SY, Narva KE

BACKGROUND: *Bacillus thuringiensis* (Bt) Cry34Ab1/Cry35Ab1 are binary insecticidal proteins that are co-expressed in transgenic corn hybrids for control of western corn rootworm, *Diabrotica virgifera virgifera* LeConte. Bt crystal (Cry) proteins with limited potential for field-relevant cross-resistance are used in combination, along with non-transgenic

(continued on page 4 - see Reading List)

CALENDAR OF EVENTS

Event	Organized by	Date and Venue	Website
INDIA			
Symposium on Biosafety, Genetically Modified Crops and Public Awareness	Chhattisgarh Infotech and Biotech Promotion Society (CHiPS)	March 18 - 19, 2013 Raipur	http://www.chips.gov.in/
Workshop on Key issues in Commercialization of Biotechnology	Department of Biotechnology and Biotech Consortium India Limited	March 19, 2013 New Delhi	http://www.bcil.nic.in/default.htm
BIRAC Foundation Day and BIRAC Grand Challenge Meet	Biotechnology Industry Research Assistance Council	March 20 - 22, 2013 New Delhi	http://www.birac.nic.in
The India Maize Summit 2013: Multidimensional Approach for Outlook, Implications & Perspective	Federation of Indian Chambers of Commerce and Industry	March 21 -22, 2013 FICCI, New Delhi	http://www.ficci.com/events-page.asp?evid=21371
National Symposium on Abiotic and Biotic Stress Management in Vegetable Crops	Indian Society of Vegetable Science and Indian Institute of Vegetable Research	April 12 - 14, 2013 Indian Institute of Vegetable Research, Varanasi	http://conference.isvs.org.in
AP-TEC 2013@TIRUPATI	Confederation of Indian Industry (CII)	June 6 - 8, 2013 Tirupati, Chittoor, Andhra Pradesh	http://ow.ly/hOefY
INTERNATIONAL			
BIT's 6th Annual World Congress of Industrial Biotechnology (IBIO-2013)	Information Research Center of International Talent, SAFEA and China Medicinal Biotech Association	April 25 - 27, 2013 Nanjing, China	http://www.bitlifesciences.com/ibio2013/
Stakeholders' Dialogue on Biosafety Regulations in Asia-Pacific	Asia-Pacific Association of Agricultural Research Institutions (APAARI)	April 16 - 17, 2013 Bangkok, Thailand (details to be posted soon)	http://www.apaari.org/events/dialogue-biosafety-201.html
Strategic Approaches in the Evaluation of the Science Underpinning GMO Regulatory Decision Making	ICGEB	July 1 - 5, 2013 Trieste, Italy	http://www.icgeb.org/~bsafesrv/training/future.html

READING LIST - *continued from page 3*

corn refuges, as a strategy to delay development of resistant rootworm populations. Differences in insect midgut membrane binding site interactions are one line of evidence that Bt protein mechanisms of action differ and that the probability of receptor-mediated cross-resistance is low.

METHODOLOGY/PRINCIPAL FINDINGS: Binding site interactions were investigated between Cry34Ab1/Cry35Ab1 and coleopteran active insecticidal proteins Cry3Aa, Cry6Aa, and Cry8Ba on western corn rootworm midgut brush border membrane vesicles (BBMV). Competitive binding of radiolabeled proteins to western corn rootworm BBMV was used as a measure of shared binding sites. Our work shows that (125)I-Cry35Ab1 binds to rootworm BBMV, Cry34Ab1 enhances (125)I-Cry35Ab1 specific binding, and that (125) I-Cry35Ab1 with or without unlabeled Cry34Ab1 does not share binding sites with Cry3Aa, Cry6Aa, or Cry8Ba. Two primary lines of evidence presented here support the lack of shared binding sites between Cry34Ab1/Cry35Ab1 and the aforementioned proteins: 1) No competitive binding to rootworm BBMV was observed for competitor proteins when used in excess with (125)I-Cry35Ab1 alone or combined with unlabeled Cry34Ab1, and 2) No competitive binding to rootworm BBMV was observed for unlabeled Cry34Ab1 and Cry35Ab1, or a combination of the two, when used in excess with (125)I-Cry3Aa, or (125)I-Cry8Ba.

CONCLUSIONS/SIGNIFICANCE: Combining two or more insecticidal proteins active against the same target pest is one tactic to delay the onset of resistance to either protein. We conclude that Cry34Ab1/Cry35Ab1 are compatible with Cry3Aa, Cry6Aa, or Cry8Ba for deployment as insect resistance management pyramids for in-plant control of western corn rootworm.

PLOS ONE. (2013) 8(1):E53079. DOI: 10.1371/JOURNAL.PONE.0053079. EPUB 2013 JAN 4,
SEE: HTTP://WWW.NCBI.NLM.NIH.GOV/PMC/ARTICLES/PMC3537739/

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