Conway, 1999a), thus contributing to increased inequity in some parts of the world.

It should be noted that while some of the social and economic effects of the Green Revolution — both positive and negative — were inherent in the technology itself, others resulted from the introduction of the new technologies into particular policy environments. For example, research by the International Food Policy Research Institute (IFPRI) showed that the widely shared benefits of adoption of high-yielding grain varieties in Tamil Nadu, India, were accompanied by the government's "active poverty alleviation strategies, including extensive social safety net programs and investment in agriculture, rural development, nutrition, and education, along with ... equity in access to resources such as land and credit" (Pinstrup-Andersen and Cohen, 2001). This experience illustrates the importance of identifying the unintended social and economic consequences of the introduction of new agricultural technologies, and taking steps to mitigate negative effects with proactive policy decisions where possible. This is true for all new technologies, and is relevant in developing countries and developed countries alike.

Of the many socio-economic issues related to modern agricultural biotechnology, a survey of which is provided in Section II of this paper, not all should be integrated into biotechnology policies or biosafety regulations. For conceptual and practical reasons, some socio-economic issues or concerns arising from modern biotechnology should be addressed through other means outside of biotechnology policy or biosafety regulations. For example, the identification of socio-economic issues to inform national research priorities or product development can be dealt with through voluntary processes implemented by research institutions and companies. Other concerns, like intellectual property rights or consumer-related issues, might be better addressed by laws that are specific to those issues rather than to biotechnology (e.g., patent laws or consumer rights laws).

Special mention should be made of the approach taken by the Cartagena Protocol on Biosafety, which is the international agreement negotiated under the Convention on Biological Diversity to provide for "the safe transfer, handling and use" of living modified organisms[2] (Secretariat of the CBD, 2000). Under Article 26 of the Protocol countries may take socio-economic considerations into account under certain circumstances when making decisions about biotechnology (see Box 1).

Section III of this paper suggests some principles and tools that countries could use to decide how socio-economic considerations should be integrated specifically into biotechnology policies or biosafety regulations — including but not limited to those under the Cartagena Protocol — as well as identifying some issues for which biotechnology and biosafety regulations are not appropriate. These principles and tools are initial ideas for taking socio-economic considerations into account in biosafety and biotechnology decisions; further analysis is necessary, both to develop international guidelines, and for individual countries to determine what types of regulations will best meet their goals and needs.

PUBLIC PARTICIPATION

A number of measures must be taken in order for socio-economic considerations to be effectively included in decisions on biotechnology, such as the provision of information and objective analysis about relevant socio-economic issues; and a strong regulatory system that includes these considerations when and where appropriate. In addition to, or perhaps as a part of, these conditions, the participation of the public is a key element for the inclusion of socio-economic considerations. It should be noted that public participation in research and in decision-making can help to identify, clarify, and resolve a number of issues related to modern biotechnology and not just socio-economic considerations.

In Section IV of this paper, we discuss the conditions necessary for successful public participation and introduce several types of public participation mechanisms or best practices that could be used by countries in biotechnology and biosafety decision-making process-

Box 1

Article 26 of the Cartagena Protocol

In negotiating the Cartagena Protocol, dealing with socio-economic considerations was a contentious issue and was not resolved until the very end of the negotiations. Most developing countries emphasized the need to include socio-economic considerations in biosafety decisions, while many developed countries argued that socio-economic considerations should be excluded (Mackenzie et al., 2003). The compromise that resulted is Article 26 of the Protocol, which reads as follows:

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.* (Secretariat of the CBD, 2000)

Because there was no extensive discussion during the Protocol negotiations on how to approach socio-economic considerations in practice, there is very little guidance on how Article 26 should be implemented (Mackenzie et al., 2003). Under paragraph 1, the Protocol appears to limit the scope of socio-economic considerations that governments may take into account in regulatory decisions to such circumstances as the impact of the import of LMOs on:

- The continued existence and range of diversity of the biological resources in the areas inhabited or used by indigenous or local communities;
- The loss of access to genetic and other natural resources, as a result of biodiversity loss, 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 the community's territory. (Mackenzie et al., 2003)

Article 26, paragraph 2, however, encourages Parties to the Protocol to cooperate on research and information exchange on any socio-economic impacts of LMOs, especially – but not limited to – impacts on indigenous and local communities. Socio-economic considerations are relevant to domestic biosafety decisions and not just to transboundary movement of LMOs. In this regard, countries may incorporate into their domestic regulatory regimes on biosafety socio-economic considerations other than those explicitly included in Article 26, as long as these rules comply with any other international obligations by which they may be bound (Garforth, 2004). At the same time, keeping to the spirit and letter of the Protocol could be prudent if Parties are to avoid disputes with their trading partners, such as complaints under the World Trade Organization.

es. This section also discusses how these mechanisms have been — and have not been — applied in two different countries, Indonesia and the Philippines.

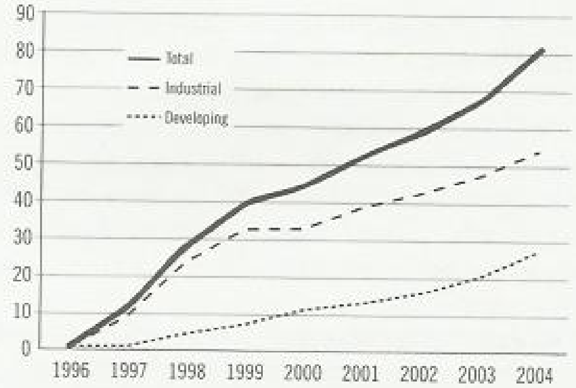
Finally, Section V includes a concluding discussion and recommendations for various actors in biotechnology and biosafety, such as the research community, industry, governments, and civil society.

II. SOCIO-ECONOMIC ASPECTS OF AGRICULTURAL BIOTECHNOLOGY

Agriculture is an important factor in many nations' economies because of the jobs and incomes it provides and because it is often an important source of hard currency. In developing countries, 51 percent of the population depends directly on agriculture for their livelihoods, and agriculture accounts for 12 percent of GDP, compared with developed countries, where only 7 percent of the population is involved in farming and agriculture accounts for less than 3 percent of GDP (FAO, 2004). Agriculture has the potential to contribute significantly to reducing poverty, not only among farming populations but throughout society. Where agriculture accounts for a large share of national income, employment, and export earnings, as is the case in many developing countries, "even a modest growth rate (in the agricultural sector) can have a significant leverage on the national economy" (Hazell and Haddad, 2001). This can occur directly, through the supply of basic foods for on-farm consumption, the production of market goods for increased farm income, or increasing employment opportunities for small farmers and landless laborers; and indirectly, through inducing growth in non-farm sectors by increasing the purchasing power of rural people or lowering food prices for all consumers.

Modern agricultural biotechnology has the potential to contribute to such growth and corresponding poverty alleviation. However, it is argued that the crops that have already been commercialized do little to meet the needs of the poor and may in fact marginalize them further (Nuffield Council, 2004; FAO, 2004). Certainly, since their introduction, the use of GM crops has increased consistently (see Figure 1) and their geographic distribution has diversified (see Table 1). The following section discusses these issues in greater detail, outlining the major claims supporting, concerns regarding, and research on, the social and economic implications of agricultural biotechnology.

Figure 1. Growth in Global Area (million hectares) of GM Crops, 1996–2004



Source: James, 2004

Distribution of benefits

Since the first GM crop was introduced on the market nearly one decade ago, researchers have made efforts to quantify and understand the benefits, as well as the costs, generated by transgenic crops. A common argument supporting agricultural biotechnology is that it could help combat one of the world's greatest challenges: food insecurity. One direct approach to combat food insecurity is to increase food production, while another is to increase incomes so that people are better able to buy food and other necessities. GM technologies could be relevant to both elements of food security (Royal Society, 2000). While so far very few GM staple food crops have become commercially available, crops such as Bt cotton have been adopted by millions of small-scale farmers in developing countries, with the potential to increase incomes and thus contribute to food security.

Worldwide, it appears that GM crops are generating significant wealth — a recent study estimated the total value of transgenic crops planted in five leading countries (amounting to 98 percent of global GM crop production) at US$44 billion in 2003-2004 (Runge and Ryan, 2004). Other economic modeling studies predict that further adoption of transgenic crops will continue to create economic benefits. One study by the Australian Bureau of Agricultural and Resource Economics estimated that GM crop adoption would result in a US$210.3 billion aggregate annual increase in gross national product (GNP) worldwide over the 10-year period from 2006 to 2015

TABLE 1. 2004 Distribution of GM Crops, by Country

Country	Types of GM Crops*	Million Hectares of GM crops	Percent of global total
Total		81.15	100%
USA	Bt maize, herbicide-tolerant maize Herbicide-tolerant soybean Bt cotton, herbicide-tolerant cotton	47.6	59%
Argentina	Herbicide-tolerant soybean Bt maize Bt cotton	16.2	20%
Canada	Herbicide-tolerant canola Bt maize Herbicide-tolerant soybean	5.4	7%
Brazil	Herbicide-tolerant soybean	5	6%
China	Bt cotton	3.7	5%
Paraguay	Herbicide-tolerant soybean	1.2	1%
India	Bt cotton	0.5	1%
South Africa	Bt maize Herbicide-tolerant soybean Bt cotton	0.5	1%
Uruguay	Herbicide-tolerant soybean Bt maize	0.3	<1%
Australia	Bt cotton	0.2	<1%
Romania	Herbicide-tolerant soybean	0.1	<1%
Mexico	Herbicide-tolerant soybean Bt cotton	0.1	<1%
Spain	Bt maize	0.1	<1%
Philippines	Bt maize	0.1	<1%
Colombia	Bt cotton	<0.05	<1%
Germany	Bt maize	<0.05	<1%
Honduras	Bt maize	<0.05	<1%

Adapted from James, 2004

* Bt plants are modified to produce an insecticidal protein derived from the bacterium *Bacillus thuringiensis*. These proteins act by selectively binding to specific receptors on the midgut of susceptible insect species, disrupting midgut ion flow and causing gut paralysis and eventual death due to bacterial sepsis. Herbicide-tolerant plants can tolerate applications of particular weed killing chemicals; the most common herbicide to which resistance has been genetically engineered into crops is glyphosate. Some crops with 'stacked' genes for both insect resistance and herbicide tolerance are also commercially available. These crops are Bt/herbicide tolerant maize and Bt/herbicide tolerant cotton.

(Abdalla et al., 2003). This scenario assumes the increased adoption of GM crops in all regions of the world, paired with reduced restrictions on the cultivation and import of GMOs in countries such as members of the EU.[3] Another economic model, applied by Anderson et al. (2001) to predict global welfare gains under different scenarios of adoption of GM grains and oilseeds, estimates annual gains of US$10 billion to 12 billion.

While models such as those discussed above help to make an economic case for the adoption of transgenic crops, at least on a global level, they do not necessarily present a complete picture of the situation. In addition, there are many factors to consider aside from the global generation of wealth. One issue that deserves attention, especially when considering the relevance of biotechnology to development and poverty alleviation, is the distribution of the value generated by transgenic crops. There are concerns that economic benefits will be enjoyed by farmers in developed countries, but not by farmers in developing countries; that companies that develop GM crops will be the primary beneficiaries, rather than farmers and consumers; and that within countries, biotechnology will contribute to inequity by favoring certain groups, such as large-scale farmers, while the needs of subsistence and small-scale farmers are ignored (Sahai, 2003; Duffy, 2001).

The concern that GMOs will benefit richer farmers while bypassing poor farmers is substantiated to some degree by the GM crops and traits that have been made available to farmers thus far. The majority of land area planted to GM crops — 66 percent — is in developed countries (primarily the USA and Canada), with the remaining 34 percent in developing countries (see Table 1). The global area of GM crops consists almost entirely of four crops — soy, maize (corn), cotton, and canola — with two traits: herbicide-tolerance or insect resistance (or a combination of the two) (James, 2004), which facilitate management and reduce loss from pests and weeds. Many argue that these crops and traits, while beneficial, are not meeting the most pressing needs of the poor (Lipton, 2001; Naylor et al., 2002; Spielman and von Grebmer, 2004). To address poverty and food insecurity, agricultural research should focus on staple crops with improved yields, enhanced nutritional values, and traits such as resistance to drought or saline soils that would allow them to grow better in marginal environments (Nuffield Council, 2004).

The choices made by companies regarding what traits to develop in which crops can largely be explained by the rules of the market: corporations that develop commercialized varieties of GM crops are responsible for making a profit for their shareholders. The consequences of this are that companies will develop products for which there is a strong market with customers willing and able to pay, i.e., large farmers in developed countries rather than subsistence farmers in developing countries (Pray and Naseem, 2003). In order to get a return on their investments in biotechnology, corporations tend to patent their transgenic products and charge higher prices for them than for conventional seeds (FAO, 2004). (For an in-depth discussion on patenting GMOs, see 'Intellectual property rights' section, below.) Under the current circumstances, where GM crops are developed and sold by the private sector, these higher seed prices have the potential to exclude farmers who can't afford such prices from enjoying benefits offered by GM crops.

It appears, though, that the high seed prices and the limited variety of GM crops available have not entirely prohibited small-scale farmers in the developing world from using — and benefiting from — GMOs (FAO, 2004). In some developing countries, adoption of modern biotechnology has occurred where small-scale farmers have begun planting GM crops already being used by large-scale operations in developed countries. For example, Bt cotton, which has been modified to contain a toxin (*Bacillus thuringiensis*, or Bt) that kills certain pests, is being planted in several developing countries in Asia, Africa and Latin America, and farmers in the Philippines are now growing Bt maize.

For national-level decision-makers, the most important issues related to the impacts of GM crops are not global ones, but rather the distribution of benefits or costs of adoption within a given country, such as which groups of people would gain and which would lose with adoption (or non-adoption); and how trade relationships will influence how particular national-level sectors are affected by the adoption of GMOs.

In terms of a sectoral breakdown of benefits, several studies indicate that, in general, farmers capture a high percentage of the wealth created by the adoption of GM crops. For example, in the case of 'Roundup Ready' soybeans in the US in 1997, 48 percent of the total (US$360 million) went to farmers, while Monsanto (the technology developer) received 22 percent, non-US consumers received 13 percent, seed companies received nine percent, and US consumers received eight percent (Falck-Zepeda et al., 1999, cited in Pinstrup-Andersen and Cohen, 2001). In South Africa, farmers received between 45 and 79 percent of the economic benefit generated by planting Bt cotton,[4] while Monsanto received from 20 to 52 percent, and Delta and Pineland (the seed supplier) received one to three percent (Gouse et al., 2004).

As GM crops are adopted in more and more countries, studies are beginning to show mixed results for actual differences in income between farmers planting these crops and those planting non-GM ones. In India, a recent study showed an average increase in yield for Bt over non-Bt cotton to be about 45 percent in 2002, and 65 percent in 2003, with Bt adopters earning much higher revenues than non-adopters (Bennett et al., 2004). Research has revealed that Bt cotton raised farmers' incomes in China (Pray et al., 2002; Huang and Wang, 2002; Huang et al., 2002) and South Africa (Shankar and Thirtle, 2003). In addition, it appears that these economic benefits are not necessarily limited to large-scale farmers. A study conducted in China, for example, indicated that smaller-scale farmers actually received a *greater* percentage increase in income from using the new seed than farmers with more land (Traxler, 2004).

However, in the US, several reports have indicated that farmers do not always gain higher returns from GM crops than from non-GM crops, and in some cases, profits decline (Fernandez-Cornejo and McBride, 2002; Duffy, 2001; Benbrook, 2001). In 1997, farmers growing Monsanto's herbicide-resistant cotton found that the crop did not perform as expected, with some cotton bolls deformed and/or dropping off plants. The problems appeared to affect about 20 percent of the transgenic cotton, and some cotton growers faced losses of US$500,000 to US$1 million (Hagedorn, 1997). In India, after several seasons in which Bt cotton has been commercially grown, the performance of the seeds is a subject of disagreement. A study carried out by the NGO Gene Campaign, for example, showed non-Bt cotton outperforming Bt cotton in terms of yield and overall profit in the 2002–2003 season (Sahai and Rehman, 2004). Research conducted by the Deccan Development Society and the Andhra Pradesh Coalition in Defence of Diversity over three years of planting Bt cotton found that adopting farmers had lower yields compared to non-Bt cotton in 2002-03, and, despite slightly higher yields in the following two years, still had lower net returns than non-Bt farmers all three years (Qayam and Sakkhari, 2005).

A complicating factor in attempts to assess the economic impact of Bt cotton in India is the apparent prevalence of Bt seeds that are not of the approved Monsanto variety, but instead illegal varieties that may have entered the supply chain from ongoing field trials (Sahai and Rehman, 2004). As farmers are reluctant to reveal what they are actually planting (and may not even be certain themselves), securing accurate data on the economic impacts of Bt cotton compared with non-Bt cotton is extremely challenging. Given this problem and the existence of conflicting studies, it is difficult to come to a conclusion regarding the actual performance of Bt cotton in India. Further studies to assess the economic impacts of modern biotechnology are necessary in all countries as farmers gain experience with GM crops.

Public sector research and development

The majority of commercialized GM crops have been developed by the private sector. While some of these have been adopted in developing countries, crops developed by public research institutes are more likely to be designed specifically for the needs of poor farmers in these countries (Cohen, 2005). Such needs include the major cereal crops and soybean (Naylor et al., 2002); staple crops that can tolerate stresses common in developing country agriculture, such as drought and acidic or saline soils; and 'orphan crops' such as tef, finger millet, yams, quinoa, cowpeas, and indigenous vegetables, roots and tubers (Naylor et al., 2002), which are planted primarily for subsistence rather than for trade on the world market and thus receive relatively little attention or investment from the private sector for research and development.

A number of public research efforts around the world are using modern biotechnology to develop crops and traits of specific use to farmers in developing countries. The Generation Challenge Program (GCP) of the Consultative Group for International Agricultural Research (CGIAR), for example, has identified drought tolerance in staple crops in developing countries, as well as some orphan crops, as an important focus for their work (Generation Challenge Program, 2004). The US Agency for International Development funds projects such as the Agricultural Biotechnology Support Program II (ABSP II), which aims to boost food security through "the safe and effective development and commercialization of bioengineered crops ... in developing countries." (ABSP II, 2004).

At the national level, some countries have invested significant public funds in agricultural biotechnology (See Table 2 for examples of public sector biotechnology research in developing countries). Bt cotton in China, for example, was introduced separately by Monsanto and by the public Chinese Academy of Agricultural Sciences (CAAS). It is difficult to determine what effects the strong presence of a publicly produced GM crop has had on the overall distribution of benefits from the crop, but some analysts suggest that the competitive pressure of the CAAS varieties may benefit farmers by forcing seed prices down and preventing Monsanto from establishing a monopoly (Eaton et al., 2003). In addition, biotechnology research and development (R&D) funded by the Chinese government has included stress-tolerant crops which, if commercialized, could be of particular use to the poor (Keeley, 2003).

According to a recent report from the International Food Policy Research Institute (IFPRI), the public sector is a "competent, but largely unproven, player for GM crop production in developing countries" (Cohen, 2005). Crops in the pipeline within public institutions face particular challenges, though; this is in part because they may include novel traits that have not yet been commercialized in other countries, while crops and traits that have already been approved in developed countries have familiar traits and are more readily approved. In addition, public institutions sometimes lack the financial resources necessary to achieve regulatory compliance. In Brazil, for example, the costs of regulatory approval for a single transformation event — including initial greenhouse and field screening, field testing for environmental impact, and food safety assessment — range from US$700,000 (virus-resistant papaya) to US$4 million (herbicide-resistant soybeans, which also require animal studies) (Cohen, 2005).

One way to address these financial problems could be for public institutions to enter into agreements or form partnerships with private companies to develop crops of particular relevance for poor farmers. Under such agreements, public institutions may negotiate to use a technology developed by a private company to modify a locally relevant crop. Terms of profit-sharing could be determined at the outset or negotiated once the product approaches commercialization (FAO, 2004).

Public-private partnerships have the potential to use resources more efficiently and thus distribute the

Table 2. Public Sector Research Grouped by Country, Crop, and Trait

Continent	Countries	No. events[a]	Crops	Phenotypic category[b]
Africa	Egypt	17	Cotton, cucumber, maize, melons, potatoes, squash and marrow, tomatoes, watermelons, wheat	AP, FR, FR/HT, HT, HT/IR, IR, OO, PQ, VR
	Kenya	4	Cotton, maize, sweet potatoes	HT, HT/IR, OO, PQ, VR
	South Africa	20	Apples, grapes, lupin, maize, melons, pearl millet, potatoes, sorghum, soybeans, strawberry, sugar cane, tomatoes, indigenous vegetables	AP, BR, FR, HT, HT/AP, IR, PQ, VR
	Zimbabwe	5	Cotton, cowpeas, maize, sweet potatoes, tomatoes	FR, HT/VR, VR
Asia	China	30	Cabbage, chili, cotton, maize, melons, papayas, potatoes, rice, soybeans, tomatoes	AP, FR, IR, VR
	India	21	Cabbage, cauliflower, chickpeas, citrus, eggplant, mung beans, muskmelon, mustard/rapeseed, potatoes, rice, tomatoes	AP, FR, HT/AP, IR, IR/BR, OO, PQ, VR
	Indonesia	14	Cacao, cassava, chili pepper, coffee, groundnuts, maize, mung beans, papayas, potatoes, rice, shallot, soybeans, sugar cane, sweet potatoes	AP, FR, IR, PQ, VR
	Malaysia	5	Oil palms, papayas, rice	HT, IR, VR
	Pakistan	5	Cotton, rice	HT, IR, PQ, VR
	Philippines	17	Bananas and plantains, maize, mangoes, papayas, rice, tomatoes	AP, OO, VR
	Thailand	7	Cotton, papayas, pepper, rice	AP, BR, IR, VR
Latin America	Argentina	21	Alfalfa, citrus, potatoes, soybeans, strawberry, sunflowers, wheat	AP, BR, FR, IR, IR/BR, OO, PQ, VR
	Brazil	9	Beans, maize, papayas, potatoes, soybeans	AP, BR, FR, HT, IR, PQ, VR
	Costa Rica	5	Bananas and plantains, maize, rice	AP, IR, VR
	Mexico	3	Bananas and plantains, maize, potatoes	IR, VR
Total		201		

Source: Cohen, 2005

Notes:

a. An event is defined as the stable incorporation of foreign DNA into a living plant cell undertaken by a given institute, resulting in a unique crop and trait combination.

b. The phenotypic categories are: AP–agronomic properties; BR–bacterial resistance; FR–fungal resistance; HT–herbicide tolerance; IR–insect resistance; OO–other; PQ–product quality; VR–virus resistance. The original title of this table is 'Transformation events grouped by country, crops and phenotypic category.'

possible benefits of biotechnology more widely than either public or private institutions acting alone. However, such partnerships have their skeptics who point to potential conflicts of interest or biases in research funded by private entities (Spielman and Grebmer, 2004; Clayton, 2001). Some critics would prefer to see the public sector avoid biotechnology research entirely while the public itself is still so divided over the universal appropriateness of such technology and while other less controversial aspects of agricultural research remain under-funded (Altieri and Rosset, 1999a). If the public sector does proceed in conducting R&D on biotechnology, this research should be geared toward public priorities — for example, developing crops that will help meet the needs of the poor. Identifying these priorities could be done through a participatory process led, for example, by the CGIAR. When such priorities are identified, mechanisms could be established to ensure that regulations are not overly burdensome so that products can be made available more quickly to those who need them.

Labor

GM crops may have an impact on labor demand and disproportionately benefit or harm certain sectors of the population. Crops that reduce the need for labor — for example, insect-resistant plants that require fewer pesticide applications (Ismael et al., 2002; Bennett et al., 2003) — could be beneficial in areas where labor supply is a restraint to production, as in parts of Africa where HIV/AIDS has reduced the working-age population (Nuffield Council, 2004). In addition, labor-saving crops are helpful to growers, who could reduce their expenditures on hired labor (Edge et al., 2001) or, where agricultural work is done by farm families rather than by hired labor, time usually spent working in the fields could be freed up for other activities such as childcare or education. However, labor-saving technologies could be economically and socially harmful in countries with low levels of mechanization or high working-age populations: in Asia, for example, working-age populations are expected to increase rapidly over the next 25 years (Nuffield Council, 2004). GM crops that reduce the need for labor, therefore, bear the potential to increase unemployment and inequity in some regions (de Janvry and Sadoulet, 2001; Nuffield Council, 2004). How changes in labor demand affect different sectors of society — particularly marginalized groups — is also important, and studies that address this issue would be useful.

Global markets

The profitability of any given crop depends in large part on its destination; the attitudes, tastes, and preferences of intended consumers; and competition in the market. In their global-economy modeling of the economic impact of GMOs, Anderson et al. (2001) suggest that trade relationships are a major determinant of a given country's benefits and losses related to the adoption of GMOs. Countries that adopt GM grains and oilseeds (which constitute most of the market for GM food crops) could suffer economically if their trade partners include countries that impose import bans or restrictions on GMOs because of consumer preference (recent and current examples include Japan and countries in the European Union). On the other hand, consumers in adopting or importing countries might benefit if GM crops result in significant yield increases, which could potentially lead to drops in commodity prices.

As an example of what these trade relationships could mean for developing country farmers, we look to Asia, where most developing countries are net importers, rather than exporters, of grains and oilseeds. As such, the model used by Anderson et al. (2001) predicts that the adoption of modern biotechnology by these countries would be more likely to bring economic benefits than losses, since domestic prices could go down as a result of increases in yield globally, and exports would not be significantly affected. If in fact the yield increases possible with GM crops result in decreases in commodity prices, it would be quite significant for poor consumers in developing countries, where people spend an average of 50 to 80 percent of their incomes on food, compared with an average of 10 to 15 percent in developed countries (Pinstrup-Andersen and Cohen, 2001). At the same time, although consumers would benefit under these conditions, farmers themselves may suffer if prices for their products fall.

Countries with significant export markets that are producers of GMOs and are able to distinguish and segregate between GM and non-GM varieties will be in a better position for international trade than those that have indiscriminately adopted the genetic engineering of crops as a core strategy in their agricultural production (Anderson et al., 2001). The separate production facilities and labeling that would be necessary for the effective segregation of GM and non-GM products, however, could have an impact on the price consumers pay. In the US and Canada, one study estimates that commodity costs could increase by 15 to 50 percent due to the implementation of parallel handling systems for GM and non-GM farm products, and final retail food prices could increase by 9 to 10 percent (Paarlberg, 2002). A study in the Philippines estimated the additional cost as 12 percent of current food prices (Leon et al., 2004). However, there is some skepticism about these figures, as it appears that a certain degree of segregation already takes place within the US food supply; therefore, according to one author, the costs of separating GM from non-GM foods may not be as high as predicted (Stabinsky, 2002).

In order to make decisions that will allow their countries' farmers to profit through trade, governments need comprehensive information on the major crops produced in their countries for which GM varieties are (or could become) available, the destinations of these crops on the global market, and the attitudes of consumers in these markets. When necessary and called for by importing countries, exporters may choose to segregate GM from non-GM crops, food, and other products.

Illustrating the challenges that GMOs could present for some countries' agricultural export industries is the reaction of several European companies when illegally grown GM papayas were discovered in Thailand in late 2004. In this case, Greenpeace and other NGOs accused a Department of Agriculture research station in Khon Kaen, northern Thailand, of 'leaking' some of their GM papaya seeds — which were not approved for commercial planting — to farmers in the region. After conducting tests, the government acknowledged the presence of GM papaya in farmers' fields and announced its intention to destroy all the papaya trees grown from the Khon Kaen station's seeds (Thais Destroy, 2004). Nonetheless, several companies in the EU stopped importing canned fruit products from Thailand, citing fear of contamination from GM papaya (Sukin and Sirisunthorn, 2004).

Competition

Within the developing world, some countries are beginning to feel pressured to legalize and develop GM crops as their neighbors adopt them, so as not to be 'left behind' or at a competitive disadvantage. Around the same time as the illegal GM papayas were found in northern Thailand, the Thai Prime Minister, Thaksin Shinawatra, announced his intention to lift an existing ban on commercializations of GM crops and to begin allowing more field trials. This decision was interpreted by many as a signal of the direction Asia would take regarding the use of modern agricultural technology to address problems of food insecurity. According to the research and conservation head of Green Power, an environmental research and advocacy organization in Hong Kong, "Generally Asia is becoming far more accepting of GMOs because many countries are developing and have growing populations that they can't feed" (Asia Heads, 2004).

In announcing his initial decision to lift the ban on growing GMOs, Prime Minister Thaksin Shinawatra expressed his concern that not legalizing field trials would cause Thailand to "miss this scientific train and lose out in the world" (Thailand May Overtake, 2004). His decision prompted concerns in other countries about being left behind; for example, in the Philippines, which was the first Asian country to approve the commercial planting of a GM food crop, a scientist criticized the local agriculture sector's "lack of resolve" to address food shortages, and warned that if Thailand lifted its ban, the Philippines could become a "laggard country" (Thailand May Overtake, 2004). However, the Thai Cabinet declined to consider the Prime Minister's plan to lift the ban on GM crops and ultimately the decision was reversed.

In addition to south-south competition, GM crops present the potential for a new form of competition between northern and southern countries. This could occur if substitutes for goods traditionally produced in the tropical climates of many developing countries, such as cinnamon, vanilla, or coconut oil, were genetically engineered to grow in the temperate climates of developed countries. Coconut oil, for example, is particularly valuable because of its high lauric acid content. A type of canola, which grows in temperate climates, has been engineered to produce lauric acid; this could potentially displace coconut production in Asia (Sahai, 2003; Stabinsky, 2000). The inverse, where crops or products currently produced in temperate countries are adapted to tropical conditions, is also possible.

Organic agriculture

Systems of production that explicitly exclude GMOs, such as organic farms, could face special challenges as a result of the presence of GM crops on the general market. There have already been reports of 'contamination' of both conventional and organic crops through cross-pollination from nearby fields containing GM plants (Freeman, 2004) and the inadvertent mixing of seeds. Standards and regulations for organic agriculture vary from country to country; in the US, organic farmers found to have GMOs unintentionally mixed in with their products will not necessarily lose their organic certification (USDA, 2000).

However, some farmers and food processors have lost business due to the presence of GMOs in their products. For example, Terra Prima, a Wisconsin-based organic food processor and wholesaler, sustained significant losses when they decided to recall and destroy 87,000 bags of tortilla chips found to contain GM corn. These losses were incurred not only from destroying the affected bags, but also from damaged consumer confidence and costs involved in instituting new testing procedures to avoid similar incidents in the future (Newell and Glover, 2003). In Thailand, the Prime Minister's intention to lift the ban on GMOs elicited concern from Thai organic trading businesses. According to a representative of an organic farmers' network, the organic market is currently worth at least 800 million baht (over US$20.5 million) per year, with expected annual growth rates as high as 20 to 30 percent (Samabuddhi, 2004).

Another concern for organic growers is the potential for pests to develop a resistance to the naturally occurring Bt toxin — which is approved as an organic pesticide — due to the toxin's dramatically increased presence in genetically engineered Bt crops (Altieri and Rosset, 1999a). Where exports or domestic consumption of organic products compose a significant percentage of a country's agricultural sector, governments may wish to consider policies that take special measures to safeguard these markets from 'contamination' or loss of pest control methods.

Intellectual property rights

Perhaps the most contentious issue related to biotechnology today is that of intellectual property rights (IPRs). IPRs, in general terms, allow developers of GMOs to patent a new transgenic variety and claim exclusive rights to that product, making it illegal for use in the countries where a patent is awarded without the user's agreement to meet conditions imposed by the company. In many cases, these conditions include payment of a 'technology fee' (to help cover the research and development investment) and signing a contract pledging not to save, replant, or sell the seeds from crops grown with the patented seed (Lambrecht, 2001).

Patenting living organisms is a recent legal development that causes concern for a number of reasons. One potential result of patenting transgenic plant varieties is the effective criminalization of centuries-old agricultural practices such as seed selection, saving, and sharing. Historically, farmers themselves have been the major innovators in agriculture, developing superior crops through their own selection processes. In the 1990s, 80 percent of crops planted in developing countries were sown from farm-saved seeds (Nuffield Council, 2004). With patented seeds, farmers' ability to save seeds for future planting is constricted and dependence on large multi-national companies increases (Yamin, 2003) because farmers must buy new seeds every season. In many communities, seeds also serve as a type of social capital, and sharing seeds provides a basis for interdependence among farmers within a community. If patented GM seeds become commonplace, the possibility exists for behaviors that form the backbone of traditional agriculture, such as seed-sharing, to become illegal, thereby eroding farming communities themselves.

IPR regimes differ from country to country, so their effect on the use of GM seeds will vary accordingly. In some developed countries, farmers have been sued by companies for patent violations (Kimbrell and Mendelson, 2005). Because most patents are filed in only a few developed countries, though, it is less likely that farmers in developing countries will face this particular problem (Pinstrup-Andersen and Cohen, 2001). However, in countries where a company does not have patent protection on a certain product, there may be other means by which to collect royalties, such as charging a fee on shipments of GM products from countries without patent protection to countries where patents are held for those products. This has been suggested for Monsanto's Roundup Ready soybean from Argentina, for example, where Monsanto does not hold a patent for this product (Argentine Farmers, 2005) and 'black market' Roundup Ready soybean seeds are sold at a lower price than the official Monsanto variety (GAO, 2000). With profits declining, Monsanto stopped selling their Roundup Ready soybean seed in Argentina in 2004, and as of mid-2005, the company was seeking greater enforcement of the country's seed certification laws (Argentine Farmers, 2005).

In addition to legal means of protecting intellectual property, some companies have developed — but have not marketed — a biological route called Genetic Use Restriction Technologies (GURTs). GURTs, broadly described, are GMOs that either produce sterile offspring (thus preventing farmers from saving and planting GM seeds from previous crops), or that require an outside stimulant — such as the application of a particular chemical — to activate an added trait's expression (Secretariat of the CBD, 2004). GURTs — nicknamed 'terminator technology' by activist groups — have generated a controversy and, although Monsanto pledged in 1999 not to commercialize products with these traits (Pringle, 2003), a worldwide debate continues regarding their use.

IPRs are a complicated issue because while they create new burdens for farmers and can slow down research and development processes by requiring scientists to negotiate with 'owners' of a technology necessary for research, they can also provide incentives for innovation and the development of new products that may be useful to society. While farmers in developing countries might benefit from weak IPR regimes by avoiding some legal challenges, such as lawsuits, ultimately they may be denied access to desirable technologies and products. For example, companies could decide not to operate in countries where they cannot patent their product and thus guarantee returns, or researchers may choose not to work in countries where they cannot patent their results (Who Owns, 2003). This could make it more difficult to develop GM crops that respond directly to the needs of farmers in such countries and could limit the access of farmers to products developed elsewhere.

Public opinion

Supporters of agricultural biotechnology often cite its potential to address world hunger by increasing the quantity of food available for the poor and hungry. This potential should be considered, though, in the context of the generally accepted statistic showing that current global food production is sufficient to supply the entire world population of six billion with an adequate diet, and that people go hungry because of issues of distribution, accessibility, and poverty rather than insufficient production (Persley, 2000;

Pew Initiative, 2004). While projections show the world population increasing by two billion over the next 30 years (FAO, 2004), beyond the current capacity of food production, without addressing the broader, systemic roots of hunger such as poverty, inequity, and poor governance, these problems may persist even if food production increases (Altieri and Rosset, 1999b). To gain broader public acceptance, GMOs will have to be perceived as something that truly addresses people's needs.

In addition, the stance that the public takes on GMOs sometimes reflects more than their opinion about the technology itself. In some cases, a deep mistrust of those who develop and market GM products, as well as those who regulate them, leads people to object to the introduction of GMOs. Particularly in the EU, after the region's experience with Bovine Spongiform Encephalopathy (BSE, also known as 'mad cow disease') despite assurances from government that the disease was not a problem (Pew Initiative, 2001; Economic and Social Research Council, 1999), people are skeptical of governments' ability to protect food safety and public health. The recent outbreaks of SARS and the avian flu in Asia could also have contributed to a heightened concern about public health and governments' ability to safeguard it. In Indonesia, concerns over government transparency and regulatory processes were significant drivers of a conflict surrounding the introduction of Bt cotton (Buchori et al., 2005).

Ethics, culture, and religion

For many people, the development and commercialization of GMOs has ethical, cultural and religious implications. One ethical consideration related to biotechnology is that of integrity or autonomy, which emphasizes the right of an individual to self-determination (Pascalev, 2003). This includes making informed choices about what one eats, which would require the segregation and labeling of GM foods. It also applies to farmers' choices about what they plant. Farmers who wish to plant GM crops should not be unnecessarily denied this opportunity where such crops have been proven to be safe for the environment and human health. On the other hand, the ability of farmers to choose not to plant GM crops should be preserved. Because of the ability of plants — including GM crops — to travel, spread, and reproduce without human aid, farmers have found unwanted GM crops in their fields (Kimbrell and Mendelson, 2004). By violating farmers' right to choose not to plant GMOs, the inadvertent spread of GM crops has ethical implications in addition to the market and legal ones discussed above.

Another common ethical principle is the 'utilitarian approach,' which uses the idea of cost-benefit calculations to determine a course of action that brings the greatest good to the greatest number (Purchase, 2002). Accordingly, supporters of biotechnology often make the case that GMOs will help address world hunger, and that this benefit for the many far outweighs possible risks (FAO, 2004). On the other hand, some people oppose biotechnology on the grounds that tampering with nature at the level of the gene is unethical regardless of the benefits it creates, or that non-human individuals, species, and ecosystems have intrinsic value and should be preserved as they are, without human-induced change (Myhr, 2000).

The use of agricultural biotechnology could also have cultural implications, in both a broad sense, wherein the concept of genetic engineering, or a particular GMO, is contrary to an individual's or community's cultural beliefs; and in the specific context of the Protocol, which recognizes cultural impacts that result from the effects of a particular GM product on biological diversity that is important to a society's cultural traditions, knowledge, or practices (Mackenzie et al, 2003). A recent example of the importance of cultural considerations in making decisions about GMOs is an ongoing controversy regarding GM maize in Mexico.[5]

There are many religious arguments both supporting and opposed to biotechnology. For example, some opposing biotechnology accuse scientists of "playing God," stating that altering creation in such a fundamental way, and patenting or otherwise claiming ownership of a life form, amounts to blasphemy (Warner, 2001). Practitioners of several religions may object to GMOs because the mixing of genes from different species could cause people to unknowingly eat something forbidden. Hinduism, Islam, and Judaism, for example, all have dietary laws that could be difficult to follow due to the presence of genetically modified foods in the market.

The above issues, however, have not led most religious leaders to speak against GMOs. On the contrary, according to Judith N. Scoville, an ethicist at Northland College, "Islam, Judaism, and Christianity concur that the process of genetically modifying plants or food animals is not in and of itself intrinsically wrong and may benefit mankind" (Pew Initiative, 2001). In fact, many religious leaders and scholars have acknowledged the potential for biotechnology to address world hunger, although some do so cautiously. One scholar, for example, provides a limited set of criteria for acceptance of GMOs, stating that "biotic rights (of non-humans) can be nullified only for 'just causes'" or as a "last resort," but that motives seen as "convenience, comfort, commodities, and commercialization" do not justify genetic modification (Scoville, 2000).

Given the diversity and subjectivity of religions and value systems worldwide, there is no single agreed-upon ethical, cultural, or religious framework within which GM crops can be evaluated. These issues should be included in biosafety decision-making on a country-by-country, or even case-by-case, basis. Research geared toward understanding some of the implications of specific ethical and religious principles for the application of biotechnology in agriculture would be a step forward in addressing people's concerns and developing more acceptable products. Thus, it has been asserted that: "To deal with the challenges presently arising from the desire for food safety we need science, to be sure, but we also need ethical reflection. To enhance mutual understanding a public dialogue about values in this complex field is urgently required." (Jensen and Sandoe 2002).

III. INTEGRATING SOCIO-ECONOMIC CONCERNS INTO BIOSAFETY DECISION-MAKING

The above discussion has introduced many of the potential social and economic impacts — both positive and negative — of agricultural biotechnology, pointing to the importance of considering these impacts when making decisions about its application. In this section, we outline what is needed to effectively take these issues into consideration when making decisions about biosafety.

The steps toward integrating socio-economic considerations into biosafety decision-making can be divided into two distinct tasks: *first*, social science research is necessary to clarify the socio-economic issues relevant to biotechnology and biosafety in different national and local contexts, as well as to generate information about the actual social and economic effects of the adoption of GMOs; *second*, the appropriate regulatory processes must be implemented and supported so that socio-economic issues are in fact adequately considered and addressed. In the latter task, effective mechanisms for public participation are critical.

CLARIFYING THE ISSUES: TOWARDS A RESEARCH METHODOLOGY

A research methodology is necessary in order to gain a better understanding of the social and economic impacts of modern agricultural biotechnology. Without such a methodology, the integration of socio-economic considerations into biosafety decisions can be problematic, as the appreciation of social and economic impacts could be left to the arbitrary discretion and judgment of political authorities. Without solid analysis and a regulatory framework in place, decisions-makers could justify the adoption of GMOs on socio-economic grounds, even in the absence of proven benefits. Conversely, even without proof of serious negative social or economic implications of a GM crop, regulatory authorities could deny approval because of purely political pressure from powerful constituencies. Good decision-making requires regulatory assessments using a credible research methodology that is based on the best available social sciences, multi-disciplinary, field-tested, peer-reviewed, and consistent with international standards as they evolve.

For developing countries in particular, the starting point for assessing any agricultural technology should be the needs of the poor. As stated by Gordon Conway, "It is very important for the 'new green revolution' to start with the socio-economic needs at the household level, and then use this information to develop research priorities, instead of the other way around." (Conway, 1999b). Broad socio-economics-based research that approaches modern agricultural biotechnology from a pro-poor food security angle, and thus considers and compares a range of potential solutions, is needed to address fundamental economic, social, ethical and cultural issues.

All research methodologies have their limitations, and this should be recognized when carrying out studies on the socio-economic impacts of biotechnology. Research needs to approach this issue from a variety of angles; both quantitative and qualitative information is useful, and some types of studies may be more appropriate than others for assessing economic versus social or cultural issues. In addition, different methodologies will be appropriate in different cultural contexts, such that what is useful in one country may not be helpful to researchers and decision-makers in other countries. The following section introduces a number of approaches that may be used to assess some of the socio-economic impacts of biotechnology discussed in Section II. This is not an exhaustive list, and further study is necessary to evaluate the effectiveness of each approach — and others — in addressing the issues at hand.

Economic modeling

An important research tool to aid in decision-making is economic modeling, which helps predict the economic effects of various policy choices. A number of researchers have used global models to examine the potential effects of the use of GM crop varieties in the context of several different policy or consumer preference scenarios. Exercises using global models and databases such as the economy-wide Global

Trade Analysis Project (GTAP) can make predictions about the overall economic impact of the adoption of GMOs, as discussed in Section II (Abdalla et al., 2003; Anderson et al., 2001). They can also help answer more specific questions, such as which countries will benefit or lose economically from their own — and other countries' — adoption of GM crops. These models take into account factors such as current and potential future policies, particularly bans on GMOs that may affect trade; patterns of trade for different crops and countries; and consumer attitudes toward biotechnology.

Cost-benefit analysis

Cost-benefit analysis (CBA) can be useful in determining the various opportunity costs and trade-offs of different approaches to biotechnology. Hall and Moran (2003) propose this technique to quantify or value the many perceived costs and benefits of the technology. Direct valuation — that is, expressing the various social, environmental, or health risks in monetary terms — is likely to be problematic, and the authors suggest an indirect approach that "clarifies the opportunity cost of not advancing the technological development and then asks whether society values the avoidance of potential costs by this much" (Hall and Moran, 2003).

Once valued, costs and benefits can be assessed within certain policy scenarios, with the end result an aggregate number; in theory, the scenario with the highest 'score' is the most desirable. In their assessment of GM crops in Scotland, Hall and Moran go a step further and consider costs and benefits under three categories of impacts: environmental, social, and economic. To take into account distributional equity questions, "costs and benefits can be considered in relation to affected parties, for example, GM farmers, non-GM farmers, local communities, biotechnology companies, research institutions, downstream industries, consumers and so on" (Hall and Moran, 2003). This creates a picture of who the winners and losers are under various scenarios. CBA would rely on socio-economic research to identify costs and benefits, and it would also require the involvement of the public in answering questions about both the value of the technology's benefits and the value of avoiding its potential costs.

Costs and benefits under various scenarios could be assessed in relation to many of the categories mentioned in the preceding section, such as labor, competition, trade, and markets; however, CBA is less applicable to ethical and religious arguments. It should be noted that different members of the public will place different values on these various benefits and costs, and that the quantification of different scenario outcomes generated through such studies should be considered along with results of other types of research, including qualitative exercises, for decision-making purposes.

Social impact assessment

The technique of social impact assessment (SIA) is incorporated into environmental impact assessments (EIAs) in many countries. SIA is defined as "the process of assessing or estimating, in advance, the social consequences that are likely to follow from specific policy actions or project development, particularly in the context of appropriate national, state, or provincial environmental policy legislation." (Burdge and Vanclay, 1995, cited in Stabinsky, 2000). SIA evaluates the probability and magnitude of potential impacts of biotechnology, in this case identifying the social groups on which these impacts may fall and investigating the equity aspects of their distribution (Lee & Bereano, 1981, cited in Stabinsky, 2000).

A wide array of techniques and variables, as well as both qualitative and quantitative data, can be used in SIA. Because of the qualitative nature of some data, assessments are not presumed to be "objectively" duplicable (Stabinsky, 2000). Therefore, the results of SIAs are subject to contest, especially when "... the benefits and the costs of the impacts are not evenly distributed, and a finding goes against the interests of either the major beneficiaries or those bearing the largest burdens of impact" (Stabinsky, 2000). Still, SIA can be used to predict — and therefore possibly avoid or mitigate — negative social impacts of developments or projects, including biotechnology. For example, using SIA to identify the distribution of benefits and costs to social groups from a particular GMO will begin to answer questions of equity raised in section II and provide a basis for decision-making. Such assessments can be carried out at any stage in a biotechnology project, from the inception of research to a final decision on commercial release.

SIA may not be applicable for all socio-economic assessments of biotechnology. It is most relevant when the regulatory system requires EIA as a condition for biosafety decisions, inasmuch as SIA is generally accepted as a complementary tool to EIA. In such a context, SIA is appropriate and should be encouraged. Box 2 summarizes internationally recognized principles of SIA that can be adapted for socio-economic assessments of GMOs.

Sustainable livelihoods framework

A method for socio-economics research at several levels is the Sustainable Livelihoods Framework (see Box 3), which was developed by the UK's Department for International Development (DfID) and has been applied to biotechnology issues by the International Food Policy Research Institute (IFPRI) (Falck-Zepeda et al., 2002).

The Sustainable Livelihoods Framework relies on surveys, focus groups, key informant interviews, in-depth household case studies, and secondary sources to generate data that is then used to analyze relationships between factors at the household, community, and regional levels to better understand causes of poverty and food insecurity. Research under such a framework could help to clarify some of the issues raised in section II, for example, the distribution of benefits. Knowing what crops are most important to small-scale farmers, how they are used, and if and how they could be improved, would help prioritize research programs so that overall agricultural R&D — possibly including modern biotechnology — could be more relevant to their needs. A better understanding of the market conditions for such crops would allow for more robust assessments of potential trade implications — especially for the poor — of particular GMOs, and focusing on livelihoods would illuminate questions of how new crops and traits might affect the demand for labor.

Box 2

Principles of Social Impact Assessment (SIA)

- Equity considerations should be a fundamental element of impact assessment and development planning.
- It is possible to predict many of the social impacts of planned interventions.
- Planned interventions can be modified to reduce their negative social impacts and enhance their positive impacts.
- SIA should be an integral part of all phases of the development process, from inception to follow-up audit.
- Socially sustainable development should be a focus, with SIA contributing to the determination of best development alternative(s) – SIA (and EIA) should be more than just an arbiter between economic benefit and social cost.
- In all planned interventions and their assessments, mechanisms should be developed to build the social and human capital of local communities and to strengthen democratic processes.
- In all planned interventions, but especially where there are unavoidable impacts, ways to turn affected peoples into beneficiaries should be investigated.
- The SIA must give due consideration to the alternatives of any planned intervention, especially in cases where there are likely to be unavoidable impacts.
- Full consideration should be given to the potential mitigation measures of social and environmental impacts, even where affected communities may approve the planned intervention and where they may be regarded as beneficiaries.
- Any assessment should incorporate local knowledge and experience and acknowledge different local cultural values.
- There should be no use of violence, harassment, intimidation, or undue force in connection with the assessment or implementation of a planned intervention.
- Developmental processes that infringe on the human rights of any section of society should not be accepted.

Source: Vanclay, 2003

Box 3

Sustainable Livelihoods Framework

The livelihoods approach emphasizes people and is aimed at attaining an accurate and realistic understanding of people's strengths (assets or capital endowments) and how they work to transform these into positive livelihood outcomes. The approach is founded on a belief that people require a range of assets to achieve positive livelihood outcomes; no single category of assets on its own is sufficient to yield all of the many and varied livelihood outcomes that people seek. This is particularly true for poor people whose access to any given category of assets tends to be very limited. As a result, they have to seek ways of nurturing and combining what assets they do have in innovative ways to ensure survival.

In assessing agricultural technologies such as modern biotechnology, researchers may ask the following types of questions:

- Which groups within society produce which crops?
- How important is each crop to the livelihoods of the groups that produce it?
- Is the revenue from a given crop used for a particular purpose – e.g., is it for child health or nutrition?
- What proportion of output is marketed?
- How do prices for different crops vary through the year, and how predictable is this price fluctuation?
- What proportion of household food needs is met by the household's own production and what portion is purchased?
- At what time of year is cash income most important (e.g., when school fees are collected)? Does this coincide with the time at which cash is most available?
- Do people have access to appropriate financial service institutions to enable them to save for the future? Does access to these vary by social group?
- How do income-earning opportunities vary throughout the year? Are they agricultural or non-farm?

Source: DfID, 2000

Systemic 'relevance assessment'

The systemic 'relevance assessment' is an emerging type of study that could prove useful in determining the appropriateness of a transgenic crop. This method applies the concept of 'relevance' to agricultural innovations such as new biotechnologies at two levels: the crop level — that is, the innovation's ability to overcome specific agricultural problems — and the broader regional level, such as the innovation's ability to meet farmer needs and fit within the general public's goals. It also uses the system approach to integrate the parts — and interactions between the parts — of an entire system, such as farming, rather than focusing on just one part of a greater system (see Box 4).

This type of assessment is a relatively new research approach, but it is unique in that it focuses on "the problem for which a transgenic plant has been created... rather than on the innovation" (Vanloqueren and Baret, 2004), and uses stakeholder interviews, a literature review, and secondary data to compare the innovation — biotechnology — with other strategies and innovations to address the problem. This emphasis on need and alternatives should be part and parcel of a research methodology on socio-economic issues related to biotechnology.

Priority-setting through participatory research

When the socio-economic implications of various applications of biotechnology are better understood, they could be incorporated into priority-setting for R&D so that new biotechnology products are geared toward expressed needs. Involving the end users of GM products — i.e., farmers — in selecting traits and crops, and, where possible, plant breeding, could be key in the development of GM products that specifically aim toward poverty alleviation (Nuffield Council, 2004).

In fact, most of the types of research described above should be participatory in nature so as to include the experience and knowledge of those whose livelihoods have been or could be most affected by agricultural biotechnology. Participatory research also lays the foundation of meaningful public participation in regulatory and other decision-making processes.

Box 4
Steps in a Systemic 'Relevance Assessment'

1. The system approach

- Determine the source of the problem for which the innovation (e.g., a particular transgenic crop) is being introduced as a solution and/or identify the main objective pursued by the innovation;
- Examine all existing current agricultural practices and innovation pathways that could contribute to this objective;
- Analyze the interactions between the strategies and their socio-economic environment (technical, socio-economic and socio-political obstacles or stimulants to the development of each innovation);
- Assess potential advantages and drawbacks of the specific transgenic plants.

2. Relevance assessment

- Identify stakeholders in the case at hand (e.g., farmers, breeders, consumers, and sellers);
- Circulate information about the problem, potential strategies, and innovations to address the problem now and in the future amongst the stakeholders;
- Solicit from stakeholders assessments of the strategies as well as their input on various policy instruments and research activities – such as biosafety regulations, agricultural policies, and crop research and development – relevant to the strategies;
- Carry out evaluation of these stakeholder opinions vis-à-vis current policies and research activities to inform recommendations.

Source: Vanloqueren and Baret, 2004

Toward a research methodology: integrating approaches

Understanding the socio-economic implications of biotechnology is complex because of the many levels at which impacts occur, as well as the potential of an innovation to generate significant positive as well as negative effects. Each of the above-described research approaches could be useful for some issues or concerns but not for others, and a comprehensive research methodology to assess socio-economic considerations requires the combination of several approaches. For example, while economic models and cost-benefit analyses are helpful for decision-making because they generate quantitative results, they can be limited in their ability to portray the actual *value* of various outcomes, which for many people and cultures cannot be assigned a dollar amount. In addition, economic models rely on a number of assumptions, such as yields produced by different plant varieties, world prices, and consumer response, and they may not be able to include all the possible factors that will determine a particular economic effect of, in this case, a new agricultural technology. Thus, their results need to be understood as potential, not certain, outcomes of different scenarios. Likewise, while research such as the sustainable livelihoods framework can generate a rich body of information, its qualitative — and potentially conflicting, as it will comprise various points of view — nature can make it difficult to use as a basis for decision-making, and the narrow, household-level research approaches could fail to address broader, country-wide issues.

Thus, a combination of research approaches, rather than any single method, is necessary to better understand the socio-economic implications of biotechnology discussed in Section II of this paper, and to inform decision-making. Table 3 illustrates this combination of approaches, providing illustrative questions that the different approaches could help to answer regarding a given issue or concern. The table also demonstrates how a given research approach may not be applicable for certain issues. For instance, most of these methodologies are not designed to assess the religious and ethical implications of GMOs. The range of research questions generated by the approaches included in the table illustrates the importance of an integrated methodology that can generate a robust understanding of the various socio-economic issues associated with biotechnology.

TABLE 3. Research Approaches to Assessing Socio-economic Implications of GM Crops

	Economic Modeling	Cost-Benefit Analysis	Social Impact Assessment	Sustainable Livelihoods Framework	Systemic 'Relevance Assessment'	Participatory Research
Distribution of benefits	Which countries will benefit or lose from the adoption of a GM crop?	How are the costs and benefits created by the introduction of a given GM crop distributed among different groups in society?	Which people or groups of people will benefit or lose from the introduction of a given GM crop?	Which crops do different groups produce or need?	What is the problem to which GM crops respond? Who is affected by these problems and could benefit from the innovation?	Primary stakeholders – such as farmers – should be interviewed regarding whether and how they benefit from GM crops.
Public sector research and development		How will different R&D approaches affect various institutions – both internationally and within countries?		What new types of crops would be most useful to farmers?	What types of R&D would produce innovations that address problems identified through a systemic relevance assessment?	Any public sector research on GM crops should be conducted in consultation with the end users, e.g., farmers.
Labor	Which labor markets – among and within countries – will be affected by the introduction of GM crops?	How will laborers and employees benefit or lose with the introduction of different GM crops?	Who performs the labor required for various crops? How would this change with the introduction of a given GM crop?	What labor requirements do various crops have, and who performs this labor?	If labor issues are identified as a problem, does a given GM crop help to solve these problems?	Both agricultural laborers and employers can help provide information about the impact of GM crops on labor supply and demand, and what types of labor are needed.
Markets (includes issues of competition and niche markets, e.g., organic)	How will international trade in agricultural goods be affected? Which countries might lose or gain export partners? Which countries might see increases or decreases in commodity prices?	Which crops and types of markets will see a gain or a loss from the introduction of different GM crops? Who depends on these markets?		Which crops are kept for household consumption, and which are sold on the market? How do prices for crops change throughout and between years?	What is the influence of markets on various agricultural systems and agricultural innovations? Does the main market system stimulate some innovations and create obstacles for others?	Farmers should be included to share information on how markets for particular agricultural products have changed with the introduction of GM crops.
Intellectual property rights	What are the economic implications – e.g., costs of agricultural inputs and products – under various IPR regimes?	Are there any costs or benefits associated with IPRs that affect producers and/or consumers? How do researchers and companies involved in biotechnology benefit or lose from IPRs?	What will the positive and negative effects of IPRs be (e.g., on seed prices or domestic research), and who will be affected?	How are seeds obtained? What role, if any, does seed saving and/or sharing play?	Do some institutional frameworks (such as IPRs) have an influence on the commercial success of different innovations in solving a particular crop problem (e.g., disease, insect damage, weeds)?	Participatory research would enable the sharing of information regarding whether and how IPRs have affected farmers' access to seeds, and any legal issues that may arise from patents on GM seeds.
Public opinion	How does public opinion affect how markets function and which countries trade with each other?		What cultural values relevant to biotechnology are held by communities that may be affected by the introduction of GMOs?			Research on public opinion is necessarily participatory in nature.
Ethics, culture, and religion		Will some farmers and/or consumers lose control over their production and consumption choices as a result of GM crops?	Do affected communities hold ethical, cultural, or religious beliefs that are violated by genetic engineering?			Members of the public, including consumers and farmers, can contribute to discussions on how their religion, culture, and/ or ethical beliefs relate to biotechnology.

CLARIFYING THE PROCESS: INTEGRATING SOCIO-ECONOMIC CONSIDERATIONS

Careful research clarifying the socio-economic issues related to biotechnology is essential, but is not in itself sufficient to integrate socio-economic considerations into biosafety decisions. To build on a credible research methodology that yields excellent information and analysis, mechanisms must be designed and implemented so that the results of socio-economic assessments are in fact taken into account in regulatory decisions about biosafety.

Socio-economic considerations can be taken into account in at least four different phases of biosafety decision-making: (1) during the development of a domestic biosafety regulatory regime; (2) during the risk assessment for a particular modified organism; (3) after a risk assessment; and (4) during the appeal, review, or renewal of a permit for import or commercialization (Garforth, 2004). Socio-economic considerations, therefore, can be integrated into policy as well as regulatory decisions. Policy decisions refer to general principles and strategies that countries may adopt with respect to the technology, while regulatory decisions involve everything from approval or denial of field trials or commercial releases of GMOs to enforcement decisions when conditions provided for such approvals are violated.

Different socio-economic aspects of biosafety and biotechnology can be addressed with different research methodologies; at different points in the product development and decision-making process; and through different regulatory mechanisms, both within and outside of biosafety instruments. For example:

- **Distribution of benefits.** Economic modeling and CBA could be conducted after a risk assessment to predict what the effects of a given GM crop or product could be on different sectors of society. A Social Impact Assessment, if it is part of a mandatory EIA, could be conducted during risk assessment. In addition, the sustainable livelihood framework could be used to gather preliminary information on socio-economic conditions that might be affected by GM crops and could be carried out before or during policy-making, or outside of biosafety.
- **Public sector R&D.** Participatory research to determine priorities for public research and product development should occur outside of biosafety processes and far in advance of any regulatory decision-making point. Guidelines or policies on such priority-setting could be a part of national agriculture policies or institutional rules.
- **Markets.** Economic modeling and CBA would be useful tools to anticipate how GMOs could affect markets. More directed studies, such as a systemic 'relevance assessment,' could be conducted after a risk assessment to provide more detailed information on how specific sectors, such as organic markets, would be affected by the adoption of a particular GMO.
- **IPRs.** Issues related to intellectual property rights can be addressed with separate IPR laws rather than through a National Biosafety Framework or other specific biosafety regulations. Models that predict the economic impact of various IPR scenarios would be useful to national level decision-makers during formulation of such laws. In addition, participatory research methods that involve farmers would help provide information about the actual and potential micro-level impacts of these IPR regimes.
- **Ethics, culture, and religion.** An SIA that includes ethical, cultural, and religious issues could be conducted after risk assessment or during risk assessment where it is part of a mandatory EIA.

A few countries have taken steps to directly incorporate socio-economic considerations into their regulatory processes (see Box 5).

Practical mechanisms and steps are necessary for socio-economic considerations, where appropriate, to actually be integrated into biotechnology and biosafety decision-making. These could include:

- Policies that mandate integration of socio-economic considerations into decision-making processes;

Box 5

Examples of Socio-economic Considerations in Regulations and Policy Processes

South Africa: The Genetically Modified Organism Act, passed in 1999, controls the production, importation, distribution, and environmental release of GMOs. The act established an Executive Council responsible for advising the government on authorizations of GMOs. The Council is to take into account socio-economic issues related to labor and trade impacts; a separate body, the Scientific Advisory Committee, assesses potential environmental risks associated with the release of GMOs into the environment. The Committee submits their findings and advice to the Executive Council, which then formulates a final recommendation on authorization. In this way, the Executive Council is able to include non-science issues in the decision-making process "without prejudicing the science-based evaluation process" (World Bank, 2003).

Argentina: All environmental releases, human food, and livestock feed uses of GE products must undergo both a scientific risk assessment and an economic analysis. The economic analysis, performed by the National Directorate of Agrifood Markets under the Argentine Secretary of Agriculture, Livestock, Fisheries and Food, studies the potential impact of the approval on domestic and international markets (World Bank, 2003).

Indonesia: The Draft Regulation regarding "safety of living organisms and foods of biotechnological products produced through genetic engineering" states in Article Three that a prudential approach shall be applied with the purpose of achieving the safety of living organisms, foods and feeds by "taking into account religious, ethical, social-cultural and aesthetic aspects." (Draft Regulation of the Republic of Indonesia, 2001).

New Zealand: Procedures for the introduction of LMOs in New Zealand fall under the Hazardous Substances and New Organisms Act. The definition of "environment" under this act includes, among other elements, "social, economic, aesthetic, and cultural conditions that affect the matters stated in paragraphs (a) to (c) of [the] definition or that are affected by those matters" (Stabinsky, 2000). Proponents wishing to release an LMO must include information with particular regard for "the maintenance and enhancement of the capacity of people and communities to provide for their own economic, social, and cultural well-being and for the reasonably foreseeable needs of future generations;" and "the relationships of Maori and their culture and traditions with their ancestral lands, sites, *waahi tapu* (special or sacred site), valued flora and fauna and other *taonga* (something valued or treasured) (New Zealand ERMA, 1997, cited in Stabinsky, 2000).

Norway: The Gene Technology Act of Norway states as its purpose "to ensure that the production and use of genetically modified organisms takes place in an ethically and socially justifiable way." The law states that for approval for environmental release of an LMO, "significant emphasis shall also be placed on whether the deliberate release represents a benefit to the community and a contribution to sustainable development" (Norway Ministry of Environment, cited in Stabinsky, 2000).

Philippines: The draft of the executive order establishing the National Biosafety Framework (NBF) of the Philippines includes several sections related to socio-economic considerations. One general principle listed is that, in implementing the NBF, "the socio-economic, ethical and cultural benefits and risks, of modern biotechnology to the Philippines and its citizens, and in particular on small farmers, indigenous peoples, women, small and medium enterprises and the domestic scientific community, shall be taken into account." The order defines risk management as a process of examining policy alternatives that includes factors relevant to the protection of, *inter alia*, socio-economic considerations. In addition, the National Committee on Biosafety will include a social scientist and an NGO representative. The framework also considers views submitted by local governments related to socio-economic considerations, and in some cases, a socio-economic impact evaluation may be conducted (Draft Executive Order, 2004).

- A clear definition of 'socio-economic considerations' and explicit criteria to determine when socio-economic assessments are required;
- Identification of the stages at which socio-economic assessments should take place;
- Efficient and cost-effective regulatory processes; and,
- Public participation mechanisms to ensure credible assessments and decisions that are more widely accepted.

National biotechnology and/or biosafety laws and policies that are explicit in requiring that socio-economic considerations be taken into account when making both policy and regulatory decisions are necessary. Such laws and policies might expressly provide that biosafety decisions shall consider national priorities such as poverty alleviation, food security and sovereignty, rural development, and the development of science and technology. They could also state that the determination of national priorities shall be based on the country's constitution and other important laws.

Decision-makers should have a clear definition of what issues and concerns are to be included under the concept of socio-economic considerations. It might be advisable, for example, to have a detailed list of what socio-economic considerations can be taken into account. However, the list should not be considered exclusive, as there may be additional issues and concerns that cannot be anticipated. It might also be useful to specify the sectors or stakeholders that could be particularly affected by biotechnology, such as small-scale farmers, indigenous peoples, women, small and medium enterprises, and the domestic scientific community.

Socio-economic assessments may not be necessary in all cases. Governments, in consultation with affected stakeholders, will have to identify criteria to determine when such assessments should be mandatory. For example, if agricultural biotechnology research is conducted for principally scientific purposes with no intent to commercialize a product, governments might decide to make socio-economic assessments voluntary. Products that address urgent health or environmental problems might also be exempted or require simplified assessment processes. When a new product is introduced that is essentially the same as other products that have undergone socio-economic evaluations, including those conducted in other countries that share social and economic characteristics, new assessments may not be required.

The stages at which socio-economic assessments are required will need to be identified in the appropriate biosafety regulations. For example, it appears that unless there are exceptional circumstances requiring an earlier evaluation, full blown socio-economic assessments are best conducted during the field trial phase or before commercial release. To require them at an earlier stage, such as when the GMO is still being tested in the laboratory or in contained use, might be too onerous to the scientific researcher or company and could thus be a disincentive for research and development. Researchers, however, should be encouraged to conduct preliminary assessments as early as possible so that issues and concerns are addressed early in the research process; such assessments will need to be integrated into project work plans and research budgets.

Governments will also need to design processes to make socio-economic assessments as efficient and cost-effective as possible. For example, strict timeframes for the assessments should be established so that there is no undue delay in making decisions. Procedures should be streamlined so that socio-economic assessments are integrated into other required regulatory processes such as EIA. Human and technical resources from government agencies, academic institutions, and other similar organizations could be combined to reduce the expenses associated with conducting such assessments.

Finally, public participation is critical for the integration of socio-economic considerations into biotechnology and biosafety decisions. Public participation, as discussed in the subsequent section, can help to identify, clarify, and resolve socio-economic concerns and issues related to modern biotechnology. Public participation related to biotechnology decisions is not limited to socio-economic considerations, but also has a role to play in identifying environmental, health, and other associated risks, and determining what levels of risk are acceptable to society. Conversely, public participation is not the only means by which to address socio-economic issues related to biotechnology; experts must also be involved in carrying out systematic social science research and analysis on socio-economic issues to guide decision-making. Nonetheless, the public has an important role to play in identifying socio-economic issues related to biotechnology and in determining how these issues should be addressed.

IV. THE ROLE OF PUBLIC PARTICIPATION

Public participation and transparency in decision-making processes are increasingly recognized as essential elements of good governance and sustainable development. When the views of all relevant stakeholders are taken into account through informed and meaningful participation, public concerns can contribute to the formation of more appropriate and acceptable policies and decisions. Governance should involve all stakeholders, even though authority may remain with state bodies (Petkova et al., 2002).

The 'Access Principles' in Principle 10 of the Rio Declaration of the 1992 Earth Summit articulated the following responsibilities of states: to provide appropriate access to publicly-held information; to give the opportunity to participate in decision-making processes; to facilitate and encourage public awareness and participation by making information widely available; and to ensure justice through liability and accountability measures (Petkova et al., 2002). These access principles represent fundamental norms of transparent, participatory, and accountable governance that are essential in realizing sustainable development objectives.

The Cartagena Protocol on Biosafety includes the right to public participation in Article 23 (see Box 6). Parties to the Protocol are urged to promote and facilitate public awareness, education, and participation in dealing with GMOs. Governments are also mandated to consult the public in the decision-making process regarding GMOs and to make the results of such decisions available to the public. Civil society has an important role to play in implementing Article 23. For example, they could develop indicators to assess the government's performance with respect to this provision.[6]

Public participation in decision-making is not a single-method, simple activity with discrete steps leading to perfect decisions; there is not a "universal prescription or standard formula. [...] What works in some places or in some circumstances will not work everywhere" (Glover et al., 2003). Instead, public participation is an adaptive, iterative process that will be unique to each setting. Governments and other bodies charged with or interested in implementing public participation in biosafety decision-making are faced with a number of questions, such as:

- What is necessary for effective public participation?
- When can and should public participation occur in the decision-making process?
- What forms can public participation take?

Box 6

Public Participation in the Cartagena Protocol on Biosafety

ARTICLE 23: PUBLIC AWARENESS AND PARTICIPATION

1. The Parties shall:

(a) Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health. In doing so, the Parties shall cooperate, as appropriate, with other States and international bodies;

(b) Endeavor to ensure that public awareness and education encompass access to information on living modified organisms identified in accordance with this Protocol that may be imported.

2. The Parties shall, in accordance with their respective laws and regulations, consult the public in the decision-making process regarding living modified organisms and shall make the results of such decisions available to the public, while respecting confidential information in accordance with Article 21.

3. Each Party shall endeavor to inform its public about the means of public access to the Biosafety Clearing-House.

Source: Secretariat of the CBD, 2000

CONDITIONS FOR PUBLIC PARTICIPATION

Information

In order for the public to participate in decision-making about biotechnology, they must have access to relevant information. Depending on the level at which decisions are being made, the public should be informed about biotechnology in general and about the basic nature and purpose of the organism or organisms being considered for import or introduction. The public should have access to information from assessments that have been performed, including scientific risk assessments on possible harms to human health and the environment and information generated through the various types of participatory social science research described above, such as SIAs. Issues such as commercial confidentiality need to be treated carefully, so as to provide maximum information to the public without allowing transparency requirements to deter companies from working in certain countries.

Ideally, the government would take responsibility for the generation and provision of information about biotechnology, taking care to preserve its neutrality. Such information would acknowledge potential negative impacts of the use of particular GMOs — for example, potential loss of export markets — but also point out possible positive impacts such as increased profits for farmers if pest damage declines with the use of GM seeds. Information should also be available on other issues that the public has identified as important to the decision-making process. On this note, it should be recognized that information-sharing is a two-way process in which consultation with the public is necessary to determine what sort of information communities want and need in order to participate effectively in decision-making (Glover et al., 2003).

Reaching the public

Even where appropriate and balanced information about biotechnology has been produced, it can be a challenge to effectively distribute this information to the public. In developing countries in particular, typical media such as newspapers, television, and the Internet, are effective in reaching only a small subset of the public, namely the educated, urban upper/middle-class. Additional effort may be necessary to reach the broader public, especially since a key group of stakeholders in biotechnology issues consists of the rural poor, who are often isolated and minimally educated. A number of other means for information-sharing have been identified, including local language literature, radio, street theater, farmer field schools, NGOs working in communities, and government extension systems. Whatever the means of communication, care must be taken to ensure that information is balanced and objective and that the distributors are generally credible and trusted.

Creating space

The public's access to information and participation — particularly related to controversial issues such as biosafety — hinges on democratic principles. The rights of citizens to request information, and the obligation of the government to provide it, needs to be incorporated into a country's legal framework (Petkova et al., 2002). In addition to providing information, the government must create the space for the public to participate in discussions and decision-making regarding biotechnology. This space should include the opportunity to discuss the public's concerns, which, experience shows, often include socio-economic considerations at the forefront (Stirling and Mayer, 1999).

In undemocratic or newly democratizing countries, both the public and the government face additional challenges in creating such conditions. If the public has not traditionally been allowed to make their opinions known on policy matters, they may be reluctant or even afraid to ask for information and to express their thoughts, even if they hold strong opinions on biotechnology. Likewise, it may be very difficult for government officials used to making decisions behind closed doors to provide information and to open up their decision-making processes to input from the public. A number of mechanisms to create the space for public involvement do exist, though, and are being

Box 7

Minimum Requirements of Public Participation

a. *Notice to all concerned stakeholders, in a language understood by them and through media to which they have access.* Such notice must be adequate, timely, and effective and posted prominently in public places in the areas affected, and in the case of field trials and commercial releases, in both national and local print media. In all cases, such notices must be posted electronically on the Internet.

b. *Adequate and reasonable time frames for public participation procedures.* Such procedures should allow relevant stakeholders to understand and analyze the benefits and risks, consult with independent experts, and make timely interventions. Concerned departments and agencies shall include in their appropriate rules and regulations specific time frames for their respective public participation processes, including a minimum of 60 days notice for public hearings and 45 days notice for solicitation of written comments.

c. *Public consultations, as a way to secure wide input into the decisions that are to be made.* These could include formal hearings in certain cases, particularly where there is public controversy about the proposed activities. Public consultations shall encourage exchanges of information between applicants and the public before action is taken on the application. Dialogue and consensus-building among all stakeholders shall be encouraged. Concerned departments and agencies shall specify in their appropriate rules and regulations the stages at which public consultations are appropriate, the specific time frames for such consultations, and the circumstances under which formal hearings will be required. The networks of agricultural and fisheries councils and community-based organizations in affected areas shall be utilized.

d. *Written submissions.* Procedures for public participation shall include mechanisms that allow public participation in writing or through public hearings, and which allow the submission of any positions, comments, information, analyses or opinions. Concerned departments and agencies shall include in their appropriate rules and regulations the stages and process to be followed for submitting written comments.

e. *Consideration of public concerns in the decision-making phase following consultation and submission of written comments.* Public concerns as reflected through the procedures for public participation shall be seriously considered in making the decision. The public must be informed of the final decision promptly, have access to the decision, and shall be provided with the reasons and considerations resulting in the decision.

Source: Draft Executive Order, 2004

used in several countries as they develop and implement biosafety regulations. As an example, Box 7 lists the minimum requirements for public participation that are being considered by the Philippine government in its National Biosafety Framework.

TYPES OF PUBLIC PARTICIPATION

A number of mechanisms can be, and are being, employed to involve the public in decision-making about biotechnology. These include formal and informal mechanisms led by both the government and by citizens. Most of these mechanisms either already explicitly include socio-economic considerations or can be adapted to do so. These mechanisms can be employed at various stages, including policy-making, approval processes for specific crops, and monitoring and enforcement actions. The case studies presented at the end of this paper give examples of how two countries — the Philippines and Indonesia — have made use of some of these public participation mechanisms.

Information-sharing

The public can play an important role in sharing its concerns and priorities with decision-makers through a number of exercises known collectively as "deliberative inclusionary processes" (DIPs) (see Box 8). Such activities usually give a small, representative cross-section of the public an opportunity to consider policy options related to a particular issue — in this case, any number of scenarios regarding GMOs — on its own terms. DIPs usually do not feed directly into policy processes, but they have the value of bringing the diverse opinions of the public to policy-makers (Glover et al., 2003).

Consultation

A more direct and focused form of participation is through consultation on a particular policy issue or decision. This can take a number of forms, including sharing drafts of policies and inviting public comment; holding public hearings at the local, state/district, and national level; and posting notifications

Box 8

Types of Deliberative Inclusionary Processes

- *Citizens' juries:* These processes convene small groups of laypeople — the 'jury' — to discuss a particular issue or question. Another group of experts, or 'witnesses,' also participates, providing evidence or testimony regarding the issue at hand. The jury has the opportunity to question the witnesses and evaluate the evidence before making recommendations. A report is usually drawn up to reflect the various views expressed by jury members.
- *Consensus conferences:* Participants include a group of laypersons selected according to socio-economic and demographic characteristics. This group receives briefings on the topic and determines the questions they wish to raise with a group of expert witnesses. Conferences take place on a public stage, and the audience and members of the press can raise their own questions. The group writes its own report after the conclusion of the conference.
- *Deliberative opinion polls:* These polls measure public opinion after people are provided information on a particular issue and time to consider this information. A demographically representative group of up to several hundred people conducts a debate, with the opportunity to cross-examine key players. In order to measure changes in opinion, the group is polled on the issue before and after the debate.
- *Focus groups:* Focus groups are usually small, but broadly representative of the citizen group being consulted. With the guidance of a facilitator, participants discuss an issue of concern; while they are not usually required to reach conclusions, the contents of the discussion are studied to learn about shared attitudes and understanding of an issue. These groups only last a few hours and do not involve testimony or briefings from experts.
- *Multi-criteria mapping:* This exercise attempts to combine the transparency and clarity of statistical approaches with the freedom of open-ended deliberations. After a topic area is selected and policy options regarding this topic defined, participants are interviewed individually to develop additional policy options and define criteria for evaluating these options. The options are scored and relative weightings are applied to the criteria. Participants come together to discuss researchers' preliminary quantitative and qualitative analysis of their scoring of the options before a final report is produced.
- *Standing consultative panels or citizens' panels:* This is a large, representative group of citizens that can be used for quantitative and qualitative research and consultation. Through periodic consultation, these panels can be used to sample changing opinions and attitudes about a range of issues over time.

Source: Glover et al., 2003

accessible to the public when applications for approval of particular GM crops are submitted, again inviting comments (Glover et al., 2003). While consultations are generally narrower in scope than DIPs because they are focused on a particular pre-determined component of decision-making, members of the public should nonetheless have the opportunity to bring up any issues of importance to them, including socio-economic considerations, in their comments.

Particularly regarding applications for approval of GM crops, public notifications should include any relevant socio-economic information that may be available. In addition to the results of scientific risk assessments, the public should have access to, for example, the results of economic assessments that could reveal information about markets for the GM crop in question; or data that could have socio-economic implications for non-GMO farmers, processors and consumers, such as the likelihood for a GM crop to mix with non-GM plants or products. Where the same or similar crops have already been introduced in other areas or countries, information on the social and economic impacts that have occurred there should be shared, if possible.

Governments may wish to conduct consultations at some points during — or directly following — the participatory research discussed above. For example, if a cost-benefit analysis has identified where the various socio-economic costs and benefits of adopting a GM crop are likely to fall within society, those members of society need to be involved in deciding whether such a distribution is acceptable and whether they are willing to accept the potential costs in order to gain the benefits they may accrue.

Committees

Some countries' biosafety regulatory systems have committees that include or consult with a 'civil society' representative or other member of the public (Glover et al., 2003; Dayrit and Gatlabayan, 2005). These committees focus on a number of aspects of biosafety; some committees have decision-making powers, while others are advisory in nature. They should be given a broad mandate that allows them to consider and make recommendations on any issues they find relevant to biotechnology. The inclusion of civil society does not guarantee that socio-economics will be considered by these advisory committees. However, it creates more room for various issues to be raised, and given the interest in socio-economic considerations expressed by many NGOs, it is likely that those groups' inclusion in advisory bodies would result in greater focus on these considerations than if only scientists and members of government agencies were involved.

Other types of committees, which may not directly include members of the public in guiding decision-making, could nonetheless give voice to public concerns. Public inquiries, for example, have been commissioned by several governments to investigate issues related to biotechnology and provide recommendations based on their findings. The New Zealand "Royal Commission" consisted of a panel of independent investigators with a mandate to look into a range of issues. In addition to reviewing the environmental and health risks and benefits of biotechnology, the commission looked into the adequacy of regulatory processes and convened workshops and forums to address the particular needs of indigenous groups and the views of young people (Glover and Keeley, 2004).

EXAMPLES FROM THE PHILIPPINES AND INDONESIA

To examine how different countries approach public participation with respect to biosafety and biotechnology decision-making, the World Resources Institute commissioned case studies in Indonesia, which ratified the Protocol in July 2004; and the Philippines, which is a signatory to the Protocol but has not yet ratified it.[7] Both countries have a number of laws and policies in place that directly regulate the products of biotechnology, as well as several regulations that are not specific to biosafety but can nonetheless be used in policy- and decision-making. In addition, under the Protocol, both Indonesia and the Philippines are in the process of developing a National Biosafety Framework (NBF) to comprehensively regulate the products of modern biotechnology. The following section discusses the case studies' findings on how these existing and proposed regulations address — or fail to address — public participation in each country. In addition, the potential for such mechanisms to take into account socio-economic considerations is explored.

Conditions for public participation

Providing balanced information regarding biotechnology is an essential first step toward effective public participation. The case study in Indonesia indicated that the public has low awareness about issues related to biotechnology and biosafety, and that there is no direct provision under the existing decree regulating biotechnology for promoting and facilitating public awareness, education, and participation. While there is an online database containing information about research on GMOs within Indonesia, this is not widely accessible to the general public, as most Indonesians do not have easy access to the Internet. The case study authors also found the type of GMO information made available by the government to be limited and point to NGOs as the main providers of information on such topics as environmental and social issues related to biotechnology.

In the Philippines, the Department of Science and Technology (DOST), Department of Agriculture (DA), and international organizations such as the Food and Agriculture Organization (FAO) have funded several activities to promote public awareness at the regional and local level. These information, education, and communication (IEC) activities include training workshops for trainers, regulators, and members of the scientific and technical review panel (STRP); seminars for agency personnel and legislators; media discussions with various stakeholders such as farmer-leaders, religious and consumer groups; radio programs and TV interviews; production and distribution of videos, comics, pamphlets, and brochures; poster exhibits; write-ups for newspapers; and consultation meetings regarding regulations. Other sources of information on GMOs include pro- and anti-GMO campaigners. However, there is no system that ensures correctness of the information and there is no accountability for the truthfulness and accuracy of the information. While the authors of the case study concluded that these education and information activities have increased the public's level of awareness overall, they indicated that a better public information education campaign is still necessary.

In addition to informed citizens, effective public participation requires that the space be available for the public to participate in discussions and decisions about biotechnology. The Philippines has a strong tradition of activism and grassroots movements, and its constitution recognizes the importance of public participation and the role of civil society. In addition to the general democratic space available for citizens to voice their opinions, Philippine legislation related to biosafety has several mechanisms for public participation in decision-making, as described in the succeeding section.

Indonesia, on the other hand, has just begun the process of democratization following the downfall of the Soeharto regime in 1998. As a result, many sectors of the community are just beginning to realize their rights and power to influence policy. While an active NGO community has become involved in efforts to exercise the rights of the public to participate in policy development, the case study authors found that this right has not been fully explored or implemented by the government itself. This condition is identified as one reason for differing perceptions of how to handle public participation in the country in general and in biosafety decision-making in particular. Dialogue among stakeholders is also a new approach that has only recently been introduced. As such, the case study concludes that public participation is still in its early stage of development, which is reflected in the degree of public participation allowed for in regulations related to biosafety decision-making.

Types of public participation

In both the Philippines and Indonesia, a number of laws and policies exist that directly regulate the products of biotechnology, as well as several that apply indirectly. Some of these laws and policies include explicit requirements for public participation, but in some cases there is confusion over how these laws and policies apply and interact with each other. In the Philippines, two legal instruments specifically address biosafety matters related to GM crops: Executive Order 430 (1990) and Administrative Order 8 (AO 8) of the Department of Agriculture (2002). Executive Order 430 established the National Committee on Biosafety of the Philippines (NCBP) to address the scientific issues of biosafety and to formulate and oversee the implementation of biotechnology policies. It is made up of ten committee members from government, academia, and community groups. Institutions engaged in biotechnology are required to form institutional biosafety committees (IBCs), which replicate the NCBP structure. These IBCs take steps to notify the public of the planned release of GMOs and to invite comments thereon. AO 8 also has provisions on public notification and comment regarding GMOs.

Under AO 8, applicants for field testing of GMOs are required, through their IBC, to notify and invite comments on proposals from the *barangay* (village) and city or municipal governments with jurisdiction over the proposed field test sites. For three consecutive weeks, they must post copies of the approved public information sheet for field testing in the language understood in the community in at least three conspicuous places in each of the concerned *barangay* and city or municipal halls. Written comments are entertained for 30 days from the date of posting. In addition, the applicant is required to make an announcement, including a copy of the public information sheet, in two newspapers of general circulation. Interested parties can send their written comments regarding the application or proposed release for propagation to the Bureau of Plant Industry (BPI).

Outside of the NCBP and AO 8 are other policies that provide for citizens' participation in biosafety decisions. The Local Government Code (LGC) stipulates that all national government agencies must conduct periodic consultations with appropriate local government units (LGUs), non-governmental and people's organizations, and other concerned sectors of the community before any project or program is implemented in their jurisdiction, and during the planning and implementation of any project or program that may cause social, health, and environmental effects. They are also required to explain the goals and objectives of the project, its impact on the people and the community, and the measures that will be undertaken to prevent or minimize adverse effects. Before government bodies implement biosafety decisions, they must consult with and get prior approval from the LGU concerned.

In addition to the consultation mechanisms described above, Philippine legislation includes community representatives on certain committees that have input to the biosafety decision-making process. The NCBP and AO 8, for example, state that IBCs should have at least two representatives from the community living near the locations where GMO experiments are conducted. The approval of the majority of the IBC members, including at least one community representative, is required before any project proposal is endorsed by the IBC to either the NCBP or BPI for assessment and approval. However, the selection process of these individuals does not necessarily guarantee that they truly 'represent' their community, and further work may be necessary to define the nature and qualifications of community representatives in the IBCs.

Since 1997, Indonesia has regulated products of modern biotechnology under a Ministerial Decree known as the Joint Decree of four Ministers (Minister of Agriculture, Minister of Health, Minister of Forestry and Plantations, and the State Minister of Food and Horticulture). The main implementing bodies of the regulation are the Biosafety and Food Safety Committee (commonly referred to as the BC) and the Biosafety and Food Safety Technical Team (BTT). These bodies make recommendations to the Minister of Agriculture (in the case of transgenic animals, transgenic fish, transgenic agricultural plants and transgenic microorganisms); the Minister of Forestry and Estate Crops (for transgenic plants for forest and industrial crops); and/or the Minister of Health (for transgenic materials to be used directly as food or for processing). Under this decree, there is no direct provision for promoting and facilitating public awareness, education, and participation. Typically, participation occurs through the involvement of several NGOs, along with seminars held for public consultation, before the BC submits recommendations to the Ministers for decision-making.

As part of the Indonesian NBF process, the State Ministry of Environment, the Department of Agriculture, the National Agency for Drug and Food Control, and other stakeholders are drafting the "Government Regulation on Biosafety for Genetically Engineered Products." While the current Decree does not mandate public consultation, the draft of the new regulation has a specific provision for public participation in decision-making that includes consultation. Under this regulation, after the BTT has conducted the biosafety assessment of a GM product, the results of this assessment will be made available through the mass media. The public will have a sixty-day period in which to respond in writing to the National Commission on Biodiversity and Biosafety, and these responses, along with the assessment results, will provide the basis for the BC to give a recommendation to the relevant ministries regarding the release of the GM product in question. The public can also report to the government if after the release, distribution, or utilization of a certain GM product there is a negative impact on health or the environment.

Under the current Joint Ministerial Decree, the Committee on Biodiversity and Food Safety (GEAP), which is tasked with providing recommendations on the safety of GM products to the appropriate Ministry, includes members of NGOs, professional organizations, and farmers' associations, although the effectiveness of this arrangement to actually ensure representation of the public is questioned (Buchori et al., 2005). Representatives of professional organizations, associations, and the public will sit on the National Commission on Biosafety and Food Safety of GM products under the new regulation.

Laws related to environmental impact assessments (EIAs) can also serve as mechanisms for public participation in biosafety issues in both countries. In the Philippines, an EIA must be conducted for all proposed projects that significantly affect the quality of the environment. Public participation is a requirement of the 'social acceptability' criterion under the EIA system, which requires that objective information about an activity be provided to the affected community. However, under the current policies, an EIA is not always conducted as part of biosafety decision-making, as it is only required for certain projects or areas declared by the Department of Environment and Natural Resources (DENR) as environmentally critical, such as a protected area. In Indonesia, EIAs provide for public participation by asserting the right to information and the right to voice concern, opinions, and responses to proposed activities. The regulations for EIAs also allow for consultation with people who will potentially be affected by the activity in question and for the representation of potentially affected individuals on the EIA evaluation committee. However, there appears to be ambiguity about whether or not EIAs are required under the current Decree, lessening their ability to provide opportunities for public participation in biosafety decision-making.

Outside of formal mechanisms such as consultations, committees, and EIAs, members of the public have found other ways to make their voices heard regarding GM crops. In both countries, controversies erupted over the approval of GM crops, specifically Bt corn in the Philippines and Bt cotton in Indonesia (see Box 9).

Participation in policy-making

As discussed earlier, public participation can occur not just during the decision-making process regarding specific GMOs, but also during policy formulation. The participation of the public in each country's NBF process provides an interesting example of how the public has or has not been involved in biosafety policy-making. In the Philippines, the NBF process involved a series of multi-stakeholder consultative workshops at the regional and national levels.

Additional consultative sessions were held within specific sectors, such as among farmers and civil society groups, to discuss issues such as labeling. Finally, the NBF draft was submitted for deliberation to a national committee consisting of representatives from government agencies, the NCBP, science sector, NGOs, and industry.

In Indonesia, public participation appears to be occurring mostly in parallel with the government process. Several Indonesian NGOs proposed making the biosafety policy in the form of a law, rather than as a regulation, as laws have a definite provision for liability and redress. Because laws have to be passed by the House of Representatives, though, they take much longer to come into effect. Therefore, the government chose to develop the biosafety policy in the form of a regulation and is drafting a related but separate law to provide for liability and redress (UNEP-GEF, 2004). In 2001, while the government developed its regulation, a group of NGOs began drafting a law on biosafety. This initiative was launched to respond to several perceived weaknesses in the current Joint Decree, including:

- The lack of policies comprehensively regulating research, export, import, release, limited utilization, and distribution of GM products in the market.
- The failure to evaluate and take into consideration the social, economic, and ethical effects of GM products.
- The limited or non-existent space for public participation, including: failure to acknowledge the right of the people to access to information — including reports on risk analysis — regarding research activities, export, import, limited utilization, release, and distribution of GM products in the market; and failure to consult and provide room for the public in the decision-making process on imports, limited utilization, release, and distribution of GM products. (Buchori et al., 2005)

If and how this initiative will actually influence the final government policy remains to be seen.

Box 9
Controversies over Bt Corn and Bt Cotton

The Philippines: Bt corn

When the Philippine government was faced with a decision about the approval of Bt corn, an extended controversy erupted that involved civil society, industry, the Church, and several levels of government. In December 2002, the Department of Agriculture approved Monsanto's application for limited commercialization of YieldGard, a variety of Bt corn. Both NGOs and Peoples Organizations (POs) mobilized against the approval, and in April 2003, a hunger strike was launched by the Network Opposed to Genetically Modified Organisms! (NO to GMOs!) to urge the government to stop field tests and the impending commercialization of Bt corn and other GMO crops in the country (Cervantes, 2003). The ten activists who participated in the hunger strike represented the groups, both nationally and locally (in the areas where GMOs were to be introduced), that opposed the testing, propagation, and distribution of the controversial corn. As part of their protest, they claimed that the worldwide debate on the safety, environmental, health, and economic concerns had not been resolved and demanded a moratorium on the field testing and commercialization of GMOs.

While there was strong vocal opposition against the approval of Bt corn in the Philippines, there was also support for the product, including some within the farming community. In 2003, Philippine farmers grew approximately 20,000 hectares of Bt corn after field trials reported yield increases of 25 to 60 percent. Trials also showed profitability increases of about 25 percent over conventional varieties (James, 2003) despite the fact that Bt corn seed costs about 80 percent more than conventional hybrid seed (CBI, 2004). One report estimates that in 2004 the area of land planted to Bt corn in the Philippines had increased to 49,000 hectares (CBI, 2004).

Although the protests attracted national and international attention, including considerable media coverage, the Department of Agriculture did not yield in a meaningful way to any of the hunger strikers' demands (Cervantes, 2003). As of this date, the controversy refuses to die down and debate continues on whether approval should be withdrawn and whether other GM crops should be approved. In the meantime, YieldGard continues to be planted in the Philippines, and two other GM crops – Bt-11 corn developed by Syngenta, and Monsanto's herbicide-tolerant 'Roundup Ready' corn – were approved by the BPI for commercialization in the Philippines in early 2005.

What is striking about the controversy in the Philippines is that the approval of Bt corn was made after a long process of scientific and public scrutiny based on updated biosafety regulations – Administrative Order 8 – issued by the Philippines Department of Agriculture. These regulations, based in part on the Cartagena Protocol on Biosafety, mandated state of the art risk assessment and incorporated generally accepted international standards and procedures on biosafety. What the new regulations fail to adequately address, however, is how these procedures should be implemented in a transparent, independent, and participatory manner. The new regulations also did not establish mechanisms through which socio-economic concerns could be addressed in the biosafety decision process.

Indonesia: Bt cotton

Indonesia's experience with Bt cotton began in 1996, when PT Monagro Kimia, the Indonesian subsidiary of Monsanto, started trials of Bt cotton that would be suitable for cultivation in Indonesia, particularly South Sulawesi (Hindmarsh, 2001). In 1998, field trials were conducted, and by 1999, the government had approved the cotton and declared it to be environmentally safe for planting in Indonesia. The company itself began conducting field trials in 2000, and on February 7, 2001, the Ministry of Agriculture issued a decree allowing the limited release of Monagro's Bt cotton for farmers to plant in

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One of the keys identified by the case study authors that could facilitate public participation in policy-making in Indonesia is bridging the gap between stakeholders at the local and national levels. At the local level, farmers are split between two groups: one that has taken action to express their views against Bt cotton and another that has supported the use of Bt cotton. At the national level, many parties are actively debating how to formulate policy related to biotechnology. However, the activities at the local level appear disconnected from those at the national level. Communication and sharing of information between the stakeholders at different levels seems to be absent or, at best, minimal. Thus, an important step toward more effective public participation in policy development could be to scale up and channel public participation from the local level to the national level.

Box 9 continued

seven districts of South Sulawesi. According to some NGO and activist groups in Indonesia, however, PT Monagro Kimia actually began distributing Bt cottonseeds in 1998 – illegally, since the government had not yet authorized it – and the harvest was allegedly sold on local and foreign markets (Hindmarsh, 2001).

A lengthy dispute followed the 2001 decree, involving the national and local governments, Monsanto and its subsidiary, NGOs, and the cotton farmers themselves. A coalition of NGOs, led by KONPHALINDO (Konsorsium Nasional untuk Pelestarian Hutan dan Alam Indonesia, or the National Consortium for Forest and Nature Conservation in Indonesia), filed a lawsuit against the government in May 2001, charging that the decree was in fact illegal. This claim was made on the premise that no environmental impact assessment had been performed and that the public's right to information and to be involved in decision-making had not been upheld (GM Agriculture, 2001). When the Panel of Justice overturned the case (September 2001), the Coalition appealed to the State Administrative Court (December 2001), and, upon defeat, appealed to the Supreme Court, where the suit was defeated in 2004. By this time, Monsanto had ceased to supply Bt cotton in Indonesia, saying it was no longer economically viable to sell Bt cottonseed in Sulawesi (Indonesia to Sign, 2004).

The South Sulawesi experience also involved a 2002 incident in which a Monsanto employee "authorized and directed" an employee of an Indonesian consulting firm to make an illegal payment of US$50,000 to a senior Indonesian Ministry of Environment official to "incentivize" him to amend or repeal a requirement for GM crops – including Bt cotton – to undergo an environmental impact study before authorizing cultivation (DOJ, 2005). Although the payment was accepted, the requirement was not actually amended. In addition, from 1997 to 2002, Monsanto inaccurately recorded, or failed to record, in its book and records approximately US$700,000 of illegal or questionable payments made to at least 140 current and former Indonesian government officials and their family members (SEC, 2005). Monsanto has accepted responsibility for its employees' conduct, and has agreed to pay a monetary penalty of US$1 million, as well as a civil penalty of US$500,000 (DOJ, 2005).

In the meantime, while the Bt cotton was growing in South Sulawesi, NGOs and farmer groups took part in a number of actions against Monagro, including burning cotton fields and holding demonstrations in front of the Ministry of Agriculture. Their opposition was based on economic concerns stemming from yield losses with Monagro's seed and credit and pricing schemes that hurt the farmers. While many farmers said they did not wish to plant Bt cotton again, they felt forced to do so because the company could refuse to buy their cotton from the previous season if they did not purchase the seeds for the next. Other farmers, though, refused to repay loans they had taken to purchase seeds and even burned their fields and/or demanded compensation for their losses. Some farmers complained that while they tried to purchase conventional seed, it was not available, making the purchase of Bt seed their only option (GM Agriculture, 2001). Not all farmers reported a negative experience planting Bt cotton, though, and many sided with Monagro during the lawsuits and protests. While Monsanto's withdrawal from Sulawesi may have quieted the dispute for the time being, stakeholders remain deeply divided.

In both the Philippines and Indonesia, the reasons for objection to the GM crops included environmental and health issues, but social and economic issues were also a frequently-cited concern. Socio-economic assessments, based on sound social science and conducted in a transparent and participatory manner, would have been helpful in addressing these issues.

Inclusion of socio-economic considerations

Some public participation mechanisms used or proposed in the Philippines and Indonesia could encourage the inclusion of socio-economic considerations in decision-making. For example, where notification is required regarding field tests or applications for approval — under AO 8 and the LGC in the Philippines, and within the new Government Regulation in Indonesia — governments could require that the notification include information about social and economic impacts, such as results from SIAs (for example, when these are conducted as part of an EIA), as well as environmental and health issues.

The Philippines' inclusion of community members in various advisory and decision-making bodies at different levels of governance, while not explicitly addressing socio-economic issues, enhances the opportunities for these topics to be raised and considered in cases where communities call for it. This of course requires that the community members on such committees work to truly represent the concerns of their communities, and points to the need for transparency and accountability in selecting participants in governance processes.

In both countries, the EIA process has the potential to heighten public participation and thereby create channels through which to raise and consider socio-economic issues. The Philippine draft NBF includes a number of provisions from the country's socio-economic impact and EIA systems, including one stating that the EIA process should integrate the evaluation of socio-economic impacts whenever applicable. Such integration could occur upon the initiative of the concerned department or upon petition by concerned stakeholders.

The Philippines and Indonesia case studies showcase some of the many approaches to regulating modern biotechnology and some of their strengths and weaknesses related to public participation and socio-economic considerations. While some of the laws and policies in each country — environmental impact assessment systems, for example — provide for public participation, they are not consistently applied. Clarification about how these laws apply and interact with each other is necessary in both countries in order for public participation to play an effective role in decision-making.

Biosafety decision-making will involve different dynamics — due to culture; environment; political situations; and scientific, regulatory, and civil society capacity — and will necessarily be handled differently from country to country. Likewise, the social and economic issues most important in biosafety and biotechnology decisions may be different for each country. However, the principles behind them, such as basic human rights, equity, and autonomy, are universal and should guide decision-making in all countries. The mechanisms described in the case studies — such as consultation and community representation on biosafety committees — are examples of the tools and processes discussed in the preceding section, which could be adapted to various country contexts to facilitate the involvement of the public in decision-making about biotechnology in general and about related socio-economic considerations in particular.

V. CONCLUSION AND RECOMMENDATIONS

Integrating socio-economic considerations into biotechnology and biosafety decisions is a difficult and complex challenge. But with objective, thorough, and independent socio-economic research and inclusive, transparent, and participatory regulatory processes, decision makers will be positioned to meet this challenge. Practical steps can be taken to integrate these considerations into decision-making (see Box 10 for a summary of the authors' recommendations).

This paper has shown the complexity of the choices governments and societies must make about modern biotechnology and its products. Some people wish to move ahead with GM crops, believing that the world's poor cannot afford to wait for a final resolution of all environmental, health, or socio-economic issues. Others, however, have called for moratoriums on the widespread adoption of agricultural biotechnology or the commercial release of genetically modified seeds while these issues are debated. In some cases, the debate over GMOs is based on a fundamental difference in people's visions of the roles of agriculture and technology in society, as biotechnology is often seen as an unwelcome extension of the industrial agricultural system that many feel is environmentally, economically, and socially unsustainable (Marsden, 1999; Jensen and Sandoe, 2002). While it may not be possible to reconcile such fundamental differences of opinion within regulatory systems, a balanced approach that acknowledges both the potential benefits and costs of modern biotechnology and calls for it to be developed and used with adequate safety measures should result in the best decisions not just for the environment and human health, but for society as a whole.

The problem of modern biotechnology is not necessarily the science itself, which could well be an important source of solutions to deal with poverty and hunger, but in the governance of its applications (Food and Ethics Council, 2004). The integration of socio-economic considerations into biotechnology and biosafety decisions through analytically excellent and participatory research, and through regulatory processes that engage the public meaningfully, is an important and essential step toward the good governance of modern biotechnology.

Box 10

Integrating Socio-economic Considerations into Biosafety Decisions: Summary of Recommendations

Recommendations for the scientific research community

1. In developing applications of modern biotechnology, scientific research institutions should establish mechanisms that enable them to conduct preliminary assessments to determine whether socio-economic issues and concerns are likely to be raised as the research progresses.
2. Research scientists should incorporate the conduct of socio-economic assessments into their work plans, project time frames, and research budgets where such assessments are mandated by law and policy.
3. Social scientists and stakeholder groups should develop research methodologies for assessing the socio-economic impacts of modern biotechnology. These methodologies should be based on the best available social sciences, multi-disciplinary, field-tested, peer-reviewed, and consistent with international standards as these evolve.

Recommendations for the biotechnology industry

1. As early as possible in the product pipeline, companies should undertake assessments to identify the social and economic issues and concerns that are likely to be raised regarding the product.
2. Product development should take into consideration results of socio-economic assessments that highlight the needs of the poor.
3. Emerging traits and technologies should be evaluated for their potential application to developing country needs.
4. Companies should incorporate into their product development and commercial release plans, including budgets, the conduct of socio-economic assessments where these are required. These assessments should use the best available social sciences and be multi-disciplinary, field-tested, peer-reviewed, and consistent with international standards as these evolve. The methodology and results of these assessments should be made publicly available.

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Box 10 continued

Recommendations for the public agricultural sector

1. Public agricultural institutions should base their biotechnology research decisions on socio-economic assessments that identify the needs of the poor and that compare biotechnology options with other alternatives.
2. Social scientists working in international public agricultural institutions, such as those active in the Consultative Group on International Agricultural Research, should take the lead in identifying existing assessment approaches and developing new research methodologies for evaluating socio-economic impacts of modern agricultural biotechnology.

Recommendations for governments

1. Governments should explicitly adopt policies or enact laws establishing the principle that socio-economic considerations shall be taken into account when biotechnology and biosafety decisions are made.
2. Governments should design and implement practical mechanisms to assess the socio-economic impacts of modern biotechnology, including developing criteria on when assessments should be required, what issues and concerns should be included, and the stages at which assessments are conducted. To ensure transparency, governments should commission independent social scientists to carry out such assessments.
3. Governments should design processes to make socio-economic assessments as efficient and cost-effective as possible, including establishing strict timeframes to avoid undue delay and streamlined procedures that integrate socio-economic assessments into other required regulatory processes.
4. In all aspects and stages of biotechnology and biosafety decision-making, governments should promote and facilitate public awareness and meaningful public participation. They should incorporate into their respective legislative and administrative issuances and processes internationally recognized best practices and mechanisms for public participation.

Recommendations for civil society and community groups

1. Non-governmental organizations and community groups should develop the technical capacity to identify and analyze relevant socio-economic information so that they can better engage scientists, companies, and government agencies on this issue. Research conducted by these groups should use the best available social sciences and should be peer-reviewed.
2. Non-governmental organizations and community groups should develop indicators that assess their governments' performance with respect to Article 23 of the Cartagena Protocol on Biosafety, which assures citizens access to information and public participation in biosafety decisions.

Recommendations for the Parties to the Cartagena Protocol on Biosafety

1. The Parties to the Protocol should encourage cooperation on research and information exchange on any socio-economic impacts of living modified organisms, especially on indigenous and local communities, as provided for in Article 26, paragraph 2, of the Protocol.
2. Bilateral and multilateral development cooperation agencies should support capacity-building programs under the Protocol that assist governments and relevant organizations to develop research methodologies that assess socio-economic considerations and implement participatory regulatory processes.
3. Over the medium term, Parties should adopt a programme of work aimed at assisting countries to implement Article 26 of the Protocol.

Notes

1. We recognize that the term 'modern biotechnology' can be interpreted to include many techniques, including cloning, gene therapy, and production of monoclonal antibodies. In this paper, however, we use the terminology of the Cartagena Protocol on Biosafety, which defines 'modern biotechnology' as the application of in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (rDNA) and direct injection of nucleic acid into cells or organelles; or 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.

2. In this paper, we will use the term 'living modified organism' (LMO) whenever the context is the application of the Cartagena Protocol on Biosafety. For contexts other than the Protocol, we will also use the term 'genetically modified organism' (GMO) and 'transgenic organism,' as these terms are more commonly used, especially in domestic legislation of many countries. Technically, LMO is a broader category in that it does not necessarily indicate the insertion of genetic material, while GMOs are a subset of LMOs, produced using modern biotechnology, particularly recombinant techniques (MacKenzie, 2003).

3. This model assumes increased productivity of 10 percent in high- and middle-income countries, and a 20 percent increase in productivity in low-income countries. This difference is due to the relatively low production achieved with current technologies in developing countries, creating more room for growth. For further information on these models and their assumptions, see Abdalla et al., 2003, and Anderson et al., 2001.

4. The difference in average share captured by farmers depended on farm size and irrigation, with large-scale irrigation farmers receiving the greatest benefit, small-scale dryland farmers receiving ten percent less, and large-scale dryland farmers receiving the least.

5. For more information, see a report issued by the Secretariat of the North American Commission for Environmental Cooperation (CEC, 2004) and a response by various US government agencies (US Calls, 2004).

6. The Access Initiative (www.accessinitiative.org), a global coalition of non-governmental organizations that promotes access to information, participation, and justice in environmental decision-making, has developed a methodology to assess governments' performance with respect to these 'Access Principles.'

7. See Dayrit and Gatlabayan, 2005; and Buchori et al., 2005 for complete case studies.

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