



Food Security and Biotechnology in Africa

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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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4.3 Unit 3 Risk and Safety Approaches toward Biotechnology (4 Hours)

For details see the corresponding course notes

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Outline of Unit 3

- Objectives
- Trust in regulation and risk management
- Concerns about genetically modified organisms
- Socio-political attitudes and values
- Acceptance of particular applications of genetically modified foods
- Demand for information about GMOs
- Public decision making processes
- Food safety standards
- Differences in food safety regulation in different jurisdictions
- Integrated assessment tools

Objectives of Unit 3

- To clarify role of public trust in risk management of GMO's
- To highlight the major public concerns of GMO's
- To outline factors that influence perception on GMO's
- To provide the known world food safety standards and explain the justification for the need of an integrated assessment tool

Trust in risk regulation and risk management

- Public trust and confidence in emerging technologies such as genetic modification may be interpreted as a statement about public recognition of its legitimacy
- Recent research suggests that public attitudes toward emerging technologies are mainly driven by trust in the institutions promoting and regulating these technologies

Trust in risk regulation and risk management

- Alternative views maintain that trust should be seen as a consequence rather than a cause of such attitudes.
- If the public is not convinced that their interest is at the forefront then the consequences may be:
 - Economic vulnerability of the industrial sector associated with the particular technology, and
 - Potential for the escalation of critical media interest
 - Constraint in adoption of the novel technology

Trust in risk regulation and risk management

- The prevalent disharmonies between the national regulatory frameworks have exacerbated the public distrust
- Yet the public demand for input into the local regulatory activities that may militate against a global governance.
- On the other hand trust could be hampered severely by
 - Media in all forms
 - Alternative scientific opinions e.g. Seralini's series of reports on the risks, albeit controversial, of GMOs

Trust in risk regulation and risk management

- In Africa there are worries about:
 - possible dumping
 - Attempts of the industrialized nations to recoup research costs
 - Development without the concerns of the public

Trust in institutions and information sources

- Social Trust
 - Important in shaping attitudes of the public
 - Trust required in the institutions and experts involved in technology such as biotechnology
 - Trustworthiness (together with competence) affect public attitude
 - Key institutions involved are the universities, industry and government
 - The institutions are majorly concerned with strategic development, regulation, and research on biotechnology

Trust in institutions and information sources

- Development and implementation of modern biotechnology depend on:
 - public perceptions and attitudes towards it
 - the psychology of the public and public trust in
 - Institutions promoting and developing the technology and
 - Institution concerned with the regulatory matters.
 - Scientists conducting research in the modern biotechnology

Trust in institutions and information sources

- Thus, key factors governing trust include:
 - Trustworthiness
 - Competence
 - Transparency
 - Public interest
 - Interest in the environment
 - Honesty
- Generally the most trusted institutions are the Evaluators (Scientists) followed by environmental watchdog
- The least trusted are the industry and Governments

Trust in institutions and information sources

- Public trust is enhanced if the public perceive that the interest of the environment, health and socio economics of general population is at the forefront
- Therefore it is important to :
 - Develop best practice in science communication about the risks and benefits of genetically modified foods (GMF) as well as
 - Involve the public explicitly in the debate about technology innovation and commercialization, and
 - To rethink the somewhat uneasy relationship between science and society

Trust in institutions and information sources

- Public risk perception is generally different from that of technical experts
 - Yet it is the public opinion that ultimately determines acceptability of regulation and products of modern biotechnology.
 - For example the ban on importation GMO products and growing of GMOs in Kenya continued even after scientific revocation of the controversial Seralini publication(s)

Trust in institutions and information sources

- Public trust in processes of science, and in scientific and regulatory institutions is the key driver to acceptability of GMO technology and its products.
- How then do you integrate values held by society into processes of regulatory decision making and scientific innovation?

Trust in institutions and information sources

- Trust in sources of information:
 - Source credibility is usually multidimensional and particularly dependent on:
 - Competence of the information source and
 - Subject under consideration.
- Two major dimensions determine trust
 - Competence - the expertise of the communicator and their ability to transmit the information
 - Honesty – truthfulness or trustworthiness of the communicator

Concerns about genetically modified organisms

Uncertainties

- Communication about GMFs should include discussion of potential uncertainties associated with risk management (whether related to unintended effects on human health or the environment)
- Failure to do so may increase public distrust in information sources and regulators, although risk perceptions themselves may be unaffected

Concerns about genetically modified organisms

Uncertainties

- Indeed, information dissemination activities must focus on uncertainties and unknown, as much as the purported benefits
- Beliefs that there is potential for negative environmental impact associated with the production processes or agricultural practices involving GM crops
- Uncertainty associated with unintended human or animal health effects,
- Concerns that GM is in some way “tampering with nature”

Concerns about genetically modified organisms

Uncertainties

- There are both safety and non-safety concerns
- Safety concerns
 - Environmental
 - Human health
- Non-safety concern
 - Economic concern like loss of export market shares
 - Lowering effects on prices
 - Sustainability

Concerns about genetically modified organisms

Safety and non-safety concerns

- Societal utility
- Effects on rural employment
- Impact on the agronomical practices in the small scale farms that are common in the African landscape.
- Impacts on the traditional varieties and may even affect centers of origin and diversity of agricultural resources
- Assurance of distribution of seeds by the industry

Concerns about genetically modified organisms

Safety and non-safety concerns

- Other non-safety issues are
 - food security
 - Religious beliefs
 - Cultural beliefs
 - Duty to the future generation
 - Animal and environmental ethical issues
 - Wealth disparities
 - Unnaturalness of the GM organisms
 - The fact that the known conservative and perceived safe method of improving food security have not been optimized

Concerns about genetically modified organisms

Socio-economic concerns

- That unintended effects are unpredictable and thus unknown to science
- That Genetic modification is like playing 'God' and so is immoral
- That there are risks to future generations and long-term food safety issues
- That transgenic crops benefit only large farms

Concerns about genetically modified organisms

Socio-economic concerns

- Uncertainties related with the outcomes of risk assessment
- The intellectual property rights and patents of transgenic foods may lead to market capture and monopoly pricing
- Increased dependence on high technology assets (like seeds) which may have monopoly of supply by transnational organizations

Concerns about genetically modified organisms

Socio-economic concerns

- Loss of entire portions of foreign market
- Possibilities of replacement of robust crop varieties and technology

Concerns about genetically modified organisms

Socio-economic Impacts

- Potential distributive impacts of GMOs - under what conditions would GM seeds be made available to farmers and to what restrictions would they be subject
- What impact might GMOs have on traditional varieties of crops relied upon by farmers in developing countries and how would they affect centres of origin and centres of diversity of agricultural biodiversity

Concerns about genetically modified organisms

- What impact might the introduction of GMOs in developed countries have on commodity exports from developing countries
- With regard to human health and environmental concerns, most developing countries have tended to emphasize their lack of capacity to assess and manage the risks associated with GMOs
- These concerns were strongly expressed during the negotiation of the Cartagena Protocol on Biosafety (Biosafety Protocol)

Concerns about genetically modified organisms

- Developing countries were, on the whole, strongly in favor of the adoption of the Protocol, They supported:
 - A stringent safety assessment
 - Advance informed agreement procedure
 - Incorporation of the precautionary principle
 - Possibility to take socio-economic considerations into account when deciding whether to allow imports of a specific GMO

Concerns about genetically modified organisms

- The primacy of the Protocol over relevant WTO obligations
- Developing countries tended to stress issues of uncertainty, capacity, social and economic concerns, and priorities relating to food security and the protection of human health and the environment.
- And example of a major concern in Africa is the fear that GM crops may have negative impacts of culturally well-known African Traditional crops landraces and local biodiversity

Concerns about genetically modified organisms

- Specifically, this may lead to increased dependence smallholder farmers on multinational companies
- Hence, the multinational may have full control on the continent's genetic resources
- In addition, the Africans are also concerned that they do not possess resources to adequately address risks that GMO's may portend
- It is also claimed that biodiversity issues in Africa are more complex making risk assessment more difficult

Concerns about genetically modified organisms

Human health concerns

- Through the consumption of food produced using genetically modified crops and their derivatives
- Two principal areas of concern relate to allergenicity of foodstuffs as a result of introduced proteins and the
- Potential transfer of antibiotic resistance, as a result of the use of antibiotic resistance marker genes in the production of GMOs

Concerns about genetically modified organisms

Environmental effects

- The potential impacts of GMOs on non-target species, such as beneficial insects or birds
- The potential for cross-pollination between GM and non-GM (and organic) crops or between GM crops and wild plants — “genetic drift” or “genetic pollution”
- The introduction of non-native or “exotic” species into the environment with the potential displacement of native species, for example, the spread of GMOs as weeds or “volunteers ”

Concerns about genetically modified organisms

- The indirect effects on the environment, for example, through changed agricultural practices, particularly changes in herbicide and pesticide spraying
- Increased monoculture with attendant loss of biodiversity

Socio-political attitudes and values

- Attitude and interest of stakeholders towards and risk and benefit of GMO have a great influence on the public opinion and policy outcomes in Africa
- What are the attitudes towards
 - Technological progress
 - Environment and nature e.t.c
- Attitude refers to:
 - Psychological tendency that is expressed by evaluating a particular entity with some degree of favor or disfavor
 - The cognitive, affective, and behavioral response that result from attitude relate to the process of evaluation

Socio-political attitudes and values

- Thus psychological tendency may be thought of as a psychological bias that predisposes an individual towards a positive or negative evaluative responses
- Thus individual who holds a negative attitude towards GMFs, for example, may use cognitive, affective or behavioral responses to reject GMF products or may display other behaviors that are congruent with this attitude.
- Attitudes are not directly observable but can be inferred from observable responses such as responses to questionnaires or interviewers

Socio-political attitudes and values

- Social scientists usually measure attitudes along a bipolar continuum that ranges from extremely positive to extremely negative and includes a neutral reference point
- Attitudes towards relatively abstract concepts (for example, the integrity of nature) have also been of interest and are normally termed 'values'
- Both attitudes and values should be considered when investigating people's responses to modern biotechnology as both influence an individual's evaluative response

Socio-political attitudes and values

Attitude change

- Depend on the context of information:
 - Whether the type of organism modified is an animal or plant (the latter being more acceptable) which connotes a moral value
 - Competence of the research scientist and motive of the stem scientist positively affected the public perception and attitude towards it
- When issues are complex persons will depend on heuristics rather knowledge to form their attitudes, thus competence of scientist and public authorities concerned with control is important

Socio-political attitudes and values

- With exposure to event, object or a situation eg after tasting GMF
- After individuals interpretation of information about GM
- Depend on the extent and methods of media coverage
- Individual's belief
 - About motives of information sources of societal actors like the industry or regulators

Socio-political attitudes and values

- About health and factors that affect good health (eg there is no scientific evidence of hazard unique to genetic modification yet the GMO's evoke fear of unknown harm to health.
- Trust in scientists will positively affect attitude while trust in watchdogs and environmentalists will do the opposite

Socio-political attitudes and values

Influence of information on attitude

- An individual's perception of risk or benefit of a technology is determined by:
 - Personally selected sources of information
 - Values
 - Interest
 - Individuals' experience

Socio-political attitudes and values

Influence of information on attitude

- Will not occur if information regarding a novel technology is hard to comprehend.
- the attitude is improved if the technology is associated with benefit to the consumers
- Information is normally processed via any of two routes

Socio-political attitudes and values

- **Central**

- Considerable amount of effort spent in trying to understand the piece of information
- More enduring, predictive and resistant to counter-persuasion

- **Peripheral**

- No amount of time is spent to process the information
- Trusted information source will receive positive evaluation.
- External cues permit inference of merit

Socio-political attitudes and values

Information processing approaches

- There are 2 orthogonal approaches
 - Rational
 - Emotion free, evidence based
 - Characterized by conscious and mental effort
 - Using objective reasoning to come to a true answer and willingness to adjust in light of new facts
 - Intuitive
 - Builds on personal experiences, feelings, concrete images and narratives
 - It emotionally appealing

Socio-political attitudes and values

- Protest groups compete with Business, science and social systems
- The latter groups have responded to protest groups negative reporting by increasing engaging in PR activities
- challenges of responding to protests have been exacerbated by protest groups' improved funding, and progress in modern information technology

Acceptance of particular applications of genetically modified foods

- **Risk perception**

- Is socially constructed, and that it is the psychological representation of risk that defines people's responses to a particular hazard, rather than the technical risk estimates traditionally provided by expert
- Understanding of risk perception is probably the 1st step in understanding possibility of uptake of modern biotechnology
- There is some evidence that, in the area of technology innovation, people will tolerate risk if they perceive some direct benefit to themselves

Acceptance of particular applications of genetically modified foods

- Benefit believed to have a higher consumer acceptance for modern biotechnology are:
 - Those that relate to sustainability – innovations that enable reduction in energy expenditure and discharge of pollutants during primary production, manufacturing or processing
 - Those that will benefit disadvantaged individuals
 - Those that will improve the health of the consumers

Acceptance of particular applications of genetically modified foods

- **The Eurobarometer survey**

- Extensive public opinion survey carried out in Europe on attitude towards biotechnology
- 16000 respondents
- Done in 2001
- In general, Europeans had a positive view of science and technology

Acceptance of particular applications of genetically modified foods

- Europeans no longer regarded scientific advance as a universal panacea for all problems
- Attitudes towards GMF's was generally negative
- It is agreed by all nations that regulations were best developed, implemented and monitored by international organizations like WHO rather than the national regulatory agencies

Acceptance of particular applications of genetically modified foods

Favored for

- Plants

Than

- Animals

- Males

Than

- Females

- Youth

Than

- Aged

- Medicine

Than

- Food

Acceptance of particular applications of genetically modified foods

- In 1997, the Eurobarometer survey was conducted in New Zealand, Japan and Canada
- NZ was found to be more +ve to GMF
- In Africa, stakeholder survey agree that biotechnology has a potential to resolve increasing levels of food deficits and rising poverty but the technology is hampered by lack of trust
- Africa favors adoption of precautionary principles like Europe

Acceptance of particular applications of genetically modified foods

- Africa decries poor capacity to carry out biotechnology and risks assessments.
- In addition, the resistance to introduction of GMF in Africa is mostly attributed to international and national NGO activities

Acceptance of particular applications of genetically modified foods

Variables positively correlating with acceptance

- Worldviews
- Moral and 'naturalness' attributes
- Trust in the institutions producing GMO
- Trust in institutions regulating use of the genetic technology-based products

Variables negatively correlating with acceptance

- Trust in watchdogs

Demand for information about GMOs

- The EU has GM-food and feed labeling regulation
- For non scientific and political reasons it fixes a threshold of 0.9% above which there must be a label (arbitrarily)
- Aim of the label - providing freedom of food choice for the consumer
- Labeling has the effect of giving a price premium to non-GMO food producer

Demand for information about GMOs

- Labeling has the effect of serving as a warning to the customer
- On the extreme – there has been introduced a new category of label 'GM free' for food that have $<0.1\%$ in France
- Zero tolerance for GMO's that are not permitted. This translated to the detection limits of analyses.

Demand for information about GMOs

- **Coexistence regulations**
 - Formulated by national governments in EU
 - Formulated according to the principle of substantiality
 - Heterogeneous buffer zones between the GMO and GMO free crops in different countries – upto 800 m for maize in Luxembourg
- **Substantial equivalence**
 - Developed by OECD and elaborated upon by FAO/WHO
 - Basis for risk assessment but not an assessment per se
 - GMF is compared with its traditional comparator which is considered safe

Demand for information about GMOs

- **Shortcoming of substantial equivalence**
 - Inability to characterize isogenicities of comparators to the GMF
 - Limited abilities to detect unintended effects
 - Limited information on natural variations in many cases

Demand for information about GMOs

EU precautionary approach informed by:

- Lowered confidence in regulatory agencies due to food scandals (e.g. the mad cow disease, and Belgian dioxin contamination of food)
- Less need for increased food production, and
- Controversial publications regarding health risks (e.g. Séralini series of publications on carcinogenicity of GMF)

Demand for information about GMOs

USA Situation

- In contrast to the EU, the USA has no GMO thresholds or obligatory GMO labeling
- However, in the risk past the USDA/APHIS has considered specific GMO regulations to curtail unwarranted contamination of US food with
- Unauthorized foreign GMO's e.g. Aventis Starlink Maize
- Foreign – developed GM food e.g. the Chinese insect-resistant rice, Xianyou63 (Bt63) already found in noodles

Demand for information about GMOs

- Analysis of GMOs is based on the intrinsic characteristic of organism or products and not on the process of producing it
- US litigation system offers adequate protection
- Litigation proceed on a contingency basis, that is without the need of the litigant paying costs a priori
- Lawyers are paid a percentage of damage on successful litigation, a fact that givens incentive to sue for high damages as their fees depend on it

Demand for information about GMOs

- This will subsequently encourage the biotechnology firms to oblige to regulations and voluntary regulatory procedure in order to discourage damage claims ([Ramjoue, 2008](#))

Public decision making processes

- Developing countries have demanded more involvement in the discussion of trade and environment issues in the WTO
- They support:
 - harmonization of international standards
 - Enhanced participation in international standard-setting bodies
 - Capacity building for the implementation of international standards

Public decision making processes

- Public awareness and participation – is entrenched in the Biosafety Protocol
- The obligation to involve the public in decision-making on GMOs is qualified by a reference to national laws and regulations
- The Protocol also provides for the protection of confidential information.

Public decision making processes

Concerns of Africa about international organizations

- They set a minimum standard for patent protection of a new crop varieties
- Possibility of increased dependence of smallholder farmers on multinational companies
- Possibility of preventions of access to biotech products
- Lack of legal protection of local knowledge and natural habitats
- They want an assurance for informed consent before biosprospecting and fair benefit sharing with local communities.

Food safety standards

- Organization for Economic Cooperation and Development (OECD)
- Codex Alimentarius
 - How these apply in the formulation of national regulations and standards for the safety of foods derived from GM crops

Food safety standards

- **OECD**

- In 1993 the OECD formulated the concept of substantial equivalence as a guiding tool for the assessment of GMO foods
- Three scenarios are envisioned for genetically modified plant or food
 - Substantially equivalent
 - Substantially equivalent except for the inserted trait
 - Not equivalent at all

Food safety standards

- **Safety issues of GM foods**
 - Genetic modification process
 - Safety of new proteins
 - Occurrence and implications of unintended effects
 - Gene transfer to gut microflora
 - Allergenicity of new proteins
 - Role of new food in diet
 - Influence of food processing

Food safety standards

- Key components of a specific crop for comparison with a genetically modified crop are described by Consensus Documents compiled by the OECD's Task Force for the Safety of Novel Foods and Feeds

Food safety standards

Non safety issues that affect decisions on GMOs in Africa

- Food security
- Health-related impacts
- Coexistence of LMOs
- Impacts on market access
- Compliance with biosafety measures
- Macro-economic impacts
- Impacts on biodiversity
- Economic impacts of changes in pest prevalence
- Farmers' rights
- Intellectual Property Rights

Food safety standards

Non safety issues that affect decisions on GMOs in Africa

- Impacts on consumer choice
- Use of pesticides and herbicides
- Cultural aspects
- Labour and employment
- Land tenure and
- Gender impacts and Rural-urban migration

Food safety standards

International Life Sciences Institute

- A consensus document has been prepared by ILSI Europe on evaluation of the safety of novel foods
- This document provides background for data requirements for all novel foods, including foods and food ingredients derived from GMOs
- For GM foods this will include data on
 - Transgenic DNA
 - Phenotype and
 - Composition including gross composition, nutrients, and toxins

Food safety standards

- Substantial equivalence of the novel food to an appropriate counterpart can then be determined
 - ILSI document defines three scenarios in which the novel food or food ingredient is characterized as
 - Substantially equivalent to a reference food/ingredient
 - Sufficiently similar or
 - Not sufficiently similar
 - For novel foods and novel food ingredients that are not substantially equivalent, nutritional and toxicological data, and data concerning allergenic potential, need to be considered

Food safety standards

- Three scenarios are considered where the source of the transgene may be:
 - A commonly allergenic food
 - A less commonly allergenic food or other known food source or
 - Without a history of allergenicity

Food safety standards

CODEX ALIMENTARIUS

- Is a FAO/World Health Organization (WHO) body that elaborates standards, general principles, guidelines, and recommended codes of practice in relation to food safety
- Has relevant processes addressing principles of risk assessment for genetically modified foods and related labeling and other issues

Food safety standards

- **Working Principles for Risk Analysis**
 - Guide work within the framework of the Codex itself
 - Address, inter alia , issues of scientific uncertainty and incomplete scientific data in the standard-setting process
- **Less participation of developing countries in the**
 - Codex committees and other bodies
 - The working practices of the Codex
- **Nevertheless**
 - The Codex Alimentarius Commission of FAO/WHO is committed to the international harmonization of food standards
 - Food standards developed by Codex Alimentarius should be adopted by the participating national governments.

Food safety standards

- The Codex ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology has the task to develop standards, guidelines and other recommendations for genetically modified foods

Differences in food safety regulation in different jurisdictions

- **In the South**
 - Greater regulatory diversity exists in the developing world than the binary logic of polarization around EU versus US
 - Competing trade imperatives interact with domestic politics and priorities, with multiple nodes of power and actor coalitions negotiating policy directions that combine elements of both US and EU regulatory approaches
- **In the North**
 - e.g. the EU, USA, Canada, Japan, Australia and New Zealand and the implications of these in the context of formulating national regulations

Integrated assessment tools

- Finally, this unit will also highlight the need for an integrated assessment tool that might help in the consideration of important environmental aspects involved in health and food safety
- International consensus has been arrived at on safety assessment
- Concept of substantial equivalence has been developed as part of a safety evaluation framework

Integrated assessment tools

- **Substantial equivalence**

- Is based on the idea that existing foods can serve as a basis for comparing the properties of genetically modified foods with the appropriate counterpart
- Differences and similarities are subject to further toxicological investigations
- principle of substantial equivalence has proven adequate, and that no alternative adequate safety assessment strategies are available

Integrated assessment tools

- **Substantial equivalence concepts**
 - Starting point of safety evaluations
 - Comparison of the GMO with its closest traditional (/conventional) counterpart
 - Identification of intended and unintended differences on which part of safety assessment should be assessed

END