Food Security and Biotechnology in Africa

This project is financed by the European Union and implemented by the ACP Secretariat

Module 4
REGULATION AND POLICY APPROACHES TO BIOTECHNOLOGY

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Module structure

- Unit 1: Cartagena protocol and regulation frameworks for biotechnology
- **Unit 2: Some relevant International regulation regimes for biotechnology**
- Unit 3: Risk and Safety approaches toward biotechnology
- Unit 4: The practice of dealing with risks by biotechnology
- Unit 5: Consumer Rights and Labeling
- Unit 6: Politicization, scientization, and democratization in the debate on biotechnology

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Objective of module 4

To provide students with a broad understanding of international policy and regulation regimes including other agreements that govern the use of biotechnology and how these offer the framework for the development of national biosafety systems and to also expose students to various issues underlying the use and management of biotechnology

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4. 2 Unit 2 Some relevant International regulation regimes for biotechnology (3 Hours)

For details see the correponding course notes

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Outline of Unit 2

- Objectives
- Introduction
- General Agreement on Tarriffs and Trade (GATT)
- Sanitary and Phytosanitary (SPS) Agreement
- Technical Barriers to Trade (TBT) agreement
- Codex Alimentarius
- Convention on Biological Diversity (CBD)
- The Cartagena Protocol on Biosafety
- Agreements on Trade Related Aspects of Intellectual Property Rights (TRIPS)
- International Union for the Protection of New Varieties of plants (UPOV)
- Other treaties relevant to plant biotechnology

Objectives of Unit 2

- To create an understanding of the relevance of selected international agreements to agricultural biotechnology
- To introduce learners to various types of intellectual property protection

Introduction: Purpose of the agreements

- To encourage/ensure safe use of biotechnology , minimising risks and potential risks to human health and the environment
- To promote free international trade
- Promote access to and equitable utilization of bioresources (= fair use)
- They protect nations and their people e.g. developing world by preventing 'dumping', exploitation and trade restrictions

https://assets.publishing.service.gov.uk/media/57a08d03e5274a27b2001593/R7626-RMwp_1_.pdf

http://www.agbioforum.org/v2n34/v2n34a11-pinstrup.htm

Introduction: How the agreements work

- There is no single regulatory instrument that applies to all the issues relating to biotechnology
- The agreements described in this unit serve to complement each other to relate to each other although some commonalities exist
- The agreements are obligatory to the member states/ signatories to specific treaties
- The oversight bodies rely on existence of well-working national regulatory systems to implement the conventions, regulations, etc

The GATTs

- Came into force in January 1948
- It was a multilateral agreement regulating international trade in goods.
- GATT's objective was to reduce the barriers to international trade through the reduction of tariffs, quotas and subsidies and eliminate preferences, on a reciprocal and mutually advantageous basis
- GATT was replaced by the WTO in 1995
- Its functions are run through the Council for Trade in Goods (Goods Council) which is made up of representatives from all WTO member countries.

https://www.wto.org/english/docs_e/legal_e/ursum_e.htm#General

Sanitary and Phytosanitary (SPS) agreement

- The SPS agreement sets out the basic rules for food safety and animal and plant health standards.
- It permits individual countries to set their own standards, but requires that:
  - The regulations set are based on science,
  - The regulations should be applied only to the extent necessary to protect human, animal, or plant life and health.
  - The regulations do not arbitrarily or unjustifiably discriminate between countries with identical or similar conditions.
- The SPS agreement, encourages nations to adopt existing international standards, guidelines and recommendations but they may define better standards provided
  - They are based on a sound scientific risk assessment
  - They do not discriminate against imports.

https://www.wto.org/english/tratop_e/sps_e/sps_e.htm

SPS Agreement

- The SPS agreement applies to regulations intended to protect the environment and biodiversity against introductions of alien species and living modified organisms (LMOs) via trade.

- All countries maintain SPS measures to prevent the spread of pests or diseases among animals and plants, and to ensure safety of food.

- SPS measures are any measures applied to:
  - protect animal or plant life from pests, diseases, or pathogens;
  - protect human or animal life from risks arising from contaminants, toxins, additives or disease-causing organisms in their food;
  - protect human life from diseases borne by plants or animals;
  - prevent or minimize other damage to a country from the entry, establishment or spread of pests.

SPS agreement: Protection Versus Protectionism

- The SPS Agreement seeks to
  - maintain the sovereign right of any government to provide the level of safety and health protection it deems appropriate (= *Protection)*
  - Ensure that these rights are not misused to create unnecessary barriers to international trade (= *Protectionism*).

- *Article 5.7* of the SPS agreement allows countries to temporarily adopt restrictive measures, on grounds that
  - a complete risk assessment may not be possible in the short term because of scientific uncertainty
  - Sufficient evidence lacks.

- With temporary restriction the countries involved
  - must obtain all the information for a full risk assessment within a reasonable period and
  - must not impose the restrictive measures indefinitely in the absence of scientific evidence of risk just as a precaution.

SPS agreement: Key Principles

- **Justification of measures*:*** to ensure food safety and animal and plant health
  - Measures imposed should be grounded on objective and accurate scientific data that is properly analysed and assessed.
- **Use international standards:** As ref for national standards
  - Participation of governments in standards development
  - Justified adoption of own national standards but without trade restriction
- **Adapting to conditions**: varying among countries
  - Climate
  - Existing pests or diseases and /or
  - Food safety conditions of the country of origin of the products

SPS agreement: Key principles

- **Alternative measures:** of protection can be used
  - Should not be unnecessarily restrictive to trade in meeting their health objective
  - Could adopt equivalent measures proven to work elsewhere.
- **Systematic risk Assessment:** the basis for SPS measures
  - For transparency
- **Transparency:** a requirement for governments
  - inform other countries of any new or changed SPS requirements that affect trade, and
  - to set up offices to respond to requests for more information on new or existing measures.
- **Communication ensures that**
  - consumers are supplied with quality products and
  - trading partners have even ground to operate.

Technical Barriers to Trade (TBT) Agreement

- **Purpose**: to prevent use of technical regulations, testing, standards and certification procedures as a cover up measures to protect domestic industries from foreign competition.
- Some regulations may be technical barriers to trade:
  - Health and environmental standards and regulations
  - Labelling of products
  - Symbols and packaging marking.

https://www.wto.org/english/tratop_e/tbt_e/tbt_e.htm

Technical Barriers to Trade (TBT) Agreement

- The TBT agreement applies to all rules excluding those specifically covered by the SPS agreement.
- Disapproves of requirements for labelling of some products where 'like products' are not labelled (*Article 2.1*).
  - For example, specific labelling of GM crop products that are substantially equivalent to their conventional counterparts are considered.
- Substantial equivalence is not always an acceptable outcome of risk assessment of GM products to some people.
- Mandatory labelling or similar demands are illegitimate under the TBT agreement (Article 2.2).
  - Article 2.2 partly states, '*Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. ……..'*
  - *Mandatory labelling = discrimination*

Technical Barriers to Trade (TBT) Agreement

- Encourages the use of international standards
  - but also recognizes the right countries to adopt the standards they consider suitable in different situations (Articles 2.4).
- Sets out a code of good practice in preparation of standards
  - governments and non-governmental / industry bodies to prepare, adopt and apply voluntary standards (Articles 3, 4 & Annex 3).
- Encourages Fair and Equitable decisions on product conformity to relevant standards (Article 5).
- Encourages countries to accept each other's procedures for assessing product conformity (Article 6);
  - Helps avoid multiple testing of products by exporters to different countries

Summary of Key TBT Principles

- Non-discrimination of products
- Avoidance of unnecessary barriers to trade
- Use of International standards encouraged
- Transparency to keep others informed.
- Technical assistance and special & differential treatment of developing countries:
  - Recognizes the difficulties and challenges that developing-country members may face with implementation of TBT agreement
  - Some critics from African perspective?

Codex Alimentarius

- A collection of international food safety standards adopted by the Joint FAO/WHO Codex Alimentarius Commission.
- The Codex Commission addresses food safety issues
  - including health and nutritional implications of GM food.
- The Commission was created to :
  - establish harmonised internationally agreed norms, directives, recommendations, or codes of practice designed to protect the health of consumers
  - ensure that procedures followed in trade of food products are fair.
- Works through reaching consensus to adopt new standards or norms of food safety.

https://www.wto.org/english/thewto_e/coher_e/wto_codex_e.htm

http://www.codexalimentarius.net

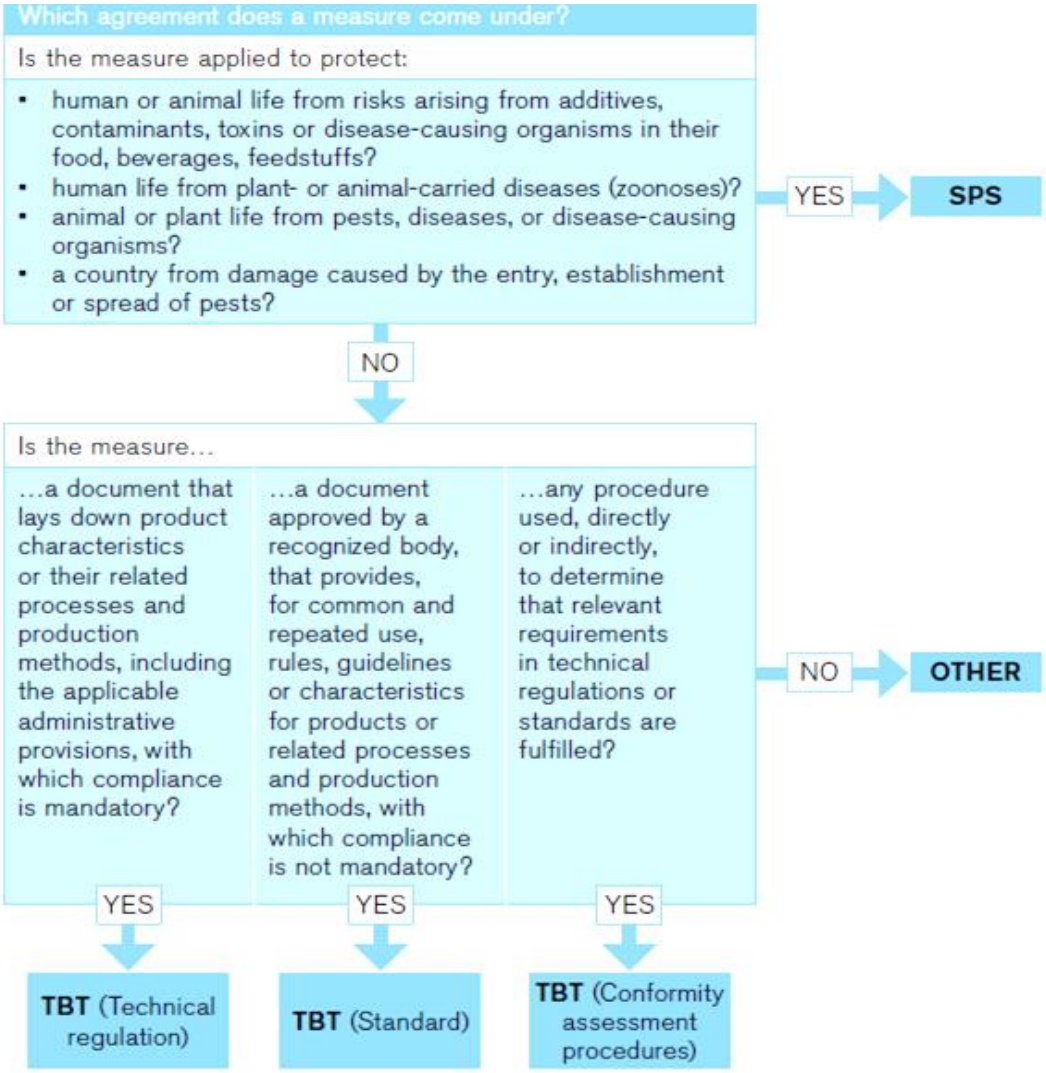
Codex Alimentarius

- The Codex commission adopts standards on the basis of
  - Risk analysis
  - Independent scientific advice from expert bodies
- The Codex provides guidelines and procedures for:
  - Food analysis and sampling
  - Risk assessment procedures for determining the safety of foods derived from GMOs
  - Food labelling (GM/non GM, presence of allergens, Nutritional composition)
  - Pesticide and veterinary chemical residues in foods
  - Food hygiene
  - Food contaminants (e.g. Aflatoxins)

Codex Alimentarius versus TBT

- Under the SPS Agreement, the Codex
  - Maintains WTO recognizable international standards for food safety
  - Determines compliance of national measures with WTO requirements
- Some Codex guidelines conflict with those of the TBT agreement.
  - For example, discrimination of substantially equivalent products ('like products') where labelling is made mandatory.
- Which agreement should be applied to products of biotechnology?
  - Need for harmonisation of regulations on biotechnology
  - Decision would be based on a close examination of the measures and their implications

Codex Alimentarius versus SPS &TBT



https://www.wto.org/english/res_e/publications_e/tbttotrade_e.pdf

The Convention on Biological Diversity (CBD)

- Biodiversity = life forms
- The CBD was among the key agreements adopted at the 1992 earth summit of the United Nations Environment Program in Rio de Janeiro.
- The CBD sets out commitments for maintaining the world's ecological base as man undertakes economic development (= 'sustainable development').
- As an international treaty, the CBD
  - identifies a common problem,
  - sets overall goals, policies and general obligations
  - organizes technical and financial cooperation.

The CBD

- Objectives of the CBD:
  - the conservation of biological diversity,
  - the sustainable use of the components of biodiversity, and
  - The fair and equitable sharing of the benefits from the use of genetic resources (i.e. access to genetic resources & transfer of relevant technologies, considering rights over the resources & to technologies).
- The CBD requires governments undertake to conserve and sustainably use biodiversity.
- The signatories to the treaty must
  - develop national biodiversity strategies and action plans,
  - integrate the strategies and action plans into broader national plans for environment and development (in agriculture, natural resource management, transportation, energy and urban planning).

https://www.cbd.int/convention/text/

The Cartagena Protocol on Biosafety

- The Protocol also establishes an advance informed agreement (AIA) procedure
  - which should ensure that countries are provided with the information necessary to make informed decisions before agreeing to import such organisms.
- The Protocol takes a precautionary approach to the movement of LMOs.
  - By consideration of associated risks
- Facilitates exchange of information on LMOs through its biosafety clearing house

http://bch.cbd.int/protocol

The Cartagena Protocol on Biosafety

- The Cartagena Protocol on Biosafety is a supplementary agreement to the CBD.
- It seeks to protect biological diversity from potential risks posed by living GMOs (LMOs) to human health and the environment, by encouraging safe transfer, handling and use of the LMOs.
- The protocol applies to all LMOs that may have adverse effects on the conservation and sustainable use of biological diversity and takes into account risks human health.
- The protocol focuses on trans-boundary movements of LMOs and establishes procedures for regulating the import and export of LMOs.

Key areas of the Biosafety Protocol related to GMOs

- Decision on import of LMOs for environmental release is based on sound risk assessment (Article 15)
- Adopting measures & strategies for prevention, management and control of risk is required in handling LMOs (Article 16.1-16.2)
- Effort should be made to prevent unintentional trans-boundary movements of LMOs (Article 16.3)
- It is critical to undertake appropriate observation of LMOs prior to use (Article 16.4)
- Parties involved in exchange must cooperate in identifying LMOs and their traits that may pose risks, and take appropriate management measures (Article 16.5)
- Guidelines for Safe Handling, Transport, Packaging and Identification of LMOs are provided (Article 18)

Key areas of the Biosafety Protocol related to GMOs

- Information Sharing-through the Biosafety Clearing-House to facilitate compliance and informed use (article 20)
- Development or strengthening human and institutional capacities in Biosafety (Article 22)
- Promotion of public awareness and participation in issues relating to safe transfer, handling and use of LMOs by Parties (article 23)
- Socio-economic considerations from the impact of LMOs on the conservation and sustainable use of biodiversity in reaching a decision on their importation (article 26)
- Liability & redress in the event that introduction of LMOs causes damage to biodiversity (article 27 and in the Nagoya Protocol)

Trade-Related Intellectual Property Rights Agreement (TRIPs)

- TRIPs is a WTO agreement covering the protection and enforcement of intellectual property rights (IPR)
- It was formed at the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) in 1994 and came into force in January 1995.
- The TRIPS agreement introduced intellectual property law into the international trading system.
- All WTO members are obliged to adopt TRIPs
  - Easy access to international markets opened by the WTO
- The TRIPs agreement has set minimum standards of intellectual property protection

https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm

IPR: Definition

- Intellectual Property Rights (IPR)
  - Legal rights granted by governments to control use of certain products of human intellectual effort and creativity (= innovations).
- Property rights are negative rights;
  - That prevent other people from doing something
  - Give the holder of the rights the ability to stop others from reproducing / copying, using, transferring or selling of the proprietary subject matter
- TRIPs recognizes seven categories of IPR:
  - Patents, Trademarks, Copyrights, Trade Secrets, Industrial Designs, Lay-out designs of integrated circuits, Geographical Indications
- Five major forms of IPR associated with plant biotechnology
  - Patents, copyrights, trademarks, trade secrets and plant breeders' rights.
  - They provide exclusive and time-limited rights of exploitation.

IPR in plant Biotechnology

- Biotechnology generates processes and products of commercial value (= Intellectual Property, IP)
- IP includes thoughts, ideas, information and tangible products of commercial value.
- The IP in plant biotechnology includes processes and products resulting from
  - recombinant DNA technology (GM plants)
  - Cell fusion
  - Tissue culture
  - Conventional plant breeding (varieties)

IPR: Trade Secrets

- Trade secret protection involves maintaining control over disclosure and use of information by imposing penalties .
- The claimant to a trade secret only allows information access to those who agree to keep it secret.
- Trade secrecy protection = protects confidential information with commercial value from use by competitors.
- Trade secrets associated with biotechnology include
  - F1 Hybrids and their pureline parents
  - DNA sequence information
  - Hybridization conditions
  - Cell lines
  - Corporate merchandise plans, etc

IPR: Trade Secrets

- Trade secrets in biotechnology are difficult to keep due to the broad research component.
- Disclosure of a trade secret before the granted period:
  - Ends the protection
  - Warrants compensation of the intellectual and punishment of the unauthorized users
- The *key requirement* of a trade secret protection is sustained confidentiality.
- *Subject matter* of a trade secret is the identifiable information that is maintained as a secret.

IPR: Trademarks

- Trademark = reservation of a (distinctive) word or symbol in association with product or service (in connection with marketing)
- Used to distinguish the goods of different companies
- Used by the public to choose whose goods they want to buy
- Examples in biotechnology include:
  - laboratory equipment
  - vectors for recombinant DNA research
  - Laboratory consumables, etc are known by their trademarks
- Examples of trademarks in agriculture:
  - Individual products e.g. FlavrSavr™ tomato,
  - Firm level products e.g. Pioneer Hi-bred...

IPR: Copyrights

- Copyrights in biotechnology protect the manner in which biological information is stored, organized, retrieved and modeled
- Copyrighting:
  - Prohibits copying of the databases, search tools and modelling tools
  - Does not protect the information in the databases e.g. DNA or protein sequences in various public databases (see http://bciptf.org/wp-content/uploads/2011/07/43-Silva_IPTF11.pdf)
- Copyright protects the expression of an idea but not the idea.
- The protection lasts between 50 and 75 years
- Copyrightable work includes all forms of publication:
  - Printed matter, video-recordings, tapes; computer software

IPR: Patents

- A patent provides the holder with the ability to exclude all others from possession, production, using, transferring, selling or importing an invention (= a process, product or both)
- To patent an innovation one must demonstrate
  - Novelty = that the invention not previously described/known
  - Non-obviousness = have an inventive step / be a notable extension of existing art or knowledge
  - Utility = the invention must have at least one specified use
- With these requirements it is difficult to patent plants.
- Possible patentable examples:
  - Purification of a bacterial strain
  - Identification of a rare mutant
  - Genetically modified organisms

IPR: Patents

- Patents are governed by various bodies:
  - Paris Convention for the Protection of industrial Property agreements (sets the priority rules)
  - Patent Cooperation Treaty (PCT), sets the international framework for searching and examination
  - Patent law Treaty, a supplement to the PCT for patent filing
  - TRIPs also has some rules on patent protection
  - Regional patent conventions in the various continents
  - National bodies/offices
- A patent remains in force for 20 years from the filling date
- To obtain a patent:
  - an inventor applies for it at the desired patent office (national/regional)
  - The invention must meet all the requirements for patenting
  - The inventor has obligation for procedural disclosure of the invention during patent processing.

IPR: Patents

- Encourage, safeguard and reward intellectual & artistic creations.
- Facilitate fast & wide dissemination of new ideas and technologies (e.g. through joint ventures, licensing).
- Protect investment in the development of technology.
- help the inventor to provide the fruits and benefits of his creation and invention to the public
- Stimulate and ensure fair competition
- Protect consumer choices
- Help to achieve the balance of rights and obligations

IPR: Plant Variety Protection and the UPOV

- New crop varieties are developed and protected through "Plant Breeder's Rights'', PBRs.
- The PBRs give exclusive marketing rights to the plant breeder who develops a particular variety.
- The Food and Agriculture Organisation's (FAO) International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) makes provision for Farmer's Rights.
- They are distinguishable from patents by allowing Farmers' rights (privileges for farmers to save seed for subsequent seasons).
- PBRs were first put in place in 1961 under the International Union for the Protection of New Varieties of Plants (UPOV)

IPR: Plant Variety Protection and the UPOV

- The UPOV was created for protection of new plant varieties:
  - To give plant breeders an opportunity to receive reasonable returns on their investment from marketing his/her variety
  - To provide incentive to continue investing in breeding
  - In recognition of the moral right of the innovator to get acknowledged and remunerated for his/her effort
  - Because patent right was difficult to work with and unsuitable for plant variety protection
- UPOV aims to encourage the development of new plant varieties for the benefit of society
- The UPOV helps harmonize variety protection between countries to prevent distortion of trade
- The UPOV Convention acts amended in 1972, 1978 and 1991
  - To enable the admission of new members (1978 act)
  - To offer better protection of new varieties (1991 act).

IPR: Plant Variety Protection and the UPOV

- A plant variety is protected under the UPOV system if it shows
  - Distinctness (D) = different from other varieties
  - Uniformity (U) = homogeneous ‘in its relevant characteristics’
  - Stability (S)= true-to-type under repeated propagation and
  - Satisfies a novelty requirement (as for patents).
- Satisfaction of the DUS criteria is conducted by the national authority responsible via performance trials.
- Under the UPOV 1978 act, any variety that is distinct in one *recognized* trait can be protected.
- Plant Breeders Rights are usually granted for 20 years.

IPR: Plant Variety Protection and the UPOV

- The UPOV harmonizes of laws and practices of the protection system of member countries.
- Has established guidelines for DUS testing of testing
- Produces technical questionnaires for variety testing
  - The questionnaire has to differ from others of the same species
- New traits can be added to aid distinction.
- Facilitates cooperation among member states in evaluating varieties to make the process of protection cost effective
  - For example, one member conducts test for others or one member accepts the result produced by others as the basis for granting plant breeder's right
  - Enabling a plant breeder to enforce the right in all member countries.

IPR: Plant Variety Protection and the UPOV

- Protects the breeder from exploitation
- The breeder only gets the protection for *developing* a variety, not just selection.
- The UPOV does not give rights to genes or gene combinations
- Once protected, a variety is free for use by other breeders in their crosses.

IPR: Conflict between Patents and PBRs

- A patent protects genes in a variety while PBRs protect the variety (= the root of conflict)
- Consequences / negative implications of the conflict:
  - Pyramiding GM genes in one genotype may prevent commercialisation until the patent period elapses e.g. the case of pro-vitamin A rice
  - Commercialization of patented genes isolated from native varieties cannot be free even in the home country
  - Restricted access to elite materials for breeding e.g. Bt gene introgression into Indian cotton varieties
- Alternative patent systems needed, e.g. those that recognize collective innovation

Access & Benefit Sharing

- The main functions of IPR
  - To provide incentives for investment into creative processes
    - that transform basic insights into commercial goods
  - Encourage access to protected creations
- IP regimes seek to determine the extent of protection while maintaining public access to innovation
- Article 15 of the CBD provides for implementation of its objective 3 on '*fair and equitable sharing of benefits:*
  - Recognises the right of States over their biological resources (Art 15.1)
  - Each country determines access to the resources (Art 15.1)
  - Access on 'mutually agreed terms' (Art 15.3)
  - Following 'informed consent' of the country of origin (Art 15.4 & 15.5)

Access & Benefit Sharing

- Article 8j of the CBD makes provisions to encourage *equitable* sharing of the benefits arising from utilization of traditional knowledge, innovations and practices
  - By promoting wider application (of traditional knowledge/practices)
  - Upon approval of the communities (to access and use)
  - Getting the communities Involved (in sharing the benefits)
- Other CBD provisions covering ABS:
  - Access to and transfer of technology (Art 16)-fair, mutual, consented
  - Exchange of information (Art 17)-facilitation, training, repatriation to source etc
  - Promoting technical and scientific cooperation (Art 18)- in conservation
  - The handling of biotechnology and distribution of its benefits (Art 19.1 and 19.2)-participation in research, priority access to results & benefits

https://www.cbd.int/abs/

Access & Benefit Sharing

- The Nagoya Protocol, a supplementary agreement the CBD
  - on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization
- The protocol aims at sharing the benefits arising from the utilization of genetic resources in a fair and equitable way:
  - by appropriate access to genetic resources and
  - by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and
  - by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components.
- Provides detailed ABS guidelines for contracting parties

Class Discussion

- Discuss case studies illustrating infringement on IP and its consequences.
  - Special focus should be given to cases relating to plant biotechnology
  - Literary works may be considered to cover all forms of IP