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Analysis for Biotechnology Innovations Using Strategic Environmental Assessment (SEA)

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ABSTRACT

Meeting the food needs of the world's growing population while reducing poverty and protecting the environment is a major global challenge. Genetically modified crops appear to provide a promising option to deal with this challenge. However there is a need to make strategic decisions on how to spend limited agricultural research funds in order to achieve a maximum impact with regard to finding sustainable solutions to end hunger and poverty. In international development institutions, there is growing interest in the potential use of Strategic Environmental Assessment (SEA) as part of a research based Environmental Management System (EMS) to promote mainstreaming of environmental considerations in policy development. SEA was developed as an approach to integrate environmental considerations at a policy level, where alternative environmental policies can be evaluated. In this paper, we propose using SEA in a policy research and priority setting process regarding new technologies, taking the development of Genetically Modified Organisms (GMOs) as an example. We propose that this method would be a useful tool for the international agricultural research centers of the Consultative Group for International Agricultural Research (CGIAR), streamlining business processes, strengthening accountability, sharpening the research agenda it supports, fostering broader partnerships, and increasing the relevance and impact of CGIAR research in achieving international development goals. Currently international law requires only Environmental Impact Assessments (EIAs) of specific biotechnology projects. The incorporation of environmental considerations only at the level of specific projects precludes the adoption of alternative environmental policies. In this review, we outline an SEA approach currently being considered at the International Food Policy Research Institute (IFPRI) for use in evaluating biotechnology policies. SEA may be a useful tool to inform the evaluation of biotechnology policies and priorities by taking account of information on the economic, social, and environmental benefits, cost and risks of adopting those policies.

Key Words: risk, Strategic Environmental Assessment, Genetically Modified, GMO, LMO, Living Modified Organism.

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1. INTRODUCTION

Meeting the food needs of the world's growing population while reducing poverty and protecting the environment is a major global challenge. There is a need to make strategic decisions on how to spend limited agricultural research funds in order to achieve a maximum impact with regard to finding sustainable solutions to end hunger and poverty. Among other research institutions, the international agricultural research centers supported by the Consultative Group of International Agricultural Research (CGIAR)⁵, identified biotechnology, and especially genetically modified crops, as a promising option to deal with this challenge. Considerable funds are spent for public research with the aim to develop GM crops that serve the needs of the poor. Past experience with developing new agricultural technologies to combat hunger and poverty, for example, the Green Revolution, shows that it is essential to take environmental concerns into account in order to develop technological solutions that are sustainable in the long run. While considerable efforts are made in the ex ante assessment of the economic and social impact of investment in agricultural biotechnology and the establishment of regulatory systems for biosafety in developing countries to make commercialization of GM crops

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⁵ <http://www.cgiar.org/>

possible, few attempts have been made to systematically account for environmental issues when deciding on the policies, programs, and research priorities regarding GM crops. At the International Food Policy Research Institute (IFPRI)⁶ a key area of analysis is the potential environmental implications of such policy recommendations and their implications for research and for agricultural policies in developing countries. Potentially Strategic Environmental Assessment (SEA) may be used as a component of an Environmental Management System (EMS)⁷ to introduce mainstreaming of environmental considerations in the policy research and priority setting process.

Historically, analysis of public policy involved both economic and social assessments, but ignored environmental considerations. With growing awareness of environmental constraints, analysis of public policy moved towards integrating economic, social, and environmental considerations within decision-making. First, environmental considerations were included using Environmental Impact Assessments (EIAs), which focused on bringing environmental considerations into project level decision-making. Currently the transboundary movement, transit, handling and use of GMOs are governed by the Convention on Biological Diversity through the Cartagena Protocol on Biosafety (CPB). The Cartagena protocol specifies the use of case-by-case risk assessments in decisions concerning these activities. The environmental or ecological risk assessments conducted in compliance with the CPB are examples of Environmental

⁶ IFPRI is one of 15 food and environmental research organizations known as the Future Harvest centers. The centers, located around the world, conduct research in partnership with farmers, scientists, and policymakers to help alleviate poverty and increase food security while protecting the natural resource base. They are principally funded through the 58 countries, private foundations, and regional and international organizations that make up the Consultative Group on International Agricultural Research (CGIAR). <http://www.ifpri.org>

⁷ An EMS is a continual cycle of planning, implementing, reviewing and improving the processes and actions that an organization undertakes to meet its business and environmental goals (<http://www.epa.gov/ems/info/index.htm>).

Impact Assessments (EIAs) of specific biotechnology projects⁸. However, project based EIAs react to development proposals instead of anticipating them, precluding the adoption of alternative policies (Therivel and Partidario 1996). Strategic Environmental Assessments (SEAs) were developed as an approach to integrate environmental considerations at a policy level, where alternative environmental policies can be considered, thus promoting sustainable development (Therivel and Partidario 1996, Bailey and Dixon 1999, Therivel 2004). SEA has been defined in a number of different ways. Sadler and Verheem (1996) define SEA as:

“as a systematic process for evaluating the environmental consequences of proposed policy, planning or program initiatives in order to ensure that they are fully included and appropriately addressed at the earliest stage of decision-making on a par with social and economic considerations.”

Therivel et al. 1992 define SEA as:

“the formalized, systematic and comprehensive process of evaluating the environmental effects of a policy, plan or program and its alternatives, including the preparation of a written report on the findings of that evaluation, and using the findings in publicly accountable decision-making.”

The common theme through these definitions is the desire to promote environmentally sustainable policies.

SEAs have become an important instrument in mainstreaming environmental concerns. The World Bank⁹ and other international organizations such as the Inter-

⁸ For a detailed comparison of risk assessment and EIA see Eduljee 1999).

⁹<http://lnweb18.worldbank.org/essd/envext.nsf/41ByDocName/AnalyticalandAdvisoryAssistanceStrategicEnvironmentalAssessment>

American Development Bank¹⁰ and donor organizations such as the Department for International Development (DFID) are increasingly looking to use SEA as a development lending analysis tool. However, in the context of biotechnology few attempts have been made to define how an SEA would work.

Biotechnology development decisions are typically complex and important, and therefore require careful and defensible analysis and stakeholder participation; decision-making often involves a variety of tangible and intangible strategic goals, conflicting stakeholder objectives, many alternative approaches, and limited resources. Methodologies are needed to guide policy makers through the plethora of biotechnology alternatives in a way that is proactive in addressing public and scientific concerns and instills public confidence in decision-making. In this context we propose a possible methodology for biotechnology related SEAs that provides a transparent, participatory, methodologically repeatable and objective basis for evaluating different biotechnology policies, plans, programs or priorities. In the remainder of this review we discuss the tools, techniques and process that might form the foundation of biotechnology focused SEAs. A rationalist model of assessment is adopted, which includes analysis, where possible, of benefits, costs, and risks. The approach uses multi-way information flow and iteration to create an adaptive learning environment for decision-making. As new information becomes available, it can be incorporated into the decision process and communicated with stakeholders.

This review is organized as follows: section (2) describes current practice compared to the SEA approach. Section (3) describes the SEA methodology that we suggest for genetically modified organisms (GMOs) and is divided into subsections on

¹⁰ http://www.iadb.org/NEWS/Display/PRView.cfm?PR_Num=239_03&Language=English

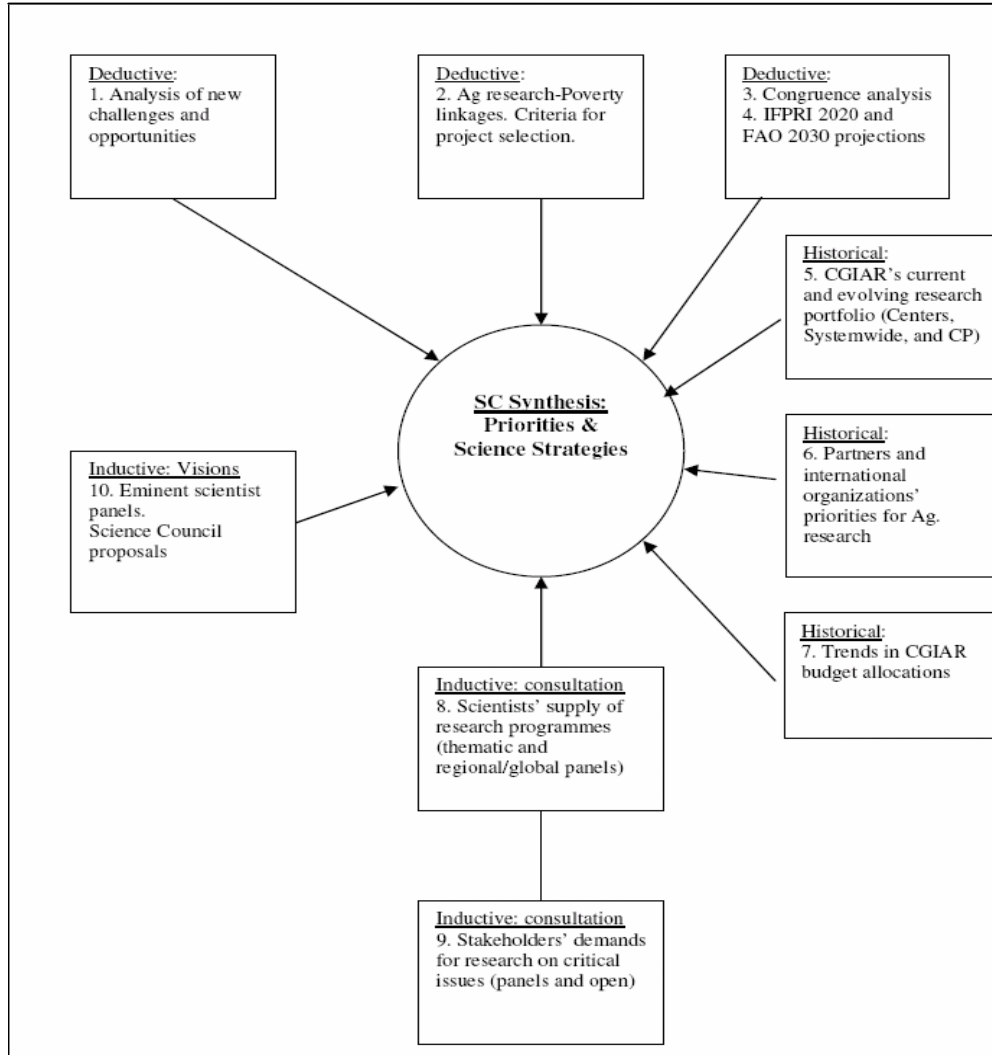
qualitative analysis of biotechnology policies which is the first stage of assessment; quantitative analysis of biotechnology policies which is the second stage of assessment; section (4) describes management; sections (5) describes participation and communication; section (6) describes legal and institutional questions and section (7) discusses the methodology with conclusions presented in section (8). Throughout the review transgenic drought-tolerant crops are used as an illustration of how an SEA might be conducted for such a technology.

2. CURRENT PRACTICE AND THE SEA APPROACH

Currently the CGIAR system approach to setting research priorities is based on three broad methods¹¹: deductive, historical, and inductive (Figure 1).

¹¹ For details see <http://www.sciencecouncil.cgiar.org/publications/pdf/draftSP5-15.pdf>

Figure 1—Science Council’s approach to setting CGIAR priorities and strategies



The deductive approach includes a broad analysis of new challenges and opportunities; the development of a set of criteria to achieve poverty reduction through agricultural research that can be used to screen future proposals; an updated congruence analysis to establish the future relative importance to be given in the overall budget to commodities (crops) and sectors (crops, livestock, forestry, and fish) by regions, and the use of global and regional projections of future supply and demand for commodities in agriculture. The historical approaches includes review of the current and evolving research portfolios for the CGIAR and the research portfolios for other selected research institutions and international organizations; and analysis of long run trends in the CGIAR's budget allocation across outputs, crops, sectors, undertakings, regions, and Centres. The inductive approach involves consultation inviting the formulation of demand for incremental research by stakeholders and of potential supply of research by scientists; with a consultative approach with eminent scientists and members of the Science Council (see <http://www.sciencecouncil.cgiar.org/activities/spps/pubs/RP0515.pdf>).

Within this existing CGIAR system approach to setting research priorities there is scope for further focused and systematic attention to mainstreaming environmental considerations. The SEA approach proposed in this paper also offers a useful governance mechanism and encompasses the three dimensions of the current CGIAR approach while ensuring that environmental considerations are adequately considered in decision-making. The approach represents a first attempt to define the SEA process specifically for biotechnology related policies and investments and as such will be further developed and refined as more research is conducted and stakeholder input is obtained.

3. SEA METHODOLOGY

EIA

Generally EIAs for GMOs concerns centre around four potential environmental hazards: introgression, invasiveness, ecotoxicity, and unintended effects on other species:

1. Assessment of Introgression (also gene flow) – gene introgression results when GMO's hybridize with non-transgenic organisms, and these hybrids backcross to the wild genotypes, the resulting offspring having similar genotypes to the wild genotypes but possibly having incorporated new genes from the domesticated, exotic or GM organisms.
2. Assessment of Invasiveness - the competitiveness of a GMO in the environment may cause other species to be displaced from their ecological niches.
3. Assessment of Ecotoxicity – characterizes any potential toxic effects and the assessment is composed of two steps:
 - a. Dose-response . This step quantifies the potential toxicological harm of the transgene product;
 - b. Exposure assessment. This step quantifies the amount of toxicant received and is combined with the dose-response model to estimate an effect, if any.

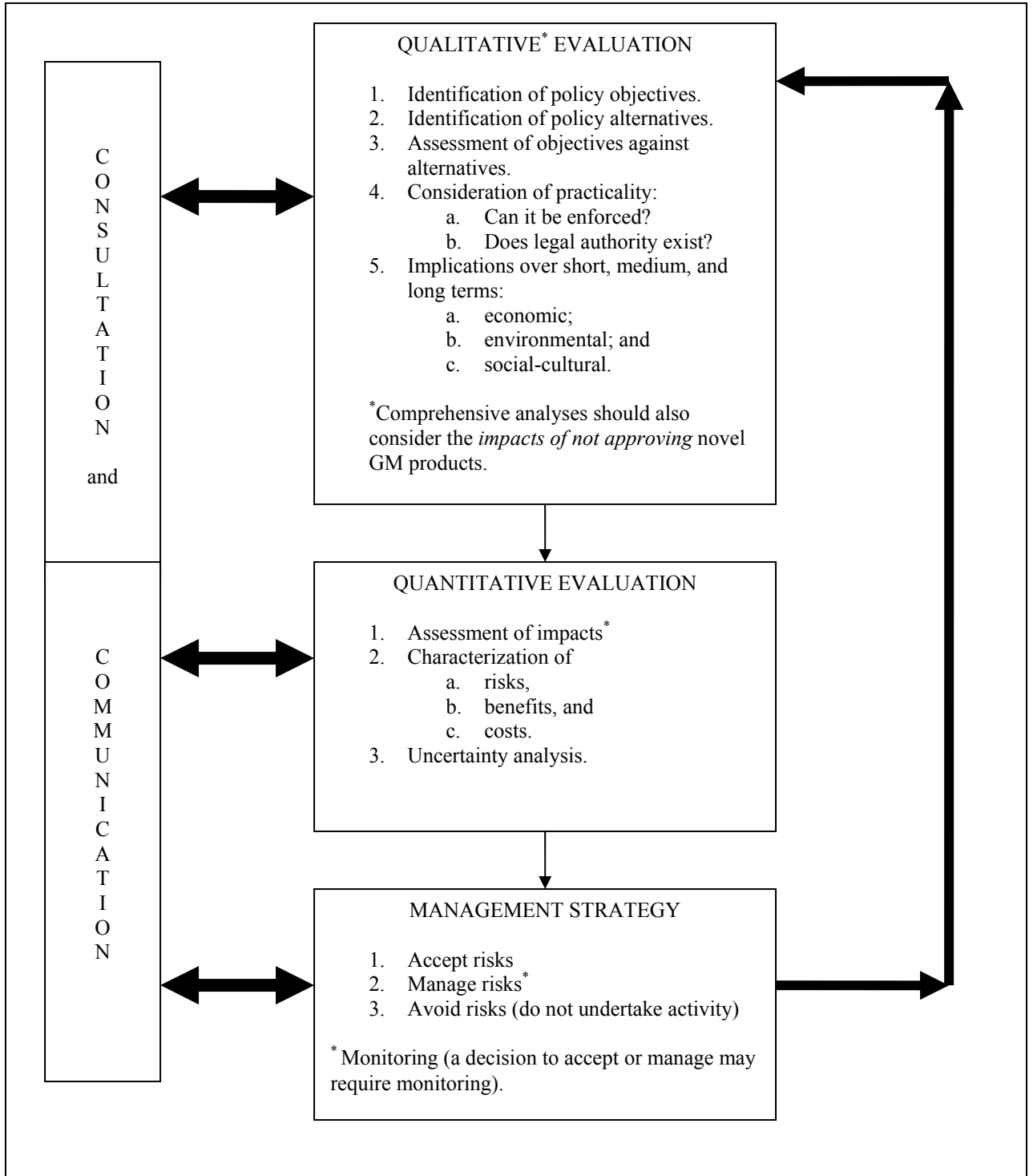
An additional concern is often raised about the unintended effects on other species. Unintended effects such as competition or ecotoxicity are considered under points 3 or 4 or both (for more details of the EIA process see Linacre 2003), but other unintended effects, such as trophic level impacts or evolution of resistance may also be a concern in some cases.

SEA

In contrast to EIA the SEA approach (Figure 2) is not just about specific assessment of the organism, trait (such as drought tolerance or insect resistance), and

environment combinations involved in the release of a GMO crop, but SEA also incorporates policy alternatives.

Figure 2--A Strategic Environmental Assessment paradigm for biotechnology policies, plans or programs. The process involves qualitative and quantitative research assessment methodologies integrated with communication, consultation, and management



For example in developing policy responses to climate change a number of alternatives might include: building large dams, building small dams, and biotechnology solutions such as drought tolerant crops. The specific assessment of the biotechnology approach is the subject of this paper.

Furthermore, data and information will often not be available to an SEA that would be needed to undertake an EIA, nor should this level of analysis be adopted. EIA provides a safety check on particular realizations of the technology, which may or may not be adopted, depending the experimental evidence of specific organism-trait-environment combinations.

Typically the information required for an SEA would be similar to that needed for a confined field trial approval and would include the follow information:

1. The crop's biology and ecology. The information required address concerns about potential invasiveness and spread.
 - a. Is the crop a weed in any of its known distribution? If so what are the environmental conditions and are these conditions similar to the proposed release regions.
 - b. Are the modifications likely to affect the reproductive biology? If so what changes are likely?
 - c. Does outcrossing occur to wild relatives? So what are the hybrids viable?
2. The genetic construct.
 - a. Is the construct stably integrated?
 - b. What is the function of the construct?
 - c. What is the source of the construct?
 - d. Have similar constructs been successful introduced without causing environmental or human health problems?
3. The gene product. The information required address concerns about potential toxicity.

- a. Is the product active in vertebrates?
- b. Pharmaceutical or industrial product?
- c. Does the construct have known allergenic effects?

QUALITATIVE ANALYSIS

At this stage policies, plans, and programs are identified that are likely to have significant environmental effects and should therefore be subject to environmental assessment. This stage includes the ‘screening’ step typical in many SEAs or a qualitative analysis within an SEA in which expert opinion and stakeholder consultation processes are harnessed to identify potential policy objectives, alternatives and impacts. While this is practically difficult for widely dispersed organizations, such as the CGIAR, the construction of list of academic and environmental organizations from whom comments are solicited and the use of internet technologies may afford a process by which submission and comment about policy and program options can be obtained documented and incorporated in the SEA.

However it is difficult to provide a prescriptive approach to the qualitative analysis because the type of analysis will depend on the nature of the policy proposal(s) and on the availability of information and data. Broadly, the qualitative analyses of policy should consider at least (for a discussion of current SEA practice see Bailey and Dixon 1999:p251-272; Therivel 2004: p8):

1. Identification of policy objectives/impacts¹².
2. Identification of policy alternatives.
3. Assessment of policy alternatives against objectives.
4. Consideration of any practical issues:
 - a. Can the policy be implemented?
 - b. Can the policy be enforced?
 - c. Does legal authority exist?
5. Consideration of policy implications or consequences over short, medium, and long-terms.

The qualitative assessment will be done using expert panels utilizing decision support methods to assess alternative policy options against multiple established objectives. Possible methods include Analytic Hierarchy Process (AHP) or Multi Attribute Utility Theory (MAUT)¹³. The multi-stakeholder and group decision approaches are envisaged to identify and develop consensus around preferred policy options.

¹² A starting point for 'screening' for potential problems is Hails (2000) definition of ecological risk for GMOs, which is:

“ecological threat is posed if the presence of a plant containing a transgene results in a negative impact on the ecosystem, relative to the status quo.”

This definition could be modified to include that the status quo is inherently risky and that strategic environmental assessments should also consider the risk of maintaining the status quo and not introducing technological innovation.

¹³ The first approach is based on the Analytic Hierarchy Process (Saaty, 1992), which is a mathematically rigorous and proven process for prioritization and decision-making. Complex decisions are reduced to a series of pairwise comparisons, providing a clear rationale for the decision. The second approach uses a simple multi-attribute rating technique (Edwards and Barron, 1994; von Winterfeldt and Edwards, 1986), based on utility theory.

The key benefits of this approach are:

- alignment of decisions with objectives or policy goals;
- implementation of a structured, methodologically repeatable and justifiable decision making approach;
- leveraging local, regional and global expertise;
- improving communication; and
- building consensus.

However, some caveats are required. The identifications of policies options may be problematic in some situations. Simon (1956) argues that individuals have a limited range of alternatives, i.e. we do not know all the decision options available to us, and, even if we do, our conceptual limitations and time prevent us from comparing all of the available options. Other evidence supports this view. For example, Slovic et al. (1974a,b) and White (1961, 1964, 1970) argue that natural resource managers rarely have all options available to them.

Applying these ideas to climate change policy, at the highest level a government has three climate change policy options:

1. accept the risk;
2. manage the risk; or
3. avoid the risk.

In the case of climate change only options (1) and (2) are available. Option (1) is the do nothing strategy and option (2) involves developing a policy response. Assuming that option (2) is adopted then investment decisions need to be made on different risk management strategies. At the highest level of assessment various options are available

including: building large dams, building small dams, investing in drought tolerance crop technologies, setting up a strategic grain reserve to provide food aid, and so on. From this perspective improving the drought tolerance of crops is a policy option for mitigating adverse affects that might be associated with climate change. At this stage expert and lay panels of stakeholders are convened to specify policy evaluation criteria, alternatives and to establish weights.

The evaluation process is illustrated only for alternative crop technologies. Evaluation criteria are specified and might include: preservation of centers of diversity of conservation value, potential weediness and ecotoxicity, and the poverty reduction potential. Next alternatives are identified and might include: crop diversification, genetically engineered drought tolerant millet, and genetically engineered drought tolerant maize. Finally weights are obtained from different stakeholder groups, ranking the relative importance of each objective. Typically sensitivity analysis is used to determine the impact changing weights will have on the final priorities emerging from the process. Next prioritization occurs with each policy option assessed against each objective and scored High (H), Medium (M), or Low (L). The combination of the weights and the scores allows the policy options to be ranked in order of group preference resulting in two or, possibly three, alternative preferred policies for detailed quantitative analysis (Table 1).

Table 1--An example of the type of information that is obtained during the qualitative assessment phase. The stakeholders rank different alternatives against the objectives. A weighted average metric is used with assumed scores High (H =100), Medium (M=50), and Low (L=0). Stakeholders may disagree about weights of objectives and the ranking of alternatives. Typically differences can be accounted using sensitivity analysis. Given the data in the table two options emerged for quantitative analysis: crop biotechnology and crop diversification.

Evaluation criteria	Stakeholder groups		Stakeholder identified alternatives		
	Weight Farmers	Weight Environmentalists	GMO drought tolerant Millet	GMO drought tolerant Maze	Crop Diversification
Improved yields ¹	50%	10%	H	H	M
Known toxicity ²	10%	10%	L	L	M
Is the modification likely to cause minimal changes to reproductive fitness? ³	10%	10%	L	L	L
Is the technology socially acceptable	50%	10%	L	M	H
Minimal impact on center of diversity	20%	60%	L	M	H
Rank Farmers			50	85	100
Rank Environ.			10	45	80

¹Criteria aims to obtain information about poverty reduction potential.

²Criteria aims to obtain information about toxicity for a food crop this may not be relevant as any technology would be evaluated in the EIA as showing no effects.

³Criteria aims to obtain information about potential weediness.

Given the data in Table 1 if two options were sort for comparison drought tolerant maze and crop diversification would be selected. The choice of options is dependent on the decision metric used to rank the competing options. Disagreements are also possible on the ranking of options and different ranks could be used for the different groups.

QUANTITATIVE ANALYSIS

Quantitative analysis may or may not be undertaken depending on the results of the qualitative assessment. Critical failings with the policy proposal may be identified

during the qualitative assessment stage, negating any value in exploring quantitative analysis. However, quantitative analysis may also be used to provide rigorous support for the qualitative assessment, which is primarily based on expert opinion, and stakeholder and community consultation. The type of quantitative assessment undertaken depends on the policy initiative. Broadly, for quantitative analysis purposes, policies related to biotechnology innovations can be divided into two groups – trait specific proposals such as the promotion of drought or salt tolerant technologies and non-trait specific proposals such as the adoption of regional environmental assessments, or biosafety regulatory systems.

Broadly, the quantitative analysis process can be divided as follows: assessment of impacts; characterization of risks, benefits and costs; and uncertainty analysis.

Assessment of Impacts

Irrespective of the type of analysis, required quantifiable risk scenarios need to be identified which characterize potentially unwanted consequences. This will partly depend on the availability of environmental and economic data for the assessment of risks, benefits and costs, which in turn requires a definition of the environment and a means of characterizing the state of the environment and quantifying change. This is achieved by setting endpoints, which are the values that we are trying to protect by undertaking the assessment (Suter 1993).

Given the diversity of the environment and the many ways in which society values it, Suter (1993) suggests the following criteria that an endpoint should satisfy:

1. societal relevance - the endpoint should be understood and valued by the public;
2. biological relevance – the endpoint must have some effect on ecologically important properties such as fecundity, mortality, and growth rates;
3. unambiguous operational definition – without this requirement endpoints provide no direction for testing and modeling;
4. accessibility to prediction and measurement – we must be able to measure the quantity and it should be able to be modeled; and
5. susceptibility to an identified hazardous agent – exposure to the agent should occur and a dose-response should be measurable.

To this list Lutter (1999) would add that endpoints should be economically assessable for integration with benefit-cost analysis. For example in biotechnology an end point from the introduction of an insect resistance crop might be changes in morbidity arising from changes in the pattern of aerial insecticide applications.

For the drought-tolerant crop example an endpoint might be no observed impact on biodiversity assessed using certain ecosystem indicator species.

Characterization of risks, benefits and costs

The consistent theme through the quantitative risk assessment¹⁴ literature is that we need to rank the magnitude of consequences and the probability of those consequences within a given time frame. Risk can therefore be viewed as the triplet (s_i, p_i, x_i) where s_i is the risk scenario with each s_i having a probability p_i of occurring and a

¹⁴ Risk assessment is the general term used to describe the array of methodologies and techniques concerned with estimating the likelihood and consequences of undesired events (Bedford and Cooke 2001).

consequence x_i if it occurs (Kaplan and Garrick 1981, Kaplan 1997). Strategic environmental assessment is then the process of identifying the risk scenarios, their probabilities and consequences and then investigating the effect of uncertainty on the probability and consequence estimates¹⁵.

We ask the following questions:

- What can happen (s_i)?
- How likely is it to happen (p_i)?
- What are the consequences should the risk scenario occur (x_i)?
- How confident are we in our estimates of p_i and x_i ?

When a strategic environmental assessment of a particular transgenic trait is required, such as drought tolerance or insect resistance, then it is important to assess -to the extent possible- how the particular trait will behave in the ecological system and how this is likely to evolve in both a specified time and space. To some extent this will depend on the specific organism, trait, and environment combinations and similar techniques will be required to those used in the EIA process. One way to address this problem is through the development of mathematical assessment models that allow us to study potential impacts in ‘compressed time’. In the case of GM organisms, mathematical models in which the assumptions and dependencies are explicit may augment expert opinion by better informing decision makers about risks and risk management options.

¹⁵ The purpose of the assessment is to help us make decisions about risky activities and identify risk remediation strategies before we undertake those activities. The assessment does not answer societal questions about what are acceptable risks.

For completeness in the following subsections: ecotoxicity, invasiveness, and benefit-cost analysis are discussed. The sections on ecotoxicity and invasiveness apply to trait specific assessments. Again it needs to be stressed that at the EIA level specific experimental evidence will be gathered for ecotoxicity and invasiveness, but at the SEA level general assessments of these issues, possibly using mathematical models, along with benefits assessments, will be undertaken to guide policy selection. Typically detail experimental evidence will not be available at the SEA stage.

Ecotoxicity. Toxicological assessments of the gene products of transgenic organisms depend on the function of the gene product and its fate in the environment. Generally, a gene product that might be toxic to a target organism, but destined for human consumption will need a food safety assessment and an environmental ecotoxicology assessment. To do this we set endpoints, which are the values that we are trying to protect by undertaking a risk assessment. In the case of human health the endpoint may be objective measures such as allergenicity, morbidity, and mortality. In the case of the environment it is often difficult to identify endpoints. Successful performance of this task requires a definition of the environment and a means of characterizing its current state and quantifying potential changes. For example, in evaluating the risk posed by a genetically modified crop such as Bt corn, we may be concerned about the ecological impacts that Bt proteins may have on rare, endangered, or other non-target insects. We may then define our endpoint to be no decrease in the population of that species.

Toxicological impacts are estimated by reference to a dose response curves derived from laboratory experiments. The dose-response assessment estimates an organism's (human, plant or animal) response to different doses.

In the drought-tolerant example a full food safety and ecological assessment would need to be done at the EIA level or the commercialization stage. However, at an SEA level expert evidence of the coding change and expected toxicity would generally be acceptable. Some relevant data may also be available from confined field trails.

Introgression and Invasiveness. Currently there are three broad approaches that could be used to estimate the distribution in time and space of a new transgene (introgression and subsequent invasiveness of genotypes into which the transgene has been introgressed), or of a GM crop itself. The problem could be modeled as a single population, meta-population, or cell model (cellular automata) (Tilman et. al. 1997).

A single population model might be used were certain restrictive assumptions are thought to apply to demographic information such as fecundity, mortality, and movement rates between the sub-populations (for example see Thompson *et al.* 2003). A meta-population model may be applicable when a number of interacting populations are separated in space but may exchange individuals. Such models use the single population model described above with the addition of immigration and emigration rates between the component populations of the meta-population. At larger spatial scales, meta-population models may be combined with climate data from geographical information systems (GIS). A cell model might be applicable when the detailed distribution of organisms in a specific area is desired. Cellular automata have found applications in ecology where the spatial position of an organism is an important component of the system. To model

location and dispersal, we envisage a physically homogeneous habitat subdivided into patches capable of supporting a single adult individual. The patches, and associated information, are stored as cells within a computer simulation that represent the location of individuals (for example see Linacre and Ades 2004).

Whatever modeling approach is used, a number of assumptions are required. For plants, we need assumptions about pollen and seed dispersal, fecundity, mortality, compatibility, viability, and competitiveness. These assumptions are very specific to the system being modeled. As an example, consider pollen dispersal, which is a critical process controlling the rate and pattern of gene flow. Pollen can be dispersed by a variety of vectors: wind, insects, mammals, and birds. Several different dispersal processes may be superimposed, the importance of particular vectors may be quite different in long versus short distance dispersal, and the resulting dispersal pattern may be particular to the crop being modeled. In the case of GM crops, the type of gene may itself affect the rate of gene flow. Glover (2002) cites the example of insect protected cotton in which there has been a 37 – 54 percent reduction in insecticide use. This reduction may increase local insect populations, increasing the abundance of pollen vectors, therefore potentially increasing the rate of gene flow.

In the drought-tolerant example an ecological assessment would need to be done at the EIA level or the commercialization stage testing competitive ability and obtaining outcrossing and pollen and seed dispersal parameters. However, at an SEA level, if needed, assessment models could be developed based on the unmodified crop and any coding changes expected to influence outcrossing rates and pollen and seed dispersal

distances could be investigated. Some relevant data may also be available from confined field trails.

Socio-Economic Impact Analysis

At a strategic decision level there is a need to consider all relevant social benefits, costs, and risks of the release of competing biotechnology options. Benefit-Cost Analysis (BCA), is a well-developed tool which assists social decision-making, the objective being the efficient allocation of society's resources. To achieve this goal BCA attempts to capture all the features of policy decisions that affect the well being of society within a single index (Boardman et al. 1996, Lave 1996, Kopp et al. 1997). BCA therefore involves the calculation of social net benefits (benefits less costs) to society for comparison of competing options (opportunity cost) and external influences on society.

Taking drought-tolerance as an example the BCA may proceed as follows:

1. Estimate at a regional, sub-regional or farm level the impact of the introduction of the technology on production. In the case of drought-tolerance, yield improvements would accrue from improved survival of plants and improved ability to recover from drought stress.
2. Estimate the adoption rate and patterns among small, medium and large farmers. Generally large commercial farmers will be in a better position experiment with new technologies, partly because they have better communication with seed producers and partly because they are in a better position to allocate part of their production to a new technology, which may appear uncertain to offer uncertain benefits.
3. Using surplus models estimate the effect of changing supply on the market price received by poor farm households. In developing countries the majority of people (60-70 percent) depend directly or indirectly on productivity increases in agriculture to get out of poverty, and commonly spend 50 percent of their household income on food (Pinstrup-Andersen et al. 1999). However, changes in supply resulting in improved production may reduce the market prices offsetting increased yields resulting from the technology.

4. Estimate income distribution or the changes in income distribution. Generally not all farm households are the same and some farm households will benefit more than others.
5. Estimate and value any environmental damage. Generally this will be difficult because technologies will confer some environmental benefits and may cause some impacts. In many situations the environmental impacts will be the same as the existing non-genetically modified crop and the introduction of a GM crop would not affect the environmental risks associated with the status quo.
6. Estimate costs.
7. Calculate net benefits (benefits less costs).
8. Integrate with risk estimates. In practice, the BCA is performed by expressing all social benefits and costs on a common scale, usually monetary. In the simplest cases, expected value theory may be used as the method of integrating benefit cost analyses and risk assessments. A societal preference is then composed of the aggregation of net benefit (benefits minus costs) combined with probabilities. Decision-makers may then use this information to help guide choices between competing policy and project options.

Socio-economic impact assessment methodologies such as BCA and economic surplus models have been criticized on a number of grounds. In particular the utilitarian assumptions of these approaches that the aggregation of individual utilities should be maximized trading one person's utility gains against another person's utility losses (Boardman et al. 1996), may be problematic¹⁶. Some individuals may be asked to carry a disproportionate cost so that others may benefit e.g. (Roy 1999). For example, MacLean (1998) argues that BCA has fundamental problems because costs and benefits cannot be put on the same scale.

Given all these limitations and caveats we believe that Socio-economic impact assessment is a useful tool in Strategic Environment Assessments. It is particularly

¹⁶ Economists use the Pareto criterion (at least one person is made better off, no one is made worse off) and the Kaldor-Hicks criterion (the winners could compensate the losers) as a way to overcome this limitation and justify the use of BCA.

valuable for evaluating the potential economic behavioral response of individuals or groups to regulations and laws. For example, consider the problem of insect resistance management. In the United States, concern about the emergence of insect resistance in the European corn borer, prompted the establishment of refugia (areas set aside for planting non-genetically modified crops). Replication of similar policies in other countries may or may not be effective in managing the emergence of insect resistance. Much depends on the economic behavioral response of farmers to this added cost and the ability of regulatory agencies to enforce the rules (see for example, USEPA 2000). Economic behavioral analysis is essential because if an economic incentive exists for non-compliance, then the rules set by the Regulator are unlikely to be followed unless adequately enforced.

Considering its application in the CGIAR System, an ex-ante assessment of the socio-economic impact, especially the impact on poverty can also be considered as a management tool in its own right. Thus, strategic environmental assessment may become part of a more general strategic technology assessment, which considers economic, social and environmental implications in an integrated way.

Uncertainty Analysis

Typically decisions are made with incomplete information or intrinsic variability, which leads to uncertainty. This uncertainty needs to be incorporated into the analysis to assess the impact this might have on a decision. Once an appropriate risk assessment model has been developed, bounds must be placed on that risk estimate. This is also true for the economic analysis where uncertainty arises over the value of the environment and other assumptions, such as discount rates. There are a number of ways of incorporating

uncertainty about parameter values and assumptions into models. The following methods allow us to set bounds on results, giving a representation of confidence in the analysis (see Ferson et al. 1998).

Scenario (i.e., what-if) and sensitivity analyses are straightforward and assess the effect of uncertainty simply by altering the parameter values and repeating the calculation. Such an approach may become unwieldy when a large number of parameters are involved.

Worst-case analysis, which recognizes that uncertainty exists but does not try to model it explicitly, is the traditional approach to ecological risk assessment. The parameter values are set so that the overall risk estimate is conservative. It can be argued that such approaches result in overtly conservative estimates of risk and impose a high cost on society for little benefit.

Monte Carlo analysis combines probability theory and numerical analysis to model uncertainty in a way that reveals the probability of each possible outcome. Its usefulness depends on the availability of data to estimate parameters for statistical distributions. In many situations these data will not be available.

Interval Arithmetic provides another method for incorporating uncertainty. Most scientific disciplines quote best estimate values plus or minus an error term to indicate uncertainty. These measures can be expressed as intervals, which are closed, bounded subsets of the real line $[a,b] = \{x : a \leq x \leq b\}$. Intervals have mathematical properties that allow us to propagate uncertainty about best estimate numbers through a series of calculations. Fuzzy Numbers are a generalization of interval arithmetic that allows the bounds to vary according to the level of confidence one has in the estimation.

In the case of drought-tolerance, uncertainty will occur in the analysis, considering only the uncertainty associated with the performance of the drought tolerant crop, it may be reasonable to use Monte Carlo simulation approaches combined with Bayesian statistical analysis.

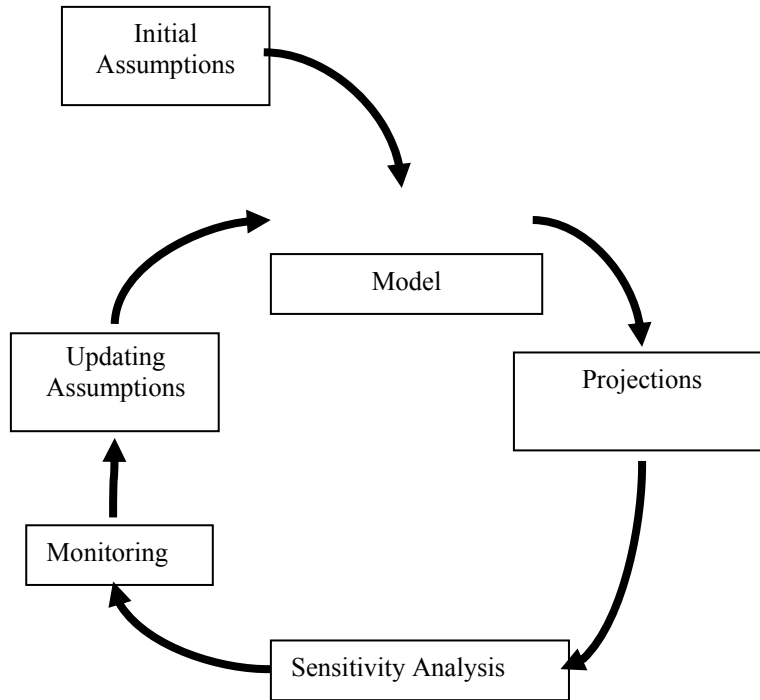
4. MANAGEMENT

It may be argued that at an SEA stage there is no need for risk management. However, potential risk management strategies may make some proposed activities acceptable. At this stage of the analysis decisions are required on risk management. There are three principle options available:

1. Accept the risk and recognize that a benefit-cost-risk trade-off was made.
2. Manage or control the level of risk, for example using confinement strategies and monitoring.
3. Avoid the risk by not undertaking the activity.

The impact of risk management can be incorporated into strategic decision-making using the control cycle paradigm (Figure 3), which integrates quantitative assessment decision-making and risk management (for example see Linacre et al. 2004).

Figure 3--The Control Cycle adapted from (Linacre et al. 2004). The Control Cycle shows an integrated way to manage risk. A model is developed and used to obtain projections. The sensitivity of the model is also used to identify important assumptions, which are then monitored and updated and feedback into the cycle.



An important use of the cycle is the identification, monitoring and feedback of critical assumptions. Once these assumptions have been identified risk management options can be investigated and incorporated in decision-making through feeding back changes in assumptions into the decision model.

5. PARTICIPATION AND COMMUNICATION

One of the principles of SEA is that it should be transparent and open. In line with this principle, participation is generally considered to be an essential step in a SEA procedure. Participation implies that “sufficient information on the views of all legitimate stakeholders (including the public affected) is available early enough to be used effectively in the preparation of the strategic decision” (Dalal Clayton and Sadler 2004: 15). The principle of openness and transparency also requires a documentation that makes the results understandable and available to all parties affected by the decision. It should also be communicated to the stakeholders, how the results of the SEA were taken into account in decision-making.

There are various forms in which public and stakeholder participation can be organized in a SEA. Birner and Alcaraz (2004) reviewed a number of approaches that have been applied in Europe for assessing biotechnology, including small-scale citizen juries (Switzerland), a national-level dialogue process among organized stakeholders (Germany), internet platforms with self-selected participants followed by conferences (France, EU), and a large-scale public deliberation process (United Kingdom). Stakeholder consultation processes on biotechnology have also been organized for developing countries.¹⁷

Even though these approaches formed part of a more general technology impact assessment, one can still draw implications for strategic environmental assessments (compare Birner and Alcaraz, 2004): The methods which are considered as appropriate and legitimate differ considerably between countries. For example, citizen juries

¹⁷ An example are the African Policy Dialogues on Biotechnology. See <http://www.ifpri.org/africadialogue/papers.asp>

involving a small number of lay persons appear to be more acceptable in countries with a small and homogenous population. Processes relying on organized stakeholder groups have the potential to achieve high legitimacy, but require that all major stakeholder groups are organized at the national level, which is hardly the case in developing countries. Large-scale deliberation processes are useful to reach a larger part of the public, but the costs and the managerial capacity required for this form of participation are high. For a SEA on biotechnology, it is recommended to draw on experiences with other participation processes in the country under consideration, and to place emphasis on creating legitimacy for the process by avoiding a “token participation” approach.

An important aspect of stakeholder and public participation in a SEA process is the communication of risk. Risk communication is probably the most important part of any risk analysis strategy for GMOs. However, for the strategy to have any credibility, it must be supported by objective and dispassionate evaluation and management of the identified risks. Over the years risk communication researches have developed some general risk communication principle that may be applicable to biotechnology risk communication (Slovic 1993, Fischhoff 1995). Any risk communication strategy needs to consider following issues:

1. A lack of communication may be misinterpreted as an attempt to ‘hide the truth’.
2. Experts and lay people often disagree about risk. Lay people appear to place greater emphasis on catastrophic consequences.
3. Risk comparisons are dangerous in risk communication. Anecdotal evidence suggests such comparisons are unpopular and may damage the risk communicator’s credibility.
4. People need information about the risks and benefits of any activity that could affect them. Together risk and benefits tell a story but neither does

alone. People are unwilling to take on additional risk, even small risks, when there are no clear benefits.

5. Market research of recipients' current beliefs and the effectiveness of the communication campaign are important.
6. Community participation and consultation are important to building relationships that are needed to dampen the social amplification of minor risks.

6. LEGAL AND INSTITUTIONAL ISSUES

Current countries international obligations are governed by the Convention on Biological Diversity through the Cartagena Protocol on Biosafety. The implementation of this convention is possibly the main driving force behind the development of biosafety legislation. However, in addition to a country's international obligations there are a number of legal and institutional questions that should be considered during an SEA for biotechnology including:

- Who has legal authority?
- Should existing legislation or new legislation used?
- Which agencies should be involved?
- Who should make the final decision?
- What activities are covered by the legislation?
- Are there any liability issues?

7. DISCUSSION

The SEA approach proposed here, which aims to promote rational and evidence-based decision-making, has potentials as well as practical challenges that must be

considered. Generally a good quality SEA process should inform decision-makers and stakeholders about the sustainability of decisions. The International Association for Impact Assessment (IAIA)¹⁸ suggests six performance criteria for SEAs: integration, sustainability, focus, accountability, participation, and iteration.

IS THE PROCESS INTEGRATED?

The process suggested attempts to integrate biophysical, social, and economic factors within the assessment. This involves challenges because biotechnology innovations may have both positive and negative impacts and it is often unclear how to treat different effects. Currently there are also impediments to integration of socio-economic impact assessment and environmental assessments. Problems arise because of the complexity of valuing the environment and the results of environmental assessments do not typically provide appropriate inputs for economic analysis. However, the progress made in environmental economics by using contingent valuation and other techniques helps to meet these challenges. Integration is achieved to some extent in current regulatory decisions processes for transgenic organisms. Typically, regulatory decisions about the release of transgenic organisms focus on the assessment and mitigation of risk, but such approaches represent only part of the decision equation. While regulators assume that private sector proposals take account of benefits, it is useful for public research institutions to assess the benefits *ex ante*, both for assessing to which extent it is worth taking risks, and for prioritizing their activities in general.

¹⁸ http://www.iaia.org/Members/Publications/Special_Pubs/sp1.pdf

IS THE PROCESS SUSTAINABILITY-LED?

The process should facilitate identification of development options and alternative proposals that are more sustainable. The identification of alternatives may be challenging, but at a minimum the proposal should be compared to current practice, which should lead to incremental improvements in environmental improvements. To some extent the options available for comparison will be defined by the political process and may not reflect the options available in an ideal world.

IS THE PROCESS FOCUSED?

The process should provide sufficient, reliable and usable information for development planning and decision making. It should concentrate on key issues of sustainable development for the area under consideration. It should be customized to the characteristics of the decision making process and it should be cost- and time-effective. The utility of the SEA process suggested in this paper will be more easily assessed after it has been applied to a number of case studies. The process is designed to provide reliable and usable information for development planning and decision making. However, there is a risk that having a defined assessment process will create a rigid and resource-intensive culture mired in endless iterations of analysis and, finally, paralysis of the decision-making process (see Therivel 2004:p3). While the approaches suggested in this paper aim to avoid this problem, we must be vigilant against the temptation to over analyze decisions.

IS THE PROCESS ACCOUNTABLE?

To make the proposed SEA process accountable, the decision-making bodies have to take the responsibility for this process and to document and justify how the

sustainability issues were taken into account in decision-making. Applying SEA in the CGIAR system involves important governance decisions. The responsibility for SEA may rest with the management of the individual centers or with governance bodies at the CGIAR level, such as the System Office. It is important to ensure that the analysis is performed from a neutral position on the technology under consideration, to the extent that this is possible. The analysis has to be made subject to independent checks and verification, such as peer-reviews of the individual steps of the analysis to increase its accountability. The usefulness of the analysis will depend on the quality, training, and objectivity of the analysts undertaking the valuation. The valuation of benefits and the choice of discount rates can be problematic, especially when non-market quantities are involved. For a variety of reasons, it can still remain difficult to optimize decisions. It is argued that cognitive limitations of the decision-makers force them to construct simplified models of the world to deal with decisions (Slovic et al. 1974b). The result is that while we strive to attain some level of satisfaction within constraints, we do not necessarily optimize (Simon 1956). There have also been few empirical attempts to justify the accuracy of BCA (Boardman et al. 1996). However, currently there is no better option as all valuation methods share almost the same set of limitations and caveats as benefit-cost methods. In addition, benefit-cost and economic surplus methods are the most widely used assessment methodology.

IS THE PROCESS PARTICIPATORY?

The process has been designed with participation and consultation as key elements. The open discussion of the process with donor organizations to the CGIAR System and other stakeholders is essential to the development of quality research. This

type of approach is contentious particularly in the area of biotechnology because of the level of opposition among some elements of civil society. To this extent careful consideration needs to be given to how the expert and lay panels are constructed and managed in the qualitative assessment phase. The risk is that a poorly managed process will not provide as such information to the analyst as it should.

IS THE PROCESS ITERATIVE?

The suggested process is designed to ensure the availability of the assessment results early enough to influence the decision making process and inspire future planning. The process should provide sufficient information on the actual impacts of implementing a strategic decision, to judge whether this decision should be amended and to provide a basis for future decisions. However, the realization of these goals will depend on the successful implementation of the process and the ability of the process and the researchers to deliver timely comprehensive policy advice. It is important to consider the process not as static. New information, for example on potential benefits or risks may alter strategic decisions taken on a program or policy. Feed-back mechanisms for new information are, therefore, important.

8. CONCLUSIONS

Few comprehensive analyses along the lines described here appear to exist in the literature. However, if informed decisions about the value of GMOs are to be made, then integrated SEAs using qualitative and quantitative assessments, covering gene flow, exposure-dose-response, decision analysis, and uncertainty estimation, are required. We

believe that such a process is likely to lead to more transparent and defensible decision-making in international agricultural research.

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