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Bangladesh Biosafety Rules 2012

Report Categories:

Biotechnology - GE Plants and Animals
Biotechnology and Other New Production
Technologies

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Report Highlights:

The government of Bangladesh published Bangladesh Biosafety Rules (BR), 2012, which provides regulations on the approval process for genetically engineered products developed domestically or by a third country. According to BR, 2012, all GE products need to be approved before they can be imported or sold domestically within Bangladesh.

This report contains an INFORMAL translation of BR, 2012.

Executive Summary:

The government of Bangladesh published Bangladesh Biosafety Rules (BR), 2012, which provides regulations on the approval process for biotech products developed domestically or by a third country.

According to BR, 2012, all GE products need to be approved before they can be imported or sold domestically within Bangladesh. BR, 2012 notes that the Ministry of Environment and Forests needs to follow the Biosafety Guidelines of Bangladesh, 2007 in approving any biotech product. Although not notified to the World Trade Organization (WTO), BR, 2012 was published on September 2, 2012.

General Information:

Disclaimer: This summary is based on a *cursory* review of the subject document and, therefore, should not under any circumstances be viewed as a definitive interpretation of the regulation in question, or of its implications for U.S. agricultural trade interests.

This report contains an INFORMAL translation of BR, 2012.

With the last 10 years, the government of Bangladesh has issued various publications on biotechnology such as the National Biotechnology Policy, 2006, Biosafety Framework (NBF), 2007, and Biosafety Guidelines of Bangladesh (BG), 2007. Bangladesh Biosafety Rules (BR), 2012, provides regulations on the approval process for biotech products developed domestically or by a third country. According to BR, 2012, all GE products need to be approved before they can be imported or sold domestically within Bangladesh. BR, 2012 notes that the Ministry of Environment and Forests needs to follow the Biosafety Guidelines of Bangladesh, 2007 in approving any biotech product. It also provides other information such as labeling and fines that may be levied against parties who harm the environment or ecosystem. Although not notified to the World Trade Organization (WTO), BR, 2012 was published on September 2, 2012.

The original text for BR, 2012 can be accessed here:

<http://www.doe.gov.bd/law/law.php?cmd=list&&page=1>

BEGIN TRANSLATION

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Circular

Date: 14 Vadra 1419 Bengali Year/29 August 2012

SRO No 302-Act/2012. The Government formulated the following Rules under the authority bestowed to it by the Section 20 of the Bangladesh Environment Conservation Act, 1995 (No. 1 Act of 1995): --

1. Title. The Rules shall be called "Bangladesh Biosafety Rules, 2012".

2. Definition. Unless there is anything repugnant in the subject or context, the Rules--

(a) 'Department' means the Department of Environment established under the Section 3 of the Act;

(b) 'Act' means Bangladesh Environment Conservation Act, 1995 (No 1 Act of 1995);

(c) 'Committee' means National Committee on Biosafety (NCB), Biosafety Core Committee (BCC), Institutional Biosafety Committee (IBC), Field Level Biosafety Committee (FBC) established under the Guidelines;

(d) 'Genetically Modified Organism (GMO)' means any creature created through application of biotechnology;

(e) 'Genetically Modified Products' mean a product or products that have been produced from Genetically Modified Organisms;

(f) 'Guidelines' means the Biosafety Guidelines of Bangladesh circular no PBM/Environment-3/01/CBBD-03/2007/17 issued by the Ministry of Environment and Forests on 31 December 2007;

(g) 'Bio Technology' means a technology which is applied to implant into an organism (plants or animals or microorganism) new characteristics or gene-carrier or gene obtained from the same organism or its wild variety or completely different organism in order to create an organism containing new Genetically Modified characteristic;

(h) 'Pollution' means the pollution defined in the Section 2 (b) of the Act;

(i) 'Environment' means the environment defined in the Section 2 (d) of the Act;

(j) 'Director General' means the Director General of the Department of Environment.

3. Restrictions on imports or exports on Genetically Modified Organism or products.

(1) Without any approval from the Ministry of Environment and Forests, an individual or a firm shall not import, export, buy and sell any Genetically Modified Organism or products, or commercially use them:

Provided that provisions of the Guidelines shall be applicable in case of carrying out any research or undertaking and implementing a project on Genetically Modified Organism or products:

Provided that approval has to be taken from the concerned ministries including the Ministry of Agriculture and the Department, if any, in order to market the outcome stemming from the research.

(2) Subject to obtaining approval under the Sub-section (1), application may be filed to the Ministry of Commerce or other concerned authorities to commercially import and export or use commercially under the existing import and export policies of the country.

(3) The Ministry of Environment and Forests shall follow the Act and other concerned rules formulated under the Act, if any, and the provisions of the Guidelines in case of issuing approval under the Sub-section (2).

4. Applying the Guidelines, etc. The provisions of the Guidelines shall be applicable in case of controlling the Genetically Modified Organism or products and their harmful and adverse impacts on the environment:

Provided that if any provision of the Guidelines is in conflict or inconsistent with any provision of any concerned Act or the Rules, the concerned Act or the Rules shall prevail.

5. Identifying or labeling. The box or package carrying the Genetically Modified Organism or products shall bear the complete information of its identification on them or bear labeling that states that the product is Genetically Modified Organism or that has been produced from Genetically Modified Organism, and it shall be done additionally, whatever stated in other Acts on the matter.

6. Taking assistance from various agencies, etc. (1) If Genetically Modified Organism or products produced from the organism pose threat to the environment, biodiversity and human health or create dangerous situation or pollute environment or cause any accident or is likely to cause any accident, the concerned committee or the Director General may seek assistance and cooperation from any ministry, agency, department etc to resolve or, in some cases, address the problem on emergency basis.
(2) Under the Sub-section (1), the concerned ministry, division, agency or department shall be obligated to extend the assistance or cooperation sought by the concerned committee or the Director General.

7. Reporting of accident, negligence to responsibility, administrative fine, etc. (1) If Genetically Modified Organism or products produced from the organism pose threat to environment, biodiversity and human health or create dangerous situation or pollute environment or cause any accident, the concerned individual or firm shall take necessary initiatives to control the situation, and inform the Biosafety Core Committee (BBC) and the National Committee on Biosafety (NCB) as soon as possible through detailed report or information about the steps taken.

(2) If any dangerous situation or accident stated in the Sub-section (1) is created due to negligence of the concerned individual or firm to their responsibility, the individual or the firm shall be held responsible for the situation.

(3) The National Committee on Biosafety (NCB) shall take any legal step including ordering a logical administrative fine against the responsible individual or firm under the Sub-section (2) after serving an appropriate show cause notice.

(4) If the National Committee on Biosafety (NCB) orders any logical administrative fine against the responsible individual or the firm under the Sub-section (3), the financial fine shall be deposited with the concerned Government office within 30 (Thirty) days of the issuance date of the order.

8. Plans to face emergency situation. (1) The authorized individual or the firm shall prepare a plan to face any potential accident or emergency situation in the experiment field or remote areas of the experiment field for conducting their activities, and inform the Field-level Biosafety Committee (FBC) about its implementation and supervision.

(2) Participation of the local residents and their advice shall be ensured in the preparation and implementation of the plan under the Sub-section (1).

(3) The authorized individual or the firm shall supply information about the management of the ongoing Genetically Modified Organism, and all other associated and necessary information including the type and extent of any potential accident, and any potential impact beyond the experiment field area, to the FBC to make it capable of supervising the necessary emergency plans under the Sub-section (1).

9. Crimes for causing environment pollution or harming the ecosystem. If Genetically Modified Organism or products cause environment pollution or harm the ecosystem management, the firms producing the organism or products, their exporters, importers, hoarders, suppliers and retailers shall be responsible for the crimes for the pollution or causing harm to the ecosystem unless they prove that they have not been directly associated with causing pollution.

10. Crimes and punishment. (1) If an individual or a firm violates the Rule 3 or 5 or causes pollution as stated in the Rule 9, it shall be considered a crime under the Rules in order to achieve the objective of the Sub-Section 2 of the Section 15 of the Act, and such crimes shall be punishable with imprisonment for a term up to two years or with financial fine Tk 10 (Ten) thousand or both.

(2) If a company is found responsible as a polluter as stated in the Rule 9, the provision under the Section 16 of the Act will be applicable for that company.

11. Appeal. An aggrieved person affected by the order of the Rule 7 shall be able to make appeal under the Section 14 of the Act and the Rules 9, 10 and 11 of the Environment Conservation Rules, 1997.

12. Review. (1) Any aggrieved person affected by the order of the Rule 3 may submit application for review within 30 (Thirty) days of the order –

- a. to the Ministry of Environment and Forests for not getting approval, or
- b. to the concerned authority where applicable,

(2) Within 30 (Thirty) days of the receiving of the application of the appeal under the Subsection (1), the Ministry of Environment and Forests or the concerned authorities shall settle the appeal, and inform the applicant about the order regarding accepting or rejecting of the application.

13. Report submission. (1) A half-yearly report containing the description of the activities performed under the Rules by the Director General or the committees established by the Director General or the Committees established in the Guidelines shall be submitted to the Government every 6 (Six) months.

(2) The Government, if necessary, may any time seek reports from the Director General on the activities or matters performed under the Rules, and the Director General shall be obligated to submit it to the Government.

By the order of the President
Dr. Abu Saleh Mostafa Kamal
Deputy Secretary

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