Socio-economic considerations in regulatory decision-making

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Addressing Africa's agricultural sector challenge

The AU considers Science, Technology and Innovation (STI) as vital in enhancing :

- agricultural productivity on-farm and along the agri-food value chain
- competitiveness
- market access

Continental decision

African Ministerial Conference on Science and Technology (AMCOST)

[now merged with education as (STC-EST)]

identified modern biotechnology as a developmental tool

stated modern biotechnology must be harnessed safely

advocates for a comprehensive approach to modern biotechnology

Rationale for regulating technology

Governments use regulations to achieve socioeconomic goals including:

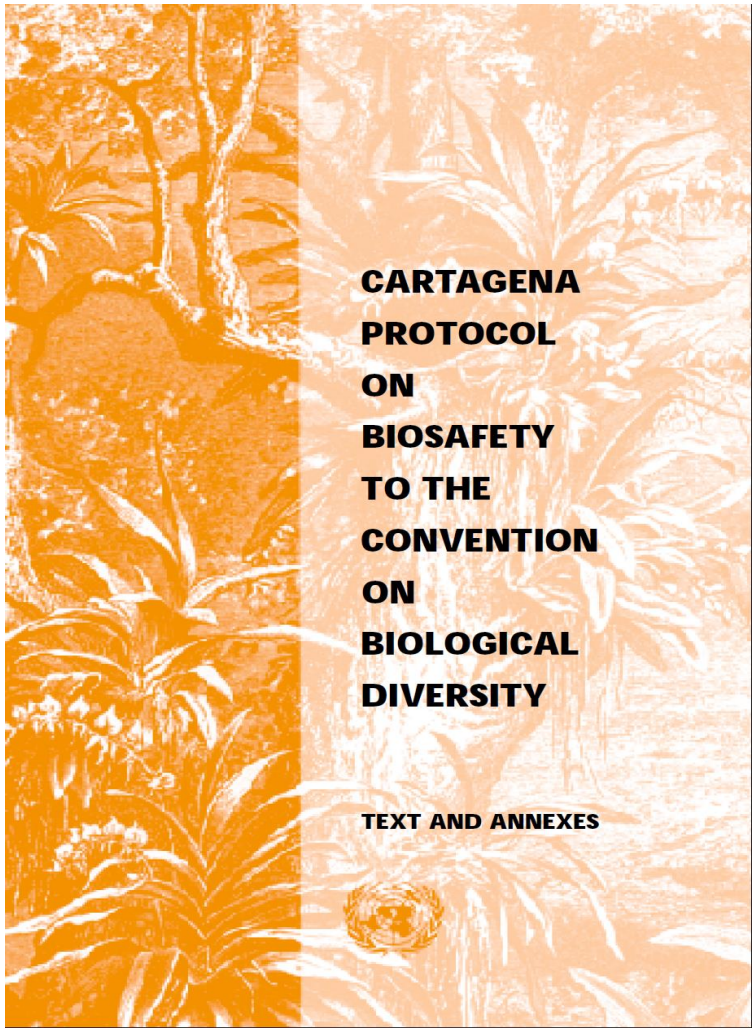
- assuring safety
- ensuring public confidence in system
- achieving equitable distribution of income
- improving efficiency of resource allocation
- protecting rights of ownership

Why socio-economics in biosafety?

Article 26 of the Cartagena Protocol for Biosafety provides for SECs

However, there are some implementation challenges of Article 26

Several African countries have varied domestic provisions on SECs



Some challenges in implementing Art. 26

- Provisions characterized largely by
  1. unclear definition of SECs or use of terminology e.g.

SE	SE + ethics	SE + ethics + culture	SEC + fabric + cultural values
SE+ culture	SE + spiritual	Social + cultural + ethical + economic	SE + ethics + culture + religion

  2. lack of clarity on the process of inclusion in biosafety
  3. inadequate information on impact assessment

Some challenges in implementing Art. 26

Several Parties requested for further guidance when choosing to take into account SECs

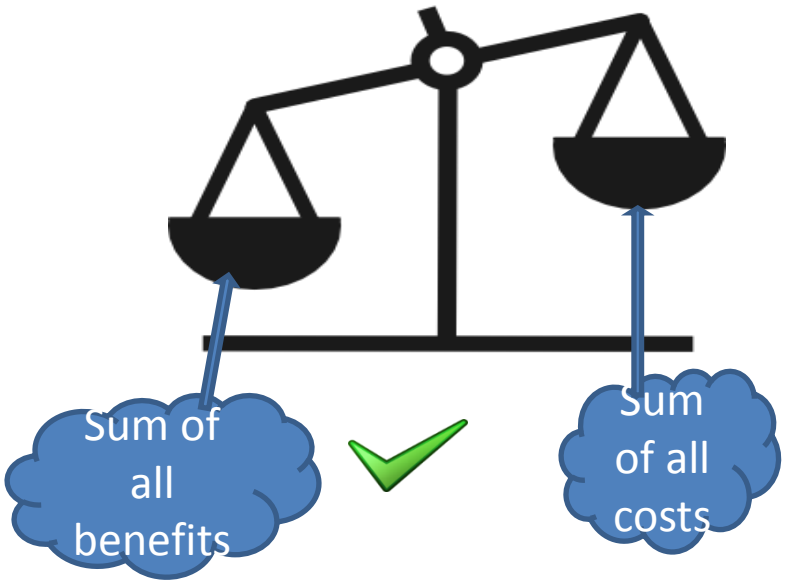
- How to define and identify SECs
- How to integrate SECs into decisions in a manner that is consistent with international obligations

For now, helpful to look at socio-economic considerations as encompassing

- social factors
- economic factors

Two sides to a coin! – benefits vs risks

- Development and application of modern biotechnology could have significant positive or negative effects
- Countries that move forward with use of the technology weigh benefits with risks in decision making



Some risk perception observations that can influence decision-making

Risks seem smaller when an individual feels he has some control over the process determining the risk faced

A new risk tends to be more frightening than the same risk after people have lived with it for some time and been able to put it into perspective

Credit: Harvard Center for Risk Analysis. Risk in Perspective. June 2003

Some risk perception observations that can influence decision-making

Natural risks are usually perceived as less worrying than human-made risks

The less people trust the institutions responsible for exposure to the risk or communication about the risk, the more frightened they become

Credit: Harvard Center for Risk Analysis. Risk in Perspective. June 2003

Some basic SECs by policy and decision makers

- Is the technology in line with national interests?
  E.g.
  - Relevance of the technology to needs/aspirations
  - Is it profitable? Accessible? Affordable? Sustainable?
    - e.g. economic advantages for farmers, processors, consumers
    - e.g. impact at household, community, national, regional levels
  - Can resource-poor, small-scale operators adopt?
  - Are there possible negative effects on human health (including farmer wellbeing)?

Ranking of the importance of assessment methods to be included in a methodological toolkit (Q40)

#	Method I: ranking system	Method II: scoring system
1	Cost effectiveness	Property right assessment
2	Macroeconomic impacts	Macroeconomic impacts
3	Cultural, ethical assessment	Cultural, ethical assessment
4	Property right assessment	Cost effectiveness
5	Community analysis	Community analysis
6	Benefit-cost assessment	Benefit-cost assessment
7	Economic risk assessment	Economic risk assessment

Some basic SECs by policy and decision makers

- Is the technology in line with national interests? ***E.g.***
  - Would adoption inconvenience other production systems?
  - Implications for domestic and international market access. Would adoption negatively impact on trade with partners especially Europe?
  - Is there possibility of failure of the technology?
  - Possible unethical applications (including animal health and welfare)?
  - Public acceptance? Varies by application area

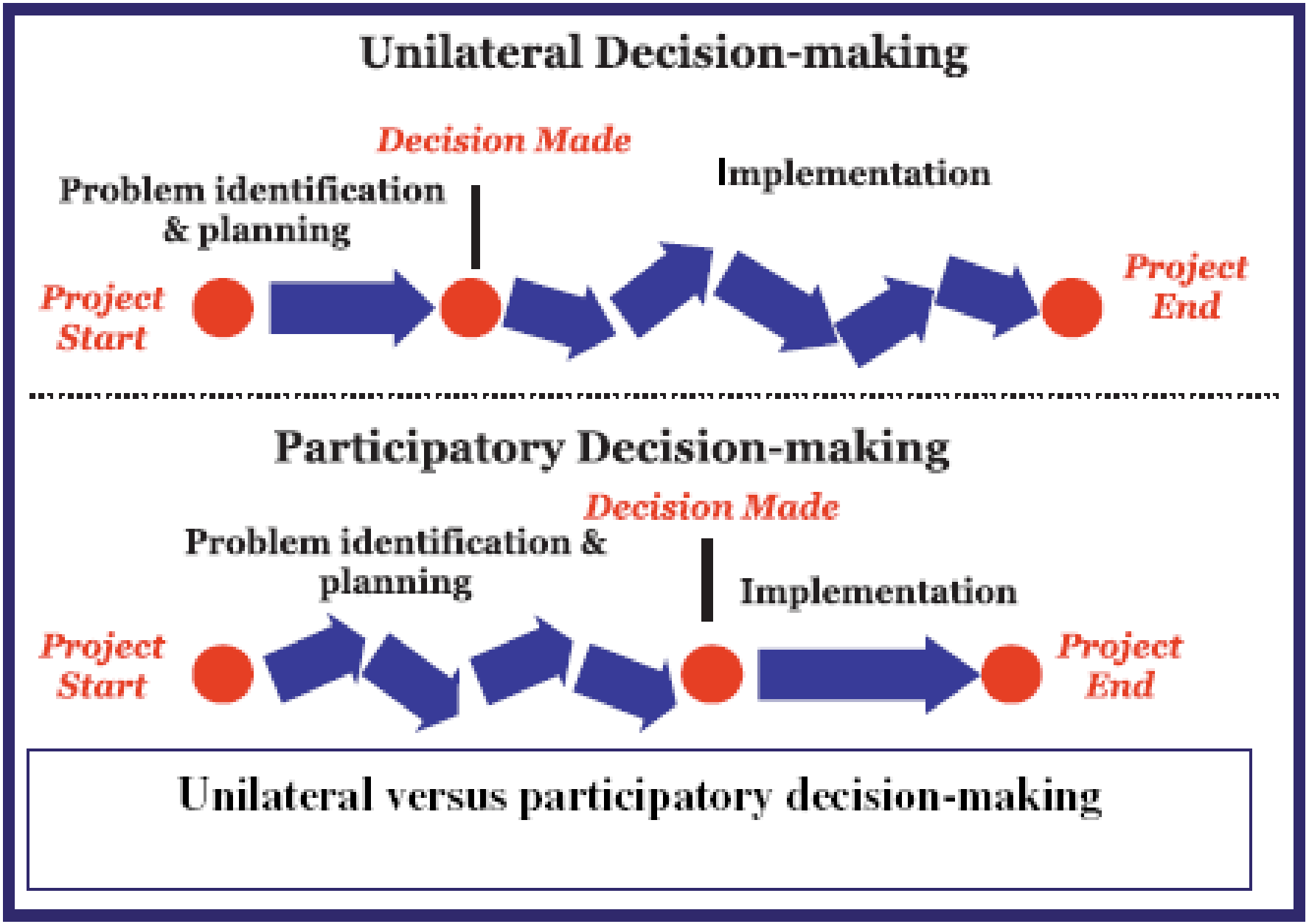
Biosafety decision-making

Decision-making body reviews the information

- application
- safety recommendation
- socio-economic review (if necessary)
- relevant public input
- national policy and needs

Who is the “public” in public participation ?

The **"public"** refers to natural or legal persons and, in accordance with national legislation or practice, their associations, organizations or groups, and who are interested in or are likely to be affected (+/-) by a decision to be made



Unilateral versus participatory decision-making

Credit: Ewing, M., 2011

Implications of harmonized biosafety regulations

A **well-structured** harmonized regulatory system would confer benefits such as

- cost efficiency
- adequate shared technical capacity
- harmonized compliance procedures
- creation of more competitive markets
- facilitation of cross-border trade
- standardised and transparent processes for predictability in international trade

Biosafety process…all applications need

Examples of SECs that impair functionality of biosafety regulatory systems

Wrong placement of Socio-economic considerations within the risk assessment process

Risk assessment is a safety consideration and must be science-based. Helpful to rather consider SECs in decision-making

Language proviso for SECs in decision-making

Useful new technology must not be penalized for competing with existing knowledge and technologies

Stakeholders' expectations of regulators

Be balanced, objective and fair in their assessments and communication with stakeholders

Be transparent and responsible in executing their mandated functions

Process (how)	Application (what, who)	Decision (when)

Concluding thoughts

A useful regulation is one that:

- ensures an adequate level of safety
- enables access to safe products that will benefit local communities

Thank you

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