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OVERVIEW OF INTERNATIONAL AGREEMENTS RELATED TO GMOS, INCLUDING THE CARTAGENA PROTOCOL ON BIOSAFETY AND THE CODEX AIMENTARIUS.

South Africa is member to the Cartagena Protocol on Biosafety and the Codex Alimentarius Commission, which set international guidelines and standards to ensure the environmental and food safety of GMOs respectively.

THE CARTAGENA PROTOCOL ON BIOSAFETY

The Cartagena Protocol on Biosafety (CPB) is a legally binding international treaty (established in September 2000) under the United Nations Convention on Biological Diversity (CBD) that:

- Establishes rules and procedures for the transboundary movement of living genetically modified organisms, (GMOs) (referred to as "living modified organisms" (LMOs), in order to ensure protect the conservation and sustainable use of biodiversity. (It does not cover non-living products derived from LMOs, (e.g. paper from GM trees, processed food products) and LMOs which are pharmaceuticals for humans), as– these are addressed by other relevant international agreements or organisations.)
- Requires signatories to establish national biosafety frameworks which encapsulate some national regulatory requirements and procedures
- Requires that exporting parties of LMOs adhere to the conditions stipulated in the Advanced Informed Agreement (AIA). The AIA is a procedure that requires notification to the importing country containing detailed information about the LMO, previous risk assessments of the LMO and its regulatory status in the exporting country. The importing country must acknowledge receiving the information within 90 days and state whether the notifier should proceed under a domestic regulatory system or under the Protocol procedure. In either case, the importing country must decide whether to allow the import, with or without conditions or deny it within 270 days. The AIA is not required for consecutive shipments (only covers first time shipments) or for LMOs not intended for release into the environment such as commodities, LMOs in transit, and LMOs destined for contained use. LMOs shipped to countries Party to the Protocol for contained use, intentional introduction into the environment or for direct use for food, feed, or processing (LMO-FFPs) to be identified in accompanying documentation as specified in the Protocol.
- Requires government decision making on imports to be based on sound scientific risk assessment and for results of such assessments to be made available through an internet based Biosafety Clearing House (BCH). The purpose of the BCH is to facilitate the exchange of scientific, technical, environmental and legal information on, and experience with LMOs and assist parties in implementing the Protocol. Examples of information contained in the BCH include: any existing laws, regulations, or guidelines for implementation of the Protocol, summaries of risk assessments or environmental reviews of LMOs, and final decisions regarding the importation or release of LMOs.
- Requires that decisions on proposed imports be based on risk assessments. Risk assessments must be undertaken in a scientific manner based on recognized risk assessment techniques, taking into account advice and guidelines developed by relevant international organisations. Lack of scientific knowledge or scientific consensus must not necessarily be interpreted as indicating a particular level or risk, an absence or risk, or an acceptable risk. Risks associated with LMOs or products thereof should be considered in the context of risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment. Risk assessment should be carried out on a case by case basis.

- Includes a clause that makes clear the Parties' intent that the agreement does not alter the rights and obligations of governments under the World Trade Organization (WTO) or other existing international agreements. Signatories are expected to ensure trade in LMO occur in a fair equitable manner in order to prevent any disruptions in food trade at both the local and international levels. Brief something on liability and redress…? (just that it's still discussed)Where disputes do occur signatories are expected to abide by Article 27 of the CPB which makes provision for liability and redress. Many signatories are yet to concluded regulations/ legislation regarding liability and redress due to the complexity of the issues involved.
- The Protocol does not address food safety issues - this is addressed by the Codex Alimentarius. It also does not require segregation of bulk shipments of commodities that may contain living modified organisms, consumer product labeling and does not subject shipments of bulk commodities to the Protocol's AIA procedure.
- The Biosafety Protocol came into force on 11 September 2003. To date, 159163 countries are party to the Protocol (i.e., have adopted it in their national legislation). Many of these countries lack adequate systems and infrastructure to handle requests for imports or to comply with the protocol requirements. The major agricultural exporters including Argentina, Australia, Canada, China, Russia and the United States are not party to the Protocol.
- The Department of Environmental Affairs (DEA) is the designated Give details on SA – e.g. competent authority and is primarily responsible for the national biosafety related policy development. The DAFF is however the custodians of the BCH.

Useful Websites

- http://www.cbd.int – Website of the Convention on Biological Diversity.
- http://www.agis.agric.za/gmo/ - The South African Biosafety Clearing-House.

CODEX ALIMENTARIUS COMMISSION

The Codex Alimentarius Commission (the CAC or 'food code') is a body of the Joint Food Standards Programme of the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) and currently accounts for 180 members (including South Africa). Codex develops and encourages implementation of standards, codes of practice, guidelines and recommendations covering all aspects of food safety, including labeling and handling and distribution. It applies to internationally traded foods (which may be processed, semi-processed or raw) but excludes perishable products. In setting international standards for food safety, Codex has a dual mandate to protect the health of consumers and to ensure fair practices in the food trade. Codex has developed a wide range of specific texts covering various aspects of food safety and quality. In anticipation of an increase in transboundary movement of genetically modified (GM) food products a Task Group focusing on intended and unintended effects of food derived from modern biotechnology was established and the following GMO related guidelines were drafted: (see

http://www.codexalimentarius.org/standards/list-of-standards/en/?no_cache=1)

a) Principles for the Risk Analysis of Foods Derived from Modern Biotechnology, 2003 (CAC/GL 44-2003) lists principles for risk assessment and risk management related to food safety of genetically modified foods, including some elements of annex III of the Protocol.
b) Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant DNA Plants, 2003 (CAC/GL 45-2003) describes considerations for the assessment and management of risks associated with foods consisting of, or derived from, genetically modified plants.
c) Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant- DNA Microorganisms, 2003 (CAC/GL 46-2003) describes considerations and approaches for the safety

assessment of foods produced using recombinant-DNA micro-organisms In addition to Codex, there are two agreements under the World trade Organisation (WTO) of specific relevance to the trade in food (i.t.o harmonization, equivalency and transparency) namely the Agreement on the Application of Sanitary and Phytosanitary Measures and the Agreement (the SPS Agreement) on Technical Barriers to Trade (the TBT Agreement). These agreements are therefore considered complementary/ relevant to GMO guidelines of Codex Alimentarius.

The CAC is a science-based organisation comprising independent experts and specialists from various disciplines responsible for ensuring that food safety standards withstand the most rigorous scientific scrutiny. The factors that have to be considered in assessing the safety of GM-food products are thus the same as for any other food not previously safely consumed. Article 18 of the codex guideline refers to the safety assessment of a food derived from a recombinant-DNA plant and follows a stepwise process of addressing relevant factors. These factors include:

A) Description of the recombinant-DNA plant;
B) Description of the host plant and its use as food;
C) Description of the donor organism(s);
D) Description of the genetic modification(s);
E) Characterization of the genetic modification(s);
F) Safety assessment:

a) expressed substances (non-nucleic acid substances);

b) compositional analyses of key components;

c) evaluation of metabolites;

d) food processing;

e) nutritional modification; and

f) Other considerations.

Many countries have adopted national food safety regulations and labeling legislation for GM products. These regulations are continuously refined as safety of GM products is demonstrated. South Africa has recently adopted Consumer Protection Act which requires the labeling of authorized GM products and its derivatives. For more information on Codex please visit the official website on -

http://www.codexalimentarius.net/web/index_en.jsp