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BIOTECHNOLOGY IN CROP PRODUCTION AND THE BIOSAFETY PROTOCOL – IMPLICATIONS FOR CEREAL TRADE

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I. INTRODUCTION

1. The aim of this paper is to present an overview of modern biotechnology in crop production, with a particular reference to genetically modified organisms (GMOs), discuss the international instruments of relevance in this area and highlight the challenges and implications for cereal trade.

2. Modern biotechnology in the crop sector covers a wide range of tools and molecular techniques including among others *molecular markers*, *recombinant DNA technology*, *genotyping* and *genomics*. In the agriculture sector, these techniques are used largely to overcome problems associated with yield, productivity, storage and processing and provide opportunities for quantitative and qualitative increases in agricultural production at quicker pace with reduced external inputs. The promises and potentials of modern biotechnology are concrete when progress in this sector is within a framework of comprehensive and sustainable agriculture development.

II. GMOs IN CROP PRODUCTION

3. GMOs are those that have been modified by the application of recombinant DNA technology or genetic engineering- a technique used for altering the genetic material of living organisms[1]. With the rapid advances in biotechnology, a number of genetically modified (GM) crops or transgenic crops carrying novel traits have been developed and released for agriculture production. This includes among others pests resistant cotton, maize, canola (mainly *Bt* or *Bacillus thuringiensis*), herbicide glyphosate resistant soybean, cotton (i.e.Roundup Ready) and viral diseases resistant potatoes, papaya and squash which are under commercial production. In addition, various transgenic crops are under development with traits for biofortification, phtoremediation and production of pharmaceuticals such as canola with high oleic acid and low linolenic acid content, rice with high level of carotenoid for production of Vitamin A and bananas with vaccines [2].

4. Commercial cultivation of transgenic crops started in early 1990s. Herbicide tolerance and insect resistance are the main GM traits that are currently under commercial cultivation and the main crops are: soybean, maize, canola and cotton. GM crops are now commercially planted on about 100 million hectares in some 22 developed and developing countries. Argentina, Brazil, China and India are the largest developing country producers of transgenic crops. The choice of GM crops varies among the developing countries, with insect resistant cotton being the most important commercially produced transgenic crop in Asian and African countries, while herbicide resistant soybean followed by insect resistant corn is predominant in the Latin American continent.

5. In most cases these GM technologies are proprietary, developed by the private sector and released for commercial production through licensing agreements. Cultivation and commercial production of GM crops are capital intensive, due to high costs of seed and technology. Nevertheless, their cultivation has generally increased, mainly due to the benefits accrued from

[1] The process by which the genetic make up of organisms is altered by inserting foreign DNA and/or genes, or fusion of cells beyond the taxonomic family. Organisms whose DNA has been altered in this manner, whether they are microorganisms, plants, trees, livestock, and fish, are referred to as Genetically Modified Organisms (GMO).

[2] FAO (2005) Status of Status of Research and Application of Crop Biotechnologies in Developing Countries – A Preliminary Assessment.

[4] Pray, C.E., Ma, D., Huang, J. and Qiao, F. 2001. Impact of Bt–cotton in China. *World Dev*. 29: 813–825.

lowered labour and production costs, reduction in use of chemical inputs, and improved economic gain[4]. The United States, Argentina and Canada are the major producers and exporters of GM crops and products with about 75 percent of the total production. The four global GM crops are overwhelmingly the major crops and commodities traded on world markets.

6. The increasing cultivation of GM crops has raised a wide range of concerns with regards to food safety, environmental effects, and socio-economic issues. From the food and health perspective, the main concerns are related to possible toxicity and allergenicity of GM foods and products. Concerns on environmental risks include impact of introgression of the transgenes into natural landscape, impact of gene flow, effect on non-target organisms, evolution of pest-resistance and loss of biodiversity. Adoption of GM technologies have also evoked a range of social and ethical concerns about restriction on access to genetic resources and new technologies, loss of traditions like saving seeds, private sector monopoly and loss of income of resource poor farmers. The scientific evidence concerning the environmental and health impacts of GMOs are still emerging but so far, there is no conclusive information on definite negative impact of GMOs on health or on the environment. Nevertheless, public perception about GMOs in food and agriculture is divided with a tendency to avoid GM food and products in many developed and developing countries[5].

III. MULTILATERAL INSTRUMENTS DEALING WITH MODERN BIOTECHNOLOGY

7. There are a number of existing international agreements that are of direct relevance to GMOs, and there is no single comprehensive legal instrument that addresses all aspects of GMOs or its products at the international level. In the area of biosafety (ie addressing the risks posed to the environment and human health when GMOs are released into the environment either for research or commercial purposes) there are at least 15 international instruments[6]. Seven of these are legally binding, namely: the UN Convention on the Law of the Sea (1982), the Convention of Biological Diversity (CBD, 1992), the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS, 1995), the WTO Agreement on Technical Barriers to Trade (TBT, 1994), the International Plant Protection Convention (IPPC, 1997), the Aarhus Convention (1998) and the Cartagena Protocol on Biosafety (2000). The Codex Alimentarius Commission (CAC) is the principal international forum that addresses food safety aspects of GMOs and along with IPPC, the Codex is the standard-setting body within the WTO-SPS Agreement. As the Codex Alimentarius, the IPPC and the Cartagena Protocol are the most relevant from the perspective of grain trade. They will be described in some detail below.

A. CODEX ALIMENTARIUS

8. The Joint FAO/WHO Codex Alimentarius Commission is an intergovernmental body with 169 member countries that sets standards for food safety and food trade, including those derived from GMOs. In 1999, it established the *ad hoc* Intergovernmental Task Force on Foods derived from Biotechnology to consider the health and nutritional implications of GM food. Based on the outcomes of the series of joint FAO/WHO expert consultations, the Task Force has been developing standards, guidelines and recommendations for GM foods on the basis of scientific evidence, risk analysis and having regard, where appropriate, to other legitimate factors

[5] Public sentiment about Genetically Modified Food, 2006 update. (http://pewagbiotech.org/research/2006update/1.php).

[6] Glowka, L2003. Law and Modern biotechnology : selected issues of relevance to food and agriculture . FAO legislative study 78, Rome (www.fao.org/DOCREP/006/Y4839E/Y4839E00.HTM).

relevant to the health of consumers and the promotion of fair practices in the food trade.[7]

B. INTERNATIONAL PLANT PROTECTION CONVENTION (IPPC)

9. This legally binding convention aims to promote legislative and other measures to prevent the spread and introduction of pests of plants and plant products, and promote appropriate measures for their control. The IPPC with its latest amendments was adopted at the FAO Conference in 1997, taking into account its role in relation to the SPS Agreement. The Secretariat is hosted by FAO and 132 countries are Party to the Convention.

10. The IPPC develops and adopts international standards, provides technical assistance and information exchange. It develops the International Standards for Phytosanitary Measures (ISPM) which largely shape the phytosanitary measures established under the WTO-SPS Agreement. The ISPM No. 11 (2004) gives guidance on risk analysis for pests of plants and plant products. In particular, it provides guidance on evaluating the potential phytosanitary risks to plants and plant products posed by living modified organisms (LMOs)[8]. It also provides details for the risk assessment and selection of risk management options. Since its adoption, ISPM No. 11 has been used to analyze the risk from LMOs when they are pest to plants.

C. CARTAGENA PROTOCOL ON BIOSAFETY

11. The Cartagena Protocol on Biosafety (Biosafety Protocol) was adopted in January 2000 by the Parties to the CBD as supplementary agreement on biosafety. It came into force in September 2004 and so far it has been ratified by 138 countries. The objective of the Protocol is "to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organism that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on trans-boundary movements"[9], in accordance with the precautionary approach of the Rio Declaration. It covers all LMOs which are meant for intentional introduction in a country, which is a signatory to the Protocol. It does not cover pharmaceuticals or any other biotechnology products that are non-LMOs.

12. The two major elements of the Protocol are the:

- Advanced Informed Agreement (AIA) procedure, whereby importing countries agree to receive LMOs from exporting countries, and
- Biosafety Clearing House Mechanism; which acts as an information exchange resource.

13. The AIA process (Article 7-12) differentiates procedures for LMOs for intentional introduction into the environment and LMOs for direct use as food, feed or for processing (LMO-FFPs). Under the AIA prior informed consent is needed for the first movement of LMOs for intentional introduction into environment. The exporter must provide detailed information in advance of 1st shipment. The importer may then authorize/refuse shipment depending on risk assessment. A simplified procedure also exists to allow importing countries to accept specified LMOs and bypass the AIA procedure. In the decision-making process of the AIA mechanism the key component is the risk assessment – which is highly specific and should be conducted as per Annex III (on Risk Assessment) in the Protocol. Importing countries may take up to a year after

[7] http://www.codexalimentarius.net/web/archives.jsp?lang=en.

[8] LMOs mean any living organisn that posseses a novel combination of genetic material obtained through the use of modern biotechnology. Simply put LMOs are living GMOs.

[9] Article 1.

notification by the exporter to come to some kind of decision. The exporter may be liable for the costs of undergoing the decision-making process.

14. The transboundary movement of LMOs – FFPs (Article 11) is monitored and documented through a considerably less demanding process. Shipment of all LMOs, including those in transit or destined for contained use, are to be identified and details on the taxonomy, origin and characteristics of donor and parent organisms, and other data on handling and storage, may also be demanded.

15. Article 18 details the requirements for documentation accompanying LMO including handling, transport, packaging and identification. It also addresses the need for and modalities of developing standards with regard to identification, handling, packaging and transport practices for transboundary movements of LMOs. The Conference of Parties in its meeting in 2006 took decisions on the detailed requirements for documentation accompanying shipments of LMOs intended for direct use as food or feed, or for processing[10]. The impact of these documentation requirements on transboundary movement would be reviewed in future meetings.

16. The Biosafety Clearing House (Article 20) facilitates information exchange and assist in implementing the Protocol. The Protocol also emphasises public awareness and capacity building (Article 22 and 28) for safe management of modern biotechnology. It further takes into account those socio-economic conditions in the decision-making process that arise from impact of LMOs on biological diversity (Article 26), including redress and liability. It also proposes basic requirements for Parties to ensure that measures are in place to manage risks posed by any LMOs to biodiversity.

17. The Biosafety Protocol has provided an important stimulus to the development of national GMO regulatory frameworks in developing countries. Through UNEP/GEF assistance, participating countries are establishing their national biosafety regime for the management of LMOs in compliance with the Protocol[11]. Although biosafety is relatively recent, there is a tremendous interest and some 82 member countries have developed their draft National Biosafety Frameworks and established a competent authority to deal with biosafety matters. However, it can be foreseen that the operationalisation of a fully functional national biosafety mechanism would vary from country to country, depending on availability of adequate technical skills, institutional infrastructure and financial resources.

IV. BIOSAFETY AND CEREAL TRADE

18. The adoption of GM crops created new opportunities to boost production and expanding trade opportunities. Within this context, commerce faces two conceptually distinct challenges: (i) compliance with international obligations that address all the safety issues (including environment and human health; (ii) compliance to market requirements, prescribed by consumer preferences that may be regulated at the national level.

19. The Biosafety Protocol is not intended to provide any direct provisions about grain trade, except for the requirement to provide the necessary information on 'may contain' as per its AIA procedures for LMOs - which regulates commerce in LMOs between Parties to the Biosafety

[10] Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP 3) 3 - 17 March 2006 Decision BS-III/8 /9/11 http://www.biodiv.org/decisions/default.aspx?m=MOP-03&id=11064&lg=0.

[11] http://www.unep.ch/biosafety/news.htm#nbf.

[14] Top grain exporters like Australia, Argentina, Canada and USA and are not party to the Biosafety Protocol.

Protocol. Bilateral negotiations compatible with the Protocol are usually conducted between Parties and non-Parties for commerce in LMOs[14].

20. Consumer preferences and increased availability of different types of products in the markets are playing a big role in market segregation in prices and demands. The concept of 'identity preservation' is frequently mentioned in separating GM from non-GM products as per the requirements of the markets. This is linked to labeling and traceability for minimizing 'adventitious presence'[15] of GMOs. Many countries are developing their own regulations on this matter based on national needs[16] and market preferences. FAO carried out a study to quantify the investments and costs involved in segregating the chains of production, transportation and embarking for GM and non-GM soya bean and maize in Argentina in conformity with the Cartagena Protocol on Biosafety.[17]

21. When the volume of GM grain trade grows simultaneously with the changes in consumer preferences, there would be a need to strengthen regulatory procedures to command the trust of both consumers and producers. Within the framework of Risk Analysis, all the risks for human and animal health and the environment must be carefully assessed and communicated for effective consumer/producer protection. At the same time the cost factor, supply chain management issues and implication of segregation on world trade would need to be analyzed. An analysis by IFPRI showed if costs of labeling and market segmentation were not large, world markets could adjust to the various scenarios without generating extreme price differentials between GM and non-GM commodities or extreme changes in the pattern of world production and trade[18].

V. FAO AND BIOSAFETY

22. As countries develop their national biosafety regimes, there is a growing demand for strengthening national skills and capacities for implementation of the biosafety rules and regulations in compliance with the Biosafety Protocol. FAO has been actively providing policy and technical assistance to member governments upon request for strengthening their national biotechnology- biosafety frameworks. The main focus has been towards assistance in developing national policies and legislations, providing scientific, technical and institutional capacity-building to shape their institutions for management of GM crops within Biosafety Protocol, strengthening research and development and raising public awareness[19]. In collaboration with partners and stakeholders, number of regional and sub–regional training workshops have also been organised for capacity building in GMO detection and analysis, safety assessment of GM foods and feeds and harmonisation of rules and regulations to facilitate regional seed trade. High level expert consultations have been organised on topical issues on biosafety, methodologies for monitoring GMOs in crop production and environmental effects of GM crops.

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[15] The term 'adventitious presence' refers to the unintentional and incidental commingling of trace amounts of one type of seed, grain or food product with another. Adventitious presence is an unavoidable reality of plant biology, seed production and the distribution of commodity crops. There are a number of factors that contribute.

[16] EU regulations requires food products containing more than 0.9% GE material to be labeled as such. Japan has a threshold of 5% GE material, while Australia, New Zealand, and Brazil have thresholds of 1%. These thresholds are not safety-based standards, but rather market specifications that trigger labelling requirements if not met.

[17] TCP/ARG/2903 (A) Evaluación de la capacidad, infraestructura y logística de manejo post-cosecha deorganismos vivos modificados e identificación de estrategias para aplicar el artículo 18, 2.a) del Protocolo de cartagena sobre seguridad de la biotecnología.

[18] Nielsen CP, Robinson S, Thierfelder K, 2002 Trade in Genetically Modified Food: A Survey of Empirical Studies, http://www.ifpri.org/divs/tmd/dp/papers/tmdp106.pdf.

[19] Since 2003 projects have been undertaken upon request or in the pipeline in, Bangladesh, Bolivia, Benin, Granada, Malaysia, Paraguay, Kenya, Swaziland, Sri Lanka Tanzania and Uganda and AsiaBionet of 10 Asian countries.

23. Majority of these activities are undertaken either through the relevant technical units or through the Interdepartmental Working Group on Biotechnology – which provides a forum for biotechnology related activities of multi-disciplinary flavour in a complementary manner. Biosafety in food and agriculture is managed within *Biosecurity* framework managed by the Interdepartmental Working Groups on Biosecurity to promote a strategic and integrated approach to analyse and manage risks in the sectors of food safety, animal life and health, as well as plant life and health.[20] Through the production and dissemination of technical publications, FAO has also taken the lead in expanding knowledge base in biotechnology and biosafety. The FAO website on Biotechnology provides a wealth of information on all these aspects and maintains an inventory of biotechnology products including GMOs from developing countries[21].

VI. NEXT STEPS

24. The powerful tools provided by technologies, such as modern biotechnology provides new opportunities for agriculture and have generated a profound interest in biosafety to ensure adequate levels of protection for health and environment through their safe transfer, handling and use. With the adoption of the Biosafety Protocol there is a great demand in many developing countries for establishing effective biosafety systems. However, the speed of implementation is variable due to limitations in technical capacity, lack of infrastructure and limited financial resources. There is definite need to provide long term continuous technical and financial support to allow the full development of national capabilities in this sector that allows full utilization of the potentials of advances in scientific research and development.

25. Moreover, there is a perceived shift in market demands for segregation of GM and non-GM products based on consumer preferences. When resources and infrastructure are limited, catering to these choices is not easy. At present, however there is very limited information or data available on the nature or implication of the costs of these new developments on the global agriculture trade or at national level. The Groups may wish to recommend that a study be undertaken to analyse in-depth the economic implications of GMOs and the effect of the national regulations on international cereal trade.

[20] TC/BRM/Rep. Technical consultation on biological risk management in food and agriculture *Bangkok, Thailand, 13-17 January 2003.*

[21] FAO- Bio Dec http://www.fao.org/biotech/inventory_admin/dep/default.asp.