

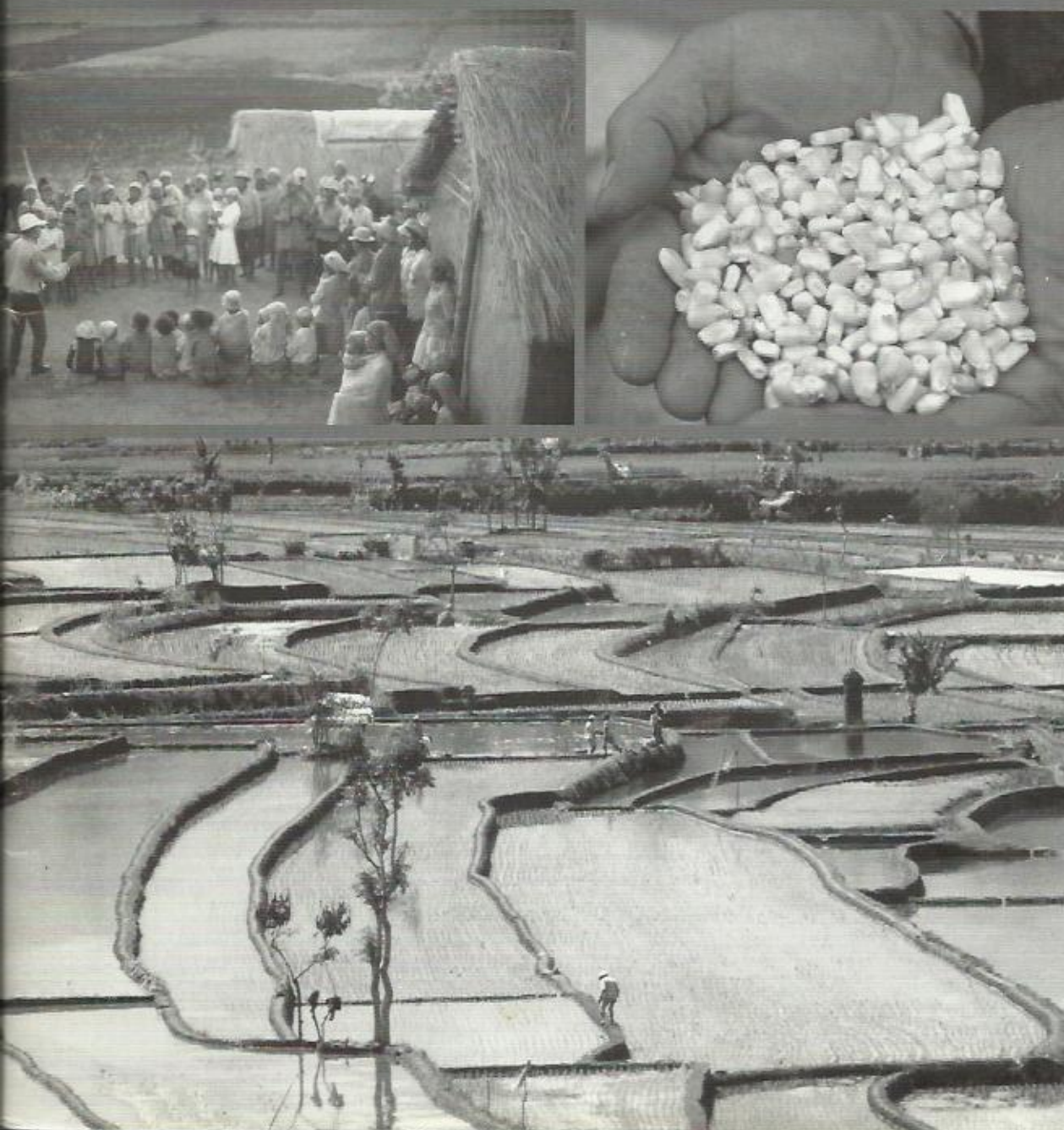


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WRI WHITE PAPER

INTEGRATING SOCIO-ECONOMIC CONSIDERATIONS INTO BIOSAFETY DECISIONS

The Role of Public Participation



LINDSEY FRANSEN

ANTONIO LA VINA

FABIAN DAYRIT

LORAIN GATLABAYAN

DWI ANDREAS SANTOSA

SOERYO ADIWIBOWO

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Lindsey Fransen
Antonio La Vina
Fabian Dayrit
Loraine Gatlabayan
Dwi Andreas Santosa
Soeryo Adiwibowo



WORLD
RESOURCES
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WASHINGTON, DC

JEN LESAR
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ISBN 1-56973-591-3

Printed in the United States of America on chlorine-free paper with recycled content of 50%, 20% of which is post-consumer.

Cover Photographs:

Rice paddies: Food and Agriculture Organization/R. Faidutti
African village meeting: Food and Agriculture Organization
Hands with corn: Photo by Tim McCabe, USDA Natural Resources Conservation Service

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Acknowledgments

This White Paper was produced as part of the World Resources Institute project 'Implementing the Biosafety Protocol.' Sections of this paper are based on case studies carried out by colleagues at Ateneo de Manila University (ADMU), Philippines, and Bogor Agricultural University (BAU), Indonesia. The authors would like to thank Damayanti Buchori, Hariadi Kartodiharjo, and Hermanu Triwidodo (BAU) for their contributions to these case studies, as well as the Indonesian Biodiversity Foundation (Yayasan KEHATI) for its support of the case study in Indonesia. Yuko Kurauchi contributed to this publication with research, editing and general support, and Denni Jayme and John Paul Ramos also provided research assistance.

The authors gratefully acknowledge colleagues Paul Faeth, Nathalie Eddy and Evan Branosky for review and revision of an earlier version of this manuscript; and David Jhirad and Frances Seymour for review and

support of this publication. The authors and the World Resources Institute also extend their thanks to the reviewers of the manuscript, Suman Sahai, Josette Lewis, Doreen Stabinsky and Anne Courtney Radcliffe. Their comments provided valuable insight and helped to improve the document; this paper does not necessarily reflect their views.

This publication was made possible through the generous support of the US Agency for International Development — East Asia and Pacific Environmental Initiative. In addition, sections of this document are based on a working paper funded by the International Development Research Centre (IDRC) as a background piece for the IDRC-IUCN regional conference 'Setting a Research Agenda on Agricultural Biotechnology and Biosafety in Asia,' 11–14 October 2004, in Colombo, Sri Lanka.

EXECUTIVE SUMMARY

Modern biotechnology, as it is applied to agriculture, poses a common challenge to countries and societies worldwide: the need for careful decision-making to ensure that society enjoys the benefits of this technology while minimizing or avoiding its potential costs.^a This paper proposes governance mechanisms and opportunities for stakeholder engagement that can assist in achieving such an outcome. In particular, it focuses on the social and economic implications of modern agricultural biotechnology and its products and how to take these issues and concerns into consideration in decision-making about biotechnology.

The integration of socio-economic considerations, through analytically sound research and regulatory processes that engage the public meaningfully, is an important step toward the good governance of modern biotechnology. However, information on and analysis of the social and economic impacts of modern biotechnology are lacking, and there is little experience in dealing with these issues in actual decision-making processes. The aim of this paper is to provide such information and analysis as a starting point for assisting national governments and other stakeholders in designing and implementing policies and mechanisms that incorporate socio-economic considerations into decision-making.

The social and economic issues related to modern biotechnology are many, and there are a number of governance strategies, mechanisms and regulatory tools that can be employed to address these issues. While some socio-economic considerations can be dealt with directly through biotechnology policies or biosafety regulations, others would be better addressed through other means, such as guidelines for scientific institutions or domestic laws not specifically related to biotechnology.

Special mention should be made of the approach taken by the Cartagena Protocol on Biosafety, which was negotiated under the Convention on Biological Diversity to provide for "the safe transfer, handling and use" of the products of modern biotechnology (Secretariat of the CBD, 2000). When making a decision on the import of such products, Article 26 of the Protocol allows countries to take into account socio-economic considerations arising from impacts on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities. This must be done in a manner consistent with existing international obligations by which countries may be bound. While Article 26 provides a fairly limited set of conditions under which socio-economic considerations may be taken into account in decision-making regarding imports, countries may also incorporate socio-economic considerations other than those explicitly included in Article 26 into their domestic regulatory regimes on biosafety, as long as they comply with other international obligations (Garforth, 2004).

SCOPE AND LIMITATIONS

This paper begins with an overview of the many social and economic considerations related to the use of modern agricultural biotechnology, with particular emphasis on its impact in developing countries. It then suggests principles and tools that countries could use to determine how socio-economic considerations should be integrated specifically into biotechnology policy or biosafety regulations, as well as identifying some issues for which biotechnology and biosafety regulations are not appropriate. A tool that we emphasize is public participation in both research and decision-making about biotechnology and biosafety. The principles and tools identified in this paper are initial suggestions for taking socio-econom-

a. 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" (Secretariat of the CBD, 2000).

ic 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.

Although examples from around the world are used, the authors draw many of the cases and experiences from Asia, as this region is particularly important for agricultural biotechnology given its high population and related concerns about food security, in combination with the advanced state of biotechnology research taking place. The findings of case studies on public participation in biosafety decision-making in the Philippines and Indonesia, commissioned by the World Resources Institute, are incorporated into this paper.

SOCIO-ECONOMIC CONSIDERATIONS IN AGRICULTURAL BIOTECHNOLOGY

The socio-economic issues related to modern agricultural biotechnology include concerns over the distribution of benefits; public sector research; labor; global markets; competition; organic agriculture; intellectual property rights; public opinion; and ethics, culture and religion.

Distribution of benefits: Research indicates that 'living modified organisms'^b or genetically modified (GM) crops are generating significant wealth in countries where they are being used. However, there are concerns about the distribution of this wealth, for example, that benefits will be enjoyed by farmers in developed countries, but not by farmers in developing countries, or that within countries, biotechnology will contribute to inequity by favoring groups such as large-scale farmers while the needs of subsistence and small-scale farmers are ignored.

Public sector research: Public agricultural institutions could play a key role in developing GM crops that are specifically designed to address the needs of poor farmers. However, the public sector, at both the domestic and international level, faces obstacles such as a lack of financial resources and challenges related to intellectual property rights. Public-private research partnerships are an important strategy in addressing these obstacles, but they must be designed properly to be credible and effective.

Labor: Some GM crops could reduce the need for manual labor, which would be beneficial in some parts of the world. In other regions — especially those with large working-age populations — they could have negative effects on the labor market or create inequity by reducing the need for certain types of labor typically performed by marginalized groups.

Global markets: Trade relationships are a major determinant of how a given country could benefit or lose economically due to the adoption of GMOs. Countries that adopt GM crops could be hurt if their trade partners include countries that impose import bans or restrictions on GMOs because of consumer preference. On the other hand, countries that adopt GMOs could benefit if such crops result in significant yield increases and associated drops in price.

Competition: GM crops are creating competitive pressures among developing countries. For example, 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. At the same time, a new form of competition could arise between developing and developed countries if goods traditionally grown in the tropical climates of many developing countries are genetically engineered to grow in the temperate climates of developed countries, or vice versa.

b. 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).

Organic agriculture: Systems of production that explicitly exclude GMOs could face special challenges as a result of the presence of GM crops on the general market. For example, organic markets may suffer if GM products inadvertently mix with organic ones.

Intellectual property rights: Strong intellectual property rights (IPR) systems can provide incentives for innovation and the development of new products that may be useful to society. However, technology fees for GM crops and restrictions on saving and sharing seeds that are sometimes associated with IPRs can create new burdens for farmers. Researchers are also affected when IPRs make scientific knowledge and techniques difficult to access.

Public opinion: 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, causes people to object to the introduction of GMOs. In this context, what must be addressed is the lack of credibility in existing institutions such as environmental, health, food, and agriculture regulatory agencies. In addition, to gain broader public acceptance, GMOs have to be perceived as something that truly addresses people's needs.

Ethics, culture and religion: Religions and value systems worldwide are diverse and subjective, and therefore no single ethical, cultural or religious framework for assessment of or decision-making processes on GM crops can be established. These issues should be addressed on a country-by-country, or even case-by-case basis, in order to be included in biosafety decision-making.

CLARIFYING THE ISSUES: DEVELOPING A RESEARCH METHODOLOGY

A solid research methodology is necessary in order to gain a better understanding of the social and economic impacts of modern agricultural biotechnology. Without a credible research methodology, it is neither possible nor desirable to incorporate socio-economic

considerations in decision-making. The methodology should be based on the best available social sciences, multi-disciplinary, field-tested, peer-reviewed, and consistent with international standards as these evolve. For developing countries in particular, the starting point for socio-economic assessments should be the needs of the poor.

This paper explores some research approaches that could be applied to understand the social and economic impacts of modern agricultural biotechnology. These include: Economic Modeling, Cost-benefit Analysis, Social Impact Assessment, Sustainable Livelihoods Framework, Systemic 'Relevance Assessment,' and Participatory Research. These approaches include quantitative models to predict the global economic effects of adopting GMOs, country- or community-level research to assess tradeoffs that may be necessary in making decisions about particular applications of modern biotechnology, and quantitative and qualitative research at the household level to analyze the social and economic issues related to the adoption of GMOs. Each of these 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.

CLARIFYING THE PROCESS: INTEGRATING SOCIO-ECONOMIC CONSIDERATIONS

Careful research to clarify the socio-economic issues related to biotechnology is essential, but is not in itself sufficient to incorporate socio-economic considerations into biosafety decisions. Practical steps are necessary for these considerations to actually be taken into account when decisions are made. These could include:

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

THE ROLE OF PUBLIC PARTICIPATION

Public participation helps to identify, clarify, and resolve socio-economic concerns and issues related to modern biotechnology. The Cartagena Protocol on Biosafety includes the right to public participation by urging Parties to the Protocol to promote and facilitate public awareness, education and participation in dealing with GMOs. A number of mechanisms or best practices can be, and are being, used to involve the public in decision-making about biosafety. These include formal and informal mechanisms led by the government and by citizens, such as 'deliberative, inclusionary processes' (DIPs), consultative processes, and participation in stakeholder committees. Such mechanisms can be employed at various stages, including policy-making, decisions on approvals of specific crops, and monitoring and enforcement actions. Public participation applies to many issues related to biotechnology and biosafety, including, but not limited to, socio-economic considerations.

The case studies presented at the end of this paper give examples of how two countries — the Philippines and Indonesia — have made use of these public participation mechanisms. These studies illustrate some of the many approaches to regulating modern biotechnology, as well as their strengths and weaknesses with regard to public participation and socio-economic considerations. The mechanisms described in the case studies are examples of the general tools and processes for public participation that could be adapted to various country contexts to facilitate the involvement of the public in ensuring that socio-economic considerations are included in biosafety decision-making. Biosafety decision-making will involve different dynamics — due to culture, environment, political situations, and scientific, regulatory, and civil society capacity — and will necessari-

ly be handled differently from country to country. But while the particular social and economic issues most important for biosafety may be different for each country, the principles behind them, such as basic human rights, equity, and autonomy, are universal and should guide decision-making in all countries.

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.

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.

I. INTRODUCTION

The use of genetic engineering in agriculture is a complex issue that presents both potential benefits and costs to human society and the environment, with implications at the local, national, and global levels. Accordingly, over the past decade, a heated global debate has erupted over the use of modern biotechnology.¹ Governments, communities, and farmers around the world face the same challenge: *how to make decisions about this powerful technology that will enable them to enjoy its benefits while avoiding or minimizing the environmental, health, and socio-economic costs posed by its application.*

Modern agricultural biotechnology allows scientists to make changes in the characteristics of crop plants in a more rapid and targeted manner than is possible using conventional breeding. As such, it has been put forth as an important tool with which to address hunger and poverty, which, despite decades of scientific, social, and political efforts, remain widespread throughout the developing world (Krattiger, 1998). In its application to agriculture, biotechnology's potential benefits include improved crops that would be more nutritious, higher-yielding, resistant to pests and disease, tolerant to physical stresses such as saline soils and drought, and more environmentally sustainable (FAO, 2004).

At the same time, it is acknowledged that modern biotechnology and its products could have adverse effects on human health and biodiversity (Secretariat of the CBD, 2000; FAO, 2004; WHO, 2003), as well as on the economic and social structures that provide livelihoods to the very people it is claimed to benefit (Nuffield Council, 2004). Thus, from the earliest stages of research and development to commercial use and release, the application of modern biotechnology requires that environmental, health, and socio-economic risks be addressed (La Vina, 2003). These risks need to be identified and understood with the best available information, reduced or mitigated through appropriate management measures, or avoided entirely where found to be unacceptable.

Careful decision-making is necessary in order to enable society to enjoy the benefits of agricultural biotechnology while avoiding its potential costs. This paper proposes governance mechanisms and opportunities for stakeholder engagement that can contribute to this goal.

A FOCUS ON SOCIO-ECONOMIC CONSIDERATIONS

The focus of this paper is on the social and economic implications of modern agricultural biotechnology and its products and taking these implications into account in decision-making. This is a challenging task, as information on and analysis of these implications are lacking, and there is little experience in actually incorporating socio-economic considerations into official decision-making processes. The aim of this paper is to provide initial information and analysis as a starting point for assisting national governments and other stakeholders in designing and implementing policies and mechanisms that include socio-economic considerations in decisions about biotechnology.

We can learn from the experience of the Green Revolution of the 1960s, which used advanced breeding techniques, chemical inputs, and mechanization to dramatically increase crop yields (FAO, 2004). By increasing world agricultural productivity, the Green Revolution is credited with helping to prevent hunger and starvation for millions of people in the developing world (Conway, 1999a). But it also had unintended consequences such as environmental and health problems caused by the increased use of chemical inputs (Conway, 1999a), as well as negative socio-economic impacts. For example, the high-yielding varieties that defined the Green Revolution performed best in favorable environments and required a higher degree of mechanization than did traditional varieties, which limited the ability of poor, small-scale farmers to use and benefit from them. In addition, some of the technologies that accompanied these varieties reduced or changed the availability of certain agricultural jobs typically performed by women (Shiva, 1991; Pinstrup-Andersen and Cohen, 2001;