Socio-economic Impacts of Living Modified Organisms in Agriculture

Towards an Assessment Guideline

RAEIN-Africa
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ACKNOWLEDGEMENTS

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About RAEIN-Africa

The Regional Agricultural and Environmental Initiatives Network-Africa (RAEIN-Africa) is a Southern African network that facilitates and promotes science, technology, innovation systems, and policy for sustainable livelihoods. Its main focus areas are sustainable management of the environment and agricultural production systems. The network mainly addresses the interface in emerging appropriate technologies, maximizing on opportunities available to the resource-constrained communities, including Indigenous Knowledge Systems, innovation systems to development and coping, adaptation and mitigation strategies to climate change and interfacing issues within them whilst addressing policies that govern access to, safe handling and use of these technologies. Conservation of natural resources and improvement of livelihoods are the main expected outcomes of the network’s activities.

RAEIN-Africa facilitates establishment of innovation platforms at national and regional levels on the focus issues. The network also provides evidence-based voices to the voiceless in policy making processes. Overall, the entire network facilitates information sharing, knowledge generation, technology generation, and evidence-based policy and lobbying and advocacy on focus issues.

The network achieves its objectives through multi-stakeholder groups of partners, who represent public research and development institutions, academic research and development institutions, policy making and regulatory bodies, civil society, farmer representative organizations, consumer organizations, and the users of both the technologies and information. The network has active contact institutions (nodes) in eight SADC countries (Botswana, Malawi, Namibia, Swaziland, South Africa (Limpopo Province), Tanzania, Zambia, Zimbabwe) and links to the other five SADC countries through science and technology authorities.
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List of Acronyms and Abbreviations Used

Bt       Bacillus thuringiensis
COGEM    Commissie Genetische Modificatie
CPB      Cartagena Protocol on Biosafety
EIA      Environmental Impact Assessment
EC       European Commission
EFSA     European Food Safety Authority
GMOs     Genetically Modified Organisms
FAO      Food and Agriculture Organization
FFP      Food, Feed & Processing
HT       Herbicide Tolerant
IFPRI     International Food Policy Research Institute
IKS      Indigenous Knowledge Systems
IPR      Intellectual Property Rights
IPTS-JRC Institute for Prospective Technological Studies of the Joint Research Centre
LDCs     Least Developed Countries
LMOs     Living Modified Organisms
NBRC     National Biosafety Regulatory Committee
PBS      Programme for Biosafety Systems
PELUM    Participatory Ecological Land Use Management
RAEIN-Africa Regional Agricultural & Environmental Initiatives Network-Africa
RIE      Rapid Impact Assessment
SADC     Southern African Development Community
SCBD     Secretariat to the Convention on Biological Diversity
SRA      Social Risk Analysis
SEC      Socio-economic Considerations
SEIA     Socio-economic Impact Assessment
SSA      Sub-Saharan Africa
UNEP     United Nations Environment Programme
UNCTAD  United Nations Conference on Trade and Development
VROM  Ministry of Housing, Spatial Planning and the Environment
WTO  World Trade Organization
1 INTRODUCTION

Traditionally regarded as a tool for predicting social impacts as part of an environmental impact assessment (EIA) of development interventions, socio-economic impact assessment (SEIA) has evolved to include a range of processes of analysing, monitoring and managing the social consequences of planned interventions, and thus the social dimensions of development in general. SEIA supports communities to achieve better development outcomes whilst also supporting development agencies and the private sector to design more appropriate interventions and policies. It also helps regulatory authorities to provide information for the development approval process and to more effectively regulate and monitor impacts associated with development interventions (Esteves, Franks & Vanclay, 2012).

Whilst SEIA in the context of project impact and environmental impact assessment is well established, its application in the context of regulation of Living modified organisms (LMOs) and monitoring their impacts is fairly new and much less well understood.

During the course of negotiation of the Cartagena Protocol on Biosafety (CPB), the debate on inclusion of socio-economic considerations (SECs) in biosafety decision-making was intense and protracted and negotiators failed to reach consensus. The compromise reached was Article 26, which gives an option for countries to include socio-economic considerations in decision-making. It is also important to take into account Article 10 which stipulates that decision-making shall be based on risk-assessment (provided for by Article 15) which must in turn be carried out in a scientifically sound manner in line with Annex 3 of the Protocol (Secretariat of the Convention on Biological Diversity, 2000). Whilst methodology for environmental and health risk assessment is well-developed (Lusser et al., 2012) the same cannot be said for SEIA. The current guideline was developed to contribute towards filling this gap.
1.1 Purpose and Scope

The purpose of the guideline is to help countries develop and implement effective mechanisms for assessing and managing the socio-economic impacts of LMOs on the conservation and sustainable use of biological diversity, especially with regards to the value of biological diversity to indigenous and local communities.

It is important to stress that the approach this guideline advocates is not a risk assessment, but rather an impact assessment which allows both the potential (ex-ante) and real (ex-post) positive as well as negative impacts are identified and assessed, depending on the option selected.

1.2 Guideline Development Process

The guideline was developed as part of RAEIN-Africa’s project entitled “Towards development of a socio-economic considerations guideline for biosafety decision making” which commenced in mid-2009. The following steps were followed:

a. In 2009, country scoping studies were commissioned to identify potential socio-economic issues that need to be considered in the introduction of agricultural technologies. The studies also documented current status of biosafety regulation in the countries, and highlighted the need for guidance on biosafety socio-economic issues. The studies were commissioned in 8 southern African countries i.e. Botswana, Malawi, Namibia, South Africa, Swaziland, Tanzania, Zambia and Zimbabwe.

b. The findings of these studies were shared at a regional training workshop held in collaboration with the University of Pretoria: Department of Agricultural Economics, Extension and Rural Development, and with presenters from the Program for Biosafety Systems (PBS) at the International Food Policy Research Institute (IFPRI) as well as the Secretariat to the Convention on Biological Diversity (SCBD) in Pretoria,
South Africa. 31 participants representing decision makers, regulators and academia from 13 of the 15 SADC countries participated in this workshop. The workshop shed light on the scope, approaches, methods and experiences on conducting a socio-economic assessment study and how it relates to genetically modified crops and regulations thereof.

c. Following this workshop, a multi-disciplinary team was established to proceed with development of the guideline. The team carried out two studies i.e.

a. Unpacking the socio-economic issues in Malawi cotton sector: Towards an ex ante study of Bt cotton
b. Unpacking of the socio-economic issues of Bt cotton and Bt / HT maize in the South African smallholder sector: An ex-post assessment
d. The findings of these studies, together with a draft framework were presented to a regional stakeholders workshop held in August, 2010 in South Africa and later shared with the international community at a side-event held at the COP-MOP 5 in October 2010 in Nagoya, Japan.

e. The guideline received further inputs from the RAEIN-Africa`s Technical Advisory Committee and subsequently from RAEIN-Africa partners at the National Biosafety Authorities Workshop held in July, 2011.
f. The draft guideline was pretested in Zimbabwe followed by an external peer review.
g. The team met in Johannesburg in May, 2012 to consider all the inputs from the RAEIN-Africa partners, the pretesting exercise and the peer review process.

2 BACKGROUND

2.1 Southern African Context

Southern Africa as a region contains a high concentration of least developed countries (LDCs) with a total of 8 out of the world total of 49. One of the main contributing factors to this is that most
of the economies are not only predominantly rural and subsistence-based but they also have weak productive capacities. In common, a significant proportion of the population, as much as 70% in most cases, is dependent on agriculture for food, income and employment (Southern African Development Community (SADC), 2003; Draper et al., 2009). Whilst the per capita agricultural food production in most developing countries increased by about 40% from 1980-2001, in Sub-Saharan Africa (SSA), it has fallen by as much as 5% in the same period. In southern Africa the number of undernourished people increased from 52.7 million to 77.2 million (from 42-51 % of the total population) in the period from 1990-92 to 1997-99 (SADC, 2003).

It has been projected based on aggregate trends that SSA can only attain Millennium Development Goals (MDGs) in 2147 (PELUM, 2005) making it one of the slowest regions to attain both MDGs and national targets (Virgin et al., 2007). Whilst China has managed to reduce the number of poverty stricken people over the past decade by half, major target countries in sub-Saharan Africa have only managed less than a 1 % reduction (United Nations, 2011; Yuan et al., 2011). A recent Food and Agriculture Organization (FAO) report observes that despite her huge potential, Africa has remained a net importer of food over the last three decades (Rakotoarisoa et al., 2011). Amongst the factors identified as contributing to this are the following:

- Declining per capita arable land due to increasing population and inadequate land management policies
- Low yield and productivity linked to:
  - Limited access to essential inputs, equipment, and market infrastructure. Factors identified here include:
  - Land degradation and poor restoration of soil fertility
  - Inadequate use of fertilizers and poor insect and disease control
  - Water constraints
  - Low mechanization, poor infrastructure and inadequate equipment
    - Slow transfer and uptake of technology
    - Negative supply shocks
Science, technology and innovation has been touted as central to addressing agricultural productivity and profitability. For example, modern biotechnology is regarded as one of the scientific tools that can be used to enhance agricultural productivity on the continent. The text of the Cartagena Protocol on Biosafety (CPB) defines modern biotechnology as

a. The application of in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles,

b. Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection (Secretariat to the CBD, 2000).

A number of other authors including Thompson (2007); Azadi & Ho (2010); Bazuin et al., (2011); Juma (2011); Morris, (2011) and Yuan et al., (2011) discuss in some detail, the potential of modern biotechnology focussing on genetically modified (GM) crops for Sub-Saharan Africa whilst Smale et al. (2009) summarize the existing economic impact literature from the adoption of transgenic crops.

Like any other technology, modern biotechnology has also been associated with a number of potential adverse effects which may have impacts on the environment, human and animal health as well as the socioeconomic and cultural conditions. Figure 1 shows the multi-dimensional nature of potential impacts of LMOs. It is important to note that socioeconomic and biophysical impacts may be interconnected and that a change in any one of these domains can lead to changes in the others (Benson et al, 2007).
Figure 1: Multi-dimensional impacts of LMOs (adapted from MacKenzie Valley Review Board, 2007)

Examples of issues which may be associated with these impacts are shown in Table 1.
**TABLE 1: Examples of Issues for Potential Consideration in Socio-Economic and Environmental Risk Assessment in Biosafety Decision Making**

<table>
<thead>
<tr>
<th>Socio-economic impacts</th>
<th>Biophysical Impacts</th>
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<tbody>
<tr>
<td><strong>Economic Impacts:</strong></td>
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<tr>
<td>1. Impacts on the economy (farm level/household, industry and general economy)</td>
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<tr>
<td>o Costs of inputs</td>
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<td>o Labour costs</td>
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<td>o Yield</td>
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<td>o Yield sustainability</td>
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<td>2. Impacts on food supply</td>
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<td>3. Impacts on food security</td>
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<td>4. Impacts on trade</td>
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<td>5. Impacts on employment</td>
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<tr>
<td><strong>Environmental Impacts:</strong></td>
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<tr>
<td>• Impacts on biodiversity</td>
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<tr>
<td>• Gene flow</td>
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<tr>
<td>o Landraces/traditional varieties e.g., loss through displacement</td>
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<tr>
<td>o Wild/weedy relatives e.g. Other weedy species of importance</td>
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<tr>
<td>• Beneficial insects</td>
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<tr>
<td>• Other non-target organisms throughout the food chain</td>
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<tr>
<td>• Impacts on soil quality</td>
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<tr>
<td>• Impacts on water quality</td>
<td></td>
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<tr>
<td>• Impacts associated with processing of GM and by products of processing</td>
<td></td>
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<tr>
<td><strong>Social Impacts:</strong></td>
<td></td>
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<tr>
<td>• Equity issues along gender, age and other aspects</td>
<td></td>
</tr>
<tr>
<td>• Impacts on consumer rights/freedom of choice</td>
<td></td>
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<tr>
<td>• Implications for resilience of food production systems under extreme conditions</td>
<td></td>
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<tr>
<td>• Intellectual Property Rights (IPR) issues</td>
<td></td>
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<tr>
<td>• Impacts on overall quality of life</td>
<td></td>
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<tr>
<td>• Ethical considerations</td>
<td></td>
</tr>
<tr>
<td>• Religious beliefs</td>
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</table>
Cultural Impacts:
- Impacts on cultural and traditional practices including:
  - Cropping practices and the associated indigenous knowledge systems (IKS)
  - Traditional seed exchange systems
  - Traditional conservation practices
  - Cultural uses of biodiversity

Health Impacts:
- Allergenicity effects
- Toxicity effects
- Changes in exposure to insecticides, pesticides etc.

The main challenge that then confronts countries in the region is how to maximize the potential benefits, whilst effectively managing the potential adverse effects that may arise from its use. This challenge is particularly important when addressing the potential impact on the more vulnerable sectors of the population. This then requires a multi-pronged approach to assessment of potential impacts of LMOs in agricultural production systems. Decisions should ideally be based on both scientific risk assessment and socio-economic impact assessment. This is particularly important in the light of past experiences with technology adoption processes, including those experienced during the Green Revolution.

Several authors have suggested that despite a lot of success being recorded in parts of Asia and Latin America, the Green revolution largely passed Africa by (Mugabe, 2003; Bazuin et al., 2011). Whilst there may be lessons for Africa from the successes of Asia and Latin America in achieving significant yield and productivity increases under the Green Revolution, these same successes have been said to have come at a price including some adverse impacts on the environment, significant loss of agro-biodiversity and the associated traditional knowledge (Kropiwnicka 2005; UNCTAD 2009).
addition, wealthier farmers tended to accrue a significant amount of benefit—especially early in the adoption process leaving many of the poorer farmers heavily in debt.

Amongst a number of other issues that would need to be addressed to ensure that modern biotechnology has the intended results in SSA, Bazuin et al., (2011) suggest attention to political, socio-economic and bio-physical interplays. Stabinsky (2000) cites direct and indirect impact of the technology, downstream effects on the ability of local communities to conserve and or use of biological diversity as well as potential for shift of crops from small-holder farmers in developing countries towards a few large-scale producers.

2.2 Provisions for Socio-economic Impact Assessment in the Cartagena Protocol on Biosafety

Socio-economic impact assessment of LMOs is provided for by Article 26 of the CPB which states:
1. The Parties, in reaching a decision on import under this Protocol or under its domestic measures implementing the Protocol, may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.

2. The Parties are encouraged to cooperate on research and information exchange on any socio-economic impacts of living modified organisms, especially on indigenous and local communities.
The possible interpretation and implications of Article 26 for SEIA are reflected on in Box 1.

**Box 1: A reflection on Article 26**

- “….in reaching a decision on import…..”: Because the focus of the CPB is on trans-boundary movement of LMOs, Article 26(1) focuses on LMOs for import and is silent about LMOs developed in-country. However, this does not imply that countries may not take domestic measures to assess LMOS nor to subject domestically developed LMOs to a SE assessment. The focus on LMOs for import probably arises from the fact that the CPB regulates trans-boundary movement of LMOs.

- “….may take into account”: Article 26(1) gives Parties the option to take socio-economic considerations (SEC) into account when making decisions about LMOs.

- “….consistent with their international obligations….”: This phrase is often a subject of contention as it can be viewed as placing limitations on the option of including socio-economic considerations in decision making. The main international obligations here are with regard to trade arrangements under the World Trade Organization (WTO).

- “……socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity….”: The question of what socio-economic issues can be included in biosafety decision-making is also another subject of debate. The wording of this text would seem to restrict socio-economic issues that can be included to those that arise as a result of impacts of LMOs on biological diversity and not the whole basket of potential issues.

- “……especially with regard to the value of biological diversity to indigenous and local communities…”: The CBD places particular emphasis on protecting the interests of indigenous and local communities. The CPB takes a similar stance in singling out indigenous and local communities in this Article.

McKenzie *et al.*, (2003) suggests that the language of the Article appears to limit SECs that may be taken into account in Biosafety
decision-making to those that arise from the impact of trans-boundary movement, handling and use of LMOs on biological diversity. They further suggest the emphasis on the “value of biological diversity to indigenous and local communities” is closely linked to Articles 8(j) of the CBD. Some of the issues they suggest may be included are the impact the trans-boundary movement, handling and use of LMOs which may have on:

- The continued existence and range of diversity of biological resources in areas inhabited or used by indigenous / local communities;
- The loss of access to genetic and other natural resources, previously available to Indigenous or local communities in their territories; or,
- The loss of cultural traditions, knowledge, and practices in a particular indigenous or local community as a result of the loss of biological diversity in their territory.

Stabinsky (2000) also emphasizes the point that for socio-economic considerations to be part of a legal instrument under the convention, harm to biodiversity must be demonstrated or shown to be possible.

2.3 Provisions for SEC in National Biosafety Frameworks in Southern Africa

A number of countries in southern Africa have included statements in their national biosafety frameworks (NBFs) that indicate a desire to include SEC in biosafety decision-making. Statements in Table 2 reflect some of them.
<table>
<thead>
<tr>
<th>Country</th>
<th>Statement(s)</th>
<th>Source and status of implementation</th>
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<tbody>
<tr>
<td>Botswana</td>
<td>“The goal of the Policy is to promote the development and application of biotechnology, taking into account the protection of biological resources to ensure sustainable use, protection of human health, and minimization of the adverse socio-economic impacts of biotechnology”. “In preparing the risk assessment, the applicant must take into account the risks posed by the activities proposed, including any risks to the health and safety of people, biological diversity, socio-economic security or risks to the environment”</td>
<td>Draft National Biosafety Document, Republic of Botswana (2006)</td>
</tr>
<tr>
<td>Malawi</td>
<td>NBRC shall consider socio-economic impact of the general release of MOs on a community living in the proposed area for release</td>
<td></td>
</tr>
<tr>
<td>Mozambique</td>
<td>Socio-economic aspects shall be taken into account in decisions on activity related GMOs.</td>
<td>Draft National Biosafety Framework</td>
</tr>
<tr>
<td></td>
<td>i. Information submitted by the applicant</td>
<td>Republic of Mozambique (2005)</td>
</tr>
<tr>
<td></td>
<td>ii. The risk assessment and management report</td>
<td></td>
</tr>
<tr>
<td></td>
<td>iii. Inputs from the public</td>
<td></td>
</tr>
<tr>
<td></td>
<td>iv. Socio-economic considerations.</td>
<td></td>
</tr>
</tbody>
</table>

1 NBFs give indication of where the country is headed in terms of Policy, the final say will be in the formal policy drafted, debated and approved by the legislation and signed by the executive.
<table>
<thead>
<tr>
<th>Country</th>
<th>Text</th>
<th>Source</th>
</tr>
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</table>
| Namibia     | “The formal regulation of biotechnology shall be by a competent authority advised by a technical body independent of both government and industry, whose decision-making process is transparent and takes full account of environmental, public health, socio-economic and socio-cultural concerns.”  

“where scientific risk evaluation of a biotechnology product, application or procedure gives rise to a negative recommendation, this shall not be over ruled on the grounds of political or economic expediency but a positive recommendation may be overruled on political and economic grounds.”  

“...to introduce a system and procedures for the regulation of genetically modified organisms in Namibia in order to provide an adequate level of protection to the conservation and sustainable use of biological diversity, taking into account: c. social, cultural, ethical and economic considerations:” | Biotechnology Policy. Republic of Namibia, (1999). Biosafety Act Republic of Namibia, (2006). |
| South Africa| The Council may in performing its function in terms of sub regulation (8), consider the socio-economic impact that the introduction of a genetically modified organism may have on a community living in the vicinity of such introduction.” (GMO Act No.15, 1997) | GMO Act. Republic of South Africa (1997) |
| Swaziland   | “Socio economic and ethical considerations: Socio economic aspects of the people of Swaziland and other ethical considerations shall be taken into consideration when biosafety decisions are made”.  

“----- consider such measures as may be necessary to avoid adverse effects on the | Draft National Biosafety Framework. The Kingdom of Swaziland (2006). |
environment, biological diversity, human health and on socio-economic conditions arising from a GMO;”

“Whilst a positive decision based on scientific risk assessment can be overturned on the basis of socioeconomic risk, a negative decision based on scientific risk assessment cannot be overturned on the basis of socio-economic gain or political pressure”.

| **Tanzania** | The NBF has the following objectives: Establish science-based, holistic and integrated, efficient, transparent and participatory administrative and decision making system so that Tanzania can benefit from modern biotechnology while avoiding or minimizing the inherent environmental, health and **socio-economic risks; and Socio-economic and ethical considerations:** In implementing the NBF, the social, economic and ethical considerations shall be taken into account in Biosafety decisions.

Tanzania shall base its decision on a risk assessment carried out in a scientifically sound manner taking into account socio-economic as well as ethical and cultural considerations |

| **Zambia** | The Authority shall not grant any approval unless it considers that the import, transit, contained use, development, release or placing on the market of the genetically modified organism shall:

a. Benefit the country without causing any risk to human and animal health, non-genetically modified crop, biological diversity or the environment,

b. Contribute to sustainable development

c. Not have adverse socio-economic impacts |

| **Draft National Biosafety Framework, United Republic of Tanzania (2004)** |

An analysis of the statements in Table 2 shows a range of stances on how countries in the region would wish to take SECs into account in biosafety decision-making. Interactions with partners within the RAEIN-Africa Network have shown that despite this desire to include SECs in biosafety decision making on the part of many countries in the region, a number of challenges militate against such aspirations. These challenges include:

- Lack of a shared understanding on the provisions of Article 26 (1) as reflected by the debate that still rages on around the issue even at international level,
- Lack of clarity on what socio-economic considerations can and/or should be included,
- Lack of clarify and understanding on the methods, costs, and feasibility for assessments,
- Lack of guidelines on how these can be assessed,
- Lack of clarity on how to balance socio-economic assessments with environmental and food/feed safety assessments,
- Limited human and financial capacity to implement socio-economic assessments.

This guideline attempts to respond to at least some of these challenges.
3 Review of other initiatives on Socio-economic considerations related to GMOs

3.1 Initiatives in the EU and in EU Member countries

EU legislation on genetically modified organisms (GMOs) provides for the possibility of ex post assessment of the socio-economic impacts of deliberate release and placing on the market of GMOs through Directive 2001/18/EC1 which requires the Commission to submit a report on the implementation of the provisions of the Directive as well as an assessment of the socio-economic impacts of GMOs. Regulation (EC) No 1829/2003 provides for the Commission to take into account, for purposes of decisions on applications for authorisation of GMOs, the opinion of the European Food Safety Authority (EFSA), relevant provisions of the Community law and “other legitimate factors relevant to the matter in consideration” presented an opportunity for taking SECs into consideration (Lusser et al., 2012).

3.1.1 Government of the Netherlands

Netherland’s Commissie Genetische Modificatie (COGEM) whose mandate is to provide “scientific advice to the government on the risks to human health and the environment of the production and use of GMO’s and informs the government of ethical and societal issues linked to genetic modification” (COGEM, 2009) developed a report on the socio-economic aspects of GMOs in agriculture, with a view to advancing the protracted discussion in the EU at the request of the Ministry of Housing, Spatial Planning and the Environment (VROM). In commissioning the report, the minister of VROM requested COGEM to draw up socio-economic criteria for assessing application of GMOs in agriculture focussing on which socio-economic themes with particular emphasis on sustainability and their implications for agriculture.
In developing the report, COGEM noted the dynamic nature of sustainable development and the fact that what is considered sustainable from a socio-economic viewpoint is time and context specific depending on knowledge and technological capacity. The report also notes that what constitutes sustainable agriculture may differ from one country or region to the next due to different cultural and other values. The report was developed on the basis of broad stakeholder engagement taking into account existing sustainability criteria in commodities such as palm oil, soy and biomass as well as results of the Ministry of Agriculture, Nature and Food Quality seminar on re-evaluating the GMO assessment framework.

Following suggestions from VROM, the COGEM report uses conventional agriculture as a reference but notes the following:

- What constitutes conventional agriculture is also not static and can vary from one country to the next depending on development level, available techniques etc.
- Whilst differences exist between organic and conventional agriculture, similarities are also noted. These include:
  - All agricultural systems involve modification of the natural environment to produce plants and animals intended for human use
  - All types of agriculture have an adverse impact on the environment though the extent is dependent on the crop and cultivation method used
- The report thus makes it clear that conventional agriculture is used as a form of reference purely because it what is most commonly used.

The report identifies and describes principles/building blocks which could play a part in assessing the contribution that GM crops could make towards ‘more sustainable’ agriculture taking into account social, economic and environmental aspects. The building blocks are related to the key themes that normally arise in the GM debate. The requirement was that GM crops should meet and even exceed conventional crops in these criteria as follows:
Table 3 Proposed Building blocks for assessment of contribution of GM crops to sustainable agriculture (COGEM, 2009)

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Explanation</th>
<th>Elements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benefit to society</td>
<td>The production of GM crops leads to an increase in yield, contributes to harvest security or offers some other form of general benefit to society.</td>
<td>• Harvest security,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Food security,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Food quality,</td>
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<tr>
<td></td>
<td></td>
<td>• Environmental benefit,</td>
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<tr>
<td></td>
<td></td>
<td>• Cost saving,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Recreation.</td>
</tr>
<tr>
<td>Economics and prosperity</td>
<td>The production and use of GM crops contributes equally to local and general prosperity and the economy and, where possible, leads to an improvement.</td>
<td>• Employment,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Efficiency of the production process,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Productivity,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Profit.</td>
</tr>
<tr>
<td>Health and welfare</td>
<td>The production and use of GM crops means that the health and welfare of workers, the local population and consumers remains at the same level and, where possible, improves</td>
<td>• Human rights and conditions at work.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Local and general food supply.</td>
</tr>
<tr>
<td>Local and general food supply</td>
<td>The production and use of GM crops means that the local food supply remains at the same level and, where possible, improves.</td>
<td>• Food security</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Fair trade</td>
</tr>
<tr>
<td>Cultural heritage</td>
<td>The production of GM crops offers room, if so desired, for the country or region concerned to conserve and continue specific cultural heritage aspects or other local applications (such as building materials, medicines)</td>
<td>• Local applications and traditions,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Autonomy of the local population.</td>
</tr>
<tr>
<td>Freedom of choice</td>
<td>Consumers and manufacturers’ freedom of choice regarding GMO (or GMO-free) is safeguarded in the production and import of GM crops.</td>
<td>• GMO (or GMO-free) labelling of products, product information, • Co-existence, • Innovation and research freedom</td>
</tr>
<tr>
<td>-------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Safety</td>
<td>The admittance and assessment of GM crops in terms of safety to humans and the environment takes place in the country concerned in accordance with the legislation on the basis of the international agreements in force concerning human and environmental safety</td>
<td>• Food safety • Environmental safety</td>
</tr>
<tr>
<td>Biodiversity</td>
<td>The production of GM crops does not lead to a) a reduction in the agrobiodiversity of the agricultural environment and where possible strengthens it, and b) damage to protected or vulnerable biodiversity</td>
<td>• Agrobiodiversity, • Protected or vulnerable biodiversity, • Centers of origin of agricultural crops.</td>
</tr>
<tr>
<td>Environmental quality</td>
<td>The production and processing of GM crops means that: a) the quality of the soil, surface and groundwater, and air, does not deteriorate and, where possible, improves and, b) the emission of greenhouse gases along the entire chain (development, production, processing and transport) remains neutral or declines relative to conventional agriculture.</td>
<td>• Emissions of hazardous substances to the soil, surface water • Air, • Soil fertility • Disease resistance</td>
</tr>
</tbody>
</table>
The report stressed that these criteria are not exhaustive but represent an initial step. The report also does not extend to operationalization of these issues but in elaborating on them considers differences between cultivation in Europe and cultivation elsewhere in the world followed by import into Europe which presents additional complications due to issues of national legislation of the country of export as well as international legislation affecting trade relations (COGEM, 2009).

### 3.1.2 JRC-FAO Workshop on SECs

Reporting on the outcomes of a recent international workshop on SECs co-organized by the Institute for Prospective Technological Studies of the Joint Research Centre (IPTS-JRC), the European Commission (EU) and the FAO, Lusser et al., (2012) note that many countries have gone beyond the provisions of Article 26.1 by including issues such as social, ethical and philosophical aspects considering Socio-economic impacts. They also suggest that where a country decides to include SEIA in the biosafety regulatory process it must also make the following decisions:

- Whether the SEIA should be voluntary or mandatory,
- If it should be carried out for approval to form part of the decision-making i.e. ex ante and/or for post-release monitoring (ex post).
- What methodology should be applied etc.?

In addition, Lusser et al., (2012) suggest that introduction of SEIAs in the biosafety regulatory process can enhance the quality and quantity of information about impacts of the technology and thus improved decision-making but they also raise a concern about increased costs of regulatory compliance, delays in regulatory processes and the risks of ending up with unworkable systems where standards are not clear. However, they report that experts participating in the workshop argued that inclusion of a robust SEIA in addition to strict science-based safety assessments could facilitate more objective and transparent regulatory decision-making on cultivation of genetically modified...
crops. The report also notes that the choice of methods is limited and that SEIAs will out of necessity tend to be based on projections and assumptions. Approaches for SEIA of LMOs are compared in three countries and the results show that:

- **Argentina:** Since the 1990s, there has been mandatory assessment of socio-economic impacts. Decision-making processes take into account developments in other countries including the EU, China and India. Three independent expert opinions inform decision making as follows:
  - Environmental risk evaluation
  - Food safety assessment and,
  - An analysis of the potential impacts on Argentina’s international trade which takes into account the stage of approval for production, consumption and import in the main importing countries as well as the competiveness of Argentina.

- **Brazil:** SEIA is non-mandatory. Decisions of what applications it is to be done for are decided on a case by case basis.

- **China:** No inclusion of SEIAs in regulatory instruments such as guidelines and regulations.

SECs discussed include:

- **Coexistence, economic compensation and liability:** The report notes that even with well formulated and well implemented policies, risks of potential consequences of GMO cultivation can affect assets of others through for example adventitious admixture in the agricultural supply chain raising issues of liability and compensation for affected individuals. Arrangements for regulating co-existence in the EU, Canada and United States were also discussed.

- **Policy framework influencing adoption of GM Crops:** The workshop also discussed the influence of policy and institutional arrangements on GM adoption using the South African case of GM cotton in the Makhathini flats. The report states that the identification of biotechnology as strategic
industry to support economic growth and thus creation of an enabling environment based on “science-based and balanced considerations and regulation of GM crop cultivation” supported fast adoption, at least during the early stages.

- Institutional framework and its implications for adoption of GM crops: Adoption of Bt cotton by smallholder farmers in the Makhathini flats was used to illustrate this whereby rapid adoption by farmers to 90% by 2001 was attributed to favourable institutional arrangements with a single ginnery providing credit, extension and ginning services to contract farmers. The collapse of the cotton sector in this area attributed to competition and low prices was also due to institutional factors rather than the technology. The important lesson the report draws is that “like conventional crops, GM crops cannot be produced profitably and sustainably without functioning markets and institutional support”. Other institutional issues experts considered important were:
  - Functional seed supply systems
  - Availability and stability of credit supply systems

The implication of this for countries in the region is that SEIA that also facilitates an understanding of the institutional arrangements and their implications for the sustainability of cultivation of GM crops not with a view to blocking the technology but rather to inform policy and planning will contribute towards sustainable livelihoods development in line with aspirations of local communities.

Other socio-economic considerations discussed by the workshop include:
- Consumer preference
- Health benefits and welfare including:
  - Reduced labour requirements in areas with HIV prevalence
  - Possibility of freeing more time for food production contributing to diversified diets
  - Reduced amount of insecticide exposure (insect tolerant crops)
- Lower toxicity of herbicides (herbicide tolerant crops)
- Reduced risk of exposure to mycotoxins and associated health problems due to reduced insect damage

4 Options for Inclusion of SEIA in Biosafety Decision Making

Article 26 of the CPB provides countries with an option to either include or not include SECs in biosafety decision making (Figure 2). A country that chooses to include SECs in decision-making may then reflect on the provisions of Article 26, other obligations with respect to international obligations and decide how these issues can best be incorporated into decision-making. The requirement of whether socio-economic considerations should be included in an application assessment should be defined in the country’s NBF (policy, laws, regulations and administrative arrangements).

![Figure 2: Options for inclusion of SECs into biosafety decision-making](image)

The procedure for inclusion of socio-economic considerations should define whether the standard or operating procedure will follow a narrow/strict interpretation of Article 26.1 of the Cartagena Protocol, or will it consider a broader mandate under national regulations.
A strict interpretation of Article 26 limits socio-economic impacts that can be considered in biosafety decision-making to those impacts that may arise as a result of the impact of the technology on biological diversity resulting from trans-boundary movement, handling and use of LMOs with particular emphasis on the value of said biodiversity to indigenous communities.

The liberal interpretation considers both potential negative and positive impacts directly as well as indirectly linked to the technology. Possible mitigating and or enabling strategies can then be suggested for any potential adverse effects.

**No inclusion**
The option of no inclusion of socio-economic considerations in the decision-making process means that the regulatory system relies only on the scientific risk assessment. The rationale behind this alternative is that developers screen the technologies for efficacy, regulators for safety, while allowing farmers / consumers to decide what the best technology / product for their context is. The possibility exists that developers may volunteer a socio-economic assessment as part of the application dossier, but in this regulatory option, it is not mandatory for the developer to include such an assessment or for the regulatory bodies to consider the assessment itself. Though this allows for a strictly scientific risk assessment based approach it is possible that the process may disregard issues that are important in some sectors of society and /or some possible positive or negative impacts that might require proactive planning and management or mitigating strategies.

**Inclusion**
If the decision is made to include socio-economic considerations in the decision-making process, this means that the regulatory system, in addition to the scientific risk assessment will consider socio-economic impacts of the LMOs. The country then has to decide how and when the SEIA will be carried out in relation to the scientific RA i.e. concurrently but separate, sequentially or embedded.
**Concurrent but separate**

One option is to have concurrent but separate processes for the scientific risk assessment and socio-economic impact assessment. In this option, the regulator later puts together both assessments and renders a decision. This option has the benefit of potentially reducing time delays and ensuring objectivity in the assessment process. Some communication or cooperation between the two assessment entities might however be necessary, especially in cases where, as Article 26.1 of the CPB suggests, there may be potential environmental impacts on the biodiversity which is of value to indigenous and local communities.

**Sequential**

Another option is a sequential approach where the scientific risk assessment is carried out first and, only if the technology meets the national safety standards, then the technology proceeds to a socio-economic assessment. A variation of this option is to grant temporary approval for commercialisation with a condition for a post release SEIA. Similar to the concurrent approach, this option isolates the scientific risk assessment from the SEIA while leaving the option open of considering socio-economic issues in the technology decision-making process. At the same time it poses the risk of unnecessarily delaying the approval process and a disadvantage of only commissioning a SEIA when the scientific studies have showed a technology to be safe, is that the potential beneficial socio-economic impacts of the technology are totally disregarded.

**Embedded**

A final option is that of a socio-economic assessment that is embedded and perhaps inter-twined with the risk assessment. In this option, the risk assessment is done at the same time as the socio-economic assessment. Depending on the specific process, the competent authority, full time assessors, commissioned external experts, or the applicant, may conduct both assessments. There is no strict separation between this option and the concurrent but separate option described previously. The difference lies only in the fact that
the implementing agency conducts both assessments. The risk here is that this authority might have difficulty in advancing the process given the multiple objectives it is pursuing and potentially conflicting approaches and methods.

In addition to deciding when a SEIA should be carried out, there is a need to also determine for which applications SEIA will need to be carried out. Furthermore, a decision has to be made on who should conduct the assessment.

A further point of consideration is that of information sharing between the SEIA entity, the entity/s conducting the scientific assessments, the technology innovator / applicant and the regulatory authority.

These questions are answered over the sections that follow.

4.1 Which applications should require a SEIA?

Provisions in the NBF need to define which applications will require SEIA for review by the regulatory body.

There are generally five types of permits an applicant can apply for:

- Contained use
  - Laboratory
  - Green houses
  - Field trials
- Import for food, feed and processing
- General release

In deciding for which applications a SEIA should be done, there are a couple of issues and trade-offs to consider. As the technology progresses through the development and regulatory pipeline, developers may gather additional information regarding the product’s characteristics and efficacy and thus it may be worthwhile waiting for later stages of the regulatory process to commission SEIAs.
If field trials are conducted with the idea of applying for a commercial release permit in the near future it might be wise for the technology developer to act proactively and gather some performance indications with the eye on a future SEIA, but for the regulator to require a formal SEIA for field trials may in some cases not be considered efficient use of resources. However, countries would need to reflect on this and decide on a case by case basis. A recent policy brief for example states “This includes field trials on LMOs also as unintended consequences of such field trials may adversely affect the in situ conservation and use of plant genetic resources” (RIS, 2011).

An application for a permit for importation of a LMO for food, feed and processing presents an interesting case. As the commodity would be destined for consumption, feed or processing under biosafety regulation, a case could be made that a SEIA may not be necessary.

The necessity for a SEIA would also depend on the nature of the technology. For third generation, qualitative traits where the novel trait is aimed at the end consumer or processor and not at the producer (for example high lysine maize vs Bt maize), a SEIA might be required for a FFP import.

Requiring a SEIA for a general release application may be easier to justify given the resource limitations that characterize the majority of countries in the region. By this stage the proponent would also have done enough field trials to inform the SEIA on the expected characteristics and performance level of the new technology.

### 4.2 Who should conduct the SEIA?

The SEIA can be conducted by the applicant, third party entities commissioned by the regulatory agency or the applicant, or by professional assessors within the regulatory system. The choice of who will conduct the assessment will largely depend on the overall design of the biosafety regulatory system. Each one of these options
has advantages and disadvantages and trade-offs in terms of resources and capacities and will depend on the nature of technology being reviewed and the volume of technologies under review. A multidisciplinary team of experts the composition of which will depend on the type, nature of the technology and the receiving environment should conduct the SEIA.

- If the SEIA is conducted directly by the applicant, the system takes advantage of the applicant’s familiarity with the technology and access to technical information that will have been gathered through the technology development process. The applicant will have control over funding and expenses and the time frame of the study. It also means that the applicant can initiate a SEIA sometime before submitting a general release application. The biggest disadvantage of such an approach is the potential conflict of interest and thus the credibility of the report. An option to ensure credibility of the assessment conducted by the applicant is to have it peer reviewed by a competent third party appointed by the regulatory authority. The third party assessor should have the authority to request all relevant background and substantive information related to methods, baseline data, estimation procedures and assumptions to competently and diligently review the proponent’s study.

- A SEIA conducted by an impartial third party albeit in or outside the regulatory body or contracted by the applicant, ought to suffer less from a conflict of interest. Based on the terms of reference of the awarded assignment and the specific crop and technology, experts can be contracted to form part of the multidisciplinary assessment team. An important advantage of this approach is thus that the third party assessor in all likelihood will have substantial capacity and experience in social and economic assessments. A potential disadvantage is that the third party might struggle to obtain correct or sufficient information or struggle to interpret information obtained from the applicant. An open line of communication and cooperation between the third party assessor and the applicant is thus crucial.
• If the SEIA is conducted by the regulatory authority there is capacity building within the system and the lessons from previous assessments can be used to inform future ones. It also ensures a level of consistency in the decision making process of the SEIAs. However, due to limited capacities and possible bureaucratic delays, a SEIA done by the regulatory authority may suffer from inefficient resource use and delays.

5 SEIA PROCESS

5.1 Principles of Socio-economic Impact Assessment

Socio-economic issues are related to people and their social environment, which can differ significantly both within communities as well as from one community to the next, it is important to accept that SEIA can be by nature, very complex, although it can differ broadly in its scope. Depending on the scope chosen by a country, a socio-economic assessment can focus on a very specific set of issues such as impacts on trade and competition, as has been the case of Argentina, or to use much broader approaches that include several socio-economic aspects. Furthermore, the highly dynamic nature of socio-economic issues also makes it impossible to develop a fully comprehensive list of potential impacts that will be applicable in all cases (Abdrabo & Hassan, 2003). In addition, there may be indications in the biosafety regulations of when to do the assessment that is for commercial approval or for post-release monitoring. These considerations of course limit the range of methods and approaches that can be used for a socio-economic assessment.

The Inter-organizational Committee on Principles and Guidelines for Social Impact Assessment (2003) defines social impacts as “the consequences to human populations of any public or private actions that alter the ways in which people live, work, play, relate to one another, organize to meet their needs and generally cope as members of society”. This also includes cultural impacts involving changes to the norms, values, and beliefs that guide and rationalize their
cognition of themselves and their society (Benson et al., 2007).

Impacts can be defined as potential changes caused, directly or indirectly, in whole or in part, for better or for worse by development activities (MacKenzie Valley Review Board, 2007).

SEIA is a systematic appraisal of the potential social impacts of economic or other activities (in this case, introduction of LMOs into agricultural productions systems) on all sectors of society including local communities and groups, civil society, private sector and government-noting that the CPB places particular emphasis on local/indigenous communities. This analysis enables management of both the intended and unintended social impacts, both positive and negative, of planned interventions and any social change processes invoked by those Interventions (International Association of Impact Assessment, 2003; UNEP, 2007).

Like biophysical impacts such as those on biodiversity, socio-economic impacts fall into various categories depending on their desirability, scale, duration and intensity of impact as shown in Table 4.

Table 4: Categories of Socio-economic Impacts

<table>
<thead>
<tr>
<th>Category</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Desirability</td>
<td>Socio-economic impacts can range from desirable on one hand to adverse</td>
</tr>
<tr>
<td>Scale</td>
<td>Their effect can be small-scale or localized or they can occur in a large-scale</td>
</tr>
<tr>
<td>Duration of impact</td>
<td>The duration can vary from short-term or they can be long-term or even permanent</td>
</tr>
<tr>
<td>Intensity/ severity of impact</td>
<td>Socio-economic impacts may range from mild to severe</td>
</tr>
</tbody>
</table>
In the assessment of socio-economic impacts, it is important to consider the distribution of impacts across different sectors of the population, focusing in particular, on the most vulnerable and marginalized sectors including for example, resource poor communities, the elderly, women etc.

Inclusion of socio-economic considerations in a biosafety regulatory process should add to accuracy in decision-making and ultimately to increase welfare to society. Inclusion of socio-economic considerations should not become an insurmountable hurdle in the regulation process depriving society from useful innovations. In order for this to happen the regulator needs to set elements of best practice not only for conducting the assessment but also for decision-making. The standard and decision-making process needs to be transparent and predictable so that participants in the biosafety regulatory process know what to expect during all stages of the biosafety regulatory process. Furthermore, the decision-making standard and assessment procedure needs to be feasible and cost effective, while ensuring that the overall process is protective and efficient.

An assessment process should be:

- Relevant (crop, technology and application specific)
- Adaptable (countries, crops and technologies)
- Affordable (i.e. within the limitations of available resources - financial and time)
- Efficient (optimal use of resources)
- Credible (rigorous and defendable)
- Consistent (scientific best practices)
- Transparent
- Inclusive to include all relevant stakeholders

Stakeholder involvement should be as broad-based as time and resources allow allowing for two-way information flows between the public and the people performing the SEIA. Whilst we recognize that it would not be possible to include everyone, it is important that those who are most likely to be affected (i.e. key stakeholders) are
identified and involved at appropriate stages of the process. Developing and implementing an effective public participation plan to engage all interested and affected stakeholders is a vital step in an SEIA as it enables gathering information about how the community may be impacted by the technology under consideration. This requires identification of stakeholders that will be affected or have an interest in the development. In the context of a biosafety, these may include but not be limited to:

- Farmers who may wish to adopt the technology
- Those who may be affected by its introduction e.g. organic farmers, consumers, communities who depend on elements of biodiversity that may be affected,
- Farm labourers
- Civil society interest groups etc.

Other principles for the inclusion and implementation of SEIA in biosafety decision making include:

- **Equity of Impacts**: Whilst it is true that every technology will have losers and winners, the important principle here is that the most vulnerable groups should not have to bear the costs of any adverse impacts of the technology. Where this is a possibility, mitigating strategies need to be designed with a view to minimizing the impacts on that sector of the population. The SEIA should therefore analyse the equity of impacts, focussing in particular on the most vulnerable groups. In the context of southern Africa, this could include in addition to age, gender, economy issues criteria such as child and women headed households and those affected by HIV/AIDS etc.
- **Focussing the Assessment**: The assessment should be focussed on issues of important concern to the public rather than those that are easy to determine or may be known.
- **Assumptions and Significance must be clarified**: Any assumptions made during the assessment must be defined. Similarly, it is important to clarify how significance was determined.
• The assessment should be performed by a multi-disciplinary team. The composition should be guided by the complexity in the case under consideration.

• Secondary data must be obtained from credible sources and as much as possible verified with key informants.

• Compare the technology under consideration with what it would be replacing or considered standard practice by the community in question.

5.2 Phases of the Assessment

This section suggests steps to be followed in conducting a SEIA. The following steps and discussions represent an ex ante SEIA but the general steps can also apply to an ex post assessment. Note that by definition in an ex ante SEIA, there is no adoption or diffusion of the technology. Any SEIA will likely be an examination of existing conditions without any technology in the field and a projection of potential effects from the future adoption of the technology. Primary and secondary data will not include any observation of the LMO performance in the field, but perhaps be limited to that collected in confined field trials and/or advanced multi-locational trials, which are quite limited in their applicability to farmer field conditions.

As the SEIA process will be part of a biosafety regulatory decision making, it is important for countries to clearly define that this is a time and resource delimited exercise.

5.2.1 Profiling of Baseline Conditions

Profiling of baseline conditions involves the gathering of information related to the social and economic environment in the context of the proposed introduction of LMO. This information should assist in identifying valued socio-economic components that could serve as measureable indicators.
5.2.1.1 Screening

The first step in the assessment would be screening i.e. a rapid, high-level assessment aimed at determining whether or not a full SEIA will be necessary. This may consider for example:

- The issues relevant to society which may be included in the implementing regulations,
- The proposed location where the technology will be released and particular sensitivities of the proposed area where the LMO is likely to be released to specific shocks and stresses,
- The proximity of proposed location to vulnerable biological diversity including wild and weedy relatives.

The screening may be able to uncover potential effects on biological diversity and thus its impact on the communities that rely on it. Impacts on biological diversity are more likely to be assessed in the environmental risk assessment process based on the findings of here; the outcome can either be a decision not to pursue an SEIA, or to proceed with the assessment and if this is the case whether it should be a comprehensive assessment or a basic SEIA focussing with a limited scope. Screening can take the form of or include a consultative meeting with key informants who at this stage may include:

- Conservation specialists,
- Government officials in key line ministries and departments,
- Civil society with links with communities etc.
- Key experts- biotechnologists, environmentalists, socio-economics etc.

If the decision to pursue a full SEIA is made, the following steps are suggested.

5.2.1.2 Commissioning the team

The National Biosafety Framework may already contain an elaboration of the structure (s) that will be used to conduct the socio-economic impact assessment. Where this is not the case, the
The competent authority will need to decide who will implement the assessment. This may range from one socio-economic assessment expert to a team that would need to be commissioned to implement such a study. In the case of broader SEIA assessments, we suggest a multi-disciplinary team that may include the following expertise within the limitations of the resources available:

- A livelihoods specialist
- An agricultural economist
- An agronomist
- A social scientist (social anthropologist)
- A scientific risk assessor/assessors (environmental/ food safety)
- Other expertise depending on the application under consideration as well as national circumstances e.g. expertise on cultural practices at local level.

The decision on the specific mix of disciplines and expertise for a specific application can be made at country level.

### 5.2.1.3 Scoping and planning

Before embarking on the SEIA, it is important that the assessment team have a clear understanding of the objectives of the specific assessment. Equally important is noting the time and resource available, as these will have a great bearing on what and how much can be achieved within the limitations of the available resources. If it turns out that a full SEIA is warranted, scoping needs to be carried out in order to guide the focus of the SEIA. Other outcomes of scoping include:

- Identification of available data and any information gaps,
- Clarification of the appropriate spatial and temporal scopes for the assessment,
- Identification of key impacts on for example, biological diversity and any others with linkages to livelihoods, social and cultural issues,
- Determination of methodologies and appropriate tools for subsequent data collection.
The screening process helps to minimise the likelihood of performing unduly burdensome hurdles in the assessment process. Bayer, Norton & Falck-Zepeda (2010) suggest that the cost of compliance is not as important as the length of time needed to complete a biosafety assessment. Thus it is recommended that the SEIA does not have an unduly adverse impact on the time needed to complete the overall biosafety assessment.

5.2.1.4 Understanding the technology under consideration
The team needs to get a clear technical understanding of the technology / novel GM product under consideration. This may require the team to obtain additional information from the applicant to have an in-depth understanding of the technology including the novel characteristics, expression and performance (efficacy) of particular traits. In addition, the team also needs to carry out a preliminary literature review to have an appreciation of experiences from other countries on similar crops/traits. Potential sources of information here include:
   i. The Biosafety Clearing House (BCH)
   ii. Socio-economic, agronomic and other applicable journals
   iii. Socio-economic assessment reports from other countries

With increasing understanding of the novel product, the team should be able to do some preliminary identification of the main potential impacts.

5.2.1.5 Stakeholder identification and analysis
These should ideally begin at national level, cascading down to provincial and local levels at this stage. The team needs to develop a plan for public consultation in line with the principles earlier discussed detailing:
   i. Who is to be consulted
   ii. At what stage they are to be consulted
   iii. How they will be engaged (the tools etc.)
A useful matrix as shown in Table 5 can be used to plan for this component of the study.

**Table 5: Matrix for Stakeholder Consultation**

<table>
<thead>
<tr>
<th>Stakeholder</th>
<th>Information to be collected</th>
<th>How?</th>
<th>Tools?</th>
<th>Where?</th>
<th>Time allocation</th>
<th>Resources required</th>
</tr>
</thead>
<tbody>
<tr>
<td>For example:</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Smallholder farmers</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Consumer</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Output buyer</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Input supplier</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Government agency</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Civil Society Organization</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

5.2.1.6 (Rapid) Participatory Appraisals with communities

This stage of the assessment focuses on gathering information about the socio-economic environment and context within which the technology will be released. This step is also important as it can provide a reference point against which future changes associated with the technology can be assessed in addition to providing information for subsequent monitoring if other issues affecting the community are more or less stable over time.

Questions that would need to be answered here include but are not limited to:

**A. Description of the area:**

a. The physiography, climate and related variables
b. Demographic Profiling (Size, structure and growth)
c. Population movement and trends
d. Population settlement patterns and spatial distribution
e. Education
f. Employment
g. Socio-economic background
   i. Household incomes
   ii. Poverty

B. Natural Resources
a. Land governance and access
   i. Land tenure
   ii. Farm size
   iii. Equity issues
b. Water issues
   i. Rainfall patterns
   ii. Irrigation etc.
c. Biological Resources
   i. What biological resources are accessed and used?
   ii. Where they are sourced from
   iii. Traditional practices around conservation and use of these

C. Agricultural practices
a. Main crops grown
b. Minor crops
c. Agricultural practices
   i. Varieties grown and associated seed management systems in place
   ii. Other inputs and associated costs
   iii. Crop management practices
   iv. Constraints associated with production of crops including pests and diseases
   v. Labour issues
   vi. Equity issues (gender, age etc.)
   vii. Post-harvest management practices
   viii. Institutions, governance structures and capabilities including: Extension services
   ix. Credit sources and arrangements
x. Other opportunities for training and empowerment
xi. Input supply systems
xii. Marketing
xiii. Other appropriate instruments

D. Other Socio-cultural issues
   a. Biological resources of value to community and their uses, traditional practices associated with their uses and conservation,
   b. Other important cultural practices that are dependent on biological /natural resources in the area.

A number of tools that can be used for data collection are summarised in Table 6.

Table 6: Some tools that can be used for data collection in the SEIA

<table>
<thead>
<tr>
<th>Tool</th>
<th>Purpose and use</th>
<th>Sources and further reference material</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stakeholder analysis Matrix</td>
<td>For ensuring involvement of a wide range of stakeholders. Applicable throughout the assessment for both collecting and sharing information, providing feedback etc.</td>
<td></td>
</tr>
<tr>
<td>Stakeholder importance / influence matrix</td>
<td>Ensures marginalised and vulnerable stakeholder groups have opportunity to voice their perceptions, priorities etc. Applicable in SEIA to facilitate identification of options and mitigation strategies</td>
<td></td>
</tr>
<tr>
<td>Semi-structured interviews</td>
<td>Provide a guide of questions to be used when engaging various stakeholders allowing them to share insights, views etc.</td>
<td></td>
</tr>
</tbody>
</table>
After identifying perceptions and concerns of the community the team should then be able to separate the issues into a number of categories.

i. Any specific issues that may arise as a direct result of the impacts of LMOs on biological resources and the environment as well as IKS in the community,

ii. Issues that may arise as a result of the socio-cultural and economic environment but not directly associated with the technology i.e. institutional issues

iii. Public concern issues that are a result of misconceptions about the technology.

5.2.1.7 Preliminary Data Analysis

The data collected at this stage can be analysed in order to identify key issues emerging with a view to focussing the assessment on those moving forward. If there are no significant issues are identified at this stage, a recommendation can be made to that effect allowing the application to move forward with the regulatory process depending on when the SEIA is done in relation to the scientific risk assessment as previously discussed.

5.2.2 In-depth household surveys

Having identified the key issues, in depth household surveys can then be carried out in order to generate data that will enable the assessment to be focussed on the key issues.

In addition, key informant interviews should also be conducted both in order to triangulate the information collected and to give a better understanding of issues at hand.

5.2.3 Impact Assessment

Issues to be considered here may include:

- Nature of the impact i.e. Is the potential impact identified beneficial or adverse?
- What downstream effects may it have?
• What prevalent social and other conditions may make the community more vulnerable to the impact?
• Which groups within the community would be most vulnerable?
• For any adverse impacts identified, how likely is each to occur?
• If the impacts occur, what magnitude of change is it likely to cause? Issues that need to be considered here include:
  • The number of people that may be affected: Significance increases with an increase in the number of people affected.
  • The duration: The longer the impact, the higher the significance.
  • Whether the impact would be reversible: Irreversible impacts carry more significance than reversible ones.
  • How quickly the change is likely to be occur- fast, intermediate or slow.

In addition, the team may need to consider the magnitude of the change compared to changes that would occur with the conventional counterpart i.e. the counterfactual. The counterfactual is the conventional counterpart of the technology under review. For instance in South Africa the counterfactual of Bt cotton is the conventional cotton based on the same germplasm but without the Bt event (NuOpal vs Delta Opal). Similarly, for Bt maize in South Africa, the counterfactual is the conventional hybrid maize, again, without the Bt event. It is important that the counterfactual be as close as possible to the new technology, but without the novel characteristic. For instance to compare the performance of a new GM hybrid with an open pollinated maize variety may give spurious results.

5.2.3.1 Predicting and Characterizing Impacts
Predicting impacts involves comparing the baseline status of the community/communities under consideration with the projected future status with use of the technology with a view to characterizing the likelihood of adverse socio-economic impacts. These include the potential direct, indirect and cumulative impacts (Mackenzie Valley Environmental Impact Review Board, 2007).
• Direct impacts are changes in the socio-economic environment that arise as a result of the use of the technology. These impacts are manifested at the same time and place.

• Indirect impacts refer to secondary or higher level impacts which occur as a result of complex interactions between the technology and the socio-economic environment. These are manifested at a later stage and often occur away from the area where the intervention.

• Cumulative impacts are impacts which are a result of the incremental impacts of the technology in combination with other past, present or reasonably foreseeable actions combined.

There are numerous methodologies and tools that can be used to predict and characterize impacts. These are summarized Table 7.

**Table 7:** Some tools that can be used for prediction and characterization of potential impacts

<table>
<thead>
<tr>
<th>TOOL</th>
<th>PURPOSE AND USE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Social Risk Analysis</td>
<td>Facilitates understanding of perceived and actual risks and also forms the basis for implementation of mitigation measures</td>
</tr>
<tr>
<td>Social Mapping and related techniques</td>
<td>These tools facilitate visualisation of differences between current and potential future situations with regards to impacts of actions- in this case use of LMOs in agriculture thus facilitating identification of mitigatory measures.</td>
</tr>
<tr>
<td>Transect walks</td>
<td>Facilitates exploration and understanding of the significant features of a location with respect to natural and biological resources, cultural sites etc. as well as potential impacts that may arise with use of the LMO.</td>
</tr>
<tr>
<td>Matrices, ranking and scoring</td>
<td>Facilitate identification of preferences / priorities based on comparisons of options during SEIA e.g. during focus group discussions with stakeholders</td>
</tr>
</tbody>
</table>
### 5.2.3.2 Evaluating significance

**Significance evaluation** involves making decisions on whether the technology being considered will alter or decrease valued socio-economic components below acceptable levels as determined by appropriate policies or other relevant instruments. These decisions can be made based on:

- Traditional / local knowledge
- Expert knowledge
- Comparable case studies where they are available.

Criteria for assigning significance include the following:

- Effects of the impact on socio-economic components of value to the community and sensitivity of those components to change
- Probability/ likelihood of the event occurring;
- The magnitude of the change measured by the number of people including that may be affected. Other issues to be considered here are
  - Prevalent social pressures and other conditions that may make the community vulnerable to the impact?
  - Likelihood of the impact exceeding the capacity of the community to absorb the change?
- How rapid the change is likely to be;
- Duration of impacts (long-term vs short-term);

<table>
<thead>
<tr>
<th>Scenario Analysis</th>
<th>These narrative descriptions of hypothetical futures can be used to describe the possible causes and effects of the direct and indirect impacts of the technology under consideration.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Livelihoods analysis</td>
<td>Facilitates an understanding of how communities live and survive as well as how their livelihoods may be impacted by the technology under consideration. The Livelihoods analysis framework.</td>
</tr>
</tbody>
</table>
- Value of benefits and costs to the community and other relevant stakeholders;
- Extent to which the impact is reversible or can be mitigated;
- Likelihood of causing downstream/secondary impacts;
- Relevance to present and future policies and other regulatory instruments;
- Uncertainty over possible effects;
- Presence or absence of controversy/public outcry over the issue.

Significance rating should ideally be done with the involvement of stakeholders.

Another approach is to use of Significance ranking. The first step is to determine the likely consequence. Table 8 has been adapted for possible use for this purpose.

Consequence ranking can either be done by the team in which case is most likely to be qualitative. It may also be done with participation of stakeholders in which case it can be quantitative.

**Table 8: Consequence Ranking of Socio-Economic Impacts**

<table>
<thead>
<tr>
<th>Consequence</th>
<th>Category ranking</th>
<th>Explanation (Based on British Petroleum, 2002)</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>0</td>
<td>No negative effects on:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Human health,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Livelihoods of individuals / households,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Ability to access particular resources</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Economy, employment etc.,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- No breach of legislation, traditional /cultural norms and values, current practice etc.</td>
</tr>
<tr>
<td>Level</td>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>-----------</td>
<td>------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Negligible</td>
<td>1</td>
<td>• Negligible negative effects on human health,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Minor disruption on livelihoods of individuals / households,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Some inconvenience in ability to access particular resources</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Some disruption in the economy, employment etc.,</td>
</tr>
<tr>
<td>Minor</td>
<td>2</td>
<td>• Minor negative effects on human health</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Disruption to livelihoods of individuals / households,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Disruption in ability to access particular resources</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Economy, employment etc.,</td>
</tr>
<tr>
<td>Moderate</td>
<td>3</td>
<td>• Moderate negative effects on human health</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Moderate disruption of livelihoods of individuals / households,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Disruption on ability to access particular resources</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Economy, employment etc.,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Compromise of legislation, traditional /cultural norms and values, current practice etc.</td>
</tr>
<tr>
<td>Major</td>
<td>4</td>
<td>Serious consequences to</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Human health,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Livelihoods of individuals / households,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Ability to access particular resources</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Economy, employment etc.,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Serious breach of legislation, traditional /cultural norms and values, current practice etc.</td>
</tr>
<tr>
<td>Catastrophic</td>
<td>5</td>
<td>Disastrous consequences to</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Human health,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Livelihoods of individuals / households,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Ability to access particular resources</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Economy, employment etc.,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Serious breach of legislation, traditional /cultural norms and values, current practice etc.</td>
</tr>
<tr>
<td>Positive</td>
<td>+ / ++/+++</td>
<td>Positive benefits can be classified as limited positive, moderate or significant.</td>
</tr>
</tbody>
</table>
The next step would be to determine the likelihood of the impact. An example of how likelihood can be ranked is shown in Table 9.

**Table 9: Likelihood Ranking of Socio-economic impacts**

<table>
<thead>
<tr>
<th>Category</th>
<th>Ranking</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Certain</td>
<td>5</td>
<td>The impact will most certainly occur within the normal activities associated with the activities associated with production of the crop</td>
</tr>
<tr>
<td>Very Likely</td>
<td>4</td>
<td>The impact is very likely to occur</td>
</tr>
<tr>
<td>Likely</td>
<td>3</td>
<td>The impact is likely to occur at some time</td>
</tr>
<tr>
<td>Unlikely</td>
<td>2</td>
<td>The impact is unlikely to but may occur at some time</td>
</tr>
<tr>
<td>Very Unlikely</td>
<td>1</td>
<td>The impact is very unlikely to occur</td>
</tr>
</tbody>
</table>

The next step is determination of significance of the impact, expressed as the product of the consequence and likelihood of occurrence of the event i.e.

\[
\text{Significance} = \text{Consequence} \times \text{Likelihood}
\]

The final step would be interpretation of the significance score which can be done using Table 10.

**Table 10: Significance ranking and interpretation**

<table>
<thead>
<tr>
<th>Significance Score (Consequence x Likelihood)</th>
<th>Significance</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; 16</td>
<td>Critical</td>
<td>Potential risk unacceptable and mitigatory measures may not be effective</td>
</tr>
<tr>
<td>9-16</td>
<td>High</td>
<td>Potential risk is unacceptable unless actions for mitigatory measures are feasible and effective</td>
</tr>
</tbody>
</table>
Some partners in the region have also suggested that this type of significance ranking may be better suited where the SEIA is preceded by scientific risk assessment as the presence of empirical data in this case makes scoring easier.

6 APPLYING THE SEIA IN DECISION-MAKING

How the findings of the SEIA fit into the decision-making will be largely dependent on the choice made by the country regarding:

a. The interpretation of Article 26 of the CPB i.e. strict or liberal as previously discussed in section 4.

b. The timing of the SEIA relative to the scientific risk assessment, i.e. concurrently but separate, sequentially or embedded, again as previously discussed in Section 4.

Here we illustrate using a scenario in which the strict interpretation is used as illustrated in Figure 3. In this case, we suggest that having identified all the potential impacts, these are grouped into two categories. The first would be those issues that are allowed for by a strict interpretation of the protocol such as potential impacts on indigenous knowledge related with conservation and use of biological diversity. The Significance of these would then need to be determined. If any are found to be highly significant and there is a possibility that mitigatory measures would be insufficient, a decision could then be made not to approve the technology.
The second category of impacts would be all other impacts outside of those allowed by a strict interpretation of Article 26. These would include institutional issues which as we have previously discussed often have a great bearing on the efficacy and even sustainability of a technology. The significance of these would again need to be determined and for any that are significant, mitigation and management strategies are developed. These issues would then not fit into the actual biosafety decision making but are rather aimed at informing policy and planning.

Figure 3: SEIA in biosafety decision-making
The benefit of this approach is that it allows countries to carry out a holistic assessment of the technology including the socio-economic context into which it is likely to be released thus allowing first, for conservation and sustainable use of biological diversity and associated indigenous knowledge and traditional practices in line with aspirations under the CBD and its instruments. Secondly, it also allows for countries to explore and institutional challenges and other impacts making it possible to develop strategies to enhance the benefits of the technology and develop mitigation and management measures against any potential adverse impacts.

The impact assessment proposed here allows countries to carry out biosafety decision making in a manner that allows them to remain aligned to their international trade obligations whilst being sensitive to their developmental aspirations.

7 MONITORING AND EVALUATION MONITORING AND EVALUATION FOR QUALITY MANAGEMENT

It is recommended that the regulatory authority establishes a quality management system as is it essential to ensure that an SEIA process is in line with core values (principles) stipulated in this guideline and provides credible evidence for decision making.

A SEIA Monitoring and Evaluation (M&E) or quality assurance process should be inclusive of all institutional, managerial, and technical arrangements made for the preparation of the SEIA, collection and analyses of data, and implementation of steps to manage the overall quality of the SEIA. The guidance in this section is intended to help SEIA commissioners develop and implement a quality management system.

All stakeholders or interest groups will demand a high quality SEIA process and hence implementation of a quality management system is important. However, regulatory agencies do not have unlimited resources committed to a quality process and a SEIA and the issues that surround it can be complex. Therefore, regulatory
agencies should ideally develop their quality management system in line with their resources and the broader evolution of their policy. A particular quality management system should provide a systematic process for preventing and correcting errors, for improvement of overall SEIA quality. However, the primary objective of quality management is ensuring the credibility of an SEIA process. The first step towards achieving this is defining SEIA quality.

7.1 Defining SEIA quality

This guideline outlines eight principles that set an implicit guidance for the faithful representation of SEIA process, these are Relevance, Adaptability, Affordability, Efficiency, Credibility, Consistency, Transparency and Inclusivity. Putting these principles into practice will result in reliable and unbiased treatment and presentation of issues and data. For a regulatory authority to follow these principles and to assure that they are put into practice, quality management needs to be an integral part of its management strategy.

7.2 M&E and quality management framework

As previously discussed, all aspects of an SEIA process should be included in a quality management mechanism, including institutional, managerial, and technical components of an SEIA.

- Methods: These are the technical aspects of SEIA process. The team conducting the assessment should select or develop methodologies for identifying SEIs that accurately represents the characteristics of their communities. This guideline provides many default methods and tools to help with this effort. The planning of a SEIA study should provide for the selection, application, and updating of methodologies as new research and best practices become available.

- Data: This is the basic information on impact levels, contributing factors, processes, and operations. Although
methodologies need to be appropriately rigorous and detailed, data quality is more important. The planning of a SEIA process should facilitate the collection of high quality data and the maintenance and improvement of collection procedures.

- **SEIA process and systems**: These are the institutional, managerial, and technical procedures for preparing a SEIA process. They include the team and processes charged with the goal of producing a high quality SEIA. These processes and systems may be integrated, where appropriate, with other NBF functions and processes related to quality.

- **Documentation**: This is the record of methods, data, processes, systems, assumptions, and estimates used to prepare a SEIA. For example ex ante and ex post studies are inherently technical (involving a rigorous scientific process) therefore high quality, and transparent documentation will be particularly important to provide credibility. If information is not credible, or fails to be effectively communicated to either internal or external stakeholders, it will not have value. NBF should seek to ensure the quality of these components at every level of SEIA process design.

### 7.3 Implementing an inventory quality management system

A quality management system for a SEIA program should address all four of the components described above. The following serve as guidance for the implement the quality assurance (QA) system.

#### 7.3.1 Establish a SEIA quality assurance team

This team should be responsible for implementing a quality management system, and continually improving SEIA quality. The team or manager should coordinate interactions between relevant NBF structures, facilities and external entities such as government agency programs, research institutions, verifiers, or consulting firms.
7.3.2 Develop a quality management plan
This plan should describe the steps a NBF is taking to implement its quality management system, which should be clear to all stakeholders from the onset. For efficiency and comprehensiveness, NBFs should integrate (and extend as appropriate) existing quality systems to cover SEIA management and reporting, such as any ISO procedures.

7.3.3 Perform generic quality checks
These apply to data and processes across the entire SEIA, focusing on appropriately rigorous quality checks on data handling and documentation.

7.3.4 Perform targeted area quality checks
This may include more rigorous investigations into the appropriate selection of target or impact areas and impact pathways.

7.3.5 Review final SEIA issues and reports
After the SEIA is completed, an internal technical review should focus on scientific, and other technical aspects. Subsequently, an internal managerial review should focus on securing official NBF level approval of the SEIA submission. NBFs may choose to allow a review involving external experts (external verifications).

7.3.6 Institutionalise formal feedback loops
The results of the reviews in step five, as well as the results of every other component of a NBF quality management system, should be fed back via formal feedback procedures to the person or team identified in step one. Errors should be corrected and improvements implemented based on this feedback.

7.3.7 Establish reporting, documentation, and archiving procedures
The system should contain record keeping procedures that specify what information will be documented for internal purposes, how that information should be archived, and what information is to be reported for external stakeholders. Like internal and external reviews,
these record keeping procedures should include formal feedback mechanisms.

8 RECOMMENDATIONS

- Where baseline information does not exist it would be beneficial to collect baseline information that can then be used as a reference point for ex post monitoring to ensure the technology is bringing about the desired change and not causing damage to valued socio-economic components.
- Countries can consider giving guidance on what information the applicant can include as part of the socio-economic risk assessment in line with their needs and priorities in this area.
- Countries need to establish and maintain vibrant multi-stakeholder platforms for open debate, engagement and collaboration to enhance the likelihood of the technology delivering on its potential benefits. These platforms should include relevant stakeholder government departments, stakeholders throughout the value chain, farmers etc.
9 REFERENCE


