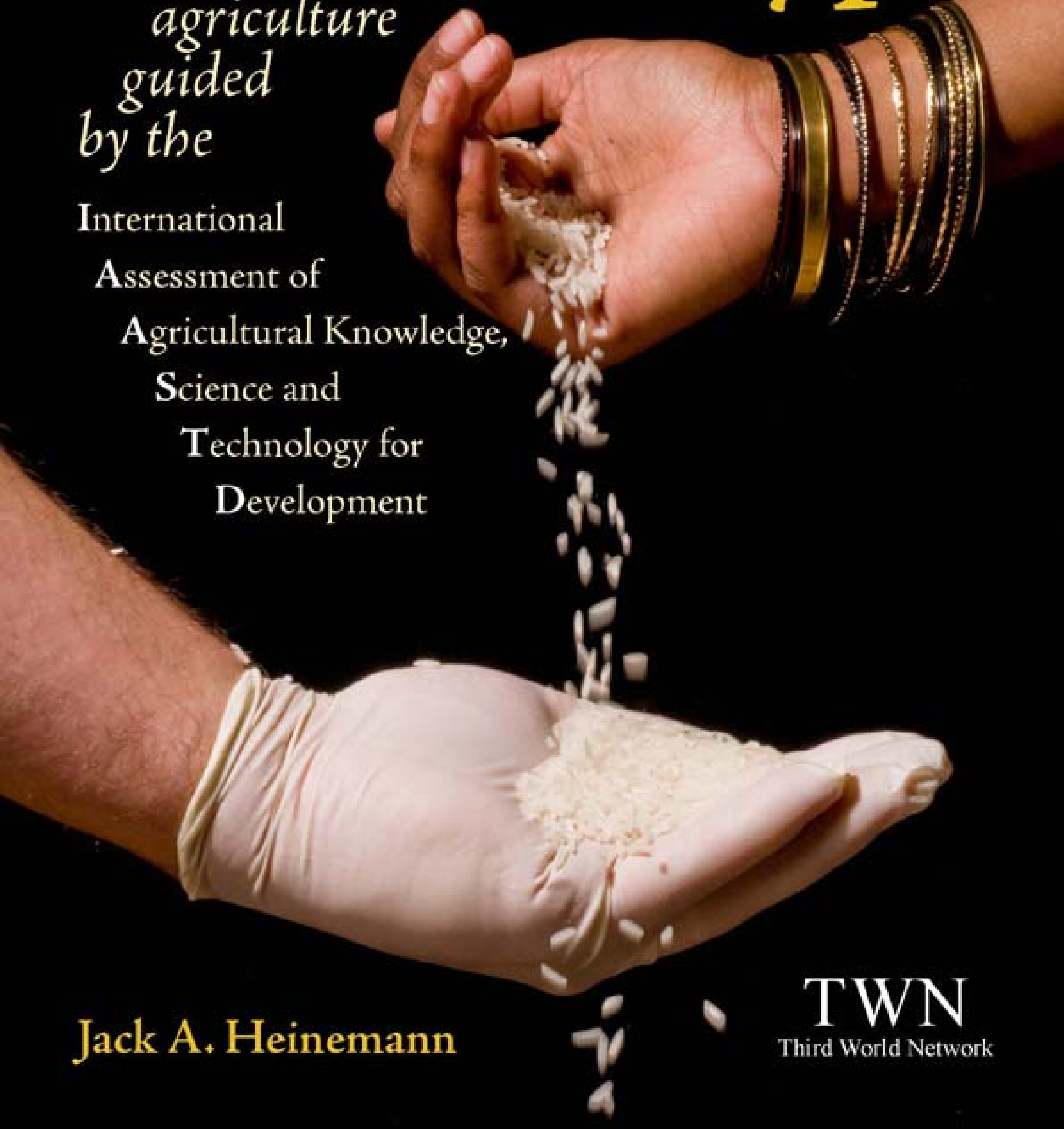
hope *not* hype

The future of agriculture guided by the

International **A**ssessment of **A**gricultural Knowledge, **S**cience and **T**echnology for **D**evelopment



Jack A. Heinemann

TWN
Third World Network

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Abbreviations and terminology

IAASTD	International Assessment of Agricultural Knowledge, Science and Technology for Development "The international Assessment on the future role of agricultural science and technology in reducing hunger and poverty, improving rural livelihoods, and facilitating equitable, environmentally, socially and economically sustainable development through the generation, access to, and use of agricultural knowledge, science and technology (hereinafter referred to as the Assessment) shall concentrate its activities on the task of a critical review of the literature, experience and knowledge pertaining to the scope of the Assessment as defined by the Panel of participating governments." (http://www.agassessment.org/docs/SCReport,English.pdf)
agroecology/ agroecological agriculture	the application of ecological concepts to the design and management of agricultural systems for sustainable production, healthy environments and resilient communities (Rivera-Ferre, 2008)
AKST	agricultural knowledge, science and technology
billion	thousand million (10^9 or 1,000,000,000)
Bt	soil bacterium *Bacillus thuringiensis* (usually refers to genetically modified plants made insecticidal using a variant of various *cry* toxin genes sourced from plasmids of these bacteria)
EFSA	European Food Safety Authority
EPA	Environmental Protection Agency (US)
ERMA	Environmental Risk Management Authority (New Zealand)
FAO	United Nations Food and Agriculture Organization
FSANZ	Food Standards Australia New Zealand
GAO	United States Government Accountability Office
GE	genetic engineering/genetically engineered
GLA	glufosinate-ammonium
GM	genetic modification/genetically modified
GMO	genetically modified organism
ha	hectare
HR	herbicide resistant (= HT in routine usage)
HT	herbicide tolerant (= HR in routine usage)
IPM	integrated pest management
IPR	intellectual property rights

IR	insect resistant (usually refers to insecticidal Bt plants)
kg	kilogram (10^3 grams)
MAB/S	marker-assisted breeding/selection
μg	microgram (10^{-6} grams)
mg	milligram (10^{-3} grams)
ng	nanogram (10^{-9} grams)
persistence	"The capacity of systems to continue over long periods" (after UNEP/UNCTAD, 2008)
PVP	plant variety protection
resilience	"Capacity of systems to resist shock and stress" (after UNEP/UNCTAD, 2008)
R&D	research and development
sustainability	A combination of resilience and persistence (UNEP/UNCTAD, 2008). May be applied to multiple goals, e.g., yield, economic, cultural, nutritional sustainability. Sustainability as applied to development is "[. . .] development that meets the needs of the present without compromising the ability of the future to meet their own needs" (quoted from another source in Maler et al., 2008).
transgene	a reference to the recombinant DNA used in a GMO
TRIPS	the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights
UNDP	United Nations Development Programme
UNEP	United Nations Environment Programme
UPOV convention	International Convention for the Protection of New Varieties of Plants
US/USA	United States/United States of America
USDA	United States Department of Agriculture
WTO	World Trade Organization

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Foreword

AGRICULTURE and the wider food system is not only at a major scientific but also social, environmental and economic crossroads, as the International Assessment of Agricultural Knowledge, Science and Technology for Development (IAASTD) has recently concluded. Relevant United Nations and other intergovernmental and international organizations have initiated and supported the IAASTD process since 2002, when it was given the go-ahead at the World Summit on Sustainable Development (WSSD), convened in Johannesburg, South Africa. Financially supported by the OECD countries, the private sector and with the active participation of all stakeholders from the North and the South, developed and developing countries, the design of the assessment and its realization were unique. The stakeholders defined the scope and content of the assessment chapters. The process and the authors were endorsed by a Bureau that represented all parties.

The reports, both at global and five sub-global levels, highlighted the great achievements of agricultural knowledge, science and technology over the past 50 years in reaching unprecedented levels of food, feed and fibre production, proving Malthus wrong on the quantity count. The reports however highlighted the major disconnects that have arisen along the way. The need to address also the "other side of the coin" – making agriculture equitable and sustainable while feeding a growing and more demanding population in the generations ahead – remains a substantial challenge.

It was not without good reason that the IAASTD saw its birth at the 2002 WSSD. Agriculture is at the centre of the multiple looming crises of water, soil degradation, energy costs, biodiversity loss, climate change, population growth, dwindling natural resources and increasing inequities.

The main IAASTD stakeholders therefore held a number of meetings around the globe to define the key development challenges that needed special consideration, in view of the challenges expressed above. The IAASTD key development challenges were four: 1. Hunger and Poverty; 2. Nutrition and Health; 3. Inequity and Rural Livelihoods; and 4. The Environment. The authors of the assessment addressed these issues in great depth and highlighted the disconnects between agriculture and the environment, between farmers and consumers and between policies and consequences. The essence of the main findings is summarized in the Synthesis and Executive Summary Reports in which the authors gave policy-makers a number of options for actions on the key findings.

This book is all about one issue that has been at the centre of controversies regarding the IAASTD, and which eventually led to the "walking-out" of Syngenta towards the end of the process and the rejection of the Report by CropLife International, the global federation representing the plant science industry. Biotechnology is without doubt a hot issue that is shrouded in layers of statements about its potential to solve the food production and nutrition issues in the future and also on how it will protect the environment and create new wealth along the way. There are different worldviews regarding the power of modern biotechnology, which includes transgenic organisms, with many convinced that it is needed and many others convinced that there are alternatives to address the problems that transgenic organisms are intended to solve – alternatives including other biotechnologies that address root causes, not symptoms. There are also others, whether they are critical, supportive or even neutral towards modern biotechnology approaches, who feel that much more research is needed in the area of ecological and health aspects before they may be used to solve some of the more intractable problems facing agriculture in the years ahead.

Hope Not Hype is exactly on target regarding what is needed today by the decision-makers, who are not specialists but need to have – in clear, comprehensive and short text – the main points to guide their decisions on biotechnology in agriculture. This book will help them to focus the picture chapter by chapter, putting its points across in language that is precise but remains understandable. Although targeted at the policy- and decision-makers in government, research and development institutions, the book will also appeal to scientists who want to know more about biotechnology. It is also useful to the education sector, providing information that can help to better educate students and the general public on the issues raised to make informed decisions at their own level. In the end, it is the public, making their choices through the market, that will have to decide what they want and the farmers will have to produce accordingly. A better-informed society will make the right decisions when it comes to future generations, but that is only possible if scientifically correct information and knowledge is available in understandable language – as in this book.

The book's sub-title indicates the link to the IAASTD and I am very pleased that the three-year writing effort by some 400 authors has inspired one of the authors to dig further and deeper into one of the more controversial aspects of the Assessment. The need to reach a consensus in such a large, multistakeholder process does not permit detail on any one particular issue; thus we welcome this in-depth exposition by the author of *Hope Not Hype*.

At a time when we need to rethink agriculture, as suggested by the IAASTD, recognizing the multifunctionality of agriculture, it is also timely to understand and reconsider the reductionism that is inherent to modern biotechnology. Even more importantly, we in the scientific and policy-making community need to pay full attention to the lessons learnt from the past. There are many lessons to be learnt from the history of agricultural knowledge, science and technology, as the IAASTD has brought to the surface. *Hope Not Hype* will help us all in moving forward with the cautionary principles that should be the standard in our moving ahead. Policy-makers in the area of agriculture as well as all involved even remotely with food security issues and increasing agricultural productivity should read this timely and inspiring book.

Hans R. Herren
Co-Chair, IAASTD

Preface

"Its robust editorial independence and its unapologetic scholarship have led its authors to say the unthinkable, and they then have the pleasure of watching conventional opinion catch up." – Foreword to the 10th *Human Development Report* (UNDP, 1999, p. v)

THIS book is meant to be a guide for the text of the Global Summary for Decision Makers and the Synthesis Report, the two summary documents of the reports prepared by the International Assessment of Agricultural Knowledge, Science and Technology for Development (IAASTD, what will be called the Assessment in these pages). The Assessment covered all scientific, technical, social and economic areas relevant to agriculture, but this book focuses only on the content relevant to biotechnology, without losing sight of the central place agriculture has in our societies and our survival.

> Agriculture has always been, and continues to be, one of the ways in which humankind has improved the basis of human existence on earth. Technologies were always an integral part of agriculture. Time and again, new technologies and developments have had a decisive impact on methods of cultivation, and our agriculture will continue in future to be based on innovations (Kern, 2002, p. 291).

I believe that international reports have value, but enormous acts of will consistently applied after publication are required to extract most of it. Without a doubt, the preparation of reports takes individual experts to new levels of understanding and thus these exercises build expertise on issues and don't just record expert knowledge. Some reports influence decision-makers and grassroots actions. Unfortunately, others have little impact or develop momentum very slowly. I don't believe that the Assessment has produced one of these latter kinds of reports, so I write this book as a contribution to the effort of making the Assessment relevant and available to those who can use it best. I believe that audience to be the farmer and farmer-centred societies who are counted among the most vulnerable human populations on Earth. Those, in short, who might be considered the orphans of agriculture.

The Assessment used the term "orphans", as have others (Kennedy, 2003), in the sense of orphan crops. In this book, the orphans of agriculture are all those who have been neglected or abandoned. The most important orphan is the starving, malnourished, dehydrated or impoverished child. She most likely lives in the poorest countries, such as those of sub-Saharan Africa or the islands of the Pacific, and has the least to benefit from the kinds of agricultural production and innovation that lately dominate in industrialized countries. Everyone knows this orphan even though so far the will to feed her has failed in us.

Another orphan is culture. While agriculture is ubiquitous, spreading through human society for an estimated 10,000 years (Gepts and Papa, 2003), societies have developed unique cultures around food and its production. For example:

> Ethiopia is known as a center of diversity hosting various flora and fauna. Traditional farmers living in the country's highly varied agro-ecological zones have developed various farming systems that are characterized by the high degree of inter- and intra-specific crop diversity across space and time. A wide range of crop diversity has been maintained by traditional farming societies in a sustainable way through the accumulated experience and interaction of farmers with their natural environment and without the need for technical scientific knowledge or external commercial inputs (Tsegaye, 1997, p. 215).

In this sense, agriculture is universal in the way that language is, but it has diverged between cultures, and defines cultures, with the same variety and difference that has marked the evolution of different languages. The reasons some of these cultures have gone extinct or are threatened may have little to do with their success at making food or providing other social goods such as jobs, feelings of self-worth, empowerment and education, and more to do with factors well outside the control of the farmer. Everything these cultures learnt and did is also not necessarily less sophisticated or successful than anything in modern industrial agriculture. These agricultures are therefore not to be judged as failed; each has its own history and local criteria for success. Indeed, as argued in these pages, the diversity of agricultures is itself a strength of humanity, rather than, as often implied, an artifact of societies in need of rescuing through homogenization with American or European approaches to industrial agriculture. The diversity of agricultures adds resilience to world food production just as wheat genetic diversity adds resilience to global wheat production. Diversity predisposes us to survive the crises we have yet to encounter. Large-scale industrial agriculture consolidating under the control of a small number of mega-corporations is a monoculture, not just a force creating monocultures.

The microbes, plants and animals being lost to the monoculturalization of agriculture are also orphans (Tsegaye, 1997).

> It is estimated that approximately 7,000 crop varieties are used world wide to produce food. However, modern large-scale agricultural production relies on an increasingly narrow and homogenous group of plant genetic resources for the majority of the world's food output. Modern agriculture tends to emphasise monoculture, which can impact plant diversity through selective cultivation and plant breeding thereby narrowing the genetic base for agricultural products. Today, less than 100 species of plants comprise 90 per cent of the world's total food crops (UNEP, 2003, p. 5) [and 14 mammals and birds comprise 90 per cent of the world's food from animals (FAO, 2006)].

As agriculture expands its footprint, it decreases not only agricultural biodiversity but all biodiversity.

Pioneer maize testing and research centre in New Zealand, February 2009. Pioneer is one of the world's largest maize seed companies, now owned by DuPont, one of the world's largest agrochemical and biotechnology companies (Pioneer, 2009).

> Because agriculture is a major land-using activity it has impacts on biodiversity. These include wildlife habitats and wild species as well as species diversity including crop genetic diversity. The main threats to wild species from agriculture originate from converting grasslands, forests and wetlands to cropland and more intensive grazing systems. In industrialised countries, in particular, the need for increased inputs such as feed grains has led to increasing field sizes, as well as other production related impacts such as diminished crop diversity, fewer crop rotations and the increased use of agrochemicals (UNEP, 2003, p. 5).

The loss of the nearly invisible biodiversity behind agriculture has a pipeline effect, strangling the demand for the human expertise needed to draw the attention of society to its value. The editor of the influential journal *Science* recognized this when he pointed to

> … the thinness of the public-sector knowledge resources that are available for some of the most important food security crops in the poorest countries. Among these orphan crops are yams and plantains, which are staple foods for many of the poorest sub-Saharan African nations. Less than half a dozen geneticists/plant breeders work on each of these crops. That's the world's only insurance against a catastrophe involving disease or stress resistance that

might affect tens of millions of people. These scientists should probably not take the same plane to their next conference (Kennedy, 2003, p. 357).

The final orphans are the externalities of agriculture that are given no explicit worth in present economic models and the ideas, thoughts, innovations and knowledge not recognized by prevailing intellectual property rights (IPR) frameworks. Too often these vital aspects of ecology and society are referred to disparagingly as "marginal", as in marginal land that hosts the biodiversity necessary to pollinate crops and clean the bodies of water we draw upon, and "common knowledge", as in the traditional knowledge that was modified for patenting.

Is the Assessment important?

The first indication that the Assessment will have an impact appeared in the few months before the final intergovernmental plenary that approved it. The big international science journals *Nature*, *Science* and *Nature Biotechnology* set upon the Assessment, arguing that it was anti-science and anti-technology. Their conclusions were drawn from anecdote using a small number of sources, and their editorial authors displayed little direct familiarity with the actual reports. What this concerted attack seemed instead to show was just who had the ear of the editors, and that seems to be the large international seed biotechnology companies.

The second indication that the Assessment will have an impact came from the overwhelming endorsement of the report by the governments. Only three governments – the United States, Canada and Australia – failed to approve the report.

Still more encouraging, 95% of the countries, including two-thirds of those that did not approve the Assessment's reports, accepted the text on biotechnology in the Synthesis Report *without reservation or debate*, despite this text being the focus of the science journals' rancour. That fact alone must have made an impact on an industry that is normally close to the ears of power.

As a lead author on the Global Report (Chapter 6), an author of the Biotechnology Theme in the Synthesis Report, and the author representing biotechnology at the intergovernmental plenary meeting, I have intimate knowledge of the Assessment's content and an insight into the arguments behind and sometimes against the text. I have prepared this guide as a resource to national decision- and policy-makers, the industry and research community, farmers, non-governmental organizations (NGOs) and citizens who, like the authors and sponsors, wish to use the Assessment as part of their own efforts to achieve the inspiring goals behind the project.

How can this book be used?

It is my hope that the book will be in the bags of those attending international negotiations on trade and biotechnology, and those sitting around the conference table during bilateral free trade agreement talks, in the libraries of fellow scientists and teachers, and on the minds of politicians.

Extensive citation to the peer-reviewed literature is provided, but I have tried to tell the story as much as possible in the words of the peer-reviewed authors upon which much of the Assessment is based. These are not necessarily the Assessment authors, but those who contributed to the research base that the Assessment draws upon. While this may at times jar the flow of the text, it has value in providing the decision-maker, civil society leader, negotiator and media with a context for important points and making it possible to recall precise language in the very words of the researchers on the cutting edge of the issues.

I even on occasion quote myself. Although it may seem odd to see, and was odd to write, when the quote was from a peer-reviewed publication this device fitted the style of the text. In any case, why rewrite something when making the point in any other way would amount to simply changing the words for the sake of it?

This book is not a comprehensive review of the literature on agricultural science and technology. For that, the reader should study the many reports within the Assessment. Instead, this book floats above the debates among experts to show how the authors reached final conclusions and recommendations. Most of the literature cited will be indicative of research that in the end was judged to be unanswered by an opposing view or, using the best judgment possible in an uncertain world, was determined to be the most consistent with research coming from other disciplines.

Acknowledgements

I want to thank my co-authors on the Assessment for teaching me so much about agriculture. This process has stirred in me respect for those who agree and disagree with the conclusions reached there and in this book. I don't believe that many individuals in industry, government, civil society or academia are disingenuous. While there is often disagreement, positions are taken on principle and not self-interest. Having said this, we cannot forget that both subtle and not-so-subtle insecurities and loyalties influence how people see the world (e.g., Katz et al., 2003; Mirowski and Van Horn, 2005). Scholars and industry scientists share the same common capacity as lawyers and environmental groups to be advocates. So while there would be no disagreement on the common goals of the Assessment, there is considerable debate on the path to those ends. Most of that debate revolves around just what is relevant to evaluating the success or failure of a technology or ideology. The great value of a project of the scale of the Assessment was to take away any possibility that a small group of people could restrict the criteria for evaluating the effects of biotechnology and market ideologies on agriculture.

I would also like to thank the Assessment's Secretariat for their encouragement and assistance with this book. I cannot forget to mention the University of Canterbury and especially my colleagues in the School of Biological Sciences and the Centre for Integrated Research in Biosafety who created space for me to participate in the Assessment and granted me a short sabbatical leave that helped me to write the book. Special mention is reserved for Camilo Rodriguez-Beltran, Thomas Bøhn, Marina Cretenet, Joanna Goven, Brigitta Kurenbach, Billie Moore and Paul Roughan. My gratitude goes to those who reviewed the manuscript and made such careful suggestions for improvement, especially

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Dedication

Lastly, this book is dedicated to my wife, Juliet Thorpe, who has made inspiring me a lifestyle.

Jack A. Heinemann
Christchurch, New Zealand
28 December 2008

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Chapter One

Précis for Policy-Makers

Key messages

1. The modern biotechnologies coming from developed countries favour large-scale farming of a small number of mega-crops. This range of crops does not fit the type and purpose of farms of subsistence and poor farmers.
2. Relatively new changes in patent and patent-like plant variety protection (PVP) intellectual property instruments influence the type of technologies dominating in developed countries, particularly in promoting the development of genetically modified/engineered (GM/GE) crops.
3. These same instruments create liabilities for farmers, by potentially extending proprietary ownership to non-GM crops contaminated through transgene flow.
4. Intellectual property and some biosafety regulations create liabilities for GM farmers and developers of GM crops, by also potentially extending proprietary ownership to inadvertently mixed GM crops containing transgenes from different developers and contaminated through transgene flow, and by linking damage to non-GM farmers or consumers to transgene flow.
5. The scale of and subsidies for farming in developed countries, along with efforts to harmonize intellectual property frameworks and protect intellectual property coming from developed countries, combine to inhibit the development of local agriculture markets in developing countries and have dampened research by and for local farmers.
6. The potential agronomic advantages of many GM crops are not realized by subsistence farmers who grow a large diversity of crops in close proximity, and GM crops make industrialized farmers and consumers vulnerable to the effects of monocropping, environmental damage from intensification, and loss of agro- and bio-diversity.
7. Policy options include a new emphasis on public funding of agriculture innovation for the poor and subsistence farmer. This may include a balanced portfolio of investment in improving agroecological methods applied at scale, farmer participatory and extension projects, and modern biotechnology research with a commensurate reduction in the emphasis on commercial control of products.

A SYNTHESIS of the best science on agriculture was the immodest goal of a project initiated in 2003 under the title of the International Assessment of Agricultural Knowledge, Science and Technology for Development, abbreviated as IAASTD. It was a joint project of the world's major agriculture and development institutions initiated by the World Bank and conducted in partnership with the United Nations Food and Agriculture Organization (FAO), UN Environment Programme (UNEP), UN Development Programme (UNDP), UN Educational, Scientific and Cultural Organization (UNESCO), World Health Organization (WHO) and the Global Environment Facility (GEF) (IAASTD, 2008a).

The large Assessment is comprised of a multi-chapter global and five multi-chapter sub-global reports with two overarching documents, the Global Summary for Decision Makers and the Synthesis Report. The entire project was supervised by a multistakeholder governing Bureau composed of representatives of the funding agencies, governments, private sector and non-governmental organizations (NGOs).

In what was a new approach to reaching global consensus, NGOs and the private sector were given equal speaking rights with government delegations during the intergovernmental plenary meetings. The Assessment was approved by an intergovernmental plenary on 11 April 2008 in Johannesburg, South Africa.

It is the single largest and most diverse global appraisal of agriculture ever undertaken (Rivera-Ferre, 2008). Hopefully, it has not been completed too late. Agriculture is coming under greater scrutiny than ever before as it is increasingly clear that the benefits and impacts of agriculture are not evenly shared between the rich and the poor.

The Assessment was set the ambitious task of answering the central question of how agriculture in 2050 will contribute to a well-fed and healthy humanity despite the challenges of vast environmental degradation, population growth and climate change, and do so in such a way that the potential to produce food has not been lost because of how we farm. One answer was simple. How we farm now will fail to achieve this goal. How we *should* farm was not as easy a question to answer.

Farming is much more than tilling the soil and herding livestock. Modern agriculture is conducted in a complex context of local environment factors, the choices imposed by poverty and disease, access to markets, international trade and the domestic policies of other countries. This larger context cannot be forgotten when making decisions on agricultural biotechnology, because these technologies must be workable and successful within this broader context.

For this reason, the Assessment covers much more than the biology behind food production. It is a rich resource on how trade rules, intellectual property rights (IPR), subsidies, mechanization and power asymmetries within and between societies and men and women collude to make the agriculture we have now. The Assessment speaks plainly about why who is funding innovation in agriculture is as important as what is funded. These are also the vital issues which must be changed or managed to get to the agriculture we need for a sustainable future.

Assuming that larger context is accessible to readers of the Assessment, this book will not dwell upon it. Biotechnology can be a technical, and to some a tedious, topic. Therefore, it deserves a guide to decode it. The large economic interests of those who sell some kinds of biotechnology can also create a knowledge asymmetry. This asymmetry arises both from the neglect of research that is not commercially oriented but is necessary for making proper evaluations of technology, and from access to existing information which can be locked behind expensive subscriptions to journals found in rich research universities.

Is biotechnology the way to improve agriculture?

Agriculture requires more land, water and human labour than any other activity (FAO, 2007). It consumes 40% of the planet's ice-free land (Jiggins, 2008) and 70-86% of extracted groundwater (FAO, 2003; Gerbens-Leenes et al., 2008; Pennisi, 2008). Half of the global workforce, or 22% of the world population, is employed in agriculture. This activity accounts for 24% of the gross domestic product in low-income developing countries (MEA, 2005).

Human activity at these scales has massive environmental and social consequences. While agricultural practices and cultural relations to food have evolved locally, globalization of trade and legal frameworks such as food/biosafety and IPR tends to homogenize agroecosystems. The result can be poor performance of crops, livestock and practices within local agroecosystems and greater damage caused to the surrounding environment (Taberlet et al., 2007; WHO, 2005).

Food security could be seen as a one-dimensional problem of producing enough food. However, even this one-dimensional view can be unpacked to reveal that food security is the combined challenge of changing human behaviour and technology to:

- increase yield (as in crop biomass),
- improve access to a balanced diet (e.g., micronutrients, variety, desired foods),
- improve access to water,
- increase agrobiodiversity which serves as a reservoir of trait diversity to adapt crops and livestock to emerging diseases or effects of climate change,
- increase and preserve biodiversity as a reservoir of microbes, plants and animals that directly or indirectly raise the productivity of the agroecosystem,
- increase capacity to breed traits from elite varieties of crops and livestock into locally adapted varieties,
- improve access to germplasm,
- improve access to markets.

Technology should be seen as part of a package of options to address problems caused by agriculture, and satisfy the needs of farmers. The Assessment was cognizant of the long history of contribution that science, technology and traditional knowledge have made to agriculture and to society. However, too much reliance on technology to increase the quantity and quality of food, reduce the social and environmental impacts of agriculture, or attempt to balance asymmetries caused by trade subsidies, will likely both create new disappointment and cause additional problems.

Many problems in agriculture are caused by *cultural* choices rather than technical problems (Heinemann, 2008a; UNEP/UNCTAD, 2008). For example, access to water may be a technological problem if the solution requires engineers to design a dam; it is social if this issue is one of crop type and purpose, as in choosing to use agricultural land to grow maize for food or fuel. In China and India, for example, 3,500 litres of irrigation water are required to produce a single litre of ethanol for fuel (EuropaBio, 2008). If they were to attempt to use their water to produce ethanol on the scale of the US, it would amount to a virtual transfer of over 100 billion litres of water per year from food production to engines (MSNBC, 2008). A non-technology change in fuel consumption habits could have a greater impact on long-term water availability than, for instance, a technological attempt to create plants that thrive on less water (Heinemann, 2008a).

This was among the lessons taken from the Assessment's historical view of both successful and failed technologies over the last 50 years. These lessons were then applied to current technologies and the problems they are proposed to solve, to extrapolate to a "best guess" of what will and will not work to meet future sustainability and productivity goals.

A multi-dimensional view of food security would include how the problems in agriculture are formulated in the first place and then, subsequently, how certain technologies and technological solutions are chosen. Only about "one-third (about US$10 billion) of all global research expenditure on agriculture is spent on solving the problems of agriculture in developing countries" (Kiers et al., 2008, p. 320), and thus it is no surprise that the needs of the largest and wealthiest farmers have been prioritized over the needs of small and poor farmers. Moreover, the private sector has usurped the public as the dominant investor in agriculture in industrialized countries and thus the problems identified for agriculture will tend to be those for which commercial technologies can be sold as a solution (Pardey et al., 2007).

A case in point is provided by the development of GM crops. These tend to be the types of crops grown in monocultures over large and near-homogenous agroecosystems that predominate in the Americas (Atkinson et al., 2003; Delmer, 2005). Changes in patents and patent-like PVP allow these crops to be protected by instruments that do not protect conventional plants (DeBeer, 2005). As a result, this technology has not been applied to crops grown by the poor, "the so-called 'orphan crops', such as cassava, sweet potato, millet, sorghum and yam" (WHO, 2005, p. 37), and in countries that do not recognize the types of patents and patent-like PVP for germplasm (Pinstrup-Andersen and Cohen, 2000; Pray and Naseem, 2007). Meanwhile, the GM plants that have been commercialized have commanded enormous resources, estimated at US$100 million per commercial variety (Keith, 2008), probably at the expense of non-GM biotechnology of value to the poor and subsistence farmer (Pinstrup-Andersen and Cohen, 2000; Reece and Haribabu, 2007; TeKrony, 2006).

On this point the World Health Organization concluded that a "needs-driven technology is a tool for growth and development which the private sector is unlikely to undertake, because [orphan] crops are of low commercial value. Governments should take the responsibility of investing in public research that is crucial to reducing food gaps between rich and poor" (WHO, 2005, p. 48). The World Bank reinforced this conclusion by saying that the "benefits of biotechnology, driven by large, private multinationals interested in commercial agriculture, have yet to be safely harnessed for the needs of the poor" (World Bank, 2007, p. 158).

For most subsistence farmers, the challenge is to produce a variety of foods (Delmer, 2005). This is a necessary practice that increases diversity in the diet and the resistance of local agriculture to a number of kinds of failures. A range of crops on the farm increases food security by decreasing the chance of complete crop failure from sporadic pest and disease infestations. Crops that can be cycled in rotation are also useful to maintain healthy soils and to discourage establishment of soil pathogens. Finally, provided that a market exists for any surplus production, the farmers can benefit from the sale of their crops. This is most likely for small crops that are not grown under the subsidies of wealthy nations and sold in local markets below local costs of production.

The goal of biotechnology policy goes beyond just producing more food because food surpluses alone will not feed the hungry (Kern, 2002; UNEP/UNCTAD, 2008; Vandermeer and Perfecto, 2007).

Present food shortages are firstly due to a failure to produce adequate amounts of quality food of the type appropriate for the community that needs it wherever those people may be, or, secondly, due to a failure to distribute the right kinds and quantities of food to wherever it is needed. In the future, food shortages may result from the inability to produce enough food because of cumulative environmental impacts of agriculture, urbanization and climate change, combined with excess reliance on limited fossil fuels for mechanization and fertilizers (Kern, 2002). We cannot address future food needs by relying on present models of agricultural innovation, from problem definition to research and development, because these models still have not adequately achieved food security for about 80% of the population (Kiers et al., 2008). Instead, biotechnologies that are understood at the local level, are amenable to local manipulation and innovative change, and that address farmers' needs are required.

Policy relevance: Few existing problems in agriculture are solely caused by a lack or failure of technology but instead derive from other social, economic or legal frameworks. It is therefore critical to first define what problems are best solved by changing legal frameworks, trade policies or human behaviour and, second, which are best solved using technology. Technology should meet the community's needs without making local agriculture less sustainable. For example, importing high-cost biotechnology seeds to grow crops for fuel on water-stressed land neither saves water nor reduces the impact this land-use decision has on food production.

Which biotechnology?

The Assessment carefully distinguished between the general term "biotechnology" and the more restrictive term "modern biotechnology", both because they mean different things in international agreements and because they can cause different social, legal and economic effects on societies that adopt them (Pinstrup-Andersen and Cohen, 2000).

The definition of biotechnology used by the Assessment was based on that in the Convention on Biological Diversity. In general terms, biotechnology is any intentional human manipulation of biological factors for some purpose.

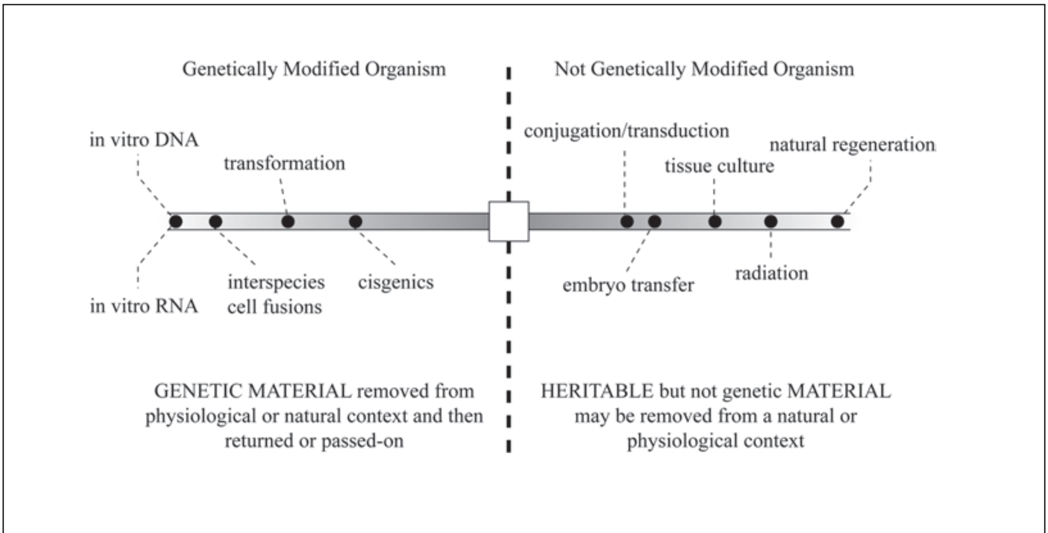
Biotechnology includes innovations such as the adoption of nitrogen-fixing cover crops, integrated pest management, and adoption of chemical herbicides and pesticides.

The selection of land races over millennia by ancient cultures was biotechnology. The maintenance of land races by modern peoples is also biotechnology (Tsegaye, 1997). Unfortunately, not all kinds of biotechnology are equally amenable to receiving the financial and other rewards appropriated by biotechnologies that can be protected by prevailing intellectual property frameworks, causing many profoundly beneficial biotechnologies to be underutilized because they are not distributed through a commercial provider or are not championed by the public sector (Gepts, 2004).

The definition of modern biotechnology was based on that used by the Cartagena Protocol on Biosafety. It is the class of human manipulations that result in unlikely or naturally unprecedented combinations of genetic material, such as DNA or RNA, or any activity that releases genetic material from its normal physiological constraints inside a cell or virus and then returns it to an organism (Figure 1.1). The most obvious product of modern biotechnology is a GM organism (GMO). GM plants are presently the main living commercial product of modern biotechnology for agricultural use.

Products of modern biotechnology are different from other biotechnologies in at least two important ways. First, their unique constitution of material means that they fall outside any human experience that might inform us about their human health or environmental impacts. Second, they are regulated by international biosafety laws and regulations and can be protected by a set of patents and patent-like PVP instruments that until very recently could not be applied to genes and living organisms anywhere in the world, and still are restricted to only those countries that have agreed to adopt this kind of intellectual property framework. While both of these differences make treatment of modern biotechnology unlike the treatment of biotechnology in general, it is the latter that has profound effects on who delivers technological solutions.

Figure 1.1: "The digital switch" (white square) between techniques of modern biotechnology that constitute the manufacture of a GMO (or "transgenic", left) and conventional biotechnologies that do not (right).



Privatization of germplasm

The ability to apply patents and patent-like PVP to transgenes has focused the vast financial resources of the largest agricultural multinational companies onto GM products (Baenziger et al., 2006; Fernandez-Cornejo and Caswell, 2006; Pingali and Traxler, 2002; Sagar et al., 2000). The adoption of new patents and patent-like PVP instruments was quickly followed by a transfer of ownership of germplasm from the public to the private domain with consequent restriction on farmers' rights (Graff et al., 2003; Sagar et al., 2000; World Bank, 2007). The industry is still consolidating under these new intellectual property rules (Adi, 2006; Fernandez-Cornejo and Caswell, 2006). The combination of industry consolidation and intellectual property has restricted the flow of technologies to farmers in developing countries and reduced agrobiodiversity (Pray and Naseem, 2007; WHO, 2005).

The Assessment did not endorse either the trend of shifting agriculture innovation to the private sector or the use of genetic engineering by the large biotechnology companies. Past major changes in agriculture were encumbered by neither this degree of privatization nor these kinds of intellectual property instruments, so there is no reason to expect that this kind of market-driven research and development will benefit the poor and subsistence farmer into the future (Srinivasan, 2003; WHO, 2005).

The new market model fails because it relies on the goodwill of the private sector to make relevant biotechnologies at a financial loss or without intellectual property protection for its products. This goodwill simply does not exist because the industry argues that "it is only if companies…protect their intellectual property that they can invest in products to benefit all. Innovation is only created through investment, and *investment must be rewarded*" (Keith, 2008, p. 17, emphasis added). The industry is thus also reluctant to make products relevant to small farmers in poorer countries because many of these countries do not have the IPR frameworks that biotechnology companies demand (Monsanto, 2008).

Even if there were sufficient incentive for these companies to make products, the exported technologies would still be "locally black box" – that is, how they worked would be opaque to small farmers or hidden in proprietary secrets – and thus create further dependencies on exporters who assist with local integration and optimization.

Policy relevance: Biotechnology has made tremendous contributions to agriculture, with some biotechnologies as old as agriculture itself. Free-to-the-public technologies and extension services are important to farmers. In contrast, modern biotechnology has a poor track record of relevance to the poor and subsistence farmer and its control by a relatively small number of large multinational companies means that adopting modern biotechnologies could also require accepting significant social changes and adopting agricultural models that may not result in poverty reduction or sustainable practices, while also increasing the dependency of local farmers on technological exports from the wealthy countries.

Liability

The fundamental identifier of a GMO, the transgene(s) that is made from recombinant nucleic acids, also provides a powerful way to track organisms' movements. As a result, the farmer takes on a quantitatively higher risk from legal actions that claim harm from the movement of GMOs (Heinemann, 2007).

On the global level, the unapproved admixtures of StarLink corn in 2000, ProdiGene pharmaceutical corn in 2002, Bt10 corn in 2005, and LLRICE601 rice in 2006 indicated the costs to developers and GM farmers when unapproved transgenes were discovered in commercial supplies (Ledford, 2007; GAO, 2008). Each of these escape events attracted fines and costs, some of which are estimated to reach up to US$1 billion (Smyth et al., 2002). This list is not exhaustive, with new escapes continuing to arise. On the local level, GM farmers may be liable if their crops contaminate those marketing under GM-free certifications, or if they fail to contain crops producing compounds that are harmful to human health and the environment, such as some pharmaceutical crops (Editor, 2007; Heinemann, 2007).

Both GM and non-GM farmers also face new liabilities from their neighbours' choices to grow GMOs. Any farmer, GM or not, may be liable if GM volunteers, feral plants or cross-pollinated plants with proprietary transgenes are found growing in their fields without permission (DeBeer, 2005; Heinemann, 2007). This legal exposure may transfer to new owners of the farm if it is sold and can extend beyond territorial limits through the use of material transfer agreements (Center for Food Safety, 2005; Correa, 2006; Thomas, 2005).

As the ability to detect transgenes is quantitatively far more effective than observing traits in plants and animals for variety protection, and because the detection can be made even in processed materials well down the supply chain, patents and patent-like PVP make the mere presence of transgenes enough to trigger liability and consequent economic harm wherever such instruments for germplasm are recognized (Heinemann, 2007).

Policy relevance: The ability to apply patents and patent-like PVP to germplasm, i.e., transgenes, creates liability for farmers and developers independently of actual human health and environmental concerns. Transgenes can be detected using powerfully sensitive molecular techniques and followed throughout the food and feed supply chain, even in highly processed end products. This unprecedented sensitivity of detection and forms of products amenable to monitoring allow developers to prosecute farmers who have purposefully grown or inadvertently been contaminated with proprietary germplasm, and can make GM farmers liable for contaminating neighbouring farms.

Evaluating the benefits of genetic engineering

The Assessment dealt almost exclusively with genetic engineering applied to the development of transgenic crops because there are currently no commercial GM animals for agriculture (Devlin et al., 2006; WHO, 2005). The complexity of achieving significant change in animals by genetic engineering also places the availability of such products in doubt (Clark and Whitelaw, 2003; Maclean, 2003). As both GM plants and animals suffer from a high degree of consumer skepticism over their safe use in human food and release into the environment (Devlin et al., 2006; Pryme and Lembcke, 2003; Stewart and Knight, 2005; van Eenennaam and Olin, 2006), coverage of GM crop plants in this précis will include most issues pertinent to all GMOs.

While genetic engineering for the production of transgenic crops holds promise, there is much agreement that genetic engineering's promise has not paid sufficient dividends while it has been within such restricted legal frameworks as patent systems and left to private sector incentive systems (Heinemann, 2008b; Pray and Naseem, 2007). Nevertheless, the Assessment came to the conclusion that genetic engineering should continue to contribute to research and development. Genetic engineering applied as a research tool to help understand the complex interplay between genes, physiology and environment is profoundly important. But not all science relevant to technology has to become a technology in the process, or result in a particular product such as GM plants. Meanwhile, the products of modern biotechnology could be developed under a strong public investment scheme that is itself largely free of the strictures of patents and that is also able to prevent the capture of public intellectual property by the private sector (Graff et al., 2003).

Policy relevance: Modern biotechnology has yet to produce a commercially viable example of GM fish, poultry or livestock. The living products are mainly crop plants. Other applications of genetic engineering do not result in GMOs as products and can contribute to agriculture research and development as well as important basic science findings.

Regardless of whether genetic engineering is done by the private or public sector, is there reason to have confidence that it will produce the food that we need in the future? This question is answered by the following focus on specific issues.

Yield

After a dozen years of commercial planting of GM crops including maize, cotton, soybean and oilseed rape, there is no evidence of sustained, reliable or consistent increases in yield. In fact, there have been strong indications that the adoption of GM crops has resulted in yield declines.

There are anecdotal reports of both yield increases and decreases. Bt cotton, GM varieties that produce an insecticide, reportedly out-produced conventional varieties by an average of 60% over a four-year study in India (Qaim and Zilberman, 2003). Meanwhile in other provinces of India Bt cotton performed poorly (Mancini et al., 2008). Bt cotton was shown to increase yields and farmer income in various short-term studies undertaken in Argentina, China, South Africa and Mexico although the yield increases were highly variable (Raney, 2006). In contrast, in the United States where Bt cotton has the longest history of cultivation, there has been an overall and significant net loss in both yield and farmer income (Jost et al., 2008).

The story is the same for other GM crops. “There is widespread consensus that yields have not increased, rather they have tended to be lower compared with conventional varieties” (Pretty, 2001). Bt corn in the United States and Canada and herbicide-tolerant soybeans in Argentina and the United States have either not increased yield or have decreased yield (Elmore et al., 2001; Ma and Subedi, 2005; Pray and Naseem, 2007; Qaim and Zilberman, 2003).

These figures should come as no surprise. Close to 99% of all commercial GM crops are engineered to be herbicide- and/or insect-tolerant (Qaim and Zilberman, 2003), but not engineered to increase yield (Fernandez-Cornejo and Caswell, 2006). Most yield benefits have derived from the use of modern varieties that are adapted to local conditions through conventional breeding rather than genetic engineering techniques. Worryingly, in two studies, one involving Bt maize and the other herbicide-tolerant soybean, the genetic engineering process was linked to damaging the yield advantages of the modern varieties that were made into GM crops (Elmore et al., 2001; Ma and Subedi, 2005).

The Assessment evaluated this data and came to the conclusion that genetic engineering has not demonstrated that it can or would produce varieties with sustained yield increases.

Policy relevance: Modern biotechnology and its products have not reliably increased yields of crops. If GMOs are being considered for inclusion in an overall national strategy on agriculture, then their proposed benefits to the agroecosystem require new evidence. Meanwhile, the adoption of genetic engineering will be accompanied by new environmental and social externalities, such as IPR frameworks, which are required to integrate them as commercial products and which do not increase food security or reduce poverty.

Pesticide reductions

The benefits of GM crops to yield may be indirect through improved pest management rather than due to an increase in biomass under all conditions (Fernandez-Cornejo and Caswell, 2006). The Assessment evaluated whether herbicide-tolerant crops and insect-tolerant (Bt) plants improved pest management and whether there were other benefits, such as a reduction in the use of other kinds of herbicides and insecticides and concomitant environmental and human health benefits (Phipps and Park, 2002; Pretty, 2001).

The data behind claims of decreases in use of agrochemicals because of GM crops is contested (Pretty, 2001). Some researchers point to dramatic decreases in overall additional insecticide use, but they neglect to include the amount of insecticide being produced by the Bt plants themselves. Claims of overall reduction in the use of pesticides must be unpacked, because the use of herbicides has probably dramatically increased and is balanced by a decrease in the use of *additional* (that is, beyond the insecticide produced by the plant itself) insecticides (Heinemann and Kurenbach, 2008).

That debate, however, was of secondary importance in the Assessment to the claim that the introduction of herbicide-tolerant crops has significantly decreased the diversity of pest management techniques used on GM crops. This has resulted in an uncontested increase in the use of glyphosate-based herbicides and an associated development of tolerant weeds (Powles, 2008; Service, 2007; Valverde and Gressel, 2006). Only GM cropping has permitted the combination of herbicide overuse and the scale of overuse on soybean and maize to make glyphosate-tolerant weeds a potential menace to production both inside and outside of GM cropping systems, and threatens the ability of conventional farmers worldwide to use this tool as part of their weed management strategies (Heinemann and Kurenbach, 2008).

Part of the impression that various GM crops outperform conventional crops comes from the design of experiments in which the differential in yield or pesticide use is measured, or because of the particular agroecosytem in which the measurements are made (Marvier et al., 2007). If Bt crops are compared to conventional crops that are grown outside of an integrated pest management system or with no application of insecticide, then the Bt crop will outperform the comparator crop. If herbicide-tolerant crops are compared to conventional crops without the use of some form of weed control, similarly the GM crop will outperform the conventional crop. However, these comparators are not realistic because farmers do practise some form of pest control regardless of how they farm. Likewise, it matters where the measurements are made (Kleter et al., 2007). For example, "data for beet and soybean also show that it is not always possible to extrapolate directly from the data previously assessed for the impacts of the same crops in the USA owing to differences in agricultural practices in the various regions" (Kleter et al., 2008, p. 487).

The largest meta-analysis ever conducted on the relative performance of agroecological and conventional (which in this case could include GM) agriculture came to a similar conclusion (Badgley et al., 2007). When land previously used for conventional agriculture was switched to agroecological agriculture, it would perform less well under this type of cultivation for up to five years post-switch. However, when comparisons were made between mature agroecological plots and conventional plots, the former equalled or significantly exceeded its conventional counterpart (Badgley et al., 2007). This is also true for measurements of indirect benefits. "[A] GM technology resulting in reduced use of pesticides could be more sustainable than a conventional system relying on pesticides, but this GM/reduced-use system would score less well if compared with an organic system that used no pesticides" (Pretty, 2001, p. 255). How the comparisons are designed has a big impact on the kind of data produced.

Policy relevance: Modern biotechnology may have indirect benefits through reduction in the quantity or type of pest control agrochemicals that are used on GM crops. These benefits are contested and likely not sustainable. Moreover, these benefits fare poorly overall in comparison with agroecological farming approaches.

Stress tolerance

Stress refers to the physiological response of plants and animals to environmental conditions normally outside their optimal physiological range. Drought stress may be the biggest single factor limiting current crop productivity (Delmer, 2005; FAO, 2007). Salinity is an associated problem, affecting 20% of all agricultural lands, but its effects are especially concentrated on irrigated land where 40% suffers from too much salt (Foster and Chilton, 2003; WHO, 2005). Drought and salinity have been longstanding challenges of agriculture intensification, and therefore one of the earliest suggested applications of genetic engineering was to create drought- and salt-tolerant crops (Heinemann, 2008a).

All stress-tolerant GMOs remain promises rather than products despite a dozen years of commercial GM agriculture and over 25 years of research (WHO, 2005). This is probably because the physiology of stress tolerance involves the interactions of many different genes working in a complex, environmentally-responsive network (Varzakas et al., 2007; WHO, 2005; Zamir, 2008). Occasionally just a few genes will be enough to create drought tolerance when measured in select environments. However, genetic engineering is unlikely to produce reliable drought tolerance in most crops grown in actual field conditions because it is unable to mix and match so many genes at once (Pennisi, 2008; Sinclair et al., 2004). There is little hope that this assessment will change (Varzakas et al., 2007; Zamir, 2008).

Despite years of under-funding when compared to modern biotechnology (Reece and Haribabu, 2007; TeKrony, 2006), conventional breeding and the use of DNA-based techniques that do not produce GMOs has achieved and can continue to achieve stress tolerance in both plants and animals (Delmer, 2005; World Bank, 2007). Marker-assisted breeding or selection (MAB or MAS) allows breeders to follow genes of interest throughout a breeding programme and in that way bring about the development of individuals with complex combinations of traits without manipulating their DNA. This approach and breeding in general is likely to be limited, however, by a startling reduction in the number of those with skills in breeding crops and livestock to develop adapted varieties (Baenziger et al., 2006; Reece and Haribabu, 2007). Another concern for MAS is that the markers themselves may be captured under some IPR frameworks and this further restricts the benefits of this technology to those who can pay (Reece and Haribabu, 2007).

Regardless of how they are developed, stress-tolerant plants and animals also have potential environmental impacts. In the case of plants, land currently “marginal” for agriculture may be recruited for agriculture by drought- and salt-tolerant crops. These lands, however, are important reserves of biodiversity, water purification, micronutrient recovery and other so-called “ecosystem services” that are necessary for mitigating the impacts of human activity (IAASTD, 2008b; MEA, 2005). Or the new plants may cause a loss of biodiversity on land providing ecosystem services (Ellstrand, 2006). “[N]ew traits such as stress-tolerance may increase competitive ability allowing the species to invade into natural habitats and/or replace natural or agricultural communities by expanding plantings into regions where the crop previously could not grow. For example, if aluminium-tolerant crops could be planted on a large scale in high aluminium, acidic soils, such as savannas or cleared rainforests, this may reduce biodiversity or endanger or eliminate the original communities” (Andow and Zwahlen, 2006, p. 208).

In the case of animals, stress tolerance is perhaps most advanced in fish, where stress includes cold, freezing, salt and disease (Dunham, 2008; Maclean, 2003). GM animals may survive through longer migrations, across season variations or the transition to new environments, possibly increasing their ability to invade new ecosystems.

Policy relevance: DNA-based techniques such as MAS could contribute to ongoing research and development of stress-tolerant plants and animals. However, to date, modern biotechnology has not produced stress-tolerant commercial GMOs for agriculture. Moreover, using genetic engineering to mitigate impacts of intensification and expansion of agriculture that increases cultivation under stress may result in additional environmental problems and therefore probably cannot be sustained. The full benefits of DNA-based technologies and modern varieties of plants and animals will only be realized if a new public effort is made to increase the number and skill of professional breeders.

Alternatives to modern biotechnology

Alternative production systems, notably those based on agroecological methods, can be competitive with or superior to conventional and genetic engineering-based methods for productivity. They must be able to avoid expansion of the agroecosystem which has profound impacts on biodiversity and ecosystem services (Ammann, 2005; Kiers et al., 2008; Marvier et al., 2007; MEA, 2005). Fortunately, these methods not only lower the environmental impacts of agriculture, they may also reverse past damage. The World Health Organization concluded that "[t]ransforming the agricultural systems of rural farmers by introducing technologies that integrate agro-ecological processes in food production, while minimizing adverse effects to the environment, is key to sustainable agriculture" (WHO, 2005, p. 35).

Agroecological methods, which include but are not restricted to those under the organic market certification label, significantly reduce the application of externalities such as petroleum-dependent fertilizers, improve water use efficiency, and restore to the soil those nutrients that are not replaced by fertilizer (Badgley et al., 2007; Schiermeier, 2008; Tilman, 1999; Zoebl, 2006).

However, these biotechnologies alone are also not solutions to the problem of attaining a sustainable and sufficiently productive agriculture (Tilman, 1999). They will require commensurate social and policy changes to ensure their success (de Jager, 2005). For example, investments in farmer participatory breeding and extension services have made significant contributions to yield increases and reduced environmental impacts (Badgley et al., 2007; Rosegrant and Cline, 2003).

There are collateral benefits of these associated social support systems. Farmer participation eliminates the "black box", making the introduced biotechnology accessible to further optimization and development at the local level, and converts the farmer into a local resource for other farmers (Gyawali et al., 2007; Harris et al., 2001).

Policy relevance: Provided that sufficient resources are identified to integrate biotechnologies such as agroecological methods, breeding and MAS through farmer participation and extension services, there are clear alternatives to the use of genetic engineering. These alternatives have demonstrated far greater potential to meet future food needs, permit production at the local level, and incur far fewer environmental and social costs.

Conclusions

The dramatic shift of responsibility for agriculture research and product development to the private sector has not been a successful experiment for farmers outside of the large economies that are also among those with the highest levels of internal agricultural subsidies. Those subsidies allow farmers to purchase high-cost biotechnology seeds even if those premiums are associated with net losses (Jost et al., 2008). Meanwhile, the adoption of revised patent and patent-like PVP instruments concentrated the seed industry, which raised prices and promoted products best suited to intellectual property protection rather than to yield and sustainable production in either developed or developing economies (Adi, 2006; World Bank, 2007).

Fortunately, the prognosis for agriculture is optimistic because many of the biotechnologies needed to both feed the world and do so in an environmentally and socially sustainable way already exist. These biotechnologies are not “high tech” as much as they are the “right tech” (and are very sophisticated). They are also “open source” because they are usually difficult to appropriate and monopolize, and are user-friendly. The option available to policy-makers is to invest not just in these biotechnologies, but to invest in the social and regulatory infrastructure necessary to implement them. It appears clear that more investment in conventional breeding augmented with MAS, a skilled workforce and greater farmer participation will pay dividends.

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Chapter Two

Setting the Scene

Key messages

1. The International Assessment of Agricultural Knowledge, Science and Technology for Development (IAASTD) achieved an international consensus and acceptance on the social, economic, policy and biotechnological direction of agriculture till 2050.
2. "Business as usual" in agriculture is not a viable option. Significant change does not require radical action, but ignoring the problem will have terrible consequences.
3. The forms of biotechnology offered by developed countries are not appropriate for the rest of the world, and the emphasis on research and development securing private wealth is frequently at the expense of both sustainability and social goals.
4. Developed countries are increasingly bidding their high per capita fuel demands against the need for food in developing countries, and subjecting poorer societies to the excesses of subsidized industrial agriculture by undercutting local markets, with consequential threats to food security and loss of rural livelihoods.
5. The solutions lie in a return to the biotechnologies that have been and will continue to be successful at both providing enough high-quality food and allowing local innovation, ownership and control.

"Before discussing orthobiotic innovations – the possibilities of human improvement from new knowledge of molecular biology and genetics – we ought to reflectively ask 'what are man's real problems in biological perspective?' We do better to look for solutions to real problems, if we can, than invent problems for our new tricks and techniques." – Nobel laureate Professor Joshua Lederberg (Lederberg, 1970, p. 34)

THE purpose of this book is to lay out the arguments and evidence used by the authors of the Assessment to reach their conclusions. The rationale for presenting the evidence in this way is to make it possible for those countries with fewer resources and with limited access to the broader research literature to have at their fingertips exactly the evidence they need when negotiating and setting legislation and policy on biosafety, biotechnology and agriculture.

The many quotes and citations in this book are not necessarily sourced from the works of Assessment authors; these are the resources *behind* the Assessment. The entire research effort of the Assessment is recorded in its bibliography. That is not reproduced here. What appears here are quotes and citations of the literature that captured the quintessential thinking at the end of the scholarly process.

My role has been to weave them into the story of the Assessment so that, for example, governments can point with confidence to the most recent science that justifies their policies on agriculture. Select text of the Assessment's two summary documents called the Global Summary for Decision Makers and the Synthesis Report is reproduced in boxes to make clear what conclusions of the Assessment are being discussed. Evidence quotes of exceptional importance to the story are also highlighted as boxes so that they may be found quickly.

Why agriculture is special

Agriculture is humankind's largest activity and it has the largest impact on environments and lives (FAO, 2003; FAO, 2007b; Gerbens-Leenes et al., 2008; Jiggins, 2008; MEA, 2005; Pennisi, 2008).

Worryingly, per capita food production fell by 0.2% in 2006, the first decline since 1993 (FAOSTAT 2008). At the same time, prices for grains in particular have been on a sharp upward trend and this is having far-reaching ripple effects.

> Rarely has the world witnessed such a widespread and commonly shared concern on food price inflation, a fear which is fuelling debates about the future direction of agricultural commodity prices in importing as well as exporting countries, be they rich or poor (FAO, 2007a).

In addition to stalling global production and a steep decline in grain stocks, the onset of higher prices has been exacerbated by demand for biofuels to supplement fossil fuels with ethanol derived from grain. Agriculture is torn between meeting food and fuel needs, both of which continue to grow (FAO, 2007a; FAO, 2007b; Rivera-Ferre, 2008).

The executive summary of the IAASTD's Synthesis Report puts it bluntly: "Business as usual is no longer an option" (IAASTD, 2009, p.3). Agriculture as practised today is not sustainable, nor can we rely upon it to meet food production and social and environmental goals if it does not chart new directions. Mainly those new directions will have to come from developed countries.

Those with food surpluses must begin to organize their agriculture so as to stimulate and sustain agriculture *outside* of their own borders. Presently many of the large food-exporting nations subsidize food production (Helling et al., 2008; Kiers et al., 2008). The amount of domestic subsidies by these economies was already US$327 billion in the year 2000 (Evans, 2005). The total estimated cost of farming subsidies in wealthy nations is an annual US$24 billion loss in income to developing economies (Helling et al., 2008).

> Thus, farming subsidies in developed countries hinder the economic development of less developed nations. Essentially, government-sanctioned agricultural subsidies in developed states, which result in subsidised farmers selling goods for less than the cost of production, deny farmers in developing countries the chance to compete in the international market, consequentially devastating local economies (Helling et al., 2008, p. 66).

This practice is a prescription for global hunger that will increase the chances of starvation. Instead, these large economies must learn to import new economic models of fairness and cooperation (Box 2.1).

Box 2.1: Cotton subsidies in the United States

The most heavily subsidized farmer in the US, and possibly the world, is the cotton farmer. Some American cotton farmers received up to US$230 per acre in 2001-2. "America's subsidised products undermine the economies of [Benin, Burkina Faso, Chad and Mali] by lowering the worldwide price. American subsidies stimulate US production of cotton, therefore increasing world supply and depressing prices. As a result, cotton farmers in developing nations find it difficult to sell their cotton for a profit" (Helling et al., 2008, p. 66).

Meanwhile, Americans pay twice for their cotton shirts. Since the cost of American cotton is about 22 cents higher than world commodity prices, the consumer pays about US$13 more taxes per year to prop up cotton production and more for imported cotton due to tariffs, for a total of up to US$4 billion.

In an opinion piece published by the *New York Times*, the presidents of Burkina Faso and Mali appealed to Americans to end cotton subsidies, arguing that up to 40% of export revenues for Benin, Chad, Burkina Faso and Mali come from cotton (Touré and Compaoré, 2003). These presidents succinctly captured the realities of these inequities when they said that "the payments to about 2,500 relatively well-off farmers [have] the unintended but nevertheless real effect of impoverishing some 10 million rural poor people in West and Central Africa".

Thus it is perhaps no surprise that various publications and industry groups who represent "business as usual" went on the attack in the few weeks before the IAASTD intergovernmental plenary met in Johannesburg in April 2008 (see, for example, Editor, 2008a; Editor, 2008b; Keith, 2008; Minigh, 2008; Stokstad, 2008). While the focus of the attack was primarily driven by their perceptions of the Assessment's conclusions on biotechnology, particularly modern biotechnologies such as genetic engineering/modification (GE/GM), there were also criticisms directed at the Assessment's findings on trade policy (Salleh, 2008). These charges have been effectively answered (e.g., Heinemann, 2008; Jiggins, 2008; Kiers et al., 2008; Leakey, 2008; Rivera-Ferre, 2009).

The larger issue that the Assessment seeks to address is, “How do we find the right balance between incentives for private profit and public good if the goal is to engineer a sustainable and productive agriculture in all societies?” To come up with an answer, the Assessment has drawn conclusions from the best possible research available, recognizing that there are knowledge gaps in humanity’s understanding of the science and technology. There are even more gaps in understanding the complex social, economic and legal contexts – in all their diversity on a global scale! – in which this science and technology exists. Undoubtedly, some of the lesser conclusions drawn from the available research will turn out to be wrong, or at least not completely correct. That can be expected of any attempt to capture a snapshot of a complex system. However, the key findings have a good chance of remaining valid or mostly so, as they have had the benefit of being drawn from such a wide range of expertise and inputs. Smaller-scale research exercises simply cannot command such diversity and facility to debate the difference as the 400-strong Assessment team mustered. The most important finding is that even if we disagree on how to set agriculture on the right course, we must agree that we have not already done so.

Biotechnology

The Assessment says loud and clear that the goal of biotechnology must be more than increasing yield, and that incentives for innovation in agriculture must re-focus on improving the lives of small, subsistence and poor farmers (see also Pray and Naseem, 2007; UNEP/UNCTAD, 2008).

> [T]he biggest risk of modern biotechnology for developing countries is that technological development will bypass poor farmers and poor consumers because of a lack of enlightened adaptation. It is not that biotechnology is irrelevant, but that research needs to focus on the problems of small farmers and poor consumers in developing countries. Private sector research is unlikely to take on such a focus, given the lack of future profits. Without a stronger public sector role, a form of “scientific apartheid” may well develop, in which cutting edge science becomes oriented exclusively toward industrial countries and large-scale farming (Pinstrup-Andersen and Cohen, 2000, p. 165).

It further argues that biotechnology must be optimized for production and for the society that applies it. Present commercial models fail to do this.

> The private sector is also unlikely to invest in research for difficult growing environments, such as drought prone or high temperature environments for several reasons. These environments tend to have poorer infrastructure and are farmed less intensively, raising unitary marketing and distribution costs. Also, the expected rate of yield gain is a key determinant of farmer demand for seed and breeding progress in stressed environments is generally slow. Therefore orphan crops in marginal (stress prone) environments are unlikely to be of interest to the private sector now or in the future (Pingali and Traxler, 2002, p. 233).

While food production is no longer steadily increasing, the world still produces more food than it needs. However, food surpluses alone will not feed the hungry because they do not feed the hungry now (Kern, 2002).

> The world already produces more food than it consumes, and there is general agreement among conventional development experts as well as so-called hunger activists that inability to purchase readily available food is normally the problem, not absolute abundance of food, certainly not at the global level and only rarely at a regional level. Indeed, even in the face of some of humanity's most famous famines, food was exported away from the famine victims (Vandermeer and Perfecto, 2007, pp. 274-275).

> Increased food supply is a necessary though not sufficient condition for eliminating hunger and poverty. The food security of any region is not simply a question of producing enough food to meet demand; it is influenced by a multitude of factors both natural and human-made. Increased food supply does not automatically mean increased food security for all. What is important is who produces the food, who has access to the technology and knowledge to produce it, and who has the purchasing power to acquire it (UNEP/UNCTAD, 2008, p. 3).

Food shortages are also likely to increase as cumulative environmental impacts of agriculture, urbanization and climate change, combined with excess reliance on limited fossil fuels for mechanization and fertilizers, become more pronounced in the decades ahead (Kern, 2002). Governments cannot address those challenges by relying on present models of agricultural innovation because these models have produced too many biotechnologies that ignore or exacerbate the problem. Instead, countries need appropriate biotechnologies that are understood at the local level, are amenable to local manipulation and innovative change, and address farmer needs. These also need to undergo comprehensive and inclusive impact assessments.

> In [the IAASTD] vision, farmers won't just have to produce enough to head off the Malthusian food crisis economists believe is threatening the planet as its population grows ever larger. They will also be made custodians of nature, crusaders in the battle to combat climate change, engines of economic growth and gurus spreading technology and education to the remotest corners of the world (Coghlan, 2008, p. 8).

Genetic engineering

Let's address, however, the issue that has attracted the most attention. The Assessment has not endorsed either the trend of shifting agriculture innovation to the private sector or the use of genetic engineering by the large biotechnology companies. With the majority of funding for agricultural innovation now coming from the private sector in the developed countries, and the total being spent by the largest companies dwarfing the research budgets of developing countries (IAASTD, 2008; Kiers et al., 2008), agriculture innovation is deterministically following a short-term, market-driven course.

> Unlike the public-sector research that launched the Green Revolution, private firms based in industrialised countries have done the majority of agricultural biotechnology research and almost all commercialisation of genetically modified (GM) crops (Pray and Naseem, 2007, p. 192).

The wealthiest countries with the largest food production systems have forgotten their own roots, their own pathway to food surplus, as they now rely on privatized research and development and, through liberalized trade initiatives, attempt to push this model onto developing economies. Simultaneously, they have left it to the poorer nations to sift through the science and technology coming from this new model to find what they need. And the poorer nations haven't found that much that is useful to them.

The new model fails in two important ways. First, it fails to acknowledge that the exported technologies are still "locally black box" – that is, how they work is largely opaque to small farmers or hidden in proprietary secrets – and thus create further dependencies on exporters who assist with local integration and optimization. Second, the model is based on the obviously false assumption that assorted and small markets of developing countries will provide sufficient incentive for relevant biotechnologies to be made by the private sector. Many of these countries do not have the IPR frameworks in place that biotechnology companies demand in order to legally ensure that they can profit from their products (Monsanto, 2008). Even the World Bank admitted in its *World Development Report 2008: Agriculture for Development* that the "benefits of biotechnology, driven by large, private multinationals interested in commercial agriculture, have yet to be safely harnessed for the needs of the poor" (World Bank, 2007). Thus, the Assessment has called for a new model of biotechnology development that has public good outcomes in poor countries independent of private wealth creation in rich countries.

The poignancy of this conclusion is brought home when contrasted with the perspective of the Assessment critic Thomas R. DeGregori who, in an open letter to the President of the World Bank, ironically asserted that the Assessment was in conflict with the *World Development Report 2008*. DeGregori took issue with the IAASTD website content, which he claimed criticized one of its sponsors, the World Bank. He said that "the IAASTD [is] ungraciously biting the hand that fed them – being a member of some of these groups requires totally lacking a sense of shame." Even if one were to accept DeGregori's characterization of the Assessment's website content, this only attests to the independence, and therefore the credibility, of the Assessment. The Assessment was brave enough to engage authors who were often unwilling to take a position that was thought to be more in line with the thinking of the sponsors (Jiggins, 2008). Recalling that the Assessment's draft reports were subject to two rounds of international peer review, involving around 500 individuals and groups, is DeGregori unconsciously conceding something unflattering about reports developed under less stringent and less public review?

Much more unfortunate is DeGregori's implication, and also industry spokesperson Deborah Keith's (Keith, 2008), that the World Bank's *World Development Report 2008* was in all ways in conflict with the Assessment. It is to be expected that the two would differ to a degree, given the very different ways in which they were developed and the large scale of resources uniquely involved in the Assessment (Jiggins, 2008). But they

Table 2.1: Selected quotes from the *World Development Report 2008: Agriculture for Development* that sound surprisingly similar to IAASTD conclusions

World Development Report 2008	**The Assessment (Synthesis Report)**
"The most controversial of the improved biotechnologies are the transgenics, or genetically modified organisms, commonly known as GMOs" (p. 163).	"Currently the most contentious issue is the use of recombinant DNA techniques to produce transgenes that are inserted into genomes" (p. 8).
"However, biotechnology applications using genomics and other tools are not controversial, and their declining costs and wider application should ensure continuing yield gains through better resistance to disease and tolerance for drought and other stresses" (p. 67).	"Conventional biotechnologies, such as breeding techniques, tissue culture, cultivation practices and fermentation are readily accepted and used" (p. 8).
"With an increasing share of genetic tools and technologies covered by intellectual property protection and largely controlled by a small group of multinational companies, the transaction cost of obtaining material transfer agreements and licenses can slow public research on and release of transgenics" (p. 178).	"The use of patents for transgenes introduces additional issues. In developing countries especially, instruments such as patents may drive up costs, restrict experimentation by the individual farmer or public researcher while also potentially undermining local practices that enhance food security and economic sustainability" (p. 8).
"However, the environmental, food safety, and social risks of transgenics are controversial, and transparent and cost-effective regulatory systems that inspire public confidence are needed to evaluate risks and benefits case by case" (p. 177).	"Much more controversial is the application of modern biotechnology outside containment, such as the use of GM crops. The controversy over modern biotechnology outside of containment includes technical, social, legal, cultural and economic arguments. The three most discussed issues on biotechnology in the IAASTD concerned: • lingering doubts about the adequacy of efficacy and safety testing, or regulatory frameworks for testing GMOs..." (p. 40).
"Biotechnology thus has great promise, but current investments are concentrated largely in the private sector, driven by commercial interests, and not focused on the needs of the poor. That is why it is urgent to increase *public* investments in propoor traits and crops at international and national levels – and to improve the capacity to evaluate the risks and regulate these technologies in ways that are cost effective and inspire public confidence in them" (p. 163).	"The nature of the commercial organization is to secure the IP [intellectual property] for products and methods development. IP law is designed to prevent the unauthorized use of IP rather than as an empowering right to develop products based on IP. Instead, there needs to be a renewed emphasis on public sector engagement in biotechnology" (p. 45).

agree in ways that might surprise the less informed readers of DeGregori and Keith's letters (Table 2.1).

The *World Development Report 2008* and the Assessment both agree that genetic engineering holds much promise as a technological solution to some problems, and that it has failed to deliver on that promise. They also agree that it will continue to fail to do so, either because the promises made are beyond what the technology can deliver (Zamir, 2008) or because the technology is dominated by a bankrupt approach to agriculture development that is held by the companies and institutions of wealthy countries, the flagship delivery vehicle for which are particular kinds of IPR instruments and their enforcement.

> With an increasing share of genetic tools and technologies covered by intellectual property protection and largely controlled by a small group of multinational companies, the transaction cost of obtaining material transfer agreements and licenses can slow public research on and release of transgenics (World Bank, 2007, p. 178).

GM for the production of transgenic crops does hold promise. This is notwithstanding the safety concerns which continue to be raised regarding genetic engineering. However, there is much agreement that GM's promise has not paid sufficient dividends while it has been within such restricted policy and legal frameworks as patent systems and left to private sector incentive systems (Heinemann, 2008; Pray and Naseem, 2007). Similarly, the Assessment came to the conclusion that continued research and development in genetic engineering has value. However, the value of its products is maximized under a strong public investment scheme that is itself largely free of the strictures of securing and defending patents or patent-like intellectual property protections. The protections afforded to the public effort should also ensure that it cannot be captured by a private intellectual property claim. In this way, the types of traits, organisms and products produced will be those that deliver on the goals of reducing poverty, hunger and malnutrition. The new focus of biotechnologies will be on sustainability. Yields must increase despite climate change and water stress. Agriculture must contribute to an environmental and social global ecosystem composed of healthy and diverse communities that can feed themselves. This concept builds on the idea that there is not a single agriculture, but a world of many agri*cultures*. Each different agriculture has something to teach the others, lessons to learn and both a right and reason to exist. Maintaining a diversity of farming systems, germplasm, *in situ* conservation techniques and appreciation for food and work is a recipe for global food security.

> Sustainability in agricultural systems incorporates concepts of both resilience (the capacity of systems to resist shocks and stresses) and persistence (the capacity of systems to continue over long periods), and addresses many wider economic, social and environmental outcomes. Agricultural systems with high levels of social and human assets are more able to adapt to change and innovate in the face of uncertainty. This suggests that there are likely to be many pathways towards agricultural sustainability; no single system of technologies, inputs or ecological management is more likely to be widely applicable than another. Agricultural sustainability then implies the need to fit these factors to the specific circumstances of different local agricultural systems (UNEP/UNCTAD, 2008, p. 6).

Could this vision work? Some of those representing the status quo do not think so. The Editor of *Nature Biotechnology*, for example, has charged that "the report and perhaps the entire IAASTD exercise appear to be an attempt to blind world leaders to any potential positive contribution from GM crops" (Editor, 2008b, p. 247). However, 58 of the 61 national delegations participating in the intergovernmental panel accepted the text of the Biotechnology Theme in the Assessment's Synthesis Report without reservation or debate. Of those who noted reservations, the United States did not agree to accept the Assessment and China did. What mystical properties does the Editor believe are possessed by these authors that they would be capable of deceiving the governments of Canada, France, the UK, India, Australia and Brazil – which together produce ~25% of world acreage in GM crops (Table 2.2)?

Conclusions

There is scant evidence that simply tinkering with global agriculture will produce either the food or social security that are both wanted and needed by 2050 and beyond. The authors of the Assessment faced this dilemma when considering some forms of biotechnology. Say that the 'bird in hand' is some old but proven approaches to addressing local and global food needs, ways which are also widely acknowledged as effective for building local knowledge and economic independence. Yet out there somewhere are 'multiple birds in the bush', undeniably promising technologies that, despite the benefit of tremendous financial and political backing over 12 years of commercial production, have not delivered on your broad production, economic and social goals (Pray and Naseem, 2007). Which would you responsibly endorse, the bird in the hand or the birds in the bush, knowing that you not only must feed everyone today, but must feed even more people in 50 years' time – and do so in a way that is both environmentally and socially sustainable? Even *Nature Biotechnology* confirmed the Assessment's disappointment with GM crops "with regard to the achievements of the past 10 years" (Editor, 2008b, p. 247). It was rational to take the benefits already in hand over those that always seem just out of reach.

Table 2.2: Estimated GM crop production by selected countries that accepted text on biotechnology in the IAASTD Synthesis Report

Country	GM crops in million hectares	Proportion of global total (%)*
Australia	0.1	0.09
Brazil	15	13
Canada	7.0	6
France	<0.05	<0.04
India	6.2	5
UK	<0.05	<0.04
Total		24-25%

*Estimated by industry sources at 114.3 million hectares (James, 2007)

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Chapter Three

Defining Biotechnology

Key messages

1. Biotechnology is all forms of manipulation of living things.
2. It is defined by international convention as either "conventional" or "modern" biotechnology, with the latter being subject to special regulations in recognition of the risks associated with modern biotechnology.

THIS chapter explores the definition of biotechnology used in the Assessment and which appears in both the Global Summary for Decision Makers and the Synthesis Report.

The Assessment combined the inclusive definition of biotechnology found in the Convention on Biological Diversity and the exclusive definition of modern biotechnology found in the Cartagena Protocol on Biosafety. These two international agreements bind most of the world into a common description of biotechnology. The Cartagena Protocol introduced the concept of "modern biotechnology", describing it this way:

> "Modern biotechnology" means the application of:
> a. *In vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or
> b. Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

Modern biotechnology is a narrow range of techniques that describes the process of taking genes out of their normal physiological context and making products by putting those genes back into a living organism (or virus). A GMO is therefore the product of modern biotechnology. The descendants of these products are also GMOs, even if they derive from normal reproduction.

For example, in New Zealand law (which has been harmonized to the Protocol), a GMO can be identified if it meets one of two tests. The first requires no more than that an organism has received *in vitro* modified genetic material (e.g., recombinant DNA). The second test captures any descendants of the original GMO, so that any organism related by descent to a GMO is also a GMO (ERMA, 2006).

The Assessment text

Global Summary for Decision Makers (p. 7)
The IAASTD definition of biotechnology is based on that in the Convention on Biological Diversity and the Cartagena Protocol on Biosafety. It is a broad term embracing the manipulation of living organisms and spans the large range of activities from conventional techniques for fermentation and plant and animal breeding to recent innovations in tissue culture, irradiation, genomics and marker-assisted breeding (MAB) or marker assisted selection (MAS) to augment natural breeding. Some of the latest biotechnologies, called "modern biotechnology", include the use of *in vitro* modified DNA or RNA and the fusion of cells from different taxonomic families, techniques that overcome natural physiological reproductive or recombination barriers.
(From Global Summary for Decision Makers *by IAASTD, ed. Copyright © 2009 IAASTD. Reproduced by permission of Island Press, Washington, D.C.)*

Executive Summary of the Synthesis Report (p. 8)
As above, but also: Currently the most contentious issue is the use of recombinant DNA techniques to produce transgenes that are inserted into genomes. Even newer techniques of modern biotechnology manipulate heritable material without changing DNA.
(From Agriculture at a Crossroads: The Synthesis Report *by IAASTD, ed. Copyright © 2009 IAASTD. Reproduced by permission of Island Press, Washington, D.C.)*

Biotechnology is of course more than modern biotechnology. The Convention on Biological Diversity defines biotechnology as:

> [A]ny technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for a specific use. Biotechnology, in the form of traditional fermentation techniques, has been used for decades to make bread, cheese or beer. It has also been the basis of traditional animal and plant breeding techniques, such as hybridization and the selection of plants and animals with specific characteristics to create, for example, crops which produce higher yields of grain.

That very broad definition recognizes that agricultural science and technology takes many forms that derive from the scientific method. It is a definition that is used by governments and is consistent with usage such as the content of *Nature Biotechnology*, a journal named for its focus on research in biotechnology (Heinemann, 2008).

Biotechnology can be seen as a series of techniques that describe a continuum from conventional to modern. Combined, the two international agreements have created a kind of "digital switch" for regulating GMOs. The switch is thrown when one goes from manipulating heritable (e.g., seeds, propagules) but not genetic (e.g., DNA) material to genetic material being removed from its physiological or natural context and then returned or passed-on (Figure 1.1).

The distinction between biotechnology and modern biotechnology is worth preserving, even if some say that the

IAASTD's "definition of biotech is so broad it's virtually meaningless" (Editor, 2008, p. 247).

First, it groups many technologies that are very regularly and purposefully separated in the scientific literature and in public understanding. This idea is shown in Figure 1.1 as the concentration of different technologies at the left- and right-hand extremes of the graph. All technologies on either side of the switch have more in common with one another than any do with a technology on the other side of the switch.

Second, to use the word "biotechnology" only to mean modern biotechnology is disparaging to the high-quality and sophisticated science and technology that has nothing to do with modern biotechnology. In addition, it might lead to premature dismissal of biotechnology when the issues that are of concern to the public, scientists, academics and policy-makers are inappropriately transferred from modern to all biotechnologies. Importantly, if the distinction is not carefully and repeatedly made, it may in time come to pass that important decisions are made without appreciating that there is a difference. Public resources could then be unintentionally maldistributed across these technologies. Whether intentional or not, this is probably already occurring. For example, some researchers

> note that the global decline in academic plant breeding, with resources being transferred to molecular genetics and transgenic technologies, means that the professionals who are needed to obtain practical benefit from advances in these technologies are no longer being trained in sufficient numbers. In particular, we suggest that the shortage of plant breeders means that the potential contribution offered by [some technologies] can only partially be realized (quote from Reece and Haribabu, 2007, p. 461; see also TeKrony, 2006).

Third, to not make the distinction between modern and other kinds of biotechnologies can cause unnecessary conflict and waste of resources. For example, to say that the public is afraid of biotechnology or is uninformed about it can simply be a way of discrediting those who hold concerns about modern biotechnology by implying that these people are "anti-science" in general. To make this assumption can lead to unsuccessful attempts to "correct" public understanding by providing more information.

> Investigations of public perception in areas of the world with relatively high resistance to GM foods indicate that lack of information is not the primary reason. The public is not for or against GMOs *per se* – people discuss arguments both for and against GMOs, and are aware of contradictions within these arguments. Also, people do not demand zero risk. They are quite aware that their lives are full of risks that need to be balanced against each other and against the potential benefits. People may also discriminate in their perception of different technologies where a general positive perception can be observed for applications with a clear benefit for society, e.g. for modern medicines. A key finding is that people do not react so much to genetic modification as a specific technology, but rather to the context in which GMOs are developed and the purported benefits they are to produce (WHO, 2005, p. 49).

Surprisingly, there are also arguments about what products of modern biotechnology look like. The Assessment's Synthesis Report makes reference to modern biotechnologies that do not explicitly change DNA, but do involve modified nucleic acids (derived from the chemically similar molecule ribonucleic acid (RNA)) that can in some organisms and circumstances cause heritable changes, in a way similar to changing their content of genomic DNA (Appendix One). The Assessment anticipated these developments in modern biotechnology and decision-makers should be aware that they will be increasingly challenged with highly technical arguments about what a GMO is. Thus, definitions will be important as decision-makers are faced with drafting regulations to adapt to developments in this field.

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Chapter Four

Presence

> **Key messages**
>
> 1. GMOs in food have raised concerns about food safety standards.
> 2. Their presence in food creates unique food safety, consumer choice, and legal issues.

THE idea that the mere presence of genetically modified organisms can cause concern for consumers is contested, most vigorously by countries that produce GMOs. The counterclaim is framed as one of safety and choice, as in consumers may be concerned about the *safety* of GMOs in food or the preservation of *consumer choice*.

Presumably, concerns about consumer choice could be dealt with by labelling or choosing brands under particular market certifications, provided of course that some food choices are not taken away first. However, the potential to choose is threatened.

> In Canada, it has been estimated that these novel [GM] foods or food ingredients are detectable in 11% of foods consumed and might be present (but often not detectable) in up to 75% of the processed foods in retail stores (Smyth and Phillips, 2003, p. 389).

Likewise, concerns about food safety could be dealt with by testing and regulatory oversight to ensure that it is safe, or through post-market labelling to shift the safety burden to those who grow or distribute the product.

On p. 15 of the final version of the Global Summary for Decision Makers (IAASTD, 2009b), the negotiated text retained the central concept of presence as a legitimate issue:

> Concerns about GMOs in food and feed as well as consumer choice, have heightened demand for food safety standards and prompted countries to develop and implement regulations to address this issue.

That text ultimately did not meet with US (or Australian) approval and they duly noted a reservation. The text retains the concept of "presence" as an issue because concerns are more than just about the safety of GMOs in food and the preservation of the consumer's right to choose whether or not to eat GMOs.

There were two significant reasons why most governments, NGOs and authors required a reference to presence. First, it is the presence of some GMOs in food that could make the food unsafe. The concern is about the safety of the food, not the safety of the GMO *per se*. For example, some forms of GM plants or animals may be designed to create compounds that in their raw form are harmless to humans, either because those plants or animals are not part of our normal diets or because we eat them raw. However, those compounds may react with the normal constituents of food during cooking and processing and be converted into derivative compounds that reduce the safety of the food. Such a hypothetical case is described below. And there are agricultural practices that are special to GM plants, such as the increase in the use of particular herbicides (e.g., Roundup) that could contribute to unique mixtures of pollutants on food, some of which may have multiplicative or synergistic effects (Benachour and Séralini, 2009).

The second reason is that the presence of a transgene is sufficient to establish some forms of damage and thus creates liability (Belcher et al., 2005; Khoury and Smyth, 2007). For example, the discovery of a commercial GM variety of corn, called StarLink, in human food in 2000 triggered a massive food recall and subsequent court cases (Kershen, 2004). The corn had been approved for animal feed but not for human food. However, segregation failed. There were allegations of allergic reactions to an insect toxin produced by the corn. While no allergic reactions were ever confirmed, a class-action lawsuit was filed by consumers who claimed that they had unwittingly consumed food unfit for human consumption, because StarLink was not approved as a human food product. The lawsuit ended with a settlement against the corn's developer, Aventis. This outcome suggests that consumers may have grounds for compensation, at least in the United States, from developers or farmers even if their health was not affected by the transgenic crop (Kershen, 2004).

Similarly, the presence of a regulated GM corn variety among unregulated soybeans was sufficient, without any demonstrated effect on human health or the environment, for the US Department of Agriculture to levy fines on the crop's developer, ProdiGene.

> In 2002, the biotechnology company ProdiGene Inc. was fined US$250,000 by the USDA and compelled to carry out a US$3 million clean-up operation after volunteer maize plants containing the gene for a veterinary vaccine were found among a soybean crop planted in the same field in the following season. Part of the cleanup process included the purchase and destruction of more than half a million bushels of adulterated soybeans, and ProdiGene was also ordered to post a US$1 million bond to fund the development of a compliance programme for future PMP [plant-made pharmaceuticals] crops (Spök et al., 2008, p. 508).

> As of August 2008, there were six documented incidents of the unauthorized release of GE crops into the food or feed supply [including ProdiGene's], or into crops meant for the food or feed supply. Although federal agencies determined that these incidents did not harm human or animal health, they did cause financial losses in some cases (GAO, 2008, p. 90).

Unintended risks to human health caused by presence

Not all GMOs in the human food chain may have benefited from a safety evaluation or been deemed to be safe as food (Table 4.1).

> Industry sources estimate that in 2000 in the Saskatchewan region of Canada alone, more than 300,000 acres of wheat were planted with unregistered or obsolete [GM] plant varieties. Exports by volume are composed of some varieties that have not been, or are no longer, approved for release in Canada. Regionally across western Canada, wheat exports contain 0.6-2.4% of these unregistered or obsolete varieties (Smyth et al., 2002, p. 537).

> In the 20 years since the USDA started to regulate field tests, it has approved nearly 50,000 field sites. But an internal audit commissioned by the USDA inspector-general and released on 22 December 2005 was severely critical. The report admonished the agency for lacking basic information about test sites, failing to inspect field tests sufficiently, and neglecting the fate of the crops after testing (Ledford, 2007, p. 132).

Even transgenes that have been deemed safe when tested in one genetic background may not be assumed safe if they are bred by accident or by chance into other genetic backgrounds of the same species or between species (e.g., by horizontal gene transfer between GMO microbes).

Once in the agroecosystem, transgenes may not be easily recalled.

> [Canada/oilseed rape:] Ten years after a trial of GM herbicide-tolerant oilseed rape, emergent seedlings were collected and tested for herbicide tolerance. Seedlings that survived the glufosinate herbicide (15 out of 38 volunteers) tested positive for at least one GM insert. The resulting density was equivalent to 0.01 plants m^{-2}, despite complying with volunteer reduction recommendations (D'Hertefeldt et al., 2008, p. 314).

> [France/oilseed rape: GM] seed admixture could still occur in the harvest of [a] conventional variety 8 years after growing transgenic OSR [oilseed rape]…admixture of transgenic and conventional seeds in a conventional OSR harvest can occur at a rate as high as 18% in a 5-year rotation, far above the European threshold [of 0.9%]…Unless appropriate management and agronomical guidelines to manage volunteers are implemented, it will indeed be hazardous for a farmer to go back to a conventional non-GM farming system, even 5 years after the last transgenic OSR harvest (Messéan et al., 2007, p. 121).

> [US and global/maize:] Despite a massive recall of food products and extraordinary efforts to recover StarLink seed, the *cry*9 transgenes still persisted at detectable levels in US corn supplies 3 years later. The lingering presence of StarLink demonstrates that once a transgene

makes its way into the general food supply, it may take many years and enormous effort to get rid of it (Marvier and Van Acker, 2005, p. 103).

[US/creeping bentgrass:] The results show that the CP4 EPSPS transgene [conferring glyphosate tolerance] escaped from the [glyphosate-resistant creeping bentgrass] fields and continued to spread for 3 years after the fields were taken out of production. As we hypothesized, it was unrealistic to think that a transgene could be contained in an outcrossing, wind-pollinated, small-seeded, perennial crop, even with expanded isolation distances and stringent production practices. This fact has implications for the deregulation and production of GE crops in the future, especially those for pharmaceutical or industrial uses (Zapiola et al., 2008, p. 490).

Unwanted or unsafe GMOs could persist in nature or agroecosystems (Heinemann, 2007).

Regardless of how effective regulations or contracts are, some producers (either deliberately or inadvertently) will misappropriate these new technologies, diluting the benefits and creating potential new risks and liabilities. Furthermore, even if all "cheating" (producers' illegal use of technology protected in a patent) could be controlled, many plant species are promiscuous sexually, creating natural gene flow to related species (Smyth et al., 2002, p. 537).

No amount of regulation can guarantee that [GM] crops will not escape and multiply (Ledford, 2007, p. 132).

Table 4.1: "Some past escapes" (Ledford, 2007, p. 132)

1997	Canadian canola contaminated with unapproved HT canola.
2001	An unapproved Monsanto GM corn pollinated a commercial crop.
2002	ProdiGene's corn producing a veterinary pharmaceutical found in neighbouring food or feed corn.
2002	ProdiGene's corn found growing among commercial soybean plants.
2004	Transgenic bentgrass found outside containment area.
2005	Syngenta's unapproved Bt10 transgenic corn found in commercial food/feed supply.
2005	Unapproved varieties of GM rice found circulating in China.
2006	BASF planted regulated corn outside of approved areas.
2006	Bayer CropScience's unapproved transgenic rice varieties found in US food supply.
2006	Chinese GM rice not approved for food or feed found in Europe.
2008	Unapproved Monsanto GM rice found mixed with commercial varieties in Texas (Hananel, 2008).

Box 4.1: Unauthorized GM corn in New Zealand in 2003

A shipment of sweetcorn grown in the Gisborne (North Island) region of New Zealand in 2003 was rejected from Japan because an independent testing company detected GM material. Subsequent testing in Australia confirmed the Japanese results and identified at least one of the events as Bt11 (an event owned by the Syngenta Corporation and designed to confer pest resistance and herbicide tolerance).

Bt11 is not approved for cultivation in New Zealand. At that time, a second GMO was detected but not identified even to the level of a specific type of modification (Heinemann et al., 2004). The New Zealand Food Safety Authority concluded that because the "[c]oncentration of [the] GM organism [was] less than 0.05 percent…well below the Australia/New Zealand standard for unintentional presence of 1 percent…no further action" – that is, testing, monitoring or recalling food contaminated by the unknown organism – was required (Heinemann et al., 2004). Subsequently, all remaining seed was seized and destroyed. However, New Zealand law, like Europe (Devos et al., 2005), has no threshold levels of safety for unidentified GMOs (Heinemann et al., 2004). Had the Food Safety Authority taken that into account, gene flow could have caused a recall of sweetcorn in New Zealand.

The evidence used by New Zealand regulators leaves open the possibility that the contaminating GMO is an uncharacterized pre-commercial outcross of the same species, a novel organism that has more than one modification including the one detected, a novel outcross that arose when an unintentional and uncharacterized DNA insert on another chromosome of a GMO was acquired by a previously unmodified conspecific, or an unknown organism engineered to attract the Bt11 event-specific primers used in the PCR tests and thus tempt regulators to look no further.

The source of the GM material was never confirmed, but it is suspected that the seed imported from the US was the source, despite it having passed tests in the US before shipment to New Zealand. This would be of no surprise since most "crops are not grown under confined conditions, and the supply chains are rarely segregated…adventitious mixing of GM material with non-GM produce can occur in all the steps of production and supply chains" (Devos et al., 2005, p. 73). A small number of GM plants were probably in the seed due to pollen flow during seed production or mixing of seeds, and then the seed was a vector for gene flow to New Zealand where the GM material was amplified during cultivation in New Zealand. This example of trade disruptions, and the cost to local farmers and ambiguities in liability of seed companies or cultivating countries, provides an acute example of the impacts of presence of GMOs in food and/or feed.

Regulations cannot ensure the safety of unknown or recalled GMOs in human food. The case study reported in Box 4.1 describes how unknown varieties can result in human health concerns and trade disruptions (Heinemann et al., 2004). In summary:

> The movement of transgenes beyond their intended destinations is a virtual certainty. It is unlikely that transgenes can be retracted once they have escaped. Human error can foil even the best designed strategies for risk management (Marvier and Van Acker, 2005, p. 99).

Not all GMOs are intended to be safe as food (Ellstrand, 2003; Heinemann, 2007; Marvier and Van Acker, 2005; Schubert, 2008). The track record on containing regulated and potentially unsafe GMOs, much less GMOs not designed to be safe, is not reassuring (Fox, 2003; Ledford, 2007; Lee and Natesan, 2006; Vermij, 2006; Zapiola et al., 2008) and thus, even when regulatory requirements are met, it is possible for future potentially "unsafe" GMOs to enter the food chain (Schubert, 2008). This is the point elegantly made by the editor of *Nature Biotechnology* when discussing so-called "pharma crops", GM food plants that produce industrial or pharmaceutical products that are not intended to be safe in food:

> The production of drugs or drug intermediates in food or feed crop species bears the potential danger that pharmaceutical substances could find their way into the food chain through grain admixture, or pollen-borne gene flow (in maize, at least) or some other accidental mix-up because of the excusably human inability to distinguish between crops for food and crops for drugs. The 'contamination' of soybeans and non-GM corn in 2002 with a corn engineered by Prodigene to produce an experimental pig vaccine shows just how plausible this is. This position is not anti-GM (something industry should appreciate) – we should be concerned about the presence of a potentially toxic substance in food plants. After all, is this really so different from a conventional pharmaceutical or biopharmaceutical manufacturer packaging its pills in candy wrappers or flour bags or storing its compounds or production batches untended outside the perimeter fence (Editor, 2004, p. 133)?...Although industry organizations, such as the Biotechnology Industry Organization (BIO), continue to support food crops for PMP/PMIP [plant-made pharmaceuticals and plant-made industrial products] expression systems, we hold to our original view that they pose too many problems (Editor, 2007, p. 167).

A related reason to consider presence comes from differences in the context of safety testing and actual use of a GMO. A GMO that is by design substantially different from the same conventional organism may be deemed safe in one context but pose risks in another. An example of such a case is provided by a GM variety of

The Assessment text

Synthesis Report (p. 42)
GMOs made from plants that are part of the human food supply but developed for animal feed or to produce pharmaceuticals that would be unsafe as food, might threaten human health.
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Table 4.2: Amino compounds unique to LY038 maize		
Compound	**Concentration in LY038 (compared to maize control lines)**	**Potential hazard**
Lysine	50% higher	advanced glycoxidation end products (AGEs)
Free lysine	50 times higher	AGEs
Saccharopine	110 times higher	AGEs
α-aminoadipic acid	at least 10 times higher	AGEs, neurotoxic
Cadaverine	unknown but expected to be higher	AGEs, accentuates reactions to histamine, evidence of further toxic properties
Pipecolic acid	≥100% higher*	AGEs, chronic hepatic encephalopathy

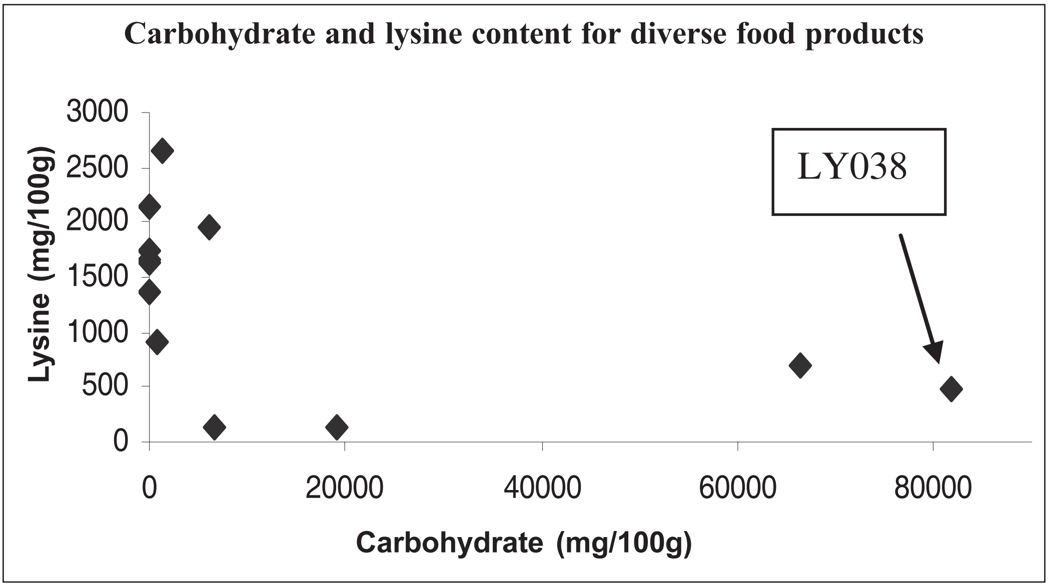
*Applicant only reports L-pipecolic acid levels. Because D-pipecolic acid can be created from L-pipecolic acid by conversion of either pipecolic acid or lysine to the D-isoform during cooking or in the gut by bacteria, pipecolic acid derived from high lysine corn or produced by gut bacteria receiving higher levels of dietary lysine may result.

Table 4.3: Carbohydrate and lysine content by food

Food[1]	Lysine content (mg/100g)	Carbohydrate content (mg/100g)
Corn, LY038	480[2]	81800[3]
Oats	701	66270
Corn, sweet	137	19020
Broccoli (raw)	135	6640
Lentils (raw)	1957	6080
Cheese (edam)	2660	1430
Egg (raw, fresh)	914	770
Chicken (broilers or fryers, back, meat only, raw)	1661	0
Fish, Pacific cod, raw	1644	0
Fish, flatfish (flounder and sole species), raw	1731	0
Fish, tuna, fresh, yellowfin, raw	2147	0
Red meat (beef, chuck, blade roast, separable lean and fat, trimmed to 1/2″fat, prime, raw)	1359	0

[1] Unless specified otherwise, source is Nutrient Data Laboratory (2006).
[2] Source: Table 11 of Appendix IV Monsanto Application to FSANZ, October 2004.
[3] Source: Table 14 of Monsanto study MSL 19172 (Reynolds et al., 2004).

Figure 4.1: Lysine and carbohydrate relationships in common foods. Illustrated are, from right to left, the values for LY038, oats, sweet corn, broccoli, lentils, edam cheese, raw egg, chicken, fish (tuna, flatfish and Pacific cod) and red meat (Nutrient Data Laboratory, 2006).



maize called LY038. This maize was ostensibly produced as an animal feed, but because it is expected to co-mingle with the human food supply, the developer has sought approval in various jurisdictions to allow this material into human food (FSANZ, 2006). It was exclusively safety tested as raw corn – the way animals eat it – but because of its unique composition it may produce food hazards only when in its cooked or processed form – the way humans eat it.

LY038 has extremely high concentrations of the amino compounds free lysine and various toxic breakdown products of lysine (Table 4.2). Vegetables are normally low in free amino acids, especially lysine (Mennella et al., 2006). There is approximately 52 times more free lysine in LY038 compared to other varieties of maize and four times the sugar of sweet corn (Table 4.3). Moreover, the ratio of free lysine to total lysine is 30 times higher in LY038 than in the comparator used by the developer (LY038(-), Table 4.4). All foods high in lysine for which proper measurements are available, are extremely low in free lysine and sugar. LY038 has an apparently unique composition with respect to these two compounds (Figure 4.1).

There are compelling reasons to believe that when prepared as human food, LY038 will be the source of products or concentrations of products unique to this corn. When cooked, amino compounds and sugar combine to form advanced glycoxidation end products (AGEs) (for reviews, see Huebschmann et al., 2006; Terry, 2007). While some AGEs might be beneficial, it is not possible in advance to know which are and which are not. Dietary AGEs are meanwhile thought to contribute "to the pathologic sequelae seen in normal aging, diabetes, and kidney disease" (quote from Goldberg et al., 2004, p. 1289;

see also Uribarri et al., 2007), including wound healing retardation (Peppa et al., 2003) in diabetics, and neurodegenerative diseases such as Alzheimer's (Elliott, 2006). Lysine-derived AGEs have been linked to cancer (Heijst et al., 2005). Higher levels of AGEs have also been detected in Creutzfeldt-Jakob Disease (CJD) patients, but the cause and consequences are unknown (Freixes et al., 2006). Glycation can increase the longevity of peptides in the intestine, possibly contributing to glycoxidation-implicated diabetes-related autoimmunity (Elliott, 2006).

LY038 and its derivatives have the potential to boost AGE exposure from all foods that have a corn component, including many processed foods which are heated to high temperatures.

> Processing of some ready-to-eat cereals, which includes heating at temperatures over 230°C, may explain the high AGE content of these products. Also, many cereals and snack-type foods undergo an extrusion process under high pressure to produce pellets of various shapes and densities. This treatment causes major chemical changes, thermal degradation, dehydration, depolarization, and recombination of fragments all of which can promote glycoxidation (Goldberg et al., 2004, pp. 1288-1289).

People in different countries are also exposed to different risks because of their culture or circumstances (also see Appendix Three for a related discussion). For example, Mexicans and Africans eat significantly more corn per capita than do New Zealanders (Table 4.5). The proportion of daily protein from corn for an African is 40 times that for New Zealanders (Table 4.5). A protein- or amino-based food hazard is therefore a quantitatively different risk for Mexicans and Africans than it is for Americans and New Zealanders. That is why international food safety guidelines (such as those developed under the Codex Alimentarius Commission) allow consumption patterns to be taken into account.

> Information about the known patterns of use and consumption of a food, and its derivatives should be used to estimate the likely intake of the food derived from the recombinant-DNA plant. The expected intake of the food should be used to assess the nutritional implications of the altered nutrient profile both at customary and maximal levels of consumption. Basing the estimate on the highest likely consumption provides assurance that the potential for any undesirable nutritional effects will be detected. Attention should be paid to the particular physiological characteristics and metabolic requirements of specific population groups such as infants, children, pregnant and lactating women, the elderly and those with chronic diseases or compromised immune systems (Codex, 2003, p. 19).

Mexicans who live in New Zealand but retain their cultural consumption patterns may be overlooked if a regulator only bases food hazard on per capita (customary) consumption. For example, Food Standards Australia New Zealand (FSANZ) discounted food hazards from LY038 based in part on average consumption data:

Even if all corn products consumed by Australian and New Zealander consumers were derived from LY038 corn, this would represent an insignificant increase in lysine consumption as Australian and New Zealand populations consume only relatively small quantities of corn-derived products (FSANZ, 2006, p. 76).

Table 4.4: Comparisons of free lysine in common foods and LY038

Food	Free Lysine (mg/100g)	Total Lysine (mg/100g)	Free/Total Lysine (%)	Annual Free Lysine (g) Consumption[1] Australia/New Zealand	Free Lysine Reference
Corn, LY038	135[2]	480	28	7.2/3.3	
LY038(-)	3[2]	320	0.9	0.2/0.075	
Lentils		1957			Rozan et al. (2000)
raw	13*		0.6		
cotyledon seedling	30*		1.5		
Fish[3]					Antoine et al. (1999)
mahi-mahi	53	N/A	N/D	11.7/14	
flounder	17	1731	1	3.8/4.5	
bigeye tuna	8	2147	0.4	1.8/2.1	

*fresh weight

1 Based on annual per capita corn consumption of 2.5kg in New Zealand and 5.3kg in Australia. Source: FAOSTAT 2006.

2 Source: Table 14 of Monsanto study MSL 19172 (Reynolds et al., 2004).

3 Based on annual per capita fish consumption of 26.3kg in New Zealand and 22.1kg in Australia. Source: FAOSTAT 2006.

Table 4.5: Country-specific dietary profiles for corn/maize

Consumer	Annual consumption/ capita (kg)	Proportion		
		Daily calories/capita	Daily proteins/capita	Daily fat/capita
Africa (developing countries)	38	0.1	0.2	0.06
Mexico	126	0.3	0.3	0.1
New Zealand	3	0.007	0.005	0.0008
USA	13	0.03	0.02	0.002

Source: FAOSTAT 2008 for year 2003.

Thus, in its different contexts, a food hazard arises from the presence of the GMO in food and not its safety *per se*, which may have been assured through different kinds of safety testing. At least one regulator, FSANZ, has steadfastly refused to ask for testing of LY038 under conditions where it was prepared as food rather than raw as animal feed. Even though FSANZ agreed that LY038 is likely to produce one or more potentially toxic AGEs during storage, cooking or processing that would not be present in conventional corn –

> [I]t is reasonable to assume that processed corn products containing LY038 may contain an altered profile of AGE/MRPs [Maillard reaction products] compared to conventional corn (FSANZ, 2006, p. 78)

– they assert without test that it will have no adverse impact as a food and do "not consider separate studies on cooked/processed LY038 products to be necessary for the safety assessment" (FSANZ, 2006, p. 84). As far as I am aware, none of the approximately 30 GMOs so far determined by FSANZ to be safe as food have been tested for toxicity or allergenicity as cooked or processed foods. In fact, I am unaware of any companies that have been asked to meet this standard of review by regulators anywhere in the world, even though the "potential effects of food processing, including home preparation, on foods derived from recombinant-DNA plants should also be considered" (Codex, 2003, p. 18), according to international food safety guidelines.

In summary, the Assessment was correct to conclude that presence *per se* was a concern. The full extent of that concern could not be limited to either just "the safety of GMOs in food" or "consumer choice". Consideration of the safety of GMOs in food has inspired regulatory procedures that do not comprehensively include contextual issues or prevent the admixture of regulated material or unapproved GMOs and the human food supply. Therefore it is reasonable to conclude that consumers have concerns about GMOs in food.

Presence is necessary and sufficient for liability

Transgenes are the units of interest in contracts, patents and national laws that regulate GMOs, and are the unit monitored in the Cartagena Protocol on Biosafety, an international agreement involving nearly 150 countries (Heinemann, 2007; Rosendal et al., 2006; Tvedt, 2005).

> As transgenes are the basis of international agreements such as the Cartagena Protocol on Biosafety, their presence and not just their impact is the level at which they have legal consequences. This creates new challenges for countries that enter into international trade of organisms that are meant to be free of transgenes (Heinemann, 2007, pp. 4-5).

The legal exposure created by transgenes extends to liability for traditional, environmental, or economic damage. (For a comparative review of legal frameworks, see Smyth and Kershen, 2006.)

Whether or not someone knowingly grows a GMO such as a GM crop, they could become exposed to legal actions, suffer market rejections (GAO, 2008) or be the subject of recalls causing loss of earnings (Box 4.1). For instance, farmers growing crops with transgenes may be prosecuted or sued if it can be determined that they did so without consent of the intellectual property holder (Heinemann, 2007). Farmers often enter into contracts, such as material transfer agreements (MTAs), with GM seed producers that may also create obligations. These obligations can even extend beyond territorial limits (Thomas, 2005).

> The industrialization of the gene has benefited from the ability to use powerful enzymatic and chemical reactions to manipulate, describe and trace DNA. Some of these techniques, particularly the polymerase chain reaction (PCR), make it possible to identify DNA sequences protected as IP [intellectual property] at profoundly low concentrations, in a way similar to their use in forensic police work. Previously, plant traits that enjoyed IP protection were identified at a phenotypic level. That is, the trait could be observed with the eye or by monitoring the use of management practices that were unlikely to be used with other varieties of the same crop. Cross-fertilization in maize, for example, has traditionally been estimated by xenia, the effect of pollen on endosperm and embryo development. As powerful as xenia is for observing cross-fertilization, and useful as it has been to develop and maintain individual lines, it pales in comparison to the ease and sensitivity of PCR which can, in theory, detect a single transgene in 10,000 genomes in a laboratory exercise taking no more than a few hours. At least from a legal liability point of view, "what is important for risk assessment of transgenic crops appears not to be the probability of gene flow itself but the traces of introduced gene(s) in subsequent generations in recipients" (p. 156 Yamamoto et al., 2006), especially as these traces do not have to produce noticeable phenotypes to make themselves noticed (Heinemann, 2007, p. 53).

Crops are segregated to secure price premiums or target goods to particular markets. In areas where GM and non-GM agriculture attempt to co-exist, GM farmers may be prosecuted for loss of income to non-GM farmers.

> Neighboring certified (e.g., GM free) organic growers in particular represent a litigation risk for farmers who elect to grow PMP/PMIP [plant-made pharmaceuticals and plant-made industrial products] food crops in close proximity. Even if certified organic growers are comparatively scarce – only 73 organic growers are certified in North Carolina – their livelihood and certification status are under threat from PMP/PMIP crop admixture/introgression/hybridization events and thus they are likely to be especially vigilant for such events (Editor, 2007, p. 167).

Transgene flow to non-GM crops may prevent organic certification or blemish reputation and thus significantly lower income. At risk is the price premium paid for organic products. This can be 20-50% in the EU, 100-200% in Japan (Zepeda, 2006), 10-40% in the US (Winter and Davis, 2006) and up to 100% for organic canola oil (Smyth et al., 2002).

In summary, presence alone triggers legal instruments that derive from intellectual property, liability or contract law. It is unlikely that the industry will renounce intellectual property claims on transgenes. Therefore, it is inaccurate to assert that concern over GMOs is only either a food safety or consumer choice issue. Doing so would fail to recognize a genuine and deeply held concern about the presence of GMOs in food and the environment.

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Chapter Five

Yield

<u>Key messages</u>

1. Yield enhancement has not been the goal of genetic engineering in existing GM crops.
2. Yield benefits have been observed, but sporadically and in a year-, location- and crop-dependent manner.
3. Either the technology itself, or the context of its application, has limited genetic engineering's ability to deliver yield-enhancing qualities to plants.

THIS chapter is dedicated to text on yield in the Synthesis Report (IAASTD, 2009). The decision-maker will learn the reasons why the reports were cautious about endorsing "business as usual" for GM crops.

As this text is written, there is an advertising campaign in New Zealand to warn folks of the various dangers that come from drinking too much alcohol. The advertisement goes: "it's not the drinking; it's HOW we're drinking". The advertisement is not attempting to say that alcohol is good for people. It is emphasizing that the context of alcohol use is the immediate problem. The message from the Assessment on modern biotechnology, particularly transgenics, is similar. The Assessment acknowledged what, and in what places, GM crops have made positive contributions to some agricultural systems and in which ways their impacts have been positive. The Assessment also concluded that transgenics might contribute to the needs of poor and subsistence farmers in the future, but as discussed in Chapter Two, certainty of contribution is low given that most of this promise has not been realized over the past 12 years of commercialization and most may never be realized because of HOW we are using genetic engineering.

GM crops not designed to increase yield

Yield increases are often used as examples of the contribution genetic engineering makes to alleviating world hunger.

> The plant science industry cares passionately about abating hunger and supporting rural development. Higher-yielding plants and protection against insects and crop diseases are critical in helping farmers produce the food the world needs (Keith, 2008, p. 17).

The Assessment text

Executive Summary of the Synthesis Report (p. 8)
[D]ata based on some years and some GM crops indicate highly variable 10-33% yield gains in some places and yield declines in others.

Synthesis Report (p. 40)
[L]ingering doubts about the adequacy of efficacy and safety testing

Some controversy may in part be due to the relatively short time modern biotechnology, particularly GMOs, has existed compared to biotechnology in general.

The pool of evidence of the sustainability and productivity of GMOs in different settings is relatively anecdotal, and the findings from different contexts are variable, allowing proponents and critics to hold entrenched positions about their present and potential value. Some regions report increases in some crops and positive financial returns have been reported for GM cotton in studies including South Africa, Argentina, China, India and Mexico. In contrast, the US and Argentina may have slight yield declines in soybeans, and also for maize in the US.

The above statement was made by a representative of the commercial genetic engineering giant Syngenta. In fact, however, commercial GM crops at the end of the first decade of development are nearly exclusively either herbicide-tolerant/resistant (HT/HR) or insect-resistant (IR), or both (Qaim and Zilberman, 2003), but they are not yield-enhancing. Amongst the few exceptions to the crops listed above are disease-tolerant crops such as GM papaya, but again these are not direct yield-increasing traits. Yield enhancement is not being effectively transferred to the world's poor farmers because of how we apply genetic engineering.

> [T]here is also sufficient evidence to suggest that the institutional design of the emerging agbiotech era falls short in several areas that are critical to the diffusion of yield-enhancing and poverty-reducing technologies (Spielman, 2007, p. 198).

GM crops simply have not been designed to directly increase yield. The yield gains are meant to be indirect (Appendix Two).

> According to USDA's Agricultural and Resource Management Surveys (ARMS) conducted in 2001-03, most of the farmers adopting GE corn, cotton, and soybeans indicated that they did so mainly to increase yields through improved pest control (Fernandez-Cornejo and Caswell, 2006, p. 9).

Whether or not this expectation has been met will be evaluated later in this chapter. At the moment, the point is that yield advantage is not the target of present GM crops, unlike the “modern varieties” that came from the intensive breeding programmes of the Green Revolution. The transgenes used to create GM crops are not yield-enhancing traits, but the GM crop may produce more under certain environmental and management conditions, may increase revenue but not more food under others, or the GM crop may produce net negative yields and revenue relative to other crops or management regimes (Pretty, 2001).

> Currently available GE crops do not increase the yield potential of a hybrid variety. In fact, yield may even decrease if the varieties used to carry the herbicide-tolerant or insect-resistant genes are not the highest yielding cultivars (Fernandez-Cornejo and Caswell, 2006, p. 9).

Fernandez-Cornejo and Caswell refer above to what is called yield lag. Lag may abate in time as transgenes are bred into high-yielding varieties, but the fact remains that yield is not among the traits that the private sector has actively promoted.

Do GM crops produce more food or revenue?

The literature provides contradictory evidence on the hypothesis that GM crops produce more food (World Bank, 2007). On the more subtle contention that GM crops produce either more food or revenue (as a result of needing fewer external inputs) per unit of environmental or human health damage, the literature is also contradictory and lacking in data.

> Although the [US National Agricultural Statistical Service] annually interviews >125,000 farmers about their land use, the data regarding acreage devoted to various GE crops are aggregated to the level of individual states – a spatial resolution too crude to allow assessments of the environmental consequences, either positive or negative, of GE crops (Marvier et al., 2008, p. 452).

As a result, the Assessment could not come to a firm conclusion that genetic engineering was an obvious path to more sustainable production increases.

Uncertainty is due, in part, to both the limited time for testing GM crops and the types of comparisons from which some of the more advertised conclusions derive.

> Initial evidence from the commercialization of the first generation of genetically modified crops tends to support many of these claims, suggesting significant gains for farmers in terms of yield increases, cost savings, and improved human and environmental health. However, these findings are based on a relatively small sample of countries, only a few years of production, a select set of highly tradable crops, and a limited number of genetic events. Moreover, the findings tend to highlight gains in those countries where intellectual property rights allow firms to capture the extraordinary profits associated with innovation rents, namely, the United States, Canada, Argentina and, to a lesser extent, South Africa and India (Spielman, 2007, p. 190).

Comments such as Spielman's above were criticized during the Assessment's peer-review process for understating the degree of environmental diversity that has been tested, on the grounds that tests span the US and it is an environmentally diverse country. This argument is fraught with difficulties, however, because it exposes a lack of easily compared and comprehensive studies that are publicly available. For example:

> There is an almost complete lack of peer-reviewed literature on the Cry1Ab [transgene] expression of Mon810 [corn] at different plant growth stages, tissue types and seasons, despite of the world-wide use of Mon810 varieties. Most of the published data on Cry1Ab expression levels derived from a very few studies and are limited to a few tissue types, such as root, stalk and anther (Nguyen and Jehle, 2007, p. 82).

This topic will be explored in more detail below. In any case, general yield benefit claims even in US cropping systems are not consistent with the data.

> Yields of [IR] cotton appear largely unchanged at most locations, and those of maize are mostly unchanged (in 12 out of 18 regions), except where there has been high corn-borer pressure. Where pressure was high, yields were 5-30% greater for GM maize. In Missouri, however, no significant differences in yield under various corn-borer pressures across the state were found and at the University of Purdue it has been concluded that farmers may not benefit by adopting Bt [IR] technologies under average pest infestation levels, given that economically-significant pest attack occurs only one [sic] in 4-8 years in most locations in the USA (Pretty, 2001, pp. 255-256).

Researchers are now aware that GM crops in very uniform environments still display variation in the expression of transgenes. To illustrate, a recent study found significant differences in transgene expression levels between identical commercial varieties when analyzed by growth phase and tissue and grown in two different locations just within Germany (Nguyen and Jehle, 2007).

> The monitoring of Cry1Ab expression showed that the Cry1Ab contents varied strongly between different plant individuals (p. 82)…our analyses are the first large-scale expression monitoring of Cry1Ab under European field conditions and provide a comprehensive data set of the temporal distribution of Cry1Ab in transgenic maize Mon810. Cry1Ab expression was lowest in pollen, very low in the stalks, low in roots, but highest in the leaves. Although our studies corroborate the tendencies of reported Cry1Ab contents of Mon810, a considerable variation in the expression levels of Cry1Ab was observed. The observed variation exceeds variation levels reported previously and may be due to the large number of analysed samples and different growing years (Nguyen and Jehle, 2007, p. 86).

Generally speaking, how variable the expression of any gene might be when the plant is grown in different environments is not well surveyed. This is unfortunate because the variation in the expression of these transgenes has benefit/harm-specific implications. For insecticide-producing GM crops, individual variation could undermine long-term resistance-management schemes even though to date management has been successful (Heinemann, 2007; Tabashnik et al., 2008).

The above discussion notwithstanding, some studies have found yield improvements in some crops, at some times and in some locations, and others have found no yield increases or actual declines. For example, contrast the following two results for GM insecticide cotton in India:

> Average yields of Bt [cotton] hybrids exceeded those of non-Bt counterparts and popular checks by 80% and 87%, respectively (p. 900)…Over the 4-year period from 1998 to 2001, Bt hybrids showed an average advantage of 60% (Qaim and Zilberman, 2003, p. 901).

vs.

> The cultivation of the genetically modified bollworm-resistant Bt cotton was recently authorised in India. Although increased yields and profits, along with reduced pesticide applications have been credited to its introduction, also many cases of poor performance have been reported, particularly in Andhra Pradesh (Mancini et al., 2008, p. 23).

A general weakness of collecting anecdotes of either yield increases or decreases is the potential variability in varieties being compared, locations, particular seasons and other parameters. However, the question here is whether confidence is justified in the general claim that GM plants increase yield and will do so under real world conditions that include environmental variables and the ways in which they are being developed and distributed by industry. The anecdotes reveal that confidence is not justified in such general claims.

The same kind of yield variability is seen with cotton in other parts of the world. For GM insect-resistant cotton, average yield increases were 33% in Argentina, 19% in China, 34% in India, 11% in Mexico and 65% in South Africa. However, the authors note that "the averages conceal a high degree of temporal and spatial variation" even though "they clearly indicate positive overall results" (Raney, 2006, Table 1 and p. 175). Considering both HT and insecticide cotton varieties in the US, the latest studies do not vindicate the claim that testing has been exhaustive and that the crops are reliably increasing yield or financial returns.

> Field experiments were conducted to compare production systems utilizing cotton cultivars possessing different transgenic technologies managed in accordance with their respective genetic capabilities. In 2001 and 2002, selection of the Roundup Ready (RR) technology system resulted in reduced returns to the producer, while higher returns were attained from nontransgenic, [insecticide-producing] Bollgard (B), and Bollgard/Roundup Ready (BR) technologies. ["This outcome is consistent with the reduced yields observed with the RR cultivars" (p. 48).] In 2003, selection of the RR technology system or the Bollgard II/Roundup Ready (B2R) system reduced returns, while similar, higher returns were attained from nontransgenic, B, and BR technologies. ["Again, lint yields generally followed returns" (p. 48).] In 2004, a nontransgenic system was superior to the BR, B2R, and Liberty Link (LL) systems in Tifton, but similar returns were achieved from nontransgenic, BR, and B2R tech-

> nologies in Midville (Jost et al., 2008, p. 42). ["At both locations, lint yields generally followed return trends" (p. 49).]

The work from Jost et al. (2008) "indicated that profitability was most closely associated with yield and not with [pest management] technology" (p. 50), at least in US cotton cropping systems. Recall that current commercial GM crops are fitted with transgenes that are meant to be pest management technologies, and not yield-enhancing. Whatever the revenue-limiting variable is in any particular cropping system, the farmer must make a choice between available technologies before planting and hope that the advantages of that technology will (1) not fail, (2) be favoured in the coming season, and (3) warrant the purchase price and produce net positive revenues from the sale of the crop (Bryant et al., 2003; Jost et al., 2008). On top of these considerations is the initial cost of the seed and the season or longer commitment to the chosen technology package which may include particular pesticides. GM seeds and their commercial co-technologies generally come with a price premium (McAfee, 2003).

> The costs of paying higher seed prices and technology fees in advance must be compared with relying on the traditional pesticide treatments used with nontransgenic cultivars. The high investment for the transgenic cultivars before any yield is realized is a predicament for growers. Cultivar performance data encompassing both yield and profitability are essential for growers to make critical comparisons (Jost et al., 2008, p. 43).

> When technology fees for genetically modified (GM) crops are added on, the risk of purchase can often be considered too high for a poor farmer who is also burdened with excessive fertilizer prices and unpredictable rainfall (Delmer, 2005, p. 15740).

And in most cases analyzed by Jost et al. (2008), "production costs in [transgenic] systems were not reduced to levels that could compensate for associated technology fees and differences in yields among production systems" (p. 48).

The data on crops other than cotton are more consistent and even less supportive of the suggestion that GM crops increase yield.

> [US and Argentina/maize and soybeans:] For insect resistant maize in the United States and herbicide-tolerant soybeans in the United States and Argentina, average yield effects are negligible and in some cases even slightly negative (Qaim and Zilberman, 2003, p. 900).

> [US/soybeans:] On average, non-GR sister lines yielded 5% (200kgha^{-1}) more than the GR [GM glyphosate-resistant] sisters when averaged over all locations and both years…Herbicide-resistant cultivars yielded from the same to 15% less than the nonherbicide-resistant cultivars included in these studies (Elmore et al., 2001, p. 411).

> [Canada/maize:] We found that some of the Bt hybrids took 2-3 additional days to reach silking and maturity, and produced a similar or up to 12% lower grain yields with 3-5% higher grain moisture at maturity, in comparison with their non-Bt counterpart…Most Bt

hybrids had similar to or lower total N content in grain with higher N in stover than their respective non-Bt near-isolines…Our data suggest that within the same maturity group, it was the superior hybrids (non-Bt trait) that led to the greatest N accumulation, and the highest grain yield. Under the conditions tested, there was no yield advantage of Bt hybrids in comparison with their conventional counterparts when stalk lodging and breakage of the non-Bt counterpart by ECB [European corn borer] was low to moderate (Ma and Subedi, 2005, p. 199).

[Argentina and China/soybeans and cotton:] Roundup Ready (RR) soybeans did not increase yields in Argentina, but did reduce pesticide costs, which increased farmers' profits. Results of Bt cotton studies were pretty consistent – Bt cotton leads to increases in yields, decreases in pesticide use and increases in profits in all four countries. The only difference was that in low pesticide-use countries – Argentina, Mexico and South Africa – use of Bt cotton led to increases in total cost of production while in China it reduced the cost of production. (Pray and Naseem, 2007, p. 201).

[Canada/oilseed rape:] Information comparing yields of HT with conventional oilseed rape varieties are contradictory, indicating either yield increases, equivalence or decreases (Graef et al., 2007, p. 115).

[Spain and South Africa/maize:] There are very few reports on the economic performance of Bt corn in other parts of the world. For the United States, the largest grower of Bt corn, on-farm evidence is limited to the early years of adoption (1997-1999) and points to very variable economic effects resulting from large differences in geographical incidences of corn borers. In South Africa, the Bt corn-yield advantage, together with reduced pesticide costs, increased income from €19.2 per hectare to €119 per hectare, a range similar to our findings in Spain (Gomez-Barbero et al., 2008, p. 386).

[Australia/oilseed rape:] The vegetative vigour, overwintering capacity, time to maturity, seed production and yield of HT canola fall within the normal range for conventional canola (Salisbury, 2002, p. 12).

Conclusions

There is no conclusive data from either developed- or developing-country agroecosystems to support generic claims that GM crops increase yield or revenue. It is undoubtedly true that any cultivar, transgenic or not, will produce more or less depending on year, location and other variables. GM crops are not being asked to achieve a higher standard than conventional crops on this point. However, any general claim that GM crops will reliably produce more than conventional crops in the same environments is not scientifically substantiated. Poor and subsistence farmers cannot gamble with their potential to produce food for their families and communities. Coupled with higher upfront costs for GM seeds, amongst other production and market risks (i.e., see liability topics in Chapters Four and Eight), reliable returns from genetic engineering are not certain.

The authors of the Assessment thus had reason to step back from endorsing bold claims of enhanced yield and/or revenue gains from existing commercial GM crops. Recalling the "bird in the hand" argument of Chapter Two, they drew the responsible conclusion that evidence of such benefits exists, but it was not of the form that allowed extrapolation of benefits to agroecosystems not already in GM production or to hypothetical future GM crops or animals.

Are other technologies more reliable and as promising? There is solid evidence for optimism that biotechnologies that do not include modern biotechnology but do make use of modern molecular tools can make the advances that are needed, again provided that we do not rely upon technology alone. These technologies are discussed in Chapter Seven, and needed associated changes in trade and intellectual property rights regimes are discussed in Chapter Eight.

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Chapter Six

Pesticides

Key messages

1. Pesticides include both herbicides and insecticides.
2. GM crops are mainly herbicide-tolerant, insecticidal, or both.
3. There is insufficient evidence to conclude that GM crops have led to consistent or sustainable decreases in pesticide use.
4. The way in which pesticides are used in GM crops is changing agriculture and taking away options for both future conventional and existing GM crop users.

UNTIL this point, we have been considering the economic decisions of individual farmers and not the larger social and environmental implications between different farming philosophies and approaches. A case has been made that the use of insecticidal or pest-resistant (IR/PR) and/or herbicide-tolerant/resistant (HT/HR) crops has human health and environmental benefits that are not easily quantified at the level of the individual farmer. Equally, the use of GM cropping can have negative effects that are only detected at the landscape level, that is, when monitoring districts, countries and regions (Graef et al., 2007).

The 12 years of commercial production of GM crops has resulted in mostly just two products (Delmer, 2005; Wenzel, 2006).

> Thus far, 99% of the global GM crop acreage relates to insect-resistance and herbicide-tolerance traits (Qaim and Zilberman, 2003, p. 900).

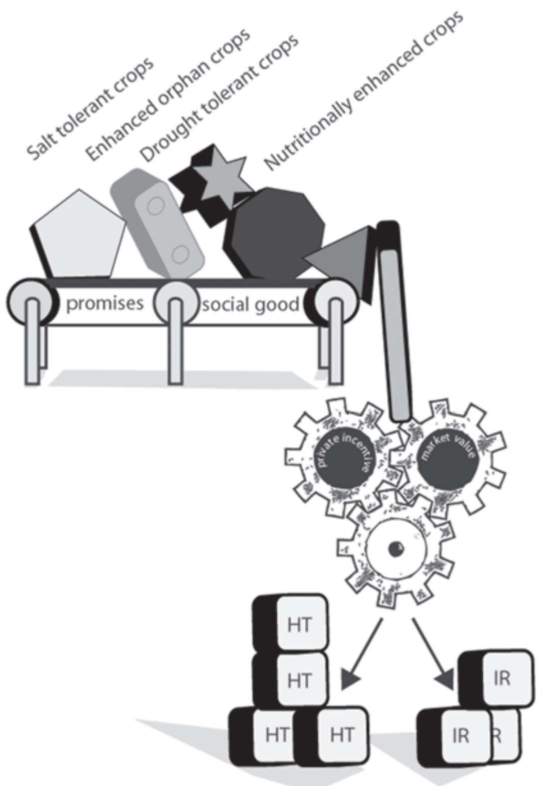
The majority of these are herbicide-tolerant, mainly to the herbicide glyphosate in the formulation called Roundup (Benachour and Séralini, 2009). While there is much talk of other traits, including drought and salt tolerance and nutritional enhancement, there are few or no commercial examples[1] (Figure 6.1). For instance:

[1] For an exception in animal feed, see Chapter Four. However, this crop was not developed to address a need in human nutrition nor does it provide a nutrient that is not already available from other sources (FSANZ, 2004; Terry, 2007).

So far, we do not have a direct gain from GM or molecular biology in terms of drought resistance (UN FAO's Pasquale Steduto quoted in Marris, 2008, p. 274).

Claims that genetic engineering would produce new drought and salt tolerant varieties were made 25 years ago. By 2005 the United States Department of Agriculture reportedly had received 1,043 applications to test genetically modified plants for agronomic enhancements including drought tolerance. So where are these crops? Do they fail under field conditions despite claims of promise from technologists? Do they not pass safety tests? Are they just too low a priority to move through to commercialisation? Are they held up by [intellectual property] disputes of the type plaguing other transgenic plants? If commercially viable transgenic drought tolerant plants can be made, then is their absence due to governments of industrialised countries having relied too much on the seed industry and its inherent profit motives (Heinemann, 2008a, p. 24)?

Figure 6.1: Processing promises through the constraints of market drivers in industrial agriculture, yields products for the largest markets and most uniform model of agriculture.



Note: IR, insect resistance; HT, herbicide tolerance; orphan crops are those identified by Kennedy (2003), Pinstrup-Andersen and Cohen (2000) and WHO (2005).

The Assessment text

Synthesis Report
Studies on GMOs have also shown the potential for decreased insecticide use, while others show increasing herbicide use. It is unclear whether detected benefits will extend to most agroecosystems or be sustained in the long term as resistances develop to herbicides and insecticides. *(pp. 40-42)*

Agroecosystems are also vulnerable to events and choices made in different systems. Some farming certification systems, e.g. organic agriculture, can be put at risk by GMOs, because a failure to segregate them can undermine market certifications and reduce farmer profits. Seed supplies and centers of origin may be put at risk when they become mixed with unapproved or regulated articles in source countries. *(pp. 43-44)*

There is an active dispute over the evidence of adverse effects of GM crops on the environment. That general dispute aside, as GM plants have been adopted mainly in high chemical input farming systems thus far, the debate has focused on whether the concomitant changes in the amounts or types of some pesticides that were used in these systems prior to the development of commercial GM plants creates a net environmental benefit. Regardless of how this debate resolves, the benefits of current GM plants may not translate into all agroecosystems. For example, the benefits of reductions in use of other insecticides through the introduction of insecticide-producing (Bt) plants seems to be primarily in chemically intensive agroecosystems such as North and South America and China. *(p. 45)*

Again, this may be because it is not easy to achieve these complex phenotypes (Sinclair et al., 2004; Varzakas et al., 2007; Zamir, 2008), it is not easy to acquire all the enabling technologies for commercialization (or even humanitarian release) (Graff et al., 2003; Spielman, 2007), possibly these products have not passed early safety tests, or there are few business models that make these kinds of products profitable for the private sector (Delmer, 2005; McAfee, 2003).

> The private sector logically focuses on crops such as corn and soybeans where markets are large, which leaves the development of small specialty crops for the United States and subsistence crops important to the developing world mostly in the hands of the public sector (Atkinson et al., 2003, p. 174).

Whatever the reasons that traits outside of the “big two” have not been a priority, the Assessment’s authors had little beyond promise and speculation to extrapolate from existing GM crops to a world in which genetic engineering would be delivering a significant number or variety of products to change the circumstances of poor and subsistence farmers (Heinemann, 2008b).

Does genetic engineering reduce use of pesticides?

Have GM crops delivered on the claim that overall pesticide use has been reduced in the agricultural systems that have adopted GM crops? Early research indicated that agrochemical applications on GM crops were less than on conventional crops and more of these kinds of benefits could be expected in the future.

> It is estimated that the use of GM soybean, oil seed rape, cotton and maize varieties modified for herbicide tolerance and insect protected GM varieties of cotton reduced pesticide use by a total of 22.3 million kg of formulated product in the year 2000. Estimates indicate that if 50% of the maize, oil seed rape, sugar beet, and cotton grown in the EU were GM varieties, pesticide used in the EU/annum would decrease by 14.5 million kg of formulated product (4.4 million kg active ingredient). In addition there would be a reduction of 7.5 million ha sprayed which would save 20.5 million litres of diesel and result in a reduction of approximately 73,000 t of carbon dioxide being released into the atmosphere (Phipps and Park, 2002, p. 1).

"Pesticides" is a term that includes both insecticides and herbicides. Unbundling these two types of agrochemicals also reveals some important statistical differences. GM crops that produce their own insecticide (i.e., IR, PR, Bt, insecticidal crops) appear to modestly reduce the amount of *other kinds* of insecticides made from agrochemicals that were previously applied, at least until resistance or secondary pests might emerge and reverse this trend (Pretty, 2001; Qiu, 2008), but this does not account for the extra organic pesticide in the form of genetically engineered insecticidal proteins or dsRNA (see discussion on GM papaya in Appendix One) introduced into the environment by the crop itself (Appendix Three).

A different picture of insecticide reduction is obtained when crop types are separated rather than grouped. For example, the maximum reduction in insecticide use comes from the adoption of Bt cotton rather than maize.

> [T]he conclusion that adoption of Bt cotton or maize may entail ecological benefits assumes a baseline condition of insecticide applications. In reality, both types of control treatment reflect farming practices: in 2005, insecticides were applied to 23% of maize acreage cultivated in 19 states surveyed by the U.S. Department of Agriculture. Moreover, the vast majority of Bt maize acreage comprises varieties used for silage or processed foods (e.g., corn syrup) for which insecticide use has typically been limited. Insecticides are more commonly used in cotton production, with 71% of surveyed cotton acreage treated in 2005 (Marvier et al., 2007, p. 1476).

The reduction in insecticide use comes mainly from cotton but is usually reported in the aggregate, implying that the benefit extends to all Bt crops. Furthermore, the data for pesticide use is often from the US (Kleter et al., 2007) and may not extrapolate to other parts of the world.

> These data for [transgenic HT] beet and soybean also show that it is not always possible to extrapolate directly from the data previously assessed for the impacts of the same crops in the USA owing to differences in agricultural practices in the various regions (Kleter et al., 2008, p. 487).

Herbicide statistics are also conflicting. On a weight or volume basis, the amount of herbicide used may have dramatically increased in the US where both the most GM crops and statistics are available (FOE, 2008; Pretty, 2001).

These figures are disputed. Cerdeira and Duke (2006) cite research that calculates a net replacement of 3.27 million kg of other herbicides with only 2.45 million kg of glyphosate-type herbicides in US soybean fields, and other research showing a net 17 million kg reduction across all relevant crops in the US because of GM crops.

A problem with this debate is that the comparisons are usually between conventional and GM agricultural technologies, both of which are pesticide-intensive choices compared with organic and integrated pest management (IPM) technologies.

> [A] GM technology resulting in reduced use of pesticides could be more sustainable than a conventional system relying on pesticides, but this GM/reduced-use system would score less well if compared with an organic system that used no pesticides (Pretty, 2001, p. 255).

Comparing GM only to agrochemical-intensive conventional agriculture inflates the benefits of existing GM crops.

> Much larger reductions in per ha insecticide use have been achieved by farmers using integrated pest management methods in both the tropics and temperate regions (Pretty, 2001, p. 256).

Two issues stand beyond this debate over quantities of pesticide used. First, there is universal agreement that more of the herbicide glyphosate is used now compared to any other time in the past, with the most dramatic increases in use corresponding to the introduction of GM crops (Kleter et al., 2007; Service, 2007). Second, the pattern of use of agrochemicals is different from pre-GM crop use and this is creating unique problems in the agroecosystem and beyond (e.g., for insecticides see Appendix Three and for herbicides see Graef et al., 2007; Powles, 2008; Young, 2006).

Human health and environmental risks from insecticidal crops

The predominant insecticide produced by insecticide-producing crops is a variant of one or more toxins sourced from genes carried by small infectious genetic elements, called plasmids, found in soil bacteria known as *Bacillus thuringiensis* (i.e., Bt). *B. thuringiensis* is closely related to *Bacillus cereus* and *Bacillus anthracis.* Members of this group are so closely related that they may be considered members of the same species, often differing only by the presence or absence of particular plasmids which may be exchanged between them and which define the particular kinds of diseases for which the different bacteria are known (Helgason et al., 2000a; Helgason et al., 2000b; Hoffmaster et al., 2004).

Bacillus producing δ-endotoxins encoded by *cry* and *cyt* genes are considered to be a pathogen of insects rather than mammals (Appendix Three; NPTN, 2000; Schnepf et al., 1998). The *cry* genes are named after the parasporal crystal proteins which form inclusions in *B. thuringiensis* spores.

All pesticides have environmental costs. Insecticidal crops are toxic to both target and non-target organisms. The full range of non-target effects of Bt crops is still to be determined (Schmidt et al., 2008). As with research on yield, the amount of research on the effects of insecticidal crops has been limited by the number of years since their commercialization and the number and quality of studies.

> [I]n the case of GM crops, scientific analyses have also been deficient. In particular, many experiments used to test the environmental safety of GM crops were poorly replicated, were of short duration, and/or assessed only a few of the possible response variables. Much could be learned and perhaps some debates settled if there were credible quantitative analyses of the numerous experiments that have contrasted the ecological impact of GM crops with those of control treatments involving non-GM varieties (Marvier et al., 2007, p. 1475).

Important organisms in freshwater, where the residues of Bt crops are expected to accumulate, are among the non-target organisms that have been found to be affected.

> Laboratory feeding trials showed that consumption of Bt corn byproducts reduced growth and increased mortality of nontarget stream insects. Stream insects are important prey for aquatic and riparian predators, and widespread planting of Bt crops has unexpected ecosystem-scale consequences (Rosi-Marshall et al., 2007, p. 16204).

> We conclude that the tested variety of Bt-maize and its UM [unmodified] counterpart do not have the same quality as food sources for this widely used model organism. The combination of a reduced fitness performance combined with earlier onset of reproduction of *D. magna* fed Bt-maize indicates a toxic effect rather than a lower nutritional value of the GM-maize (Bøhn et al., 2008, p. 584).

Human health effects of Bt crops are more uncertain. However, there are very few studies on human consumption of GM crop plants and no studies on effects of inhalation; even animal studies are rare (Domingo, 2007; Pryme and Lembcke, 2003). Worryingly, some research as recent as late 2008 is warning of potential adverse effects (Appendix Three; Finamore et al., 2008; Seralini et al., 2007; Velimirov et al., 2008).

> Until now, assessment of GMO immune adverse effects was based on the potential allergenic evaluation of the pure recombinant proteins, and only a recent study has considered the potential immunotoxicological effects of whole GMO given to rats for different periods. In addition, no studies have considered the intestinal immune response for such a purpose. However, the intestine interacts continuously with food-derived antigens, allergens, pathogens, and other noxious agents, and the gut immune system, which is the largest lymphoid tissue of the body, is crucial for mounting a correct immune response while maintaining a quiescent status toward innocuous antigens (Finamore et al., 2008, p. 11533).

Preparations of *B. thuringiensis* have been used as insecticides for many years. In general, Bt is considered far more benign to humans than chemical insecticides. However, this confidence does not extend automatically to the *cry* toxin proteins when they are expressed in plants for several reasons.

> First, it is reasonably clear that Bt sprays do cause allergic symptoms, as detailed at the beginning of this case study. Expert advisers to the [US Environmental Protection Agency] EPA told the Agency that more studies are needed to determine the allergenic risk posed by Cry proteins in general – whether from Bt sprays or crops. Secondly, there is likely much greater chronic exposure to Cry proteins in Bt crops than in sprays. Cry proteins in Bt sprays break down within several days to two weeks upon exposure to UV light, while this is obviously not the case with Bt crops, which produce the toxin internally in grains and other plant tissues. Thirdly, Bt sprays are composed primarily of endotoxins in an inactive crystalline form. They are only toxic to insects with alkaline gut conditions that permit solubilization of the crystal to the protoxin, followed by proteolytic cleavage to the active toxin. Bt crops, on the other hand, are generally engineered to produce the Bt toxin (e.g. Bt11), which is active without processing, or a somewhat larger fragment (e.g. MON810). There is also evidence indicating that Cry toxins are more immunoreactive than Cry protoxins. Finally, the trend to increased Cry protein expression fostered by the EPA's "high-dose" strategy to slow development of pest resistance to Bt crops may result in an increase in consumers' dietary exposure to Bt proteins…Thus, even if one ignores the evidence of allergenicity and concedes that Bt sprays have a history of safe use, this is clearly not adequate grounds on which to judge Bt crops and their incorporated plant pesticides as safe (Freese and Schubert, 2004, pp. 312-313).

In addition, proteins are modified differently in plants and this kind of modification creates the potential for new activities or the potential for a protein to become an allergen (Heinemann, 2007). Finally, the concentration and context of the Cry toxin proteins in food plants subjects humans to new ways of exposure which never materialized when these proteins were only in bacteria (Appendix Three).

> A whole-plant study, which was not conducted with GM-Maize MON810, would also consider other important exposure routes that have been previously dismissed by GMO panel (inhalation of pollen as well as dust e.g. during handling and processing of the plants). GM crops may, however, exhibit allergenic activity also via other routes, particularly in case of large scale cultivation and processing. For example, pollens represent much more potent and frequent allergen sources than plant-derived food and it should, therefore, be considered that GM crops may also release allergens via pollen production and hence cause respiratory sensitization. Furthermore, processing of maize may lead to respiratory sensitization in bakers who are exposed to flour. In this context it has been reported that soybean dust caused severe outbreaks of asthma in Barcelona, Spain when the soybeans were unloaded in the city harbour (Dolezel et al., 2006, p. 39).

In summary, there is conflicting data on environmental harms and benefits of GM insecticidal crops in the sense that measured benefits are crop type- and environment-

Box 6.1: Do insecticidal GM plants reduce the level of some fungal mycotoxins?

A much-celebrated potential benefit of Bt crops is a reported decrease in some mycotoxins (Munkvold, 2003). As with other reported benefits, this one has only been noted in a few varieties of commercial insecticidal plants, primarily corn.

Mycotoxins are produced by some fungi that contaminate food. The most important sources are fungi of the *Fusarium* and *Aspergillus* genus. Toxins derived from *Fusarium* are found almost exclusively only in corn (Wu, 2006). There are also a few reports that some Bt-based insecticidal crops can reduce *Aspergillus* toxins (e.g., Abbas et al., 2008). Since these toxins are threats to animal and human health, food products with high levels of toxin must be removed from the food and feed supply, which also creates the potential for economic losses from these fungi (EPA, 2001; Wu, 2006).

> One of the benefits of Bt corn (a genetically modified, pest-protected corn) is that it has demonstrated drastically reduced occurrences of contamination by the mycotoxin fumonisin [from *Fusarium*]. This is because Bt corn is far less prone to insect injury, which in turn prevents the growth of fumonisin producing fungi. Certain events of Bt corn, such as MON810 and BT11, can reduce fumonisin levels by as much as 90%. This implies both private and social benefits: economic returns on corn sales would increase, and there would be potential reductions in mortality and morbidity among livestock and, presumably, humans (EPA, 2001, p. IIE14).

Those fungi that are thought to gain a foothold on corn using the wounds created by insect pests are most affected by insecticidal GM plants; other fungal pests are not (Munkvold, 2003). And insect damage is not absolutely required for colonization by the fungus. Where the greatest benefit of insecticidal corn lines has been recorded has been during high corn borer years in lower- and mid-latitude growing areas using conventional (i.e., not organic/agroecological) plots for comparison.

> Transgenic insect resistance in maize has provided an effective tool to reduce the risk of some mycotoxins, especially fumonisins, because of the association between insect injury and mycotoxin accumulation in maize grain. This approach, however, is not sufficiently robust to constitute a long-term solution for fumonisins, because Fusarium spp. can enter kernels unassisted by insects (Munkvold, 2003, p. 110).

Studies reporting benefits have been generally positive, but also highly variable. In many cases, the highest reported benefits come from studies where corn borer levels between control and Bt fields have been manually manipulated (Munkvold, 2003). Moreover, control of *Aspergillus* toxins (e.g., aflotoxin) has not been consistently observed or of significant health or economic benefit (Munkvold, 2003).

> No published study has compared natural insect damage in corn and mycotoxin levels in organically managed fields, compared to nearby fields planted to GM-corn (Benbrook, 2005, p. 31).

(Box 6.1 continued)

The claim of an indirect benefit through lower costs or higher profits is also questionable. It would appear that any benefit of insecticidal crops for reducing mycotoxins is to reduce the cost of using high-rent GM seeds and chemically intensive farming practices. Integrated pest management and agroecological methods are far more promising and sustainable strategies for controlling insect damage to crops (Chapter 7). The benefit of insecticidal plants would be to reduce the high cost of using GM seeds and proprietary insecticides rather than a net benefit to the food supply. This benefit claim requires more systematic study including using the best alternative agricultural models (see Chapter 7) as controls (Benbrook, 2005).

Felicia Wu, in a paper on the economic benefits of Bt plants, found that there could be a maximum economic benefit to the US of US$23 million/year (Wu, 2006). But even the economic benefit needs to be kept in perspective. Recall that the US corn farmer is heavily subsidized. According to a report of the Congressional Research Service, corn subsidies in the US averaged US$4.5 billion per year, with a peak of US$10.1 billion in 2000 (Schnepf and Womach, 2007). At US$23 million/year, the net reduction in the costs of mycotoxin would amount to a scant 0.5% of the public loss on corn in general. Sadly, the maximum possible economic benefit of insecticidal plants would not even recover the amount that the corn biofuel lobby paid to US politicians on average per year over a recent 15-year period (Schubert, 2006).

specific (Delmer, 2005) (Box 6.1). The reporting of benefits and harms has been heavily generalized, which has the effect of reducing the accuracy of reporting. Furthermore, there are clear gaps in some aspects of safety testing, including human health and non-target effects. The main point for the Assessment was that it was not possible to extrapolate to a definitive endorsement of genetic engineering from the existing context-dependent data.

Human health and environmental risks from herbicide-tolerant crops

Like with other herbicides, there is a price to pay for using commercial formulations of glyphosate and glufosinate even though they are claimed to be less toxic to humans and less harmful to the environment.

> Environmental benefits centre around the use of more benign herbicides than many of the alternative products that may be used in the equivalent non-HT crop, fewer herbicide applications, and reduced tillage, since herbicide incorporation into the soil is not necessary (Devine, 2005, p. 313).

Herbicide formulations can also have non-target effects. Glyphosate formulations can be toxic to some animals (e.g., see Relyea, 2005; Relyea et al., 2005, but also challenged by Thompson et al., 2005) or tissues (Benachour and Séralini, 2009; Richard et al., 2005). Although glyphosate is claimed to have a lower toxicity to humans than many other alternative herbicides (Alan, 2000), these claims may be oversimplifications of the true impact of glyphosate-based commercial formulations which rely on a number of other chemicals that can be toxic (Benachour and Séralini, 2009; Richard et al., 2005). For example, glyphosate mixed with common adjuvants found in commercial herbicide formulations caused the death of human umbilical, embryonic and placental cells at much lower concentrations than glyphosate alone (Benachour and Séralini, 2009).

> For embryonic or neonatal cells, POEA [polyethoxylated tallowamine], the major adjuvant [of Roundup formulations], has the highest toxicity, either by itself or amplified 2-5 times in combination with G [glyphosate] or AMPA [aminomethylphosphinc acid, the major glyphosate metabolite]…we demonstrate that AMPA is more toxic than G in human cells, especially on cell membrane. AMPA is also more stable in soil, in plants, and in food or feed residues, and more present in wastewater (2-35 ppm) than G [0.1-3 ppm]. It is not toxic alone at these concentrations in our experiments, but it amplifies G or POEA toxicity in combination. The synergic toxicity of all of these compounds is now more obvious (Benachour and Séralini, 2009, pp. 103-104).

Commercial herbicides also inhibit non-target enzymes, resulting in other unintended effects. For example, glyphosate inhibits ferric reductase, resulting in iron deficiencies in some cropping systems (Ozturk et al., 2008).

Glufosinate-ammonium has toxic effects on soil microbial communities as measured in microcosms.

> [O]ur results suggest that the widespread use of glufosinate may have injurious effects on soil microorganisms and on their activities. The toxicity exerted by glufosinate induced shifts in the microbial community structure with apparent long lasting significant effects. Changes in soil microbial populations can also affect soil functionality, thereby influencing nutrient turnover and the restoration process of the soil (Pampulha et al., 2007, p. 330).

The commercial formulation also has deleterious effects on non-target organisms such as insects.

> In fields of GLA [glufosinate-ammonium] treated crops, caterpillars may consume a sufficient amount of leaf tissue to accumulate a lethal dose of GLA. We did not investigate the toxicity of GLA to earlier caterpillar instars which, being smaller than the 5th instar, may be more sensitive to GLA. Furthermore, our studies examined only the active ingredient (GLA) and not its commercial formulation, which contains a surfactant that aids in the penetration of GLA into the leaf surface. Indeed, studies have shown that GLA-containing products were more toxic to aquatic organisms than GLA alone. Similarly, GLA formulations applied topically to mammals were found to be 2.5 times more toxic than GLA alone. The formulated herbicide may also prove more toxic than GLA alone when ingested or applied topically to caterpillars (Kutlesa and Caveney, 2001, p. 31).

Moreover, with the rise of herbicide-resistant weeds, which are linked to the growing use of HT crops and resultant change in weed control approaches, farmers may again turn to the “replaced” herbicides and tillage (Valverde and Gressel, 2006), and thus negate these claimed benefits of HT crops to human health and the environment.

> Future changes in herbicide use patterns will likely be driven by reductions in the effectiveness of glyphosate due to weed shifts and weed resistance that will motivate growers to utilize other herbicides in combination with glyphosate (Young, 2006, p. 306).

Glyphosate effects are particularly pronounced probably because it has been on the market longer and GM Roundup Ready crops, which tolerate glyphosate, dominate the market. The same outcomes are expected for any combination of herbicide and HT crop, including the Liberty Link (GLA) system, which permits the same pattern of herbicide usage.

> The results of this unprecedented change in agriculture have been many, but perhaps most dramatic is the simplification of weed-control tactics; growers can now apply a single herbicide (glyphosate) at elevated rates of active ingredient and at multiple times during the growing season without concern for injury to the crop (Owen and Zelaya, 2005, p. 301).

For example:

> [T]he use of tank mixtures and sequential applications of more than one herbicide has declined as many growers have elected to rely exclusively on glyphosate for weed control in soybean, which may increase the risk of selecting for glyphosate-resistant weeds. The number of active ingredients used on at least 10% of the treated soybean hectares has declined from 11 in 1995 to only one (glyphosate) in 2002 (Young, 2006, p. 302).

In conventional cropping systems, glyphosate is primarily used as a "burndown" agent. It is usually applied early in the season before planting or after harvest to purge weeds, or between rows in perennial crops, and it is also used outside of agriculture to control weeds in urban and industrial areas (Powles, 2008; Reddy, 2001).

While resistance had arisen before the introduction of HT crops, burndown did not create large resistance problems, presumably because this pattern of usage neither exposed as many potential weeds to glyphosate nor did it stifle a diversity of companion techniques for controlling weeds, such as the use of biocontrol, hand-weeding or rotations with other herbicides, reducing the selection for resistance to any particular herbicide (Graef et al., 2007; Powles, 2008). Resistance arising in burndown applications was most likely to be observed where the use of glyphosate was intensive and usually resulted in replacing other weed-control strategies (Powles, 2008).

In contrast, with the introduction of GM glyphosate-tolerant crops, the herbicide can be used throughout the cropping year and at higher concentrations (Owen and Zelaya, 2005; Powles, 2008; Young, 2006). The amount of glyphosate usage in the US has increased 15-fold since 1994, with the period of 1994-2002 seeing the largest increase in both glyphosate use and herbicide-tolerant crops (FOE, 2008; Young, 2006). Large increases in glyphosate use are also reported in Argentina, one of the four largest GM crop-producing countries (Pengue, 2005). There, its potency and spectrum of activity lend it to recruiting what was previously marginal land for large-scale agriculture using herbicide-tolerant GM crops (Pengue, 2005). While these lands may be marginal for agriculture, they are nonetheless important for supplying ecosystem services (GEO-4, 2007). Finally, the use of glyphosate has reduced the diversity of chemical agents used for weed control and this significantly contributes to the selection of glyphosate-tolerant weeds (Powles, 2008; Young, 2006).

The agronomic attractiveness of glyphosate as a simple solution to the problem of weeds is what will ultimately limit its longevity as a herbicide and simultaneously increase the potential human health and environmental risks that rise with increased usage.

> Glyphosate-resistant crop systems are suggested to be simple and without great environmental consequences. However…there are major ecological and economic consequences from these presumed simple systems (Zelaya et al., 2007, p. 669).

Since both crops and some weeds are glyphosate-tolerant, and not fully resistant (despite sometimes being called herbicide-resistant), applying more glyphosate can for a while control the weeds (Pengue, 2005; Young, 2006). However, this strategy creates a cycle whereby using even more glyphosate reinforces the evolutionary drive in weeds to achieve ever-higher levels of tolerance, and exposes larger potential weed populations to the herbicide (Heinemann and Kurenbach, 2008).

With the price of glyphosate herbicides falling (Service, 2007), the utility of this herbicide should be more easily captured by poor farmers, and allow the herbicide to be used in urban settings where other herbicides might be less desirable. However, as resistance spreads, these comparative advantages will be lost. Adoption of other GM crops with tolerance for different herbicides, for example glufosinate or dicamba (Behrens, 2007; Service, 2007), is not an obvious solution to the problem so long as herbicide application patterns remain the same for these crops.

In summary, there is conflicting data on environmental harms and benefits of the agrochemicals associated with HT crops. There are gaps in some aspects of safety testing.

These facts created a conundrum for the Assessment's authors. On the one hand, the authors could accept the view that glyphosate and GLA were superior herbicides and their use should be welcomed. However, that meant that the use of these herbicides in GM HT cropping systems had unique potential to destroy their effectiveness in all other cropping systems and urban applications. On the other hand, the authors could accept the view that these herbicides have significant and perhaps underestimated human health and environmental risks. Therefore their increased use in GM HT cropping systems was quantitatively more threatening. Either way, the benefit of HT cropping systems was in doubt.

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Chapter Seven

Biotechnologies for Sustainable Cultures

Key messages

1. Alternative production systems, notably those based on agroecological methods, can be competitive with or superior to conventional and genetic engineering-based methods of productivity.
2. These alternative methods, moreover, not only lower the environmental impacts of agriculture, they may reverse past damage.
3. An emphasis on farmer-initiated and conducted innovation, research and manipulation of biotechnologies is a proven method for achieving higher levels of food security and has collateral benefits of building social capacity, community independence and ongoing local research and knowledge sharing.
4. To capture the benefits of alternative production systems, the world must readdress the imbalance in funding between genetic engineering and agroecological research, establish workable policies for farmer participation, and agree to eliminate developed-country subsidies for agriculture intended for export.

RECALL that the Assessment did not reject modern biotechnology as a source of some solutions to impending problems. The authors were well aware of the promise, and promises made in the name, of this technology. For example:

> In the late 1980s and early 1990s, rapid advances in molecular biology and related fields led many scientists to predict that their application in agriculture would result in significant productivity gains and would usher in the "Gene Revolution". It was felt that tools of biotechnology would allow scientists to develop novel crop and animal technologies that would not have been possible through conventional methods. Genetically modified (GM) crops would not only overcome the yield plateau that had been reached for many major crops in the period after the Green Revolution, but also could be engineered to be higher quality and more nutritious (Pray and Naseem, 2007, p. 192).

The Assessment simply found that the inherent ability of this technology, or as it is applied under current intellectual property frameworks with an emphasis on agriculture innovation being driven by private wealth creation incentives (Figure 6.1), was

The Assessment text

Executive Summary of the Synthesis Report (p. 8)
Conventional biotechnologies, such as breeding techniques, tissue culture, cultivation practices and fermentation are readily accepted and used. Between 1950 and 1980, prior to the development of GMOs, modern varieties of wheat increased yields up to 33% even in the absence of fertilizer. Modern biotechnologies used in containment have been widely adopted; e.g., the industrial enzyme market reached US$1.5 billion in 2000. The application of modern biotechnology outside containment, such as the use of GM crops is much more contentious. For example, data based on some years and some GM crops indicate highly variable 10-33% yield gains in some places and yield declines in others… A problem-oriented approach to biotechnology R&D would focus investment on local priorities identified through participatory and transparent processes, and favor multifunctional solutions to local problems. These processes require new kinds of support for the public to critically engage in assessments of the technical, social, political, cultural, gender, legal, environmental and economic impacts of modern biotechnology. Biotechnologies should be used to maintain local expertise and germplasm so that the capacity for further research resides within the local community. Such R&D would put much needed emphasis onto participatory breeding projects and agroecology.

Synthesis Report
In addition to above: Biotechnologies in general have made profound contributions that continue to be relevant to both big and small farmers and are fundamental to capturing any advances derived from modern biotechnologies and related nanotechnologies. For example, plant breeding is fundamental to developing locally adapted plants whether or not they are GMOs. These biotechnologies continue to be widely practiced by farmers because they were developed at the local level of understanding and are supported by local research… *(p. 40)*

Biotechnology and the production system are inseparable, and biotechnology must work with the best production system for the local community. For example, agroecosystems of even the poorest societies have the potential through ecological agriculture and [integrated pest management] to meet or significantly exceed yields produced by conventional methods, reduce the demand for land conversion for agriculture, restore ecosystem services (particularly water), reduce the use of and need for synthetic fertilizers derived from fossil fuels, and the use of harsh insecticides and herbicides. Likewise, how livestock are farmed must also suit local conditions. For example, traditional “pastoral societies are driven by complex interactions and feedbacks that involve a mix of values that includes biological, social, cultural, religious, ritual and conflict issues. The notion that sustainability varies between modern and traditional societies needs to be" generally recognized. It may not be enough to use biotechnology to increase the number or types of cattle, for instance, if this reduces local genetic diversity or ownership, the ability to secure the best adapted animals, or they further degrade ecosystem services. *(p. 43)*

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unexceptional at best and possibly counter-productive at worst. To the degree that it might offer benefits, these are disputed and either the industry or regulators, or both, have not risen to the challenge of closing the research uncertainties. The scientific risks are both plausible and demonstrated if not always conclusive outside of the laboratory or field test. The legal risks have been amply demonstrated.

> Until recently, it was thought that "there are fewer options available than previously to address current problems through traditional breeding techniques" and that genetic modification technologies would largely replace classical breeding. The science of plant breeding is still waking up from this transgenic dream. Although genetic modification technologies have proven to be very powerful for introducing single gene traits (for example, resistances to insects and herbicides), the success rate for more complex traits, determined by numerous interacting genes, is much lower (Zamir, 2008, p. 270).

The authors of the Assessment were not depressed by Zamir's prognosis. They believed that there was reason to be optimistic that agriculture could be sustainable *and* more productive either with or without modern biotechnology (Tilman et al., 2002).

> Traditional breeding technologies have been immensely successful, and indeed are largely responsible for the high yields associated with contemporary agriculture. These technologies should not be considered passé or out of date…This is because selective breeding operates on whole organisms – complete sets of coordinated genes – while genetic engineering is restricted to three or four gene transfers with little control over where the new genes are inserted. For the most important agronomic traits, traditional breeding remains the technology of choice (Varzakas et al., 2007, p. 336).

Like all visions, the Assessment's will be incomplete or wrong in some details, but it is a vision that arises from the largest single research effort on this topic in all of human history. It is the most authoritative statement on current knowledge.

The Assessment found that the drive to use the private sector for such an enormous proportion of agriculture research innovation fails to be relevant to the circumstances and needs of poor and subsistence farmers (Tilman et al., 2002).

> There is a vast difference between what happens in the fields of a farmer growing just one or two different crops on 500 hectares in Iowa and another growing many more different crops on <1 hectare in Africa. The former will use varieties developed from highly inbred lines

> adapted to temperate climates, sophisticated agronomic practices, and optimal amounts of fertilizer and pesticides and, at least in most years, will operate with reliable and adequate rainfall. The latter, usually a woman, may live in any one of a number of diverse agroecologies. She will also grow many different crops that will minimize her risk, growing for example some maize and beans in case rainfall will be plentiful and perhaps sorghum, cassava and cowpea in case of drought (Delmer, 2005, p. 15740).

Industrial agriculture encourages a false sense of simplicity

As described in Chapter Six with the overuse of glyphosate, attempts to apply simplistic or incorrectly scaled solutions to problems in agriculture create new problems. For example:

> Kong Luen Heong, an entomologist at the International Rice Research Institute in Los Baños, the Philippines, calls pest-resistant GM crops a short-term fix for long-term problems caused by crop monoculture and overuse of broad-spectrum pesticides. “Pests thrive where biodiversity is at peril,” says Heong. “Instead of genetic engineering, why don’t we engineer the ecology by increasing biodiversity?” Indeed, such ecological engineering has proved beneficial. Zhu Youyong, president of the Yunnan Agricultural University in Kunming, and his colleagues have found that growing a mixture of rice varieties across thousands of farms in China could greatly limit the development of rice blast – a fungal rice disease – and boost the yield. They have also tested similar practices using different crops and found beneficial effects (Qiu, 2008, pp. 850-851).

Nutrition transition is another symptom of simplification resulting from the globalization and subsequent narrowing of the food base (Hawkes, 2006; Stix, 2007; Tee, 2002). Ever more calories and essential nutrients are coming from foods high in fats and sweeteners. This is correlated with increases in diet-related diseases such as type 2 diabetes and heart disease, and susceptibility to infectious diseases because of micronutrient malnutrition.

> Forces of globalization, commercialization, industrialization, population increase and urbanization change patterns of food production and consumption in ways that profoundly affect human diets. High-input high-yield agriculture and long-distance transport increase the availability and affordability of refined carbohydrates (wheat, rice, sugar) and edible oils. While making greater numbers of the population secure in terms of energy, modern food systems also underpin the nutrition transition. Where high rates of infectious illness persist, undernutrition and overnutrition combine to produce a double burden of communicable and non-communicable disease. In addition, the globalization of culture and commerce fosters a Westernization of food systems and diets in developing countries (Johns and Eyzaguirre, 2006, p. 183).

While increasing globalization of agriculture and agribusiness has been associated with large average decreases in undernutrition, globalization is exacerbating the plight of sub-groups. For example, while the urban populations of Latin America have seen decreases in undernutrition, rural areas are suffering more. Only because there are more people in urban areas does the problem of undernutrition appear to be being addressed (Chávez and Muñoz, 2002).

> The improvement is explained by the change in the proportions of the rural and urban populations [in Mexico]. The prevalence of malnutrition in rural areas actually worsened, increasing from 16% in 1980 to 19.8% in 2001, but its impact on the national figures was low because only 24% of the population is rural. The situation is similar in Brazil and Colombia, two of the largest countries in South America (Chávez and Muñoz, 2002, p. 349).

These trends will continue as the heavily subsidized agribusinesses of wealthy countries undermine local agriculture. Locals simply cannot compete with those who sell their goods below true market price (Chávez and Muñoz, 2002). In contrast, an emphasis on local and sustainable agroecological agriculture offers different outcomes.

> Promoting a diverse local food supply, accessible to poor households, has proven to be a simple and successful way to improve malnutrition. The cropping diversity found on organic fields, coupled with rotation crops of minor economic value but high micronutrient and protein content, enriches household diets and health (Scialabba, 2007, p. 221).

Target: sustainability

Agriculture has a massive footprint.

> In 2000, arable and permanent cropland covered ~1497 million hectares of land, with 3477 million hectares of additional land classed as permanent pasture. The sum represents ~38% of the total available land surface (13 062 million hectares) (Ammann, 2005, p. 388).

It may be the single largest threat to biodiversity through its unrivalled demand for land and water (Kiers et al., 2008). The expansion of agricultural activity further undermines sustainability by taking away ecosystem services: land, water and reservoirs of plants, animals and microbes that replenish what is taken from the earth during cultivation or grazing.

> Agricultural output must keep pace with a steadily increasing human population, yet must do so without destroying critical habitat for biodiversity or severely impairing ecosystem services (Marvier et al., 2008, p. 452).

This has led many commentators to suggest that "[m]ore food and feed have to be grown on less land" (Wenzel, 2006, p. 642). In this scenario, agriculture must become more intensive, by the application of agrochemicals, mineral and fossil fuel-derived fertilizers and through irrigation, so that more food is produced without increasing the land and water area used in agriculture (see discussion in Badgley et al., 2007). Other commentators say that the "assumption that further land clearing is inevitable because of either inefficient agricultural production or a more globally envisioned need for more food is wrong" (Vandermeer and Perfecto, 2007, p. 274). As discussed in Chapter Two, the world currently produces food surpluses and thus expansion of agricultural land is not necessarily inevitable.

The capacity to produce food locally rather than to import food from subsidized agricultural systems would better address the problem of food insecurity than would further intensification (UNEP/UNCTAD, 2008). This can be achieved without environment-damaging practices. For example, water stress is the most common limiting factor for yield (Delmer, 2005). Adopting techniques that preserve soil moisture and make water uptake more efficient can improve yield (Heinemann, 2008; Schiermeier, 2008). Increasing the yield of low-yield farmers to within 80% of the yield of high-yield farmers under the same limiting water conditions would close the food gap (Molden, 2007).

The more intensive agriculture becomes, the more it demands of "marginal" or non-agricultural land and water to replenish what is taken through production and repair the damage from planting, harvesting, grazing and so on. Intensification has therefore been associated with declines in biodiversity.

> Modern agricultural practices have been broadly linked to declines in biodiversity in agro-ecosystems. This has been found to be true for a wide variety of taxonomic groups, geographic regions and spatial scales. More specifically, various researchers have found significant correlations between reductions in biodiversity at various taxonomic levels and agricultural intensification. For example, a review of published studies on arthropod diversity in agricultural landscapes found species biodiversity to be higher in less intensely cultivated habitats…Across Europe, declines in farmland bird diversity are correlated with agricultural intensity (Ammann, 2005, pp. 388-389).

In this regard, it has been argued that cropping systems dominated by GM plants are less damaging to biodiversity (Ammann, 2005). However, as discussed in Chapter Six, GM plants either are not unique in the ways that they are biodiversity-friendly or are undermining their short-lived contributions because of the promotion of simplistic agrochemical weed controls. What is more, conclusions on these putative gains from GM cropping are largely derived by comparison to the most damaging conventional methods rather than by comparison to cropping systems based on integrated pest management and agroecological methods.

Agricultural systems that were less damaging to begin with would require less from non-agricultural land for ecosystem services and would support the key species necessary to maintain biodiversity both on and off the farm. Agriculture biotechnologies such as organic agriculture achieve this, but are criticized as being incapable of producing enough food. "It takes three times the land to produce the same yield [through organic agriculture as] grown conventionally, so going organic could remove wild spaces, compromise biodiversity and mean hunger for many" (Keith, 2008, p. 18).

Fortunately, such assertions from the agrochemical industry are now facing serious contention from the peer-reviewed research literature (Badgley et al., 2007; Posner et al., 2008). The World Health Organization concluded that "[t]ransforming the agricultural systems of rural farmers by introducing technologies that integrate agro-ecological processes in food production, while minimizing adverse effects to the environment, is key to sustainable agriculture" (WHO, 2005, p. 35). A study commissioned by the UN Environment Programme (UNEP) and UN Conference on Trade and Development (UNCTAD) found from extensive African research that all "case studies which focused on food production in this research where data have been reported have shown increases in per hectare productivity of food crops, which challenges the popular myth that organic agriculture cannot increase agricultural productivity" (UNEP/UNCTAD, 2008, p. x).

In the largest meta-analysis ever conducted, researchers based at the University of Michigan have drawn the conclusion that agroecological agriculture (including organic methods) may be capable of feeding the world and rebuilding depleted agricultural lands in time.

> Model estimates indicate that organic methods could produce enough food on a global per capita basis to sustain the current human population, and potentially an even larger population, without increasing the agricultural land base (Badgley et al., 2007, p. 86).

This Michigan study is important for another reason. It provided evidence that past unfavourable evaluations of organic agriculture productivity were in large part the consequences of short-term studies where conventional yields were being compared to organic yields on land that had only recently been converted from conventional agriculture (UNEP/UNCTAD, 2008).

> [M]any agricultural soils in developed countries have been degraded by years of tillage, synthetic fertilizers, and pesticide residues. Conversion to organic methods on such soils typically results in an initial decrease in yields, relative to conventional methods, followed by an increase in yields as soil quality is restored (Badgley et al., 2007, pp. 91-92).

The yields of conventional industrial agriculture are maintained through intensification. Conventional agriculture draws heavily on inputs such as irrigation and mineral and fossil fuel-derived fertilizers. Agricultural intensification masks the depletion of soil resources through the use of external inputs.

> The recent intensification of agriculture, and the prospects of future intensification, will have major detrimental impacts on the nonagricultural terrestrial and aquatic ecosystems of the world. The doubling of agricultural food production during the past 35 years was associated with a 6.87-fold increase in nitrogen fertilization, a 3.48-fold increase in phosphorus fertilization, a 1.68-fold increase in the amount of irrigated cropland, and a 1.1-fold increase in land in cultivation (Tilman, 1999, p. 5995).

Reliance on many conventional techniques, such as fossil fuel-derived fertilizers, however, is not sustainable (Uphoff, 2007). It is estimated, for example, that even in high-yield systems over half of the nutrients that crop plants extract from the soil are not replaced by added fertilizers (Zoebl, 2006).

Future productivity increases must "come from increases in productivity of the existing land through restoration of degraded soils and improvement in soil quality" (Lal, 2006, p. 197). Again, agroecological approaches not only look promising, they appear to be delivering.

> The main limiting macronutrient for agricultural production is biologically available nitrogen (N) in most areas, with phosphorus limiting in certain tropical regions (pp. 89-91)…Our global estimate of N fixed by the use of additional leguminous crops as fertilizer is 140 million Mg, which is 58 million Mg greater than the amount of synthetic N currently in use. Even in the US, where substantial amounts of synthetic N are used in agriculture, the estimate shows a surplus of available N through the additional use of leguminous cover crops between normal cropping periods (p. 92)…These results imply that, in principle, no additional land area is required to obtain enough biologically available N to replace the current use of synthetic N fertilizers (Badgley et al., 2007, p. 93).

Making agriculture more productive under times of impending climatic change and other challenges, while simultaneously reducing its ecological costs, will require multiple rather than "one size fits all" approaches.

> What might be done to decrease the environmental impacts of agriculture while maintaining or improving its productivity, stability, or sustainability? This major challenge will have no single, easy solution. Partial answers will come from increases in the precision and efficiency of nutrient and pesticide use, from advances in crop genetics including advances from biotechnology, and from a variety of engineering solutions. Some additional insights may come from a consideration of the principles that govern the functioning of all ecosystems, including agroecosystems (Tilman, 1999, p. 5998).

Indeed, the most important alternative to "a technological solution for a technological problem", as various biotechnologies seem to have become, are changes to human behaviour. "The most direct way to reduce poverty is to raise the productivity of those factors of production controlled by the poor: first of all, their labor, but also their knowledge and skills, and for many though not all, small areas of land" (Uphoff, 2007, p. 218). Investment in agriculture innovation by investing in people-oriented biotechnologies, such as integrated pest management, agroecological agriculture, participatory breeding and farmer extension, produces results.

> Agroecological approaches that seek to manage landscapes for both agricultural production and ecosystem services are another way of improving agricultural productivity. A study of 45 projects, using agroecological approaches, in 17 African countries shows cereal yield improvements of 50 to 100 percent. There are many concomitant benefits to such approaches, as they reduce pollution through alternative methods of nutrient and pest management, create biodiversity reserves, and enhance habitat quality through careful management of soil, water, and natural vegetation. Important issues remain about how to scale up agroecological approaches. Pilot programs are needed to work out how to mobilize private investment and

> to develop systems for payment of ecosystem services. All of these issues require investment in research, system development, and knowledge sharing… Another priority is participatory plant breeding for yield increases in rainfed agrosystems, particularly in dry and remote areas. Farmer participation can be used in the very early stages of breed selection to help find crops suited to a multitude of environments and farmer preferences. It may be the only feasible route for crop breeding in remote regions, where a high level of crop diversity is required within the same farm, or for minor crops that are neglected by formal breeding programs (Rosegrant and Cline, 2003, p. 1918).

> The most unexpected aspect of this study is the consistently high yield ratios [organic:conventional] from the developing world. These high yields are obtained when farmers incorporate intensive agroecological techniques, such as crop rotation, cover cropping, agroforestry, addition of organic fertilizers, or more efficient water management (Badgley et al., 2007, p. 92).

Farmer participation builds local, national and regional capacity in several ways (UNEP/UNCTAD, 2008). This capacity is a prerequisite for sustainability. First, it results in accessible technologies, those that can be understood and manipulated by the farmers themselves, and thus reduces reliance on imported "black box" technologies that require outside experts and a tendency towards "one size fits all" solutions. Studies on the practice of seed priming illustrate the advantage of locally accessible technology and its spread.

> On-farm seed priming is not a new technology. Indeed, it is a recommended practice in many states of India but is not common in the project area or elsewhere…We believe that farmers cannot appreciate the wide range of benefits from seed priming unless they are given the opportunity to experiment for themselves; to do their own research and development. The participatory approach used in this study has been highly effective in empowering farmers to test, develop and adapt seed priming and to appreciate its effects. It is difficult to overstate the importance of group and community participation in evaluating potentially useful technology (Harris et al., 2001, p. 162).

Second, it builds a capacity within the community to innovate and to teach, spreading locally-appropriate technologies.

> Involving farmers more actively in plant breeding has been much advocated and described as participatory plant breeding (PPB). The reasons for involving farmers can vary from empowerment to increasing the efficiency of classical breeding. Such increases in efficiency are achieved because farmer participation better orients the breeding programme to the needs of the clients (Gyawali et al., 2007, p. 88).

Third, involving the community preserves local and traditional knowledge by securing it within evolving biotechnologies.

> The traditional small scale farms are store houses of diversity managed by men and women sharing the responsibilities. Farmers (men and women) play a conscious and determinant role in the generation and maintenance of diversity through dynamic interaction with the biotic and abiotic factors within the agro-ecosystem. In order to understand and enhance the traditional practices of farmers, it is necessary to acknowledge and learn more about the complex and diverse nature of the indigenous resource exploitation system. Conserving biodiversity also needs conservation of these traditional farming systems that have nurtured the presently existing diversity (Tsegaye, 1997, p. 225).

These approaches require ongoing active engagement at all levels to introduce, maintain and grow their effectiveness.

> [P]romoting and supporting participatory technologies have limited impact when no attention is paid to participatory policy development and implementation (de Jager, 2005, p. 57).

> Furthermore, unless reward structures also reflect the value of ecosystem services, there will be little incentive for the private sector to invest in sustainable agricultural methods (Tilman et al., 2002, p. 676).

In summary, biodiversity and agrobiodiversity are best maintained, even promoted, in agroecosystems composed of small-scale farming wherein multiple crops are grown using many different pest control and soil restoration practices. While some industrial-scale technologies can have lower negative impact than other conventional methods, these technologies appear to only slow and not reverse the ecological impacts of agriculture and any benefits may be short-term. Social equity and national capacity-building goals are best achieved by policies that involve the farmer, often women, in ongoing innovation and secure the benefits of that innovation for the farmer and local community. In this regard, there has been no obvious benefit of genetic engineering technologies which are dominated by a small number of mega-corporations. Agroecological methods may not only better suit the social structures and agroecosystems of developing countries, they may in time out-produce the present industrial conventional methods of developed countries.

Target: increased yield and disease resistance

GMOs have not been designed to directly increase yield, although yield gains might be derived indirectly from more effective pest management in some cropping systems (see Chapter Five). On the whole, any such yield and financial return gains have been sporadic and highly crop- and year-dependent, with researchers concluding (e.g., for Africa) that there "is still not enough evidence to generalize about the returns to GM crop improvement research" (Eicher et al., 2006, p. 523).

This is the good news: biotechnologies not based on transgenics remain technically capable of meeting our food needs (UNEP/UNCTAD, 2008). However, this will not be achieved by simply eliminating modern biotechnology. We cannot rely on agroecological and intensive conventional agriculture suddenly creating a new balance of economic and social justice in agriculture without also addressing the problems of broader context created by existing trade and IPR frameworks, a topic to which we will return in Chapter Eight. And we must seriously invest in research on agricultural science and technology that is sustainable and applicable in the neglected agroecosystems such as sub-Saharan Africa's. Nevertheless, as part of a broader reform of the socio-economic and legal cultures of agriculture, there is a promising way forward that is not reliant on transgenes.

Yield enhancement has been achieved through both traditional crop breeding approaches and breeding assisted by genetic technologies that are not genetic engineering, such as MAS/MAB (marker-assisted selection/breeding). These approaches have two benefits over genetic engineering. First, they are readily accepted and accessible.

> [B]iotechnology applications using genomics and other tools are not controversial, and their declining costs and wider application should ensure continuing yield gains through better resistance to disease and tolerance for drought and other stresses (World Bank, 2007, p. 67).

Second, these conventional approaches work and are relevant. The breeding programmes have been working towards developing traits for environments that are appropriate for the majority of the world's farmers and can help repair past environmental degradation and prepare for impending climate change effects.

> The International Maize and Wheat Improvement Center (CIMMYT), after more than 30 years of research to produce drought-tolerant maize varieties and hybrids, is now seeing results in eastern and southern Africa. Evaluated against existing hybrids, the new ones yield 20 percent more on average under drought conditions. Similarly, recent evidence points to significant yield gains in breeding wheat for drought and heat-stressed environments. New varieties of rice that survive flooding have also been identified. Such advances in drought, heat, and flood tolerance will be especially important in adapting to climate change (World Bank, 2007, p. 162).

Some speculate that even the "best of traditional breeding is too slow" (Marc van Montagu quoted in Marris, 2008, p. 274) or limited by genetic diversity (e.g., Sarker and Erskine, 2006) to reach our goals in the absence of genetic engineering. Even amongst those who argue strongly in favour of transgenic approaches, however, there is recognition of the primary contribution from breeding.

> As a higher plant contains 20,000 to 60,000 genes (Arabidopsis 25,000; rice 46,000), recombination of this huge amount of alleles by combination breeding is today and will be in the future the central process for the development of new varieties. Increasing knowledge about the specific function of genetic material will be helpful in parent selection and offers reliable tools for a more efficient selection within the new combinations of the $\sim n^{20,000}$ alleles (n=number of alleles per locus). It should be stressed that even though there is a spectrum of new technologies, the present breeding progress documented by the annual registration of new cultivars all over the world is the result of classical breeding, and this will continue (Wenzel, 2006, p. 643).

Critically, the places to be most optimistic about gene pool diversity are the centres of crop origin, where landraces form large *in situ* conservation areas, and even in exotic locations that may nevertheless support some interbreeding distant relatives or diverged varieties (Damania, 2008).

> [T]here is also enormous diversity in wheat landraces and wild relatives. It is still not clear just how much of the natural variability within the Triticeae family has been harnessed: in bread wheat, there are predictions that it might be as little as 10-15% of the available gene pool (Able and Langridge, 2006, p. 261).

> Others take advantage of an accidental 500-year breeding experiment. Wheat came to Mexico with the conquistadors…In the half-millennium since, farmers have adapted it to the dry local conditions. Many of these strains have very deep roots (Marris, 2008, pp. 275-276).

While the wealthiest nations may have exhausted many of the yield optimization traits appropriate for their intensive and well-irrigated agroecosystems, there may be more and more relevant yield-enhancing genes available in the agroecosystems that dominate in the developing world. Increasing output in these agroecosystems is critically important (Molden, 2007).

> A large-scale farmer in subSaharan Africa can get a yield of 10 metric tons (MT) per hectare for maize, whereas a poor farmer using a comparable variety with little or no inputs will obtain a yield <2 MT per hectare. What may be considered small gains in yield for the large-scale farmer, therefore, can be a quite significant increase for crops grown under low-input conditions, so crop improvement strategies that focus on optimizing yield under stress and minimal inputs may be, at least in the short-to-medium term, more appropriate than those that focus on enhancement of yield potential under optimal conditions (Delmer, 2005, p. 15740).

In fact, there is another surprise regarding yield. Plants grown under agroecological methods may possibly be raising what is understood to be the theoretical maximum possible yield of some crops, estimates developed almost exclusively from industrial conventional cropping systems.

> Critics have argued that some of [the examples of yield from organic agriculture] exceed the intrinsic yield limits set by crop genetics and the environmental context…Yet alternative agricultural methods may elicit a different pathway of gene expression than conventional methods do. Thus, yield limits for conventionally grown crops may not predict the yield limits under alternative methods (Badgley et al., 2007, p. 92).

This observation requires more research for confirmation. Note, however, that organic/agroecological methods are clearly demonstrating competitiveness with industrial agriculture for food production, now and also into the future, and superior indications of sustainability (UNEP/UNCTAD, 2008).

> Our calculations probably underestimate actual output on many organic farms. Yield ratios were reported for individual crops, but many organic farmers use polycultures and multiple cropping systems, from which the total production per unit area is often substantially higher than for single crops. Also, there is scope for increased production on organic farms, since most agricultural research of the past 50 years has focused on conventional methods. Arguably, comparable efforts focused on organic practices would lead to further improvements in yields as well as in soil fertility and pest management (Badgley et al., 2007, p. 94).

What is even more remarkable and worthy of highlighting is that organic/agroecological methods are already outpacing conventional/industrial agriculture in the very places that are most in need of a new path to food security, for example, Africa (Box 7.1). The UNEP/UNCTAD-commissioned study (UNEP/UNCTAD, 2008) presents a stark contrast to the claims of critics that the Assessment just got it wrong. Robert Wager, writing on the industry-friendly blog site AgBioView, asserts that "[m]ost of the 6000 year history of agriculture is by definition organic. This type of poor yield agriculture is exactly why we have significant problems with hunger, malnutrition, soil degradation and poverty in much of the developing world" (Wager, 2008). Wager dismisses the poor and subsistence farmer while arguing for more biotechnology, equating that word with modern biotechnology, the type that is captured by the intellectual property instruments available to the mega-agrochemical companies. Wager makes two mistakes. First, he fails to acknowledge the great advances of organic/agroecological agriculture even though it has not benefited from the long history of research funding that underpins modern biotechnology (Rivera-Ferre, 2008), and does not benefit equally from integration on the local level via the same network of extension services. The former is already producing more than the latter and, with a change in research funding emphasis, organic/agroecological agriculture shows even greater promise. Second, he lumps traditional farming practices over the previous 6,000 years with the sophisticated and modern applications of sound agroecological approaches developed in the last 100 years (see Figure 1 of UNEP/UNCTAD, 2008), creating the misleading impression that there is no difference.

> Organic farming can lead to increased food production – in many cases a doubling of yields has been seen – which makes an important contribution to increasing the food security in a region. The [case] studies outlined in this report support the growing body of evidence that yield increases are possible and indeed likely, with a switch to organic farming in a variety of different contexts, particularly in marginalized areas or where traditional farming methods are used. Food availability increased in 11 out of 13 cases centred on food production examined in this study (UNEP/UNCTAD, 2008, p. 11).

In addition, as discussed in Chapter Five, there is no convincing evidence that the major transgenic crops have been superior to conventional crops for raising yields or achieving other sustainability goals (Box 7.2) such as poverty and hunger reduction with less impact on the environment. In contrast, there is evidence that conventional breeding is a successful strategy for introducing complex traits into plants –

In places like subSaharan Africa, once breeders began tailoring their efforts to breeding targeted specifically to African conditions, it became apparent that significant crop improvement is possible through conventional approaches (Delmer, 2005).

– and for "multigene traits like intrinsic yield and drought resistance, [conventional techniques] surpass genetic engineering" (Varzakas et al., 2007, p. 336).

As some have attempted to argue for plants, others speculate that the genetic diversity of animal species is too low or breeding will be too slow to meet our goals in the absence of transgenic approaches.

> [C]onventional breeding is limited, because animals produced by mating selected individuals are a genetic mixture of their parents. Unknown or undesirable traits can inadvertently be co-selected. In addition, only those genetic loci that are present in the parents can be selected, which limits the range and extent of genetic improvement. Gene addition through the use of transgenic technology has the potential to overcome these limitations (Clark and Whitelaw, 2003, p. 826).

Again, these predictions have not been borne out. The World Health Organization concluded recently that foods "derived from GM livestock and poultry are far from commercial use" (WHO, 2005, p. 9). This conclusion was reached either because of the limits to the commercial model for GM livestock production or because transgenic approaches are not obviously superior to conventional approaches.

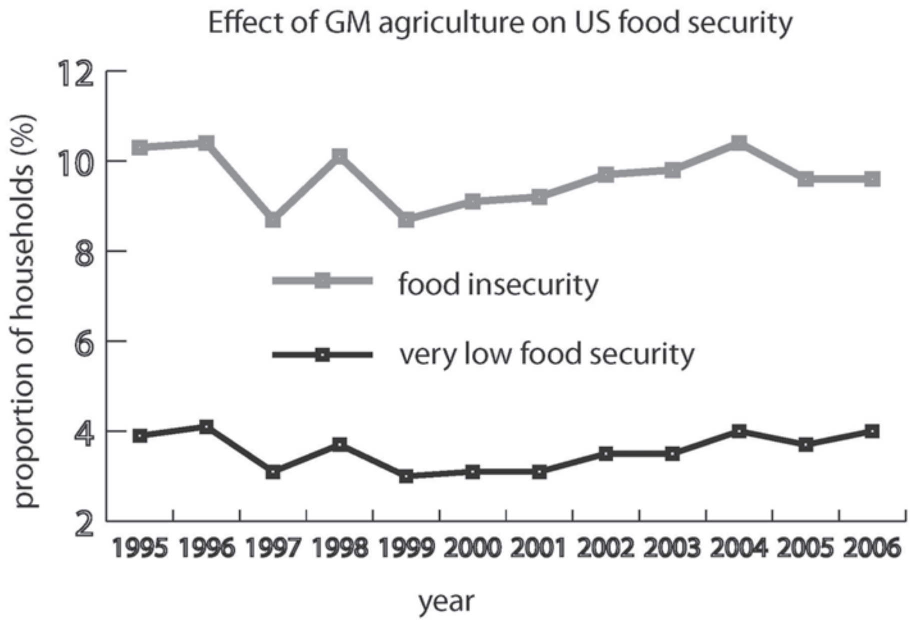
Box 7.1: Agroecological agriculture is effective and sustainable in Africa

The inherently holistic approach of "organic"/agroecological agriculture as defined by leading agriculture agencies (for definitions, see UNEP/UNCTAD, 2008) promotes food security through food availability, not just through food production increases.

Food availability is improved through the development of resilient agroecosystems, that is, those that continue to produce despite year-by-year variation in rainfall, pests and other factors. These systems tend to put more food on the tables of subsistence farmers and others in their communities. Organic approaches are more resilient for a number of reasons, including their relative independence from the external inputs (e.g., fertilizers) that conventional agriculture depends upon and which vary according to price speculation in global markets.

The UNEP-UNCTAD study found that in Kenya, food production increased by up to 179% when farmers changed from conventional to organic agriculture. The average increase was more than a doubling of production, with 116% increases across all of Africa and 128% increases in East Africa (UNEP/UNCTAD, 2008).

Box 7.2: No evidence that GM cropping feeds the poor



By way of illustration, let's have a look at the countries that have switched significant proportions of their arable land to GM cropping beginning in the mid-1990s. While industry analysts refer to GM "mega-countries" as those with 50,000 or more hectares in GM crops (James, 2007), here mega-countries are defined as those with ≥20% of their arable land (plus land planted in permanent crops according to year 2003 figures from FAOSTAT, 2008) converted to GM cropping. This is because 50,000 hectares is a very tiny proportion of agricultural land in most countries (e.g., 2% in Chile, 1% in Colombia, 0.3% in France and 3% in Slovakia). Among the industry-labelled 13 mega-countries, the bottom three have a mere 0.4% (Mexico), 0.5% (Spain) and 0.2% (Australia) of arable and permanent cropland in GM cropping. Only a total of seven countries have ≥10% in GM cropping. In addition to those listed in Table 7.1, this list includes the US (32%), Canada (13%) and South Africa (11%). Worryingly, the two countries with 40% or more in GM cropping have seen an increase in their undernourished populations since the introduction of GM crops, and a decreasing food supply (Table 7.1).

Even for the United States, undernourishment statistics have remained static throughout the GM era (ERS, 2006). According to USDA statistics, rates of food insecurity in US households have hovered between 8-10% from 1995 (reflecting pre-GM agriculture) to 2006 (post-GM agriculture), and very low food security has hovered between 2-4%.

GM fish production also has an uncertain future (Maclean, 2003). Although fish are "particularly amenable to genetic manipulation" (van Eenennaam and Olin, 2006, p. 126), the fact that they also are prone "to escape confinement and potentially invade native ecosystems elevates the ecological concerns associated with their genetic modification" (van Eenennaam and Olin, 2006, p. 126). Meanwhile, the industry again has failed to close critical research gaps to allow GM fish to be properly evaluated.

> However, for most transgenic fish, insufficient publicly accessible data are available to resolve the complex issues that are necessary both for risk assessments and to develop consumer and commercial confidence. For transgenic fish technology to move forward, empirical risk assessment research needs to be undertaken and presented in parallel with strain development, enabling this maturing technology to have the essential information available to support regulatory and social requirements (Devlin et al., 2006, p. 89).

Table 7.1: Food security among the developing GM "mega-countries"[1]

Mega-Country[2]	Proportion in GM Cultivation (%)	Food Supply
Argentina	65	Decreasing since 1995-1997
Brazil	23	
Paraguay	66	Decreasing since 1995-1997
Uruguay	35	

1 Based on hectares in GM cultivation according to James (2007) and total arable land plus permanent crops according to FAOSTAT in 2003.

2 Shading indicates growth in undernourished population (FAOSTAT).

So while progress "in transgenic technologies has allowed the generation of genetically modified large animals for applications in agriculture and biomedicine" (Kues and Niemann, 2004, p. 286),

> [i]n contrast to the undoubted efficacy of conventional genetic selection, which delivers sustained improvements year-on-year, transgenic strategies for genetic improvement have simply not delivered. Explicitly put, no transgenic livestock have been generated that were deemed worthy of incorporation into livestock breeding regimes (Clark and Whitelaw, 2003, p. 827).

Both the World Bank and advocates of transgenic approaches have recognized the solid track record of livestock improvement through conventional approaches.

> The cross-breeding of dairy cows with exotic breeds has improved the livelihoods of smallholder farmers in high-potential areas in the tropics. About 100 million cattle and pigs are bred annually in the developing world using artificial insemination. And thanks largely to artificial insemination, about 1.8 million small-scale farmers in the highlands of East

> Africa draw a significant part of their livelihood from the higher milk yields they obtain from genetically improved dairy cattle (World Bank, 2007, p. 162).

> Breeding based on conventional selection has been the mainstay of livestock genetic improvement for more than 70 years, and it still is today…For example, continuous selection for growth rate in chickens bred for their meat has produced birds that are now four times heavier than those bred to lay eggs (Clark and Whitelaw, 2003, p. 825).

The reasons behind this success are varied, from the accessibility of the technology to the farmer to the wide variety of conventional techniques for livestock improvement, many of which can be augmented using DNA technologies but not requiring genetic engineering.

> Many different biotechnologies have been incorporated into livestock breeding programs to accelerate the rate of genetic improvement. These include artificial insemination (AI), sire-testing programs using data collected from thousands of offspring, synchronization of estrus, embryo transfer, cryopreservation of gametes and embryos, and DNA-based marker-assisted selection of genetically superior animals (van Eenennaam, 2006, p. 133).

> [Quantitative trait loci] have been identified for several livestock species and marker-assisted selection is now used in commercial livestock breeding programmes alongside conventional selection (Clark and Whitelaw, 2003, p. 825).

Conventional approaches continue to demonstrate their relevance and usefulness without needing modern biotechnological approaches.

> Marker-assisted selection breeding technology for both plants and animals is likely to allow controlled, increasingly complex genetic traits in animal and plant reproduction, without the need for genetic modification (Futurewatch, 2005, p. 11).

Moreover, transgenic technologies are lagging far behind the relevance of conventional technologies.

> It will take both a better understanding of the genomes of livestock, with the anticipated increase in candidate genes to choose from, and a major practical success before transgenic technology seriously challenges genetic improvement of livestock through selection for most conventional traits (Clark and Whitelaw, 2003, p. 830).

In summary, conventional approaches to producing new animal breeds and plant varieties are nowhere near exhausted. Their relevance is current and will continue to produce, in the terminology of Chapter Two, “bird in the hand” products. There are no unanswered criticisms of conventional approaches that make transgenic approaches inevitable. Continued research and experimentation inspired by public good rather than private wealth creation, however, may yield new benefits and presently unrealized opportunities for GMOs in the future, and thus the context of modern biotechnological research should be changed to foster the promise it offers.

Meanwhile, numerous studies are indicating that agroecological agriculture delivers on its promises and it builds sustainable societies. This, more than industrial/GM agriculture, is a holistic solution to the problems of food availability and poverty. Since agroecological agriculture is more productive, it leads to local production above the needs of the farmer and the development of local markets, increasing community wealth. Agroecological agriculture also better integrates food production into the community than does the conventional/industrial type, and thus encourages employment. Overall higher employment levels lead to societies more capable of purchasing food. Moreover, this practice increases the skill level of the workforce and creates training opportunities that span generations.

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Chapter Eight

Growing More Food on Less (Intellectual) Property

Key messages

1. Agriculture is changing due to recent changes in and burgeoning globalization of intellectual property rights (IPR) frameworks.
2. The use of IPR on transgenes creates new risks and liabilities for farmers whether or not they choose to adopt GMOs.
3. Excessive reliance on private wealth incentives in agriculture innovation, enforced through IPR, exacerbates inequities between societies, promotes the wrong kind of biotechnology, and inhibits public good research and philanthropy.

THIS chapter is dedicated to text on intellectual property rights (IPR) in the Synthesis Report and the reasons why the Assessment advocated change in existing IPR frameworks especially for modern biotechnology. While the Assessment recognized that there is value in IPR frameworks in general, it nevertheless found reason to recommend how this framework ought to be revised for agriculture. In particular, the Assessment did not endorse a trend towards increasing the ownership of germplasm.

What makes modern biotechnology attractive to large companies is the ability to receive utility patents and revised plant variety protection (PVP) instruments on processes and products in ways that they could not before countries such as the United States allowed such protections to be applied to living things (Gepts, 2004; Gepts and Papa, 2003; Mascarenhas and Busch, 2006; Williams-Jones, 2002). This was followed by an effort to harmonize IPR internationally.

> Transnational seed companies and their respective governments in developed countries are pressuring developing countries to establish their own IPR legislation. This pressure…has culminated in the so-called Trade-Related Aspects of Intellectual Property [Rights (TRIPS)] agreement, which falls under the purview of the World Trade Organization and came into force in 1995. The [TRIPS] agreement is a partial compromise between developed and developing countries. On one hand, the developing countries have committed themselves to developing an IPR system. On the other hand, they can refuse to include plants, animals, and "essential" biological processes as patentable subject matter (but strangely enough microorganisms and nonbiological and microbiological processes, including genetic engineering techniques, have to be eligible for patents). Crop cultivars have to be eligible

either for patent protection or through a system created specifically for the purpose ("sui generis"), or a combination of the two. The sui generis system is generally believed to be akin to a PVP system (Gepts, 2004, p. 1296).

What followed was a shift in intellectual property from the public to the private sector.

Early scientific excitement led to major investments by the private sector in [modern] biotech – especially in the US and Europe. These investments were driven, in part, by changes in patent law in industrialised countries which began to allow patenting of biotechnology tools and products, including living organisms. Since the mid to late 1980s, firms have been able to protect biological innovations through patents and hence appropriate more of the returns to their research investments. The prospects of greater appropriability – and greater profits – led them to invest even greater amounts in biotechnology research (p. 192)…production of technology [in agriculture] is almost entirely in the hands of the private sector. All plant biotechnology that has been commercialised in the world, with the exception of China, was developed by the private sector (Pray and Naseem, 2007, p. 196).

Patents and patent-like PVP are the instruments of IPR change in agriculture. Patents "provide more control since [plant variety protection] certificates have a research exemption allowing others to use the new variety for research purposes" (quote from Fernandez-Cornejo and Caswell, 2006, p. 2; see also Mascarenhas and Busch, 2006). The use of IPR in this way is seen not just as an entitlement by the industry, but as a pathway to world salvation –

As for intellectual property rights, it is only if companies like Syngenta protect their intellectual property that they can invest in products to benefit all. Innovation is only created through investment, and investment must be rewarded – another seemingly obvious fact which was overlooked [in the IAASTD reports] (Keith, 2008, p. 18).

– according to an industry representative (and former Assessment author).

It is unclear why these new IPR protections were needed for agriculture, considering that they have neither been necessary for, nor successful at, increasing yields over Green Revolution advances (see Chapter Five), nor for a sustained reduction in pesticide use (Chapter Six).

More remarkable perhaps has been the intensive adoption of Monsanto's Roundup Ready soybean since its introduction – in spite of the lack of any significant yield increase. For example, Monsanto accounted for 91 per cent of the worldwide GM soybean area in 2004. However, Ervin et al. suggest that when examined worldwide, all currently available transgenic crops account for a yield increase of no more than 2 per cent. In fact, in some instances farmers actually experienced a yield decrease (Mascarenhas and Busch, 2006, p. 129).

The general argument that patent and patent-like IPR instruments on biotechnology create net social benefits, by encouraging and then capturing wealth for developers whether they be private or public (Pray and Naseem, 2007), also ignores significant effects on the innovation pipeline (see below). Were these effects to be removed, it is also not obvious that the current IPR frameworks would spark a modern biotechnology revolution in developing countries.

> [F]ew technologies of importance to poor farmers can be cost-effectively protected by IPRs…the potential advantages of IPRs should not be overrated in most developing countries. Relative to broader investment climate issues, IPRs do not seem critical in the initial development of a private seed sector, but they could help to support a maturing commercial seed industry (World Bank, 2007, p. 167).
>
> Despite the increase in availability, new plant varieties continue to be inaccessible or inappropriate for poor farmers, and the rate of innovation remains largely unchanged in countries with a PVP system. Studies have indeed shown that in middle-income countries, the principal beneficiaries of PVPs are commercial farmers and the seed industry (WHO, 2005, p. 42).

The Assessment came to the view that IPR instruments were not developing agricultural transformations effectively in the developing world, possibly in part because of the differences between developed- and developing-country IPR frameworks, and in the meantime existing IPR frameworks were creating real barriers to the future development of economic equity and food security.

Gene vs. Green Revolutions

Transgenics are a dream (in the words of Zamir, 2008) for policy models that require agricultural innovation for the public good to be provided by the drive for private wealth, and a nightmare for the starving or the future generations that must adapt to the planet that these policies leave behind. Genes from the broader biodiversity of Earth can be modified and introduced into agricultural organisms using IPR frameworks to retain control of their production and sale. The ability to capture genetic diversity has been aptly characterized as the flow of intellectual property from the developing world to the IPR of the developed, because most genetic diversity and the associated traditional knowledge (TK) resides in developing countries (Adi, 2006; Gepts, 2004). Such misappropriation of genetic resources and associated TK, often facilitated by IPR systems, has been called "biopiracy" (Gepts, 2004).

The modern varieties of annual plants of the Green Revolution came with their own built-in loyalty to the developer, in essence giving "developers what was tantamount to a patent on the seed" (Mascarenhas and Busch, 2006, p. 127). "In the case of hybrids, seeds will grow but the crop will yield 15 to 20 per cent less. This is usually sufficient incentive for farmers to purchase new seeds each year" (Pray and Naseem, 2007, p. 204). Importantly,

The Assessment text

Executive Summary of the Synthesis Report (p. 8)
Higher level drivers of biotechnology R&D, such as IPR frameworks, determine what products become available. While this attracts investment in agriculture, it can also concentrate ownership of agricultural resources. An emphasis on modern biotechnology can alter education and training programs and reduce the number of professionals in other core agricultural sciences. This situation can be self-reinforcing since today's students define tomorrow's educational and training opportunities.

The use of patents for transgenes introduces additional issues. In developing countries especially, instruments such as patents may drive up costs, restrict experimentation by the individual farmer or public researcher while also potentially undermining local practices that enhance food security and economic sustainability. In this regard, there is particular concern about present IPR instruments eventually inhibiting seed-saving, exchange, sale and access to proprietary materials necessary for the independent research community to conduct analyses and long term experimentation on impacts. Farmers face new liabilities: GM farmers may become liable for adventitious presence if it causes loss of market certification and income to neighboring organic farmers, and conventional farmers may become liable to GM seed producers if transgenes are detected in their crops.

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[S]uitability of GMOs for addressing the needs of most farmers while not harming others, at least within some existing IPR and liability frameworks… *(p. 40)*

[U]se of IPR to increase investment in agriculture has had an uneven success when measured by type of technology and country. In developing countries especially, too often instruments such as patents are creating prohibitive costs, threatening to restrict experimentation by the individual farmer or public researcher while also potentially undermining local practices that enhance food security and economic sustainability. In this regard, there is particular concern about present IPR instruments eventually inhibiting seed-savings and exchanges… *(p. 42)*

[L]argely private control of modern biotechnology is creating both perverse incentive systems, and is also eroding the public capacity to generate and adopt AKST [agricultural knowledge, science and technology] that serves the public good. The integration of biotechnology through the development of incentives for private (or public-private partnership) profit has not been successfully applied to achieving sustainability and development goals in poor countries, especially when they include the success of emerging and small players in the market. Consolidation of larger economic units can limit agrobiodiversity and may set too narrow an agenda for research. This trend might be slowed through broadening opportunities for research responsive to local needs.

The rise of IPR frameworks since the 1970s, and especially the use of patents since 1980, has transformed research in and access to many products of biotechnology. Concerns exist that IPR instruments, particularly those that decrease farmers' privilege, may create new hurdles for local research and development of products. It is unlikely, therefore, that over regulation per se inhibits the distribution of products from modern biotechnology because even if safety regulations were removed, IPR would still likely be a significant barrier to access and rapid adoption of new products. This may also apply to the future development of new GM crops among the largest seed companies, with costs incurred to comply with IP requirements already exceeding the costs of research in some cases. *(p. 43)*

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however, the process of breeding was not protected. Under then prevailing PVP instruments, farmers and breeders had considerable freedom to experiment with these plants and develop their own sources of seed (Heinemann, 2007).

> A second, and related, difference between the Green and Gene revolutions involves the patenting of processes as well as products. The main process behind the Green Revolution was conventional plant breeding technology, which lies in the public domain, carried out by public institutions. Today, the processes used in modern agricultural biotechnology are increasingly subjected to IPR protection, along with the products that result (Pinstrup-Andersen and Cohen, 2000, pp. 162-163).

> [T]he degree of appropriability is a function of the strength of intellectual property laws, the degree to which government agencies can enforce the laws, the structure of industry that reduces the cost of enforcing IPRs, and the technical capacity of firms to protect their varieties through the use of hybrids or [genetic use restriction technologies] GURTs[1] (Pray and Naseem, 2007, p. 204).

The built-in loyalty of modern varieties is lacking in some crop plants and most transgenics (Mascarenhas and Busch, 2006). GM plants (and one day perhaps, animals and microbes) can breed and spread the transgene to others. Intellectual property rights substitute a legal instrument for the biological barriers of some modern varieties. To achieve this, however, required germplasm to be "ownable".

In the context of plants, intellectual property (IP) theory has forgotten its roots. Plants have long been objects of private property; germplasm has not. But most jurisdictions now recognize IP rights in plants' genetic information (DeBeer, 2005, p. 5).

1 See Heinemann (2007) for an extended discussion on the use of GURTs and their potential impact on the agroecosystem and wild plants.

The sexual flow of transgenes is an advantage when a company wants to breed a transgene-controlled trait into varieties that suit particular markets and then sell them to farmers. It is a disadvantage when the transgene spreads outside of the developer's control, or when the presence of the transgene causes environmental harms, triggers regulatory actions or causes a loss of market certifications to non-GM farmers (Heinemann, 2007; Khoury and Smyth, 2007). And these are not just hypothetical harms. Transgene flow has been the cause of herbicide-tolerant weeds (Chapter Six), lawsuits (Appendix Four), fines and product recalls (CBS News, 2008; Center for Food Safety, 2005; Heinemann, 2007; Heinemann et al., 2004; Herrera, 2005; Vermij, 2006).

> He also knows that one of those [rice] lines, LLRICE601, was grown on less than one acre. What he is not clear on is how the line then wended its way into the food supply. That little mystery is now the subject of an official investigation and a class-action lawsuit…Meanwhile, Bayer CropScience, the company that created the rice strain, put the blame squarely on farmers and an "act of God". By that logic, this would not be the first time that a deity has aided and abetted the escape of a genetically engineered crop. On 21 December, Syngenta was fined $1.5 million for allowing its unapproved pest-resistant Bt10 corn (maize) to mix into seed distributed for food. The past decade is smattered with examples of unapproved crops sneaking through containment barriers. When they make it into the food supply – as with LLRICE601 and Bt10 – public outcry and financial losses follow (Ledford, 2007, p. 132).

Using a legal instrument to secure intellectual property also introduces legal liabilities. As discussed in Chapter Four, these liabilities are based on presence of the transgene rather than the harm of a trait *per se* (GAO, 2008), leading to exceptional quantitative levels of risk exposure (Heinemann, 2007).

> "Who is, or is not, liable for damage caused by genetic modification? Who should be? To what extent?" These questions presuppose that damage will inevitably flow from the genetic modification of plants, animals, or microbes. This is, to some extent, true. For instance, international trade could potentially be damaged should a commodity export be tested and found to contain unacceptable levels of transgenic varieties. Domestic production of non-GM crops could also be affected by the widespread cultivation of GM crop varieties. Ultimately, one overriding query has begun to emerge in recent years: Is liability incurred if a sales market is lost as a result of the comingling of GM seeds with non-GM seeds, and if so, who is to be held liable? Beyond the financial losses that GM crop production could cause, one can question whether there can be liability on the part of GM producers and users should the release of this biotechnology into the environment be proven to cause injury to human health or to ecosystems (Khoury and Smyth, 2007, pp. 220-221).

Intellectual property rights are consolidating the seed industry

The patenting of germplasm is concentrating IPR-based control of the seed supply under a very small number of multinational corporations (Adi, 2006; Barlett and Steele, 2008; Graff et al., 2003; Sagar et al., 2000).

> The combination of the molecular technology and the capability of protecting molecular inventions by IPR has led to significant activities in the private sector in the area of genetic engineering of crop plants. While large chemical companies did have the financial wherewithal to engage in genetic engineering research, they have had to complete their IPR portfolio by taking over biotechnology companies (often start-ups)…They also needed the necessary seed marketing channels. The last two objectives were achieved by buying smaller seed companies, which had neither the financial wherewithal nor technological track record to survive in this new environment. This has led to a situation in which only five major firms now sell genetically improved seeds: Monsanto, DuPont/Pioneer, Aventis, Syngenta, and Dow. These same companies account for about a quarter of total seed sales (Gepts, 2004, p. 1299).

> By 1997, the share of U.S. seed sales (including GE and conventional varieties) controlled by the four largest firms providing seed of each crop reached 92 percent for cotton, 69 percent for corn, and 47 percent for soybeans (Fernandez-Cornejo and Caswell, 2006, p. 3).

A concern arising from this reorganization of the industry is that it also generates very powerful forces against reform of the basic rules around which the multi-billion-dollar companies are now consolidating (Barlett and Steele, 2008). The scale of vested interests in biotechnology patents in particular is growing rapidly (Fernandez-Cornejo and Caswell, 2006; Pinstrup-Andersen and Cohen, 2000). Recognition of this trend is useful for understanding why there was such concern in the industry when the Assessment found reason to criticize how IPR instruments were shaping the biotechnology landscape. For example:

> [Biotechnology industry lobby group CropLife does] not believe that the current draft assessment adequately reflects the role that modern science and technology, and in particular our own industry's technologies, have played in supporting agriculture. In our view, the IAASTD's treatment of biotechnology, crop-protection chemistry, the importance of intellectual property and the role of the private sector has been superficial and negative (Minigh, 2008, p. 685).

The consolidation of the seed industry also has resulted in lower competitiveness (Pinstrup-Andersen and Cohen, 2000) as the "concentration of the top four" (CR4) seed companies breached a critical threshold.

> In some subsectors, global concentration is much higher – in 2004 one company had 91 percent of the worldwide transgenic soybean area. It is generally believed that when an industry's CR4 exceeds 40 percent, market competitiveness begins to decline, leading to higher spreads between what consumers pay and what producers receive for their produce (World Bank, 2007, pp. 135-136).

The World Bank analysis is corroborated by the observations of other prominent researchers in the field (e.g., Delmer, 2005), and of the poor farmers.

> From new drugs to better seeds, the best of the new technologies are priced for those who can pay. For poor people, they remain far out of reach (UNDP, 1999, p. 6).

The consolidation of the seed industry has been led by the agrochemical companies which are rapidly converting into biotechnology companies as a result of IPR law changes.

> The large multinational agro-chemical companies were the early investors in the development of [transgenic cotton, corn, canola, and soybean] crops. One of the reasons that agro-chemical companies got into the act was that they foresaw a declining market for pesticides. The chemical companies got a quick start in the plant improvement business by purchasing existing seed companies, first in industrialized countries and then in the developing world…Acquisitions also represented an efficient means of obtaining the smaller firms' intellectual property and know-how, much simpler than replication or 'inventing around' it. The industry can now be characterized by a few 'mega-firms', with combined capabilities in biotechnology, agrochemicals, and seeds (Pingali and Traxler, 2002, p. 227).

The private sector in developed countries outspends the public on agricultural innovation 55% to 45%, with the top six agrochemical/biotechnology companies spending US$3.5 billion, or eight times the research budget of the Consultative Group on International Agricultural Research (CGIAR) system (Spielman, 2007). The combination of agricultural innovation shifting to the "mega-corporations", and the appropriability made possible through the unprecedented changes in IPR laws, is altering long-term and successful agricultural practices and farmers' rights such as seed saving, while threatening long-term sustainability of agricultural innovation coming from both the private and public sectors. The Assessment came to agree that:

> Much of the economics discussion of agricultural R&D and agricultural R&D policy refers to the public goods nature of agricultural R&D, and the market failures associated with the reliance on private provision. It would seem to follow that the natural solution is for the government to intervene to correct the market failure by providing agricultural R&D, like other public goods, financed by general government revenues. Such analysis and prescription is too simple, however, because most forms of agricultural R&D are not pure public goods; and, consequently, other interventions may be fairer, more effective, or more efficient ways to correct problems of underinvestment (Pardey et al., 2007, p. 38).

To achieve a path where investment in agricultural innovation follows the needs of the majority, there will have to be systematic and far-ranging changes. These must extend well beyond tinkering with IPR laws. The changes will require that trade policies and subsidies be the subject of major renovation. The details of trade policy revision are beyond the scope of this book. What will be discussed below are the immediate prevailing costs of the current and growing concentration of legal and economic power in the mega-corporations.

Patent and patent-like protections undermine agricultural knowledge, science and technology (AKST)

The new IPR frameworks and biotechnologies limit seed saving and exchanges –

> Equally critical to local food security strategies is farmers' ability to save and exchange seeds and to experiment with the planting and breeding of traditional and new varieties, options which would be eliminated by the enforcement of IPR claims on crop varieties and by new biotechnologies for seed sterility[2] (McAfee, 2003, p. 213).

– reduce agrobiodiversity and associated traditional knowledge without proper compensation (Figure 8.1). The IPR frameworks allow the corporations to build on the knowledge and contributions of farmers in developing agrobiodiversity, and appropriate the rewards for the corporations.

> Many are concerned about the implications if multinational agribusinesses are able to use IPRs over bioengineered seeds to legally prevent farmers who use the new seeds from reusing and trading seeds collected from their own fields, practices especially crucial for communities of small farmers who depend on small batches of traded seed to adapt to changing land conditions. The prospect that the promise of high yields could then push out traditional varieties and thereby force farmers to purchase new seeds for every crop has induced anxiety about farming communities becoming ever more dependent on foreign seed merchants. Furthermore, as multinational seed companies reap great rewards from their innovations, many farmers believe that their and their communities' historical contributions to biodiversity and seed development are going largely unrecognized (Borowiak, 2004, p. 512).

The Assessment text

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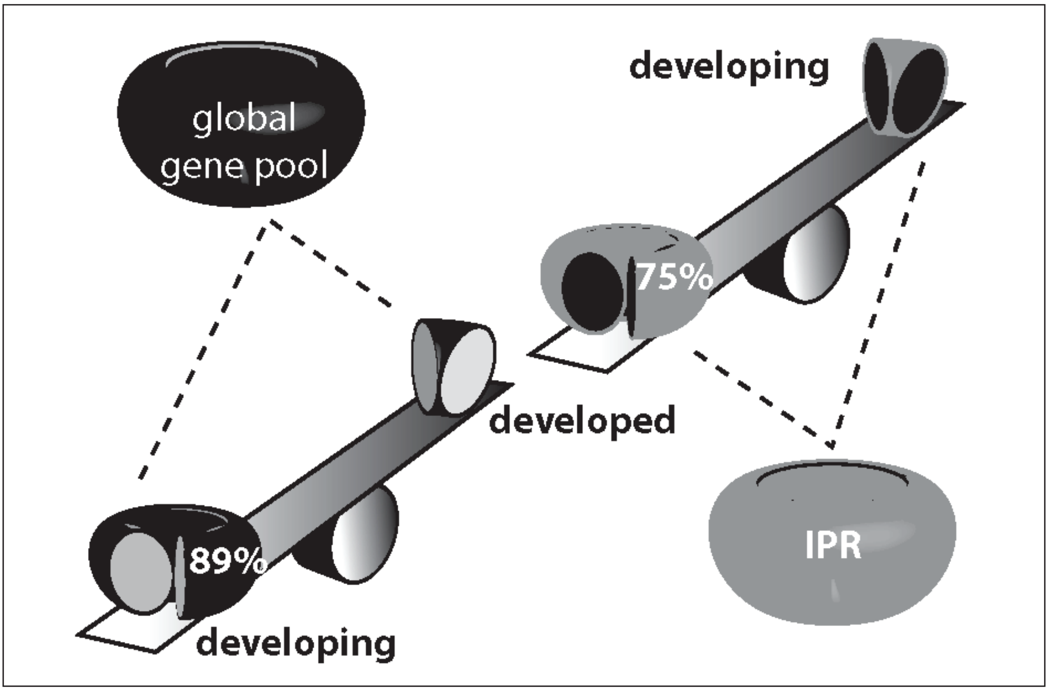
This ability to develop biotechnologies to meet the needs of IP protection goals may undervalue the past and present contribution by farmers and societies to the platform upon which modern biotechnology is built. It is not just the large transnational corporations who are interested in retaining control of IP. Public institutions including universities are becoming significant players and in time, holders of TLK [traditional and local knowledge] may also… *(p. 43)*

[T]here needs to be a renewed emphasis on public sector engagement in biotechnology. It is clearly realized that the private sector will not replace the public sector for producing biotechnologies that are used on smaller scales, maintaining broadly applicable research and development capacities, or achieving some goals for which there is no market. In saying this, an IP[R]-motivated public engagement alone would miss the point, and the public sector must also have adequate resources and expertise to produce locally understood and relevant biotechnologies and products. *(p. 45)*

2 In other words, GURTs.

Figure 8.1: The global distribution of IP in the form of genetic diversity and IPR in the form of patents and PVP (after Adi, 2006)



> New patent laws pay scant attention to the knowledge of indigenous people. These laws ignore cultural diversity in the way innovations are created and shared – and diversity in views on what can and should be owned, from plant varieties to human life (UNDP, 1999, p. 7).

Seed saving and exchange is relevant and important and a means to the realization of farmers' rights.

> Farmers in most developing countries depend on farm-saved and public-supplied seeds. The latter provide seeds for the most important crops, while farm-saved seeds account for over 90% of the planted crops (WHO, 2005).

Seed saving is neither limited to the developing world nor the small farmer. Before the US moved to the present types of IPR frameworks, seed saving was frequent (Pretty, 2001).

> [T]he data illustrates two historical trends with respect to soybean seed-saving practices in the US prior to the introduction of GM soybean in 1996. Firstly, farmers have historically been engaged in seed-saving practices. More importantly perhaps is that significant proportions, sometimes as much as 70 per cent, of soybean varieties have been grown from homegrown

> seed. The second trend suggests that it was the larger capital intensive farming operations, not the small family farm, that typically saved seed. Below we argue that in the US intellectual property rights have had a profound role in terminating these trends and re-structuring this industry (Mascarenhas and Busch, 2006, p. 126).

The correlation between the adoption of new IPR frameworks and GM crops is instructive for other countries considering adopting certain IPR instruments. Seed saving and exchange not only helps farmers achieve greater independence, and countries to achieve higher levels of food security, the practice also builds local AKST.

> [S]eed saving is a long-standing global institution, probably as old as agriculture itself. It helps farmers control their enterprises and maintain their independence; it allows them to predict how well a crop will perform in the following season; it allows them to participate in maintaining the crop; it serves as insurance against inadequate supplies of seed; it helps to maintain food security and it creates a viable market that ensures that seed prices remain affordable (Mascarenhas and Busch, 2006, p. 124).

The ongoing importance of seed saving and exchange in much of the world is a barrier to adopting the IPR frameworks that the large biotechnology companies require to invest in biotechnologies for the developing world.

> In countries where IP[R] systems do not exist, are weak, or are not enforced, innovative companies are not investing their resources (Monsanto, 2008).

The increasing pressure on developing countries to adopt more restrictive IPR frameworks (Gepts, 2004) is putting seed saving at risk. Farmers are being forced to choose between the products of modern biotechnology and the proven contribution to AKST and agroecosystem resilience provided by seed saving and exchange. The Assessment exposed this false choice and argued for a rational solution: change the IPR frameworks.

Patent and patent-like protections threaten long-term oversight and innovation

The “academy” of scholars in research-active government agencies and universities is sometimes criticized by industry as being out of touch in their ivory towers, but they provide an indispensable social service. Society needs a competent but financially disinterested research community to advise and forewarn it on impacts of technology, and to reflect both backwards and forwards on significant trends. To provide this public good, the academic research community must have credible practitioners at the state of the art in science, technology, economics, philosophy, sociology and law.

> Ironically, at the same time that the public sector is generally making more information available about itself, both private industry and academia have witnessed increases in secrecy. The allowance of patents for biotechnology discoveries has negatively affected traditional norms of scientific inquiry, typified by openness of research and timely access to the results

> of research...While intellectual property rights serve as an incentive to investments in and commitments to scientific innovation, the reduction of scientific investigations to largely commercial endeavors whose rewards are largely contingent on obtaining patents *will continue to erode informed public and academic discourse* [emphasis added]…And unless there are radical changes in position on the part of the biotechnology industry, these same concerns are likely to thwart progress in other important policy areas, such as biological disarmament (Wright and Wallace, 2000, p. 55).

Several prominent commentators have made the case that the traditional role of the academic and government researcher is being worn away as governments place more emphasis on, and bind more funding opportunities to, industry service. Regardless of whether the industry intends to be controlling, mixing the public and private together influences what is researched and how research is conducted (Heinemann and Goven, 2006; Katz et al., 2003; Kleinman, 2003; Krimsky, 2004).

> [F]aculty with corporate sponsorship are more likely to produce favorable findings and to withhold data from the scientific community to protect proprietary interests (Shorett et al., 2003, p. 124).

The results of the private wealth incentive system organized around IPR are seen in the massive maldistribution in research and development spending that has emerged in the past few decades. According to a leading science commentary magazine, for the US the "trend is undeniable. In 1965, the federal government financed more than 60 percent of all R&D in the United States. By 2006, the balance had flipped, with 65 percent of R&D in this country being funded by private interests" (Washburn, 2007, p. 66). Internationally,

> [a] meager one-third (about U.S. $10 billion) of all global research expenditure on agriculture is spent on solving the problems of agriculture in developing countries, home to ~80% of the global population. This amount is less than 3% of the total value of agricultural subsidies that countries of the Organization for Economic Cooperation and Development (OECD) pay to maintain their agricultural output…Private sector investments in agricultural research and development (R&D) reached more than $12 billion in 2000, 30 times the budget of the entire CGIAR international agricultural research system (Kiers et al., 2008, p. 320).

As governments increasingly tie public biological research investment with industrial goals (Wright and Wallace, 2000), the private spending tends to leverage more from the public purse than is immediately apparent just from the ratio of public to private funds (Crump, 2004).

> [F]or scientific knowledge subject to both Open Science and private property institutional regimes, the granting of IPR is associated with a statistically significant but modest decline in knowledge accumulation as measured by forward citations (in academic publications)…Overall, we are able to reject the null hypothesis that IPR have no impact on the diffusion of scientific knowledge…These patterns provide a novel perspective on the

> economic consequences of the privatization of the scientific commons. Rather than simply serving to facilitate a "market for ideas," IP[R] may indeed restrict the diffusion of scientific research and the ability of future researchers to "stand on the shoulders of giants," at least for research of the type published in *Nature Biotechnology* (Murray and Stern, 2007, p. 683).

Murray and Stern were careful in their interpretations. They would neither claim to know how IPR might inhibit the knowledge commons nor whether this would produce a net negative balance on social innovation or commercialization. Their research should be noted for definitively demonstrating that the quest for IPR in the public sector is decreasing the size of the knowledge commons.

The Assessment text

Global Summary for Decision Makers
While public private partnerships are to be encouraged the establishment and enforcement of codes of conduct by universities and research institutes can help avoid conflicts of interest and maintain focus on sustainability and development in AKST when private funding complements public sector funds. *(p. 7)*

Universities and research institutes receiving substantial private funding may need to set in place oversight mechanisms and codes of conduct that preserve their independence. *(p. 20)*

Modern biotechnology is largely in the possession of the private sector.

> The private sector accounts for 74% of the [intellectual property in agriculture biotechnology], much of it aggregated into a few very large IP[R] portfolios at major corporations, the top five of which control 41% in the United States. This percentage is likely to be an underestimate, as a portion of the public-sector portfolio has also been licensed to companies in the private sector. The rest of the private sector, including independent biotechnology startups, holds 33% of agricultural biotechnology IP[R] (Graff et al., 2003, p. 994).

While there is some intellectual property held by individuals and companies from the developing world, most of these owners reside in developed countries.

> Industrialized countries hold 97% of patents worldwide, and more than 80% of patents granted in developing countries belong to individuals or corporations based in industrialized countries…even pragmatic analysts from the North are concerned that future innovations will be limited under an emerging industry structure where the top five biotechnology firms control more than 95% of gene transfer patents (Sagar et al., 2000, p. 3).

The huge proportion of private innovation largely limits the range of biotechnology products that will become available. These limitations will persist if the industrialized countries continue to push for IPR frameworks that are too simplistic and inappropriate.

> Western-style IPRs for biodiversity (including TK about biodiversity) associated with local or indigenous societies are inadequate…In the Western tradition, they recognize individuals rather than groups of individuals. In indigenous societies, the development of landraces cannot be attributed to specific individuals. They are often the result of selection [by] generation after generation of farmers. Furthermore, landraces or ethnobotanical knowledge are often exchanged among farmers or indigenous people, primarily from the same extended family of the same or different villages. In addition, farmers sometimes actively promote hybridization between landraces and modern cultivars. Thus, there is no specific act of invention in the development of landraces that can be traced to documented events as in Western inventions (Gepts, 2004, p. 1303).

Present frameworks provide too much coverage compared to the intellectual property being claimed (Heinemann, 2002; Williamson, 2002).

> There are also suggestions that redesigning patent laws to narrow the type and scope of patent coverage ought to make more technologies accessible to public institutions. The thinking behind these suggestions is that applying a stronger standard for rejecting patent applications for inventions that are 'obvious' should deter the patenting of minor inventions. In addition, a law that requires an invention to be genuinely useful in theory should reduce the number of patent applications being submitted. At present, it is possible in some countries to submit patent applications for abstract concepts that potentially protect large areas of research and thereby exclude innovation by others (WHO, 2005, p. 43).

The Assessment agreed with other expert groups that IPR frameworks were in need of significant reform.

As the rush to patent DNA sequences progresses, there is legitimate concern that a few large companies will own too much of the world's crop and domestic animal germplasm for the public sector and individual farmer to continue to make progress in research for sustainability and social equity goals. In one sense, it might seem reassuring that the large companies are pursuing the identification of genes related to adapting plants to stresses caused by climate change (Appendix Two), for example, because it implies an interest in applying modern biotechnology to traits relevant to yield. However, since these kinds of genes are involved in many aspects of plant physiology and reproduction, it amounts to capture of plant germplasm (Weis, 2008).

> These mega firms are now competing in a new race: the race of plant genomics, which would allow them rapid access to genetic information on the qualitative or agronomic traits of cultivated plants; and allow them to secure their research and development through patents (Pingali and Traxler, 2002, pp. 227-228).

There are hundreds of different genes that may be involved just in drought resistance (Herdt, 2006). Conventional breeding assisted by genomics is far more realistic for making progress than genetic engineering at this stage (Varzakas et al., 2007), but there are those who claim progress using transgenes in model plants (Jauhar, 2006), and "Monsanto now has a large-scale program screening for genetic enhancements that can improve yield despite water shortages" (Pennisi, 2008, p. 172).

There are more rewards to be had by owning these genes than just commanding transgenes, though. Recall that the IPR claims of biotechnology reach beyond the DNA sequence of genes themselves and extend to the enabling technologies behind, and applications of, this information. Owning the DNA sequence of a gene allows a company to also own the diagnostic used to identify the gene as a molecular marker in applications such as marker-assisted breeding/selection (MAB/S). Genome "studies have identified DNA markers that speed the identification and selection of plants worthy of further study" (Pennisi, 2008, p. 172). There is concern among leading researchers that the use of molecular markers will be restricted by registering them as IPR-protected.

> The public interest would not be served if valuable markers remained as trade secrets, nor if breeding programmes were deterred from using them by the level of royalties that would be payable (Reece and Haribabu, 2007, p. 476).

This worry is not theoretical. Such a scenario played out in the pharmaceutical industry with the patenting of a diagnostic kit for molecular markers common in variants of the human BRCA genes. These genes are associated with greater susceptibility to hereditary breast cancer and ovarian cancers. The DNA sequences of BRCA1 and BRCA2 were exclusively owned or controlled by a Utah-based company called Myriad. While other patents or filings for patents on these two genes occurred contemporaneously, they were either in other jurisdictions, abandoned or transferred to Myriad. "The immediate purpose of these patents was to protect Myriad's new genetic test, as well as to establish control over the U.S. and international markets (and thus be exclusive provider) for genetic testing for hereditary breast cancer" (Williams-Jones, 2002, p. 128).

This is of course the concern of those who use molecular markers to augment conventional biotechnologies such as plant and animal breeding. While the BRCA gene diagnostic had a medical application, the same technology would be involved in identifying and enriching among the offspring those that had the right combination of genes or variants of genes. MAB saves time because a researcher does not have to wait for an adult to demonstrate the desired trait and it allows highly complex combinations of genes to be brought together incrementally over multiple generations where only a few genes would not be enough to confer the desired trait. The long arm of the modern biotechnology-based mega companies would now extend to the control of conventional and traditional biotechnologies. "The Myriad case is a harbinger of an increasing number of instances where gene patents provide companies with monopolies on the development, marketing, and provision of genetic tests and therapeutics" (Williams-Jones, 2002, p. 123).

An important restriction on the use of proprietary DNA sequences became apparent early on in the Myriad story. Their diagnostic was shown to miss some variants of the

BRCA genes that also indicated susceptibility to cancer. However, because Myriad aggressively pursued its IPR, it attempted to prevent competitors from supplying a test that would detect these gene (i.e., allele) variants.

> A new French method developed at the Institut Curie (using combed DNA colour bar coding) is able to detect large deletions and re-arrangements of BRCA1 and BRCA2 which the full DNA sequencing offered by Myriad misses. Despite these disagreements about appropriate testing methodology, it is perhaps not surprising that Myriad maintains that their full sequencing approach is the gold standard. Due to their numerous U.S. and international patents – Myriad holds patents on the two BRCA genes in the U.S., Europe, Canada, Australia and New Zealand – they have been successful in overcoming their initial commercial competitors (p. 131)…The researchers at the Institut Curie argue that Myriad's testing method misses 10% to 20% of expected mutations, seriously jeopardising the quality of test results and usefulness of this information for patient care. Their position is that the Curie test for large scale deletions should be used at least as a supplement, if not an alternative, to the full sequencing approach used by Myriad. The broad nature of the European BRCA patents – which cover any diagnostic or therapeutic use of the BRCA1 and BRCA2 genes – means that clinicians using this new technique would be infringing the patents and thus open to legal suits, thereby undermining their ability to provide patient services (Williams-Jones, 2002, p. 132).

The ability to own genes, DNA sequences actually, creates a basket of proprietary applications that are concentrated in the hands of the IPR holder. It is premature to claim to know how many kinds of ways IPR on germplasm create and cost society real opportunities. However, there remains no question that the vigorous enforcement of IPR practised by the biotechnology mega-companies has effects on future research.

The aggressive pursuit of IPR by public institutions may also have long-term and undesirable impacts on research. The public sector in developed countries has been securing IPR on research since this was allowed in the early 1980s first in the US (Wright and Wallace, 2000). Now:

> Collectively, the universities and government institutions of the public sector have created a set of IP that is larger in number and estimated value than even the largest of the individual corporate portfolios (Graff et al., 2003, p. 991).

> At five California universities alone, former and current faculty members have founded over 300 biotechnology companies (Shorett et al., 2003, p. 123).

This portfolio is uniquely large in biotechnology, despite the fact that such instruments only recently became available for biological entities.

> In agricultural biotech, the public sector plays an important role in fundamental research and represents a substantial source of [intellectual property], to a degree perhaps unique among industry sectors (Graff et al., 2003, p. 994).

Another example of the entrepreneurial interests of public researchers is revealed in the co-ownership (US Patent 5,723,765) of one of the most controversial biotechnologies of all time, the so-called "terminator technology" (the original GURT), by the US Department of Agriculture and the Delta and Pine Land Company (Lee and Natesan, 2006), now owned by Monsanto.

The "bio-entrepreneurial" activity of public research institutions can have unpredictable effects on the conduct of research. A troubling development with research-active universities and government agencies equating routine research with an obligation to generate IPR is that they may also be placing at risk their traditional "research exemption". As the business of research increasingly becomes business, there may be no special reason for universities to be exempt from the same requirements to acquire licences on proprietary materials or processes. Developments in the United States may be instructive here.

> The limited experimental-use exception in the United States was further narrowed by the U.S. Federal Circuit Court in the Judgment Madey v. Duke University. It was held that such exemptions are not available when the research carried out is in line with the infringer's legitimate business. Furthermore, the Court asserted that academic research conducted by a university was the university's 'business' and therefore infringes the patent (Thomas, 2005, p. 713).

In summary, neither the public nor the private preoccupation with "western-style" IPR instruments is being balanced with a strategy to develop and release biotechnologies that are suited to the needs of the world's poor, encourage and promote traditional knowledge and sustainability, or encourage communication and transparency in the science and technology necessary to ensure that the impacts of biotechnology are properly measured and understood. In the long term, current IPR instruments may significantly weaken the global public capacity to innovate.

Biosafety vs. IPR

Some critics of biosafety regulations claim that it is a combination of "over the top" regulations and a lack of biosafety capacity in developing countries that drives up the costs of modern biotechnology and prevents the development of useful GM crops (Enserink, 2008).

> The major government policy that restricts the private role in spreading biotechnology is the regulatory system. If there is no regulatory system for GM varieties, companies will not do biotech research on the problems of a country. If the regulatory system is unnecessarily strict, companies may have to spend millions of dollars on biosafety research, which will reduce their incentive to invest (Pray and Naseem, 2007).

> [T]he cost of regulation in developing countries does not encourage the commercialization of products of modern biotechnology developed by public-sector research institutes. In most cases, the regulatory costs far exceed the research costs (WHO, 2005).

The Assessment text

Synthesis Report (p. 43)
Two framing perspectives on how best to put modern biotechnology to work for achieving sustainability and development goals are contrasted in the IAASTD. The first perspective argues that modern biotechnology is over-regulated and this limits the pace and full extent of its benefits. According to the argument, regulation of biotechnology may slow down the distribution of products to the poor. The second perspective says that the largely private control of modern biotechnology is creating both perverse incentive systems, and is also eroding the public capacity to generate and adopt AKST that serves the public good.

The Assessment acknowledged that safety testing could be a barrier to development of some products based on genetic engineering, but not all. The use of contained GM microbes for the production of enzymes (Kirk et al., 2002) has not invoked the same responses from society as the use of released GM crops, for example. Recalling the discussion on testing and safety from Chapter Four, clearly some of the cause of the complex and expensive biosafety regulations comes from a failure of regulators (Fox et al., 2006) and the industry to conduct decisive and transparent safety assessments. Those countries that mix the responsibility for safety review and trade promotion, such as the UK, New Zealand and Australia, are especially prone to incurring skepticism of the objectivity of their assessments (Millstone and van Zwanenberg, 2002; Terry, 2007). Frustration with the apparent reluctance to be seen as on the leading edge of safety, coupled with spectacular food safety blunders such as the Mad Cow Disease epidemic in the United Kingdom in the 1990s, corrodes trust and generates a cycle of increased demands for more testing (Millstone and van Zwanenberg, 2002).

The Assessment also concluded that another, if not the major, barrier to development was in the form of IPR frameworks. The critical test for this comes from the realization that if all governments were to decide tomorrow to completely do away with all regulatory review of GMOs, the industry would still guard its IPR. The costs of licensing would still be in place; liability for being in possession of a transgene without permission would still be a risk for non-GM farmers.

One does not have to rely on thought experiments to demonstrate the point that IPR is a key factor in preventing the use of GMOs in poor countries. A poignant example is provided by the so-called “golden rice”, a GM version of rice that has a golden colour because it has been engineered with a multi-gene ß-carotene (vitamin A) pathway (Enserink, 2008; Jauhar, 2006).

> [A]s with nearly all academic research in crop biotechnology today, Golden Rice was produced using techniques that are patented in some countries and materials obtained under legal agreements that restrict further dissemination. As the inventors sought permission to share

> Golden Rice, a number of intellectual property (IP) constraints surfaced that appeared difficult to resolve. An additional concern was testing (Toenniessen, 2000, p. 4).

In fact, the number of claimants on golden rice was substantial.

> The potential for hold-ups in crop R&D was exemplified in the development of ß-carotene-enriched rice by public-sector researchers who used at least 40 patented or proprietary methods and materials belonging to a dozen or more different IP[R] owners in the gene transfer process (Graff et al., 2003, p. 989).

Golden rice has become a sort of "poster child" (Herdt, 2006, p. 270) in the promotion of public good GM crops by the industry because of the potential for the crop to be of humanitarian value. Vitamin A deficiency is the cause of significant debilitation in some developing countries (Enserink, 2008). The mega-company Syngenta donated its IPR on golden rice and took the lead in organizing a consortium of interested parties to gather all the necessary permissions from various IPR claimants to allow the rice to be freely developed (Herdt, 2006).

> These costs are exemplified in the research and development program for beta carotene enriched ("Golden") rice. Initial efforts to expand research were complicated by some 70 process and product patents associated with the technology that were owned by 32 companies and universities. Corporate and philanthropic negotiations (for a crop and trait of limited commercial value) were required to make further research efforts possible (Spielman, 2007, p. 196).

Even though golden rice was not exclusively the industry's to give away, since its funding came from philanthropic (i.e., Rockefeller Foundation) sources (Herdt, 2006), and it has been noted that the gifting of IPR was more symbolic than actually necessary because many poor countries do not have IPR frameworks anyway –

> [I]n the case of "golden rice", where permission was required for the use of about 70 patents, the impression was that the patents were being relinquished in favour of the poor. In fact, most of the patents involved are not valid in the major rice-consuming countries (WHO, 2005, p. 42).

– this story illustrates the massive commitment required to make humanitarian gestures. Golden rice is also not unique. This example would be representative of just about any transgene or GMO owned by the private sector.

> And even for commercially viable technologies such as the pest resistance traits conferred by *Bacillus thuringiensis* (Bt), the playing field is no less complex: just a small number of firms are continuously litigating over hundreds of valuable patents, suggesting that the majority of benefits may not accrue to smallholders (Spielman, 2007, p. 196).

Conclusions

The change in IPR frameworks in the latter half of the 20th century in the developed countries set in motion a type of revolution in agriculture. That revolution has extended private control of the fundamental sources of food and nutrition on this planet. It is sobering to realize that only 30 crops supply 95% of the calories and protein, and only 14 “domesticated mammalian and bird species provide 90 per cent of human food supply from animals” (FAO, 2006). This number is slightly larger, but still surprisingly small, when analyzed on a country basis. “Analysis of food energy supplies on a country by country basis shows that 90% of the per caput food plant supplies of all nation states are provided by only 103 plant crops” (FAO, 1997, p. 15). The “six most widely grown crops in the world are wheat, rice, maize, soybeans, barley and sorghum. Production of these crops accounts for over 40% of global cropland area, 55% of non-meat calories and over 70% of animal feed” (Lobell and Field, 2007, p. 1). By no coincidence, the crops that are most quickly being appropriated by the IPR of the private sector are represented in this list.

The change in IPR has been a combination of changing some longstanding intellectual property instruments and the extension of patents to germplasm. The freedom to do research and to innovate on plants, animals and microbes is taken away by the extension of patent and patent-like instruments to this level. The concurrent commercialization of the publicly funded research sector accelerates the pace at which the world’s germplasm is being described, catalogued and removed from the knowledge commons.

> Through the patenting of their inventions, public-sector research institutions could transfer rights over a technology to established commercial partners or to new entrepreneurial startups, which could then finance further development of the technology. In plant molecular biology the result has been a proliferation of patenting by both private and public-sector institutions. The proliferation of [IPR] among multiple owners in agricultural biotechnology appears to have affected the rate and direction of innovation, a result of the so-called intellectual “anticommons” as has been observed in biomedical research (Graff et al., 2003, p. 989).

Meanwhile, IPR instruments undermine the stability of local agroecosystems by inhibiting the development of local markets based on a cash or barter system. The concentration of IPR-holding entities in the developed world moves the products of traditional knowledge, plants and animals bred and optimized for generations or maintained consciously or unconsciously through *in situ* conservation, out of the local conditions, and thus undermines local control and the integrity of the AKST itself, which may not transfer with the product or may be lost in the more focused activities of the IPR holders.

The Assessment was not naïve to the benefits of IPR instruments. However, they evolved through a different iterative process in the developed world, where actors were more evenly matched during the process. Imposition of IPR instruments in their modern form – notably a form that is optimized to wealth generation in developed countries – on societies and economic and legal systems in the developing world is not a formula for poverty reduction and growth of AKST, at least not at the proportion of control they are being given by the maldistribution of large corporate control of innovation.

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Afterword

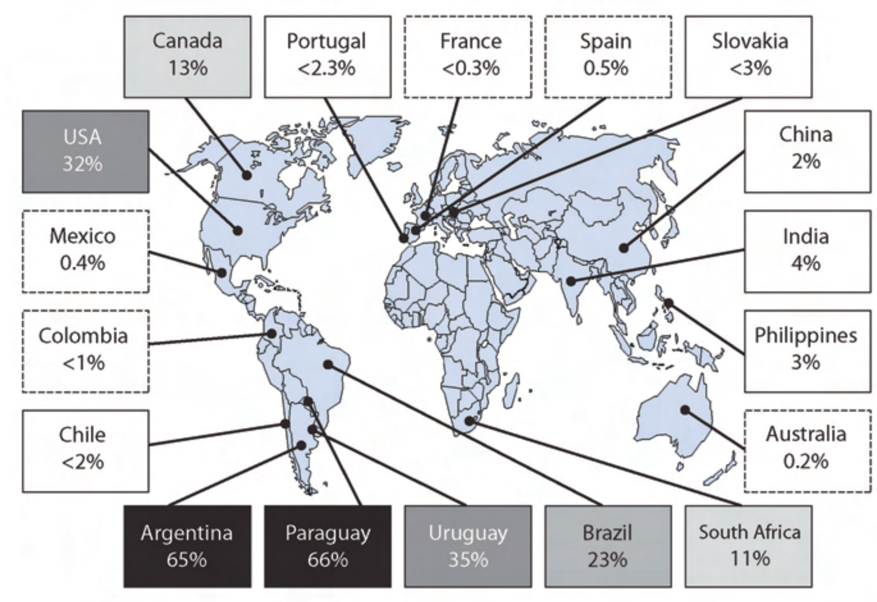
"Agriculture is not just about putting things in the ground and then harvesting them…it is increasingly about the social and environmental variables that will in large part determine the future capacity of agriculture to provide for eight or nine billion people in a manner that is sustainable." – Achim Steiner, Executive Director, UNEP

NO one can know for sure if there will be a technology capable of feeding the world forever. At least for now, we should be as attentive to limiting our appetites as we are to our capacity to produce more food, fuel and materials. The Assessment had hard words for the societies that have long disproportionately consumed. Harder words still for their attempts to maintain their consumption using subsidies and market-distorting trade mechanisms and asymmetric IPR frameworks.

What is clear is that modern biotechnology – at least in the way we have been developing and implementing it – cannot feed the world. What the Assessment found with regard to GMOs was:

1. There is no evidence of a general, sustained or reliable increase in yield from GM crops over the 12 years since the first commercial release.
2. There is no evidence of a sustained reduction in costs to farmers adopting GM crops, nor a sustained and reliable increase in profits to such farmers.
3. There is no evidence of a sustainable reduction in pesticide use. In fact, there is a dramatic increase in the use of some herbicides and the special way that they are used on GM crops is undermining the conventional farmer's weed control options.
4. The overwhelming majority of GM crops were not designed to increase yield, they were designed to sell particular agrochemicals or biological pesticides.
5. There is no evidence that genetic engineering has been effective at delivering the crops and animals needed by the majority of the world's farmers, or at prices they can afford.
6. The wholesale grab of plant germplasm as the intellectual property of a few mega-corporations is consolidating the seed industry and threatens long-term plant agrobiodiversity and biodiversity. Should GM animals ever become viable commercial products, there is every reason to expect the same contraction in animal germplasm.

Figure 9.1: Degrees of commitment to GM agriculture



Only two countries in the world have converted the majority of their agroecosystems to GM cropping (black boxes). According to industry figures, Argentina and Paraguay are true "mega-countries" of GM (James, 2007), and according to UN FAO figures (FAOSTAT, 2008), they also have suffered from increased undernutrition and decreasing food supply since the introduction of GM cropping, reversing pre-GM trends (see Chapter Seven). The majority of the top 20 GM-producing countries commit <1-5% of their agroecosystems to GM (white boxes with solid lines above 1%). Even the world's largest producer, the US, commits no more than about a third of its cropping capacity to GM (grey boxes for countries above 10%).

7. New GMOs must be subject to uniform safety and ecological assessments of higher standard, transparency and independence than has benefited existing GM crops.

The adoption of GM crops is consistent with a number of "oversimplification", or monoculturalization, trends in agriculture over the last few decades. The most literal are the large monocultures that characterize cropping systems in countries such as the US, Canada and Argentina, which also boast some of the largest land areas devoted to GM crop production (Figure 9.1). Monocultures require high levels of external inputs to attempt to restore the soil, and high levels of pesticides because of the large populations of specialist pests that they support. Oversimplification of the agricultural landscape through both intensive plant and animal monocultures undermines agroecosystem resilience and thus sustainability. GMO commercialization shows no signs of working outside the monoculture model. The attempt to simplify pest management through genetic engineering has resulted in increased applications of a very small number of agrochemicals. This practice has increased the frequency of resistance to those chemicals and reduced the diversity of alternative products. Consequently, it threatens the sustainability of yields in both GM and non-GM agroecosystems. Finally, the industrial model of agriculture is also correlated with the oversimplification of diets (Chávez and Muñoz, 2002; Hawkes, 2006; Scialabba, 2007; Tee, 2002). In many countries, malnutrition is marked by larger numbers of both the underweight and the overweight, often within the same households. The sources of fats, proteins and carbohydrates are from a smaller number of kinds of plants and animals, leaving people vulnerable to disease because of micronutrient malnutrition.

Oversimplification is a lazy way to attempt to solve real problems with undesirable results. In the words of Nobel laureate and former Rockefeller University president Professor Joshua Lederberg: *“Our imperfect solutions aggravate every problem”* (Lederberg, 1970, p. 33).

What the Assessment found with regard to other solutions was:

1. There is substantial evidence that investment in agroecological methods would contribute to feeding the world in a sustainable way.
2. We must immediately re-invest in proven technologies such as conventional breeding and marker-assisted breeding.
3. IPR frameworks must be urgently revised. If biological material is to continue to be protected by patent and patent-like instruments, then the way in which intellectual property is described and the incentives on public institutions to develop intellectual property must be changed.
4. Large agriculture exporting countries must immediately adopt trade and aid policies that promote food security and sovereignty outside their own borders.

What characterizes the present is that the world lacks the will and not the means to feed everyone. What characterizes the future is that we may also lack the means. We must prepare now for that day.

The purpose of this book is not to pit modern biotechnology against other biotechnologies, but to chart the course for development of the right biotechnology to meet our mutual goals of having plentiful nutritious and tasty foods that are fit for purpose and locally prized, and to do so without losing the ability to continue to feed future generations. It is also essential that the pathway to this future of food also strengthens local communities and builds local economies. The Assessment is confident that the pathway to feeding the world in a sustainable way will not only achieve a more resilient agriculture but also, in the process, restore our diverse global ecosystem and halt the loss of our diverse human agri*cultures*.

To the degree that modern biotechnology, transgenics included, can contribute and be compatible with the larger social and ecological solutions discussed in Chapter Seven, it is welcome. But it is time, as they say, for GMOs to put up or shut up. Those readers who know hunger should now also have a sense of the massive research base behind the Assessment and what it means for their own societies, including the difference between the promises and payouts of genetic engineering.

To feed the world and build sustainable agroecosystems and societies at the same time will require more than current knowledge of agroecology (Tilman et al., 2002). Governments, philanthropists and industry must invest in research and institutions that will build knowledge and improve methodology, as well as help to customize implementation. This knowledge must be made in collaboration with farmers and be distributed through extension services, non-governmental organizations and the private sector.

Can the world follow agroecological agriculture and make a profit? The likelihood is high but there is no question that we need new economic models. To meet the goals discussed above requires more than tinkering with technology and tariffs. We need to be able to account for the true cost of using non-renewable resources, such as fossil fuels. The value of "marginal land" and water as ecosystem services must be identified.

> [D]espite this substantial, rich literature, values for services of an ecosystem remain elusive largely because there are few market transactions of the services and consequently few market prices for them (Sinden and Griffith, 2007, p. 397).

The contribution of *in situ* conservationists, largely farmers, must be recognized. Ultimately, we have to change the question from "How much can be made on the crops from this land, or the animals grazed on this paddock?" to "How much will it cost to not have this land, these crops, these animals or these farmers?".

The right biotechnologies are both sophisticated and effective at what they do.

> A frequent misconception is that organic agriculture means turning back the clock to a primitive mode of farming. While organic agriculture does build on traditional knowledge and practices, what it offers is a modern, ecologically intensive farming system that can perform successfully without any synthetic fertilizers or pesticides (Scialabba, 2007, p. 217).

A return to the low-yield, low-input agricultural systems that characterize much of Africa is not the answer. But modern agroecological approaches are not low-yield. However, they are comparatively low-input in many cases. Reducing input in most agroecosystems will provide the necessary flexibility to apply external inputs in others, without losing global sustainability. The right biotechnology is available. It can be implemented right now, provided that poor and subsistence farmers receive access to institutions that build local knowledge and spread innovation, and are not prevented from developing their own markets. The recipe for success is in the Assessment.

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Appendix One

What is a GMO?

JUST saying what a genetically modified organism (GMO) is, is complicated. Text approved in the Biotechnology theme of the Synthesis Report drew attention to this issue in connection with the definition of modern biotechnology and its products, particularly transgenic organisms:

> Currently the most contentious issue is the use of recombinant DNA [rDNA] techniques to produce transgenes that are inserted into genomes. Even newer techniques of modern biotechnology manipulate heritable material without changing DNA.

To illustrate the importance of this issue, I will use the case of double-stranded RNA (dsRNA, Box A1.1) and how it is viewed under New Zealand's regulations. As this case involves concepts that are highly technical, the following is an overview of the generic issue at stake.

Box A1.1: Double-stranded RNA is genetic material

Double-stranded RNA is an alternate means of creating genetic modifications that can affect the properties of organisms without necessarily changing their DNA.

RNA is genetic material for two reasons. First, it is unambiguously the nucleic acid genome of some viruses. Second, RNA molecules that are reproduced using ubiquitous enzymatic activities can in some organisms or circumstances demonstrate the ability to transfer traits or characteristics infectiously or across generations. These are the same criteria used to originally identify DNA as genetic material (Heinemann and Roughan, 2000).

The use of dsRNA in genetic modification is growing and it is currently the basis for pre-commercial research to develop products such as caffeine-free coffee and insecticide plants (Gordon and Waterhouse, 2007; Ogita et al., 2003). Yet because its heritability has not been understood until relatively recently, it will not always be covered by appropriate legal and regulatory standards set for risk assessment even though it is a nucleic acid and therefore covered by the Cartagena Protocol on Biosafety. Definitions will often determine whether a new understanding in science is covered or not, and it is in such instances that these definitions carry considerable importance.

In New Zealand, the Environmental Risk Management Authority (ERMA) regulates activities involving genetic modification under the Hazardous Substances and New Organisms (HSNO) Act. In 2005, ERMA adopted a policy that identified certain forms of RNA that cause gene silencing, e.g., RNAi, antisense, dsRNA-mediated methylation and so on, as lying outside the scope of its governing legislation (ERMA, 2006).

Gene silencing by so-called "regulatory RNAs", because they modulate gene expression, is a recently discovered phenomenon that is operative in organisms of all biological kingdoms. The RNA molecules involved are called, variously, dsRNA, short/small interfering RNAs (siRNAs), repeat-associated short interfering RNAs (rasiRNAs), microRNAs (miRNAs) and short-hairpin (sh)RNA (Denli and Hannon, 2003; Meister and Tuschl, 2004; Paddison et al., 2002). These cause the related phenomena known by many different names such as RNAi, RNA silencing, inhibitory RNA, quelling, MSUD, co-suppression and post-transcriptional gene silencing (PTGS) and even paramutation (Ashe and Whitelaw, 2007; Chandler and Vaucheret, 2001). The precursors of dsRNA-mediated-silencing replication are provided by the reaction transcription and include dsRNA as a co-factor.

Gene silencing is rapidly being adopted as a GM technology, making more widely available the tools necessary to construct the recombinant DNA, or transgenes, that produce dsRNA when inserted into a recipient organism. *In vitro* synthesized dsRNA also can be introduced directly without creating recombinant DNA because dsRNA is far more horizontally mobile (i.e., infectious) than DNA (as discussed below).

Regulatory RNA molecules that are derived from *in vitro* manipulated DNA, such that the DNA was made a stable part of an organism's genome, were deemed to be covered by the HSNO Act (ERMA, 2006). On the other hand, regulatory RNA molecules derived through *in vitro* synthesis or extracted from one organism and then introduced into another, were considered not to be subject to the HSNO Act. The rationale for the exclusion of the latter set of approaches resulting in gene silencing is stated as follows:

> Treatment of organisms with these molecules affects protein expression in the cell but <u>not</u> by modifying the organism's genome. The use of RNAi technology is not therefore considered to be the development of a genetically modified organism under the HSNO Act as the genes of the host organism are not modified, although it is acknowledged that the pattern of gene expression in the host is modified (ERMA, 2006, p. 58).

This interpretation of "genome", a term not defined by the Act, is unclear, but it has the effect of excluding the evaluation of the risks arising from certain types of *in vitro* modified RNA, or RNA derived from modified DNA and synthesized in a cell-free system; these same molecules are unambiguously captured under the Biosafety Protocol. It would also be inconsistent with a common definition of the term "genome" as all material that could transfer traits to other organisms and to descendants.[1] ERMA's flawed description

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[1] "Genome" is a derivative of "genetics", which is defined by the US Congress Office of Technology Assessment as "The study of the patterns of inheritance of specific traits" (US Congress Office of Technology Assessment. http://www.bis.med.jhmi.edu/Dan/DOE/prim6.html. Date of access: 4 January 1999). This definition is inclusive and does not assume the physical basis of traits as DNA.

of RNAi (ERMA, 2006, pp. 57-58) could have contributed to this policy conclusion. While ERMA considered gene silencing that arises from direct and ongoing activity at the level of mRNA (the intermediate molecules used in protein synthesis), it fails to mention important heritable pathways of RNAi caused by other pathways, such as chromatin modification (Chong and Whitelaw, 2004; Lippman and Martienssen, 2004; Meister and Tuschl, 2004).

In discussions with ERMA on this issue[2], staff stated that they considered that there were cases where even the use of rDNA does not constitute the creation of a GMO. In such cases, they said that ERMA therefore may not require a developer to seek regulatory approval when using the same techniques and molecules that are unambiguously covered by the Act (section 2 and 1998 Regulations) and the Biosafety Protocol for other developments.

What is a gene?

DNA is an obvious chemical form of genes because it has the properties necessary to make accurate copies via a reaction called DNA replication, and thus be passed on either infectiously or from parent to offspring. Each strand of the double helix is used as a co-factor in DNA replication so that two identical double helices are produced through replication.

> In considering the term replicate the Authority has adopted a broad definition that encompasses "can be copied" as well as "copies itself" (ERMA, 2006, p. 44).

In the strictest sense, nothing biological and smaller than a cell has the ability to autonomously copy itself, since even DNA is the product of a series of biochemical reactions in which it is a co-factor and a product (Figure A1.1). ERMA presumably relates "copies itself" to the common understanding of DNA replication where the existing molecule serves as a co-factor, or template, for the synthesis of descendant molecules. The concept of "can be copied" presumably relates to other biochemical pathways where the element that is inherited is a product and the product influences the existence of the pathway that creates it. They apply this to inheritable protein structure states evident in prions, the agents of diseases such as Mad Cow Disease. However, it would also apply to some instances of regulatory RNA.

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2 Meeting with ERMA staff, 20 August 2007.

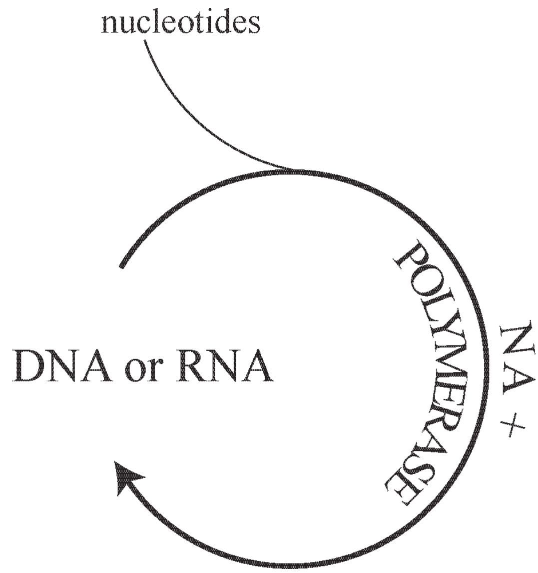

Figure A1.1: Molecules that are co-factors and products of a biochemical pathway "replicate". This unites the molecules of DNA and RNA when they are functioning as genetic material. DNA and RNA are polymers, or chains, of nucleotides. The circular arrow represents the biochemical pathway from substrate (nucleotides) to product (DNA or RNA); polymerase represents the enzymes necessary for replication and they use an existing polymer of the product (nucleic acid, NA) to synthesize descendant molecules.

In general, when a molecule (e.g., DNA) is both a co-factor and a product of a series of biochemical reactions within a biological system, it can operate as a gene (Heinemann and Roughan, 2000; Strohman, 1997). DNA is synthesized using one strand as a co-factor and free nucleotides as precursors. Gene silencing, caused by dsRNA molecules, is a phenomenon that is sometimes heritable and self-replicating. Gene silencing is a trait determined by materials that are involved in their own synthesis but through biochemical pathways that are different to DNA replication.

Is RNA just a chemical?

ERMA's General Manager of Strategy and Analysis noted that ERMA's task (and thus, that for reviewers) was to assess under the HSNO legal framework whether the material to which an organism was exposed was "genetic material" or was instead equivalent to a "chemical".[3] Under a literal interpretation of the definition of modern biotechnology from the Cartagena Protocol –

[3] Meeting with ERMA staff, 20 August 2007.

> "Modern biotechnology" means the application of:
> a. *In vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles…

– transformation of an organism by any *in vitro* modified RNA would constitute the creation of a GMO because RNA is a nucleic acid. The Protocol does not make a distinction between chemical and gene, nor does it invite one to be made.

A distinction between genetic material and chemicals is the ability of the former material to contribute to its own amplification. Amplification is often taken as an indicator of a material's ability to carry traits across generations or through infectious transfer (e.g., such as a virus). In contrast, chemicals do not participate directly as co-factors in an amplification pathway. While both RNA and some antibiotics (e.g., rifampicin) can change patterns of gene expression, the former is not equivalent to the latter in classification as a chemical because it can be amplified by "can be copied" as well as "copies itself" pathways. RNA can be amplified in the sense of "can be copied" through biochemical pathways that organize around the existence of a particular dsRNA molecule and produce new equivalent dsRNA molecules not by polymerization but by degradation of other RNA molecules in the same cell. RNA can cause the transfer of characters and traits in the sense of "copies itself" through dsRNA-mediated *de novo* methylation of DNA and histones; that methylation is perpetuated by still other biochemical pathways.

Gene silencing is a trait that can amplify but not by the same biochemical pathways as DNA. Evidence of this amplification is:

> [Infectious transfer:] The small amounts of dsRNA required for gene silencing and larval mortality suggest an amplification pathway in which ingested dsRNAs are processed to siRNAs, presumably within insect gut epithelial cells, which may prime the synthesis of more abundant secondary siRNAs…Northern blot analysis of total RNA from whole WCR larvae revealed almost complete suppression of targeted transcripts from several housekeeping genes, suggesting systemic spread of silencing beyond gut epithelial cells, the presumed initiation site of the RNAi response (Baum et al., 2007, p. 1323).

> One of the most intriguing aspects of RNA silencing is that it is non-cell-autonomous: in both plants and *Caenorhabditis elegans* it can be induced locally and then spread to distant sites throughout the organism. The systemic spread of silencing reflects the existence of an as yet unidentified mobile silencing signal as an integral component of the RNA silencing pathway…In grafting experiments, systemic silencing was transmitted across a graft junction from spontaneously silenced transgenic tobacco rootstocks to isogenic scions that had not silenced spontaneously (Mlotshwa et al., 2002, pp. S289-S290).

> The transmission of PTGS also occurred when silenced stocks and non-silenced target scions were physically separated by up to 30 cm of stem of a non-target wild-type plant, indicating long-distance propagation (Vaucheret et al., 2001, p. 3084).

> [Generation-to-generation transfer:] [T]he RNAi effect is remarkably long lived. Potent interference is routinely observed not only in the injected animal but also in all of the injected animal's progeny. Thus, interference can be inherited…For many genes, interference can persist for at least one full generation after the one receiving the injection, and for certain genes, interference can be observed to transmit in the germ line apparently indefinitely (Tabara et al., 1998).

However, ERMA explicitly rejected RNA of this type as genetic material:

> siRNA, antisense RNA, shRNA, micro-RNAs and dsRNA molecules that have been produced and purified are not genetic material (ERMA, 2006, p. 58).

The HSNO Act is silent on what constitutes genetic material, but ERMA equates genetic material with "genetic element" (ERMA, 2006). Genetic element is defined by the Act as "any genes, nucleic acids, or other molecules from the organism that can, without human intervention, replicate in a biological system and transfer a character or trait to another organism or to subsequent generations of the organism" (Part 1 s2). By virtue of RNA being able to form replication pathways without human intervention, it is genetic material and/or a genetic element. Therefore, it can be directly deduced that organisms exposed to *in vitro* RNA or that have any ancestral history deriving from RNA manipulated *in vitro* or synthesized from DNA that has any ancestral history of *in vitro* manipulation, have been genetically modified.

It appears that ERMA is correct in thinking that genetic elements are at least a subset, if not the full set, of all that can be considered genetic material. However, because dsRNA is clearly a genetic element as per the definition of the Act, it is not clear how ERMA excluded it as a molecule that creates GMOs.

Replication of dsRNA and inheritance of gene silencing by various biochemical pathways

The ability to replicate dsRNA molecules is nearly ubiquitous.

> Pioneering observations on PTGS/RNAi were reported in plants, but later on RNAi-related events were described in almost all eukaryotic organisms, including protozoa, flies, nematodes, insects, parasites, and mouse and human cell lines (Agrawal et al., 2003, p. 657).

This is also the case for bacteria (Gottesman, 2005; Tchurikov et al., 2000). Thus, in theory, many organisms exposed to dsRNA will be capable of replicating and "expressing" a gene silencing trait, just as they would be able to replicate DNA and potentially express DNA-mediated traits, depending on certain conditions being met. For example, expression of a gene composed of DNA requires compatibility between various important DNA sequences and proteins that serve as transcription factors. Similarly, gene silencing will require compatibility between existing genes and the small dsRNA molecule that first enters the cell (Buratowksi and Moazed, 2005).

Once these conditions are met, then gene silencing results from "the cleavage or translational repression of complementary single-stranded RNAs, such as messenger RNAs or viral genomic/antigenomic RNAs. The short RNAs have also been implicated in guiding chromatin modification", DNA methylation, or histone modifications, the latter of which are heritable by separate pathways (see also Chong and Whitelaw, 2004; Lippman and Martienssen, 2004; quote from Meister and Tuschl, 2004, p. 343).

> The classification of RNAi/PTGS as an epigenetic [heritable] phenomenon rests largely upon its ability to provoke heritable changes in gene expression. Inheritance of silencing could derive from either of two sources. The first is persistence of the signal. The second is persistence of the silenced state (Bernstein et al., 2001, p. 1516).

When dsRNA is a signal that is maintained through sequence-specific degradation and/or RNA-dependent RNA polymerase (RdRP) amplification (Mello and Conte Jr., 2004), the trait is dependent on propagation of the signal (e.g., dsRNA). One way for this to occur is through "stable incorporation of transgene arrays into the genome, the presence of endogenous repetitive elements such as transposons, or the enforced expression of hairpin RNAs. Such cases require no additional mechanisms to explain heritable silencing because the trigger is expressed from an endogenous and heritable genetic element" (Bernstein et al., 2001, p. 1516). By "heritable genetic element" these authors mean DNA, a case already recognized by ERMA. "The latter case is more provocative and requires consideration of mechanisms that propagate either the signal or the silenced state independently of the silencing trigger" (Bernstein et al., 2001, p. 1516). This is the case I argue should also be recognized by ERMA as a GMO under the existing wording of the Act.

Numerous types of instigating events lead to gene silencing, including: *in vitro* synthesized dsRNA, a novel mRNA precursor (as could arise from a transgene, a new open reading frame resulting from a DNA insertion, or a new intron), or a product of transcription expressed in a cell type or time of development where it would not normally occur, as could happen if a transgene activated a region of heterochromatic DNA (Denli and Hannon, 2003; Grewal and Elgin, 2007). New dsRNAs could arise when endogenous RNA editing pathways act on a foreign RNA substrate (Heinemann and Bungard, 2005; Yang et al., 2006). Finally, novel dsRNAs may be created in one organism and transferred through food to, and amplified in, another organism (Baum et al., 2007; Mao et al., 2007).

The initiating event can require nothing more than common promoters or other types of DNA-level regulatory elements on two different genes or any "aberrant RNA" (Al-Kaff et al., 2000; Bhullar et al., 2003; Heinemann, 2007; Herr et al., 2006). Thus, a new form of dsRNA can arise when two different transgenes run by common promoters combine through breeding in the open environment, or when a virus, such as the CaMV, that carries the original promoter for a transgene, for example the 35S promoter[4], infects a transgenic plant.

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4 Currently the most commonly used promoter in GM crops.

> Transgene RNAs would be particularly prone to aberrancy…especially if they have non-plant derived elements, because they may not have the precise structures necessary for efficient interactions with the full complement of mRNA-binding proteins associated with most cellular mRNAs. In addition, if transcription terminates prematurely or late, it would produce truly aberrant RNAs. Premature or late termination of transgene transcription may be affected by structural features of the transgene DNA or RNA or, as suggested many years ago, by DNA methylation within the transcribed region (Herr et al., 2006, p. 14999).

There are numerous examples of signal amplification and the ability of the signal to act infectiously. "Our findings support the hypothesis that siRNAs themselves or intermediates induced by siRNAs could comprise silencing signals and are generated in a self-amplifying fashion" (Klahre et al., 2002, p. 11981). "Notably, RNA silencing can spread over the plants from one region to another, and RdRP has been proposed to have a role in this 'spread of silencing'" (Tang and Galili, 2004, p. 464). The most compelling mechanisms for signal amplification refer to the regeneration of dsRNA molecules from either fresh transcripts targeted by existing dsRNA molecules, or *de novo* amplification by RdRP (Mello and Conte Jr., 2004).

> [I]njection of dsRNA in a *C. elegans* hermaphrodite generates RNAi that can be stably inherited to the F2 generation [indicating] that dsRNA acts catalytically and/or is replicated by cellular proteins. The fact that RNAi resulting from the injection of dsRNA into worm intestine or by the feeding of worms with bacteria expressing dsRNA are as equally efficient as direct injection into the germline, indicates that RNAi can spread from cell to cell in much the same way as gene silencing occurs in plants (Cogoni and Macino, 2000, p. 639).

It is worth, at this point, recalling the Protocol text:

> "Modern biotechnology" means the application of:
> a. *In vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and *direct injection of nucleic acid into cells or organelles* (emphasis added)…

The animals described above that were infected by dsRNA and not a DNA transgene, passed the silencing trait throughout the cells of their own bodies and to their offspring for two generations. So although in these cases the trait faded in later generations (Bernstein et al., 2001), this material did transfer "a character or trait to…subsequent generations of the organism" (HSNO Act s2).

Therefore, dsRNA-mediated gene silencing meets the description of traits determined by genetic material. These traits are dependent upon DNA methylation, chromatin modification or the continued production of small dsRNA molecules, all of which constitute different replication pathways for the trait (Matzke and Birchler, 2005). In all three cases, there are examples where the DNA that is responsible for instigating the gene silencing pathway is not necessary for its infectious spread or inheritance. Thus there is no question that species of dsRNA can be critical components of genetic elements that either are propagated in part by direct replication of dsRNA or indirectly through maintenance of a pathway that includes dsRNA molecules.

These observations are incompatible with the policy statement that "dsRNA molecules that have been produced and purified are not genetic material" (ERMA, 2006, p. 58). The incompatibility was evident to some ERMA staff who said during policy development that "no matter how hard I try I cannot bring myself to say that RNA, *per se*, is not genetic material. Thus the addition [of dsRNA molecules to organisms], which results in 'gene products' albeit indirectly from the specific RNA in question, seems to me to meet the statutory definition."[5]

In summary, RNA should be seen as genetic material for two reasons. First, it is unambiguously the nucleic acid genome of some viruses. Second, RNA molecules that are reproduced using ubiquitous enzymatic activities can in some organisms or circumstances demonstrate the ability to transfer traits or characteristics infectiously or across generations.

RNA and DNA have common techniques of manipulation

GMOs can be created using dsRNA in ways similar to how GMOs can be created using DNA (e.g., see list on pp. 38-39 of ERMA, 2006). A dsRNA of a particular organism is identified or synthesized, it is purified and delivered by some method to another organism, and the recipient is transformed. dsRNA "transformation" is achieved using techniques such as bioballistics and injection (Agrawal et al., 2003; Kusaba, 2004). It can be introduced into at least some animals through food (Baum et al., 2007; Gordon and Waterhouse, 2007; Mao et al., 2007) or direct uptake into epidermal cells when animals sit in a pool of buffer and dsRNA (Agrawal et al., 2003).

Once inside a cell or organism, gene silencing can transmit systemically in plants and animals (Klahre et al., 2002). This was shown in plants by the flow of dsRNA-determined traits separate from DNA into graft recipients (Vaucheret et al., 2001). It was shown in animals using worms either fed bacteria expressing dsRNA or soaked in dsRNA (Fire et al., 1998). dsRNA-mediated silencing can be induced by virus-mediated transfection/transduction (Shen et al., 2003).

DNA is genetic material but not always "heritable"

While GMOs are not defined by a change in phenotype *per se*, equally they are not defined by their retention of the original modified material. **The GMO must only have been modified by nucleic acids with any ancestral history of *in vitro* manipulation**.

There are occasions when DNA sequences that do not pass from generation to generation may heritably modify a recipient: for example by changing a pattern of gene expression. Examples range from the use of vectors for transient transformation/transfection (Heinemann et al., 1996) to phase variation in bacteria (Tam et al., 2005). To illustrate

[5] Email from Donald Hannah to Fleur Francois, 16 June 2005. Obtained under the Official Information Act.

using an already familiar example, imagine the case where the allele of a gene that encodes a protein more likely to form into a prion was introduced into a recipient by transient transfection (using a hypothetical DNA vector that could not replicate and would not recombine[6]). The DNA for the allele might be lost, but the prion could persist (Caughey and Baron, 2006; Prusiner, 1998; Weissman et al., 2002; Weld and Heinemann, 2002) through its own amplification and may pass through organism generations and by infectious transfer (ERMA, 2006).[7]

Another example is common in bacterial genetics. Bacteria are transiently transformed using DNA that encodes a transposase that may act on a transposon, cause its mobilization and re-insertion without retention of the transposase (used by Cooper and Heinemann, 2000; Heinemann et al., 1996). A further illustration comes from a genetically modified corn plant called LY038. This plant was created by the transient expression (through breeding) of a Cre recombinase acting at *loxP* sites and causing a DNA deletion that was heritable. Even when DNA deletion is not the outcome, Cre can cause chromosome instability and rearrangements (Qin et al., 1994). While this example is based on a GMO, it derives from a natural recombinase system. This system should be of immediate interest to regulators because it is seen as becoming a normal way to create GMOs (Ow, 2007). A final point that this example illustrates is that excision of a transgene, by the actions of a recombinase or any other event, does not make the resulting organism not a GMO. This is because the organism's genes or other material were modified by the original use of rDNA.

In the above examples, the potential for replication or recombination of rDNA is incidental to evaluating the risk of the genetic modification. ERMA appears to draw this same conclusion when it states: "It is likely that the [lawmaker's] intent of the definition of genetic material, as opposed to heritable material, was to include any nucleic acid regardless of whether it produced an effect. The effect of such transfer is considered in the evaluation of the application" (ERMA, 2006, p. 44) rather than in the evaluation of the necessity of making an application.[8]

6 This is the hypothetical vector that was raised as an example by ERMA staff during the 20 August 2007 meeting.

7 Note that I do not think that this is a special case for at least two reasons. First, which proteins can become prions is not known, and prions are known to exist in many kinds of organisms. Thus, their environmental implications must be assessed. Secondly, this is one of a number of characters or traits that may be propagated epigenetically and is not dependent on the stable propagation/amplification of an instigating nucleic acid (Heinemann and Roughan, 2000; Strohman, 1997; Weld and Heinemann, 2002).

8 However, I do not agree that ERMA or most applicants could prove that there was so little or no replication or recombination that it would always be irrelevant. While replication may be so inefficient that the DNA is lost from a population eventually, recombination of all or part of the manipulated genetic material can never be prevented. This is the outcome of the "massage model" of recombination (Heinemann et al., 2004). The efficiency of DNA replication can be low enough to escape detection most times, but still cause persistence of the DNA (Srivastava and Ow, 2003).

Therefore, heritability is sufficient but not necessary as evidence to establish the need for a risk assessment, and exposure to modified nucleic acids is sufficient to conclude that an organism is genetically modified. It would not appear to be appropriate to counsel potential applicants that the use of rDNA that "did not replicate or recombine" is exempt from the legal requirement of an ERMA risk assessment.

RNA is genetic material but not always "heritable"

DNA may modify the genes or other material of an organism without being heritable, as described above. There is no reason *a priori* to believe that this would be a characteristic unique to DNA. Many of the above examples could be recreated by re-introducing the mRNA molecule in place of the DNA molecule. Thus, ERMA's determination as to the intent of lawmakers would also make clear that all organisms modified by exposure to RNA should be considered GMOs and require an ERMA risk assessment (ERMA, 2006, p. 44). However, the use of *in vitro* synthesized dsRNA, or dsRNA isolated from an organism and then re-introduced into a recipient organism would presumably not be subject to regulatory oversight as long as ERMA retained its policy (ERMA, 2006). In so doing, the policy makes this application of RNA distinct from equivalent treatments using DNA. The only way that can be done is to assume that: (1) RNA is not genetic material, (2) gene silencing is not a heritable trait or character, and/or (3) the instigating dsRNA, amplified or persistent, or chromatin modifications/DNA/histone methylation that maintain the effect, are not the product of replication.

The use of dsRNA in genetic engineering is growing (Ivashuta et al., 2008). Though unintended, it appears in retrospect to be behind the trait in the now defunct FlavrSavr™ tomato first produced by Calgene (Ivashuta et al., 2008; Sanders and Hiatt, 2005). dsRNA is the basis of pre-commercial research to develop caffeine-free coffee through gene silencing (Ogita et al., 2003) and the basis for viral resistance in papaya (Tennant et al., 2001). dsRNA has been intentionally tested as an insecticide (Baum et al., 2007; Mao et al., 2007). The researchers demonstrated that dsRNA produced by transgenes in plants can be infectiously transferred through food to gut cells in insects, and subsequently spread within the animals separately from the rDNA (Gordon and Waterhouse, 2007). In contrast perhaps with the New Zealand regulator, the Monsanto Company declared that "[e]stablishing a well-documented history of safe consumption for RNA molecules including those that mediate RNAi (e.g. miRNAs and siRNAs) will be an important component of this weight of evidence approach for evaluating the safety of crop products developed utilizing RNAi-mediated gene suppression" (Monsanto study published under Ivashuta et al., 2008).

Conclusions

From the above discussion it is clear that RNA is unambiguously among the materials that through *in vitro* modification would create a GMO as defined by the HSNO Act. Meanwhile, decisions on whether particular applications of RNA or DNA (where they are purposely manipulated *in vitro* and then re-introduced into an organism) should require an application to ERMA are apparently being made by advisors based on an informal process that may not result in even the exchange of recorded scientific evidence.[9]

Since regulators show an unexpected diversity of thought on the definition of genes and modern biotechnology, the authors of the Synthesis Report felt that it was necessary to clarify these definitions. When considering both the value and costs of modern biotechnology for meeting the Assessment goals, all its forms must be recognized, understood and properly regulated.

9 I refer here to the hypothetical case where ERMA said it might not require DNA used in a transient transformation procedure to require ERMA approval when ERMA was satisfied that the DNA could not either replicate or recombine with an existing DNA molecule in the recipient. I conflate that case with the actual case where an applicant was not required to submit an application for the use of dsRNA molecules that cause a change in the pattern of gene expression in recipients through several different amplifiable, and in some organisms heritable, pathways. The information upon which informal advice was given was based on standards of evidence that could not be immediately or uniformly articulated even by those present in the meeting and which, I argue, should be available for oversight and review in the way that evidence in an application is.

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Appendix Two

The Indirect Benefits of Genetic Engineering are Not Sustainable

THE use of genetic engineering to improve weed control could have a significant impact on crop yields. Weeds are an important problem in agriculture. The annual cost of weeds has been estimated at US$20 billion in the US (reported in Basu et al., 2004) and ~A$4 billion in Australia (Sinden et al., 2004). Generally, these costs are incurred by both loss of crop because of the direct influence of weeds and the cost of weed control. In Korea, 5-10% of rice yield is lost to weedy rice (Chen et al., 2004). "Volunteer wheat and barley, at 7 to 8 plants/m^2 (6 to 7/yd^2) can reduce canola yield by 10 to 13%" (Canola Council, 2007). The DuPont company estimates that without some form of weed control, "the average crop losses for U.S. corn, soybean and cotton growers would be approximately 65%, 74% and 94%, respectively" (DuPont, 2008). There can also be environmental benefits of weed control, but these are poorly quantified (Sinden and Griffith, 2007).

The Assessment text

Synthesis Report (p. 44)
Regardless of how new varieties of crop plants are created, care needs to be taken when they are released because through gene flow they can become invasive or problem weeds, or the genes behind their desired agronomic traits may introgress into wild plants threatening local biodiversity. Gene flow may assist wild relatives and other crops to become more tolerant to a range of environmental conditions and thus further threaten sustainable production. It is important to recognize that both biodiversity and crop diversity are important for sustainable agriculture. Gene flow is particularly relevant to transgenes both because they have tended thus far to be single genes or a few tightly linked genes in genomes, which means that they can be transmitted like any other simple trait through breeding (unlike some quantitative traits that require combinations of chromosomes to be inherited simultaneously), and because in the future some of the traits of most relevance to meeting development and sustainability goals are based on genes that adapt plants to new environments (e.g., drought and salt tolerance).

The predominant trait in GM crops is herbicide tolerance (HT) for the purposes of consolidating weed control under a single or small number of proprietary agrochemicals. Introducing HT traits into crops also creates the risk of HT weeds through gene flow (Heinemann, 2007; Zapiola et al., 2008). For example, a weed may arise from the transfer of the gene that confers herbicide tolerance to a non-crop plant, or the flow of crop seeds to land being used to cultivate other kinds of crops. Wherever the associated herbicide is being used, the undesired plant will prosper. The speed of spread of HT canola attests to this (Marvier and Van Acker, 2005). Sometimes weeds created by transgene flow persist even outside of the normal usage of the herbicide. This case is dramatically demonstrated by the development of glyphosate-resistant creeping bentgrass (GRCB) in the United States following a brief field trial.

> Our results document not only the movement of the glyphosate resistance transgene from the fields, but also the establishment and persistence of high frequencies of GR plants in the area, confirming that it was unrealistic to think that containment or eradication of GRCB [*Agrostis stolonifera* L.] could be accomplished (Zapiola et al., 2008, p. 486).

The presence of transgenes can affect market certifications and introduce the risk of litigation against farmers found to possess the transgene without permission, even if the gene is not in the farmer's intended crop. The impacts on the agroecosystem can also be long-lived.

> This finding of [HT oilseed rape] volunteers, despite labour intensive control for 10 years, supports previous suggestions that volunteer OSR [oilseed rape] needs to be carefully managed in order for non-GM crops to be planted after GM crops (D'Hertefeldt et al., 2008, p. 316).

Special risks from complex traits

Since GM traits are usually created in continuous arrays of transgenes, the effect of gene flow from GM crops to other plants can be more severe than general gene flow for traits that are based on multiple genes (Heinemann, 2008). This is because it is less likely that all necessary genes will be transferred by breeding when they are distributed between different chromosomes.

The recent rush to produce greater tolerances to stresses, such as drought, salt and temperature, in crops through genetic engineering creates additional risks for weed generation (Pennisi, 2008).

> Organisms that greatly overcame [currently limiting physiological or morphological constraints], perhaps through gene transfers, would be supercompetitive species that could potentially invade into and change the structure of nonagricultural ecosystems (Tilman, 1999, p. 5997).

Since the stress tolerance traits would arise from transgenes, their close linkage and perhaps multiple copies would create a quantitatively higher risk over the normal problems associated with the bi-directional flow of genes between crop and sexually compatible weeds (Heinemann, 2007). Weed plants that also could extend their vigour under these conditions would have the potential to persist and invade non-agricultural lands that currently are inhospitable to these plants (Heinemann, 2008).

> [New transgenic] traits such as stress-tolerance may increase competitive ability allowing the species to invade into natural habitats and/or replace natural or agricultural communities by expanding plantings into regions where the crop previously could not grow. For example, if aluminium-tolerant crops could be planted on a large scale in high aluminium, acidic soils, such as savannas or cleared rainforests, this may reduce biodiversity or endanger or eliminate the original communities. This might be particularly devastating in savannas, such as the Brazilian cerrado, because they often sustain a high biodiversity (Andow and Zwahlen, 2006, p. 208).

That kind of invasion could have severe environmental consequences.

> Biological invasions are believed to be the second largest cause of current biodiversity loss, after habitat destruction (Keane and Crawley, 2002, p. 164).

The estimated cost of biological invasions in just six countries – the US, the UK, Australia, South Africa, India, and Brazil – is US$314 billion (Pimentel et al., 2001).

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Appendix Three

Potential Human Health Risks from Bt Plants

BT PLANTS are those that have been genetically engineered to express an insecticidal toxin. The insecticidal toxins are produced from genes of the *cry* (for crystal) family, which are actually found on mobile genetic elements called plasmids. There are many different genes in this family. The plasmids are usually isolated from the bacterium *Bacillus thuringiensis* (or Bt), but these plasmids are not necessarily only found in *B. thuringiensis*.

There are uncertainties about the effects of *cry* toxins on mammals and humans (Box A3.1). Very few have been tested for their effects on humans (Tayabali and Seligy, 2000). Some Cry proteins are cytotoxic to human or mouse cells, but surprisingly not to insects (Ito et al., 2004; Vázquez-Padrón et al., 2000). Moreover, the toxicity was cell-type specific, meaning that if the wrong kind of cellular tissue culture is used in the assay, toxicity may be underestimated. Some Cry proteins are even being considered for use as new chemotherapy agents due to their ability to kill certain kinds of human cells (Akiba et al., 2004; Kim et al., 2000). Cry toxin proteins may also stimulate an immune response leading to the need to test them as allergens.

> Assessment of the immunotoxicological effects of GMOs has mainly focused on the allergenic potential of genetically modified proteins whereas general immunotoxicological investigations of whole GMOs are not described in the literature…This finding, together with the findings of a Bt-specific IgE response in humans working with Bt pesticides reported by Bernstein et al. (1999, 2003) and Doekes et al. (2004) highlights the importance of evaluating the sensitization of consumers, especially atopic fieldworkers, of "foreign" proteins or GM food prior to their introduction to world market (Kroghsbo et al., 2008, p. 32).

Historically, *B. thuringiensis* strains have been isolated based on their toxicity to target insects. This has given rise to the common claim that their Cry toxins are essentially specific to insects (Betz et al., 2000). Recent screens of *B. thuringiensis* have not been restricted to that criterion. These screens are finding many strains with the parasporal inclusions characteristic of the crystal proteins, but with no detectable toxicity to insects.

> [These] observations suggest that *B. thuringiensis* as a species is not characterized by insecticidal activity of parasporal inclusions. This raises a question of whether noninsecticidal inclusions have any as yet undiscovered biological activity (Kim et al., 2000, p. 16).

Box A3.1: A new trend in food safety findings?

Some studies have found no particular toxicity or threat of either *B. thuringiensis* or Cry toxins to human health (Monsanto review published under Betz et al., 2000; He et al., 2008; DuPont/Dow/Pioneer study published under Malley et al., 2007). However, of late significantly different studies have been indicating otherwise. These studies differ in a number of ways, including that they are among the first to use the whole GMO as the source of the test rather than a surrogate source of Cry toxin (from laboratory bacteria or *B. thuringiensis* itself), proper statistical methods or animals at developmentally important stages or under stress, when important but not acute toxic effects would be most easily detected in short-term experiments.

In May of 2007, French researchers published their reanalysis of Monsanto data and concluded that there were indications of liver/kidney toxicity in rats fed Bt corn MON863, saying that “with the present data it cannot be concluded that GM corn MON863 is a safe product” (Seralini et al., 2007, p. 596). This conclusion was rejected but not invalidated by various food safety regulators (Terry, 2007). The importance of this study was its ability to show how poor the designs of industry studies have been and that, when proper statistical analyses are used, previously undetected toxic effects can sometimes be revealed.

Likewise, in March of 2008 Turkish researchers reported liver “[g]ranular degeneration level in 10% of examined sections was maximum (level 4) in Group III [fed on Bt GM corn] while no degeneration was observed at level 4 in Groups I and II” (Kiliç and Akay, 2008, p. 1166) which were fed on a standard diet or the isogenic conventional corn. In this case the researchers did not feel that their statistically significant results indicated “severe” effects on the health of rats. However, few foods would be expected to cause severe effects. The importance of long-term studies is to reveal chronic and sub-chronic effects.

In July of 2008, Austrian researchers found significant effects on mice fed a diet that contained a stacked Bt GM corn variety, called NK603 x MON810, when these rodents were under reproductive stress, with effects revealed by the third litter from the same breeding parents. In addition to some effects on kidneys, the researchers concluded that “multi-generation studies, especially based on the [reproductive assessment by continuous breeding (RACB)] design are well suited to reveal differences between feeds. The RACB trial showed time related negative reproductive effects of the GM maize under the given experimental conditions. The RACB trial with its specific design with the repeated use of the parental generation is a demanding biological factor for the maternal organism” (Velimirov et al., 2008, p. 4).

In November of 2008, Italian researchers concluded that “the consumption of [Bt] MON810 maize…induced alterations in intestinal and peripheral immune response of weaning and old mice. Although the significance of these data remains to be clarified to establish whether these alterations reflect significant immune dysfunctions, these results suggest the importance of considering the gut and peripheral immune response to the whole GM crop, as well as the age, in the GMO safety evaluation” (Finamore et al., 2008, p. 11537).

There are two reasons to draw attention to *B. thuringiensis*. First, there has been a change in the environmental interface between *B. thuringiensis* or its *cry* genes (in plants) and other bacteria. Second, there has been a dramatic change in the environmental interface between *B. thuringiensis* and humans in the last few decades. These changes are to the concentration of human exposure to the bacterium and/or its toxins, and the variety of ways in which we are being exposed.

A change in **B. thuringiensis***'s environment*

Worldwide at the turn of the century, 13,000 metric tons of *B. thuringiensis* were annually produced in fermenters (Anonymous, 1999). Corn and cotton engineered with *cry* genes covered a claimed 114 million ha in 2007 (Youngsteadt and Stokstad, 2008), an area of the Earth's surface over 4 times the size of the country of New Zealand (26.8 million ha). Particular strains and alleles of *cry/cyt* genes are being selectively and significantly amplified by an intervention that takes them outside their natural ecological context. Human enrichment of these sequences provides unprecedented opportunity for recombination with many uncharacterized homologues in the environment. Moreover, transgenic *cry* genes have a different DNA sequence (de Maagd et al., 1999), making the range of possible recombination products different from simple amplification of the same genes.

A change in our environment

The scale of human exposure to *B. thuringiensis* and its toxins also increases with commercial production of *B. thuringiensis* products and transgenic crops. Traditionally, *B. thuringiensis* might have been ingested because it is common on grains and in soil that might adhere to raw foods. We may have breathed it in with blowing dust or become infected in a scraped knee. The quantity of *B. thuringiensis* from these sources is likely extremely low, however. Although it is very difficult to find studies that quantify vegetative *B. thuringiensis* or spores in soil, my best estimate is that the soil burden is usually under 1,000 spores/g. From a variety of studies it appears that the detection limit varies from 1,000-100,000 spores/g soil, and most sampling regimes fail to detect *B. thuringiensis* in all soil, grain and water samples that they test (e.g., Apaydin et al., 2005; Martin and Travers, 1989; Quesada-Moraga et al., 2004). A study in New Zealand reported a detection limit for one strain of Bt at 1,000 spores/g soil, and detected none in eight samples (Anonymous, 2003).[1] From the available data, an estimate of 1,000 spores/g would probably err on the generous side and be within an order of magnitude of the correct figure.

Routine exposure by ingestion of natural soil is unlikely to be significant. No disease was established in human volunteers fed 3 x 10^9 spores per day for days or rats fed 2 x 10^{12} spores per kg (discussed in Drobniewski, 1994).[2] The minimum dose of *Bacillus cereus*

1 It was not possible to tell from this study whether they failed to detect any *B. thuringiensis* or failed to detect the particular target strain.

2 I have switched to scientific notation because the numbers get exceedingly large and the nomenclature for naming large numbers can vary by country. For those unfamiliar with scientific notation, the exponent is the number of zeros, so 10^3 = 1,000.

estimated to cause disease is 10^5 cells or spores (range 200-10^8) (Schoeni and Lee Wong, 2005). *B. cereus* and *B. thuringiensis* are unreliably distinguishable on the genetic level, meaning that if *B. thuringiensis* were capable of causing disease, it would probably be no more pathogenic than *B. cereus*. The best available extrapolation from these data indicates that a minimum of 200 g of soil enriched for an unknown variant of *B. thuringiensis* would have to be consumed for the minimum disease-causing exposure.

After aerial spraying of Bt over the city of Auckland, the New Zealand Ministry of Agriculture and Forestry detected between 10^4 and 10^6 spores of Bt/g soil (up from $<10^3$ before spraying), and this population was stable for the next two years of testing. That experiment demonstrated that a single bout of *B. thuringiensis* spraying could reduce the accidental minimum ingestion of soil from 200 g to as little as 2 g, within close range of the average, and probably within normal extremes, of the daily amount consumed by some adults[3] (Davis and Mirick, 2006).

B. thuringiensis is also found in our drinking water. Studies of *B. thuringiensis* loads in drinking water in Japan found on average 0.45 (and up to 8) colony forming units/ml (Ichimatsu et al., 2000). I could find no data on *B. thuringiensis* loads in drinking water of developing countries or in freshwater available to livestock in either developed or developing countries. Since run-off into water supplies is an obvious route to concentrating spores, this should be an area of investigation.

Aerial spraying and airborne soil also present *B. thuringiensis* in aerosol form. The concentration of Cry toxins in crop plants presents another important exposure mechanism, as do high concentrations of *B. thuringiensis* on milled material. During food preparation, for example, corn flour becomes airborne and is inhaled. Even less is known about the long-term effects of breathing *B. thuringiensis* and its toxins, especially their potential to induce allergic responses.

The yield of Cry protein ranges from $1.7 \times 10^{-7} - 7 \times 10^{-7}$ μg/spore produced in a fermenter (Ghirbi et al., 2005). Fermenter yields could be as much as 10-100 times the yield in nature. Using fermenter numbers would be conservative because they overestimate the historical exposure to Cry protein. Using these conservative figures, the Cry toxin load in soil at the *B. thuringiensis* detection limit (1,000 spores/g) is $1.7 \times 10^{-4} - 7 \times 10^{-4}$ μg/g. At the highest estimate of Cry protein in soil (0.7 ng/g) and at the highest average daily ingestion of soil by an adult (625 mg), the maximum dietary exposure to Cry protein would be 4×10^{-10} g/day.

Although Cry toxin concentrations vary considerably among cultivars, the average American eating the commercial corn producing at the low end of the scale (MON810 at 0.29 μg/g) would consume 10 μg of Cry protein per day, the equivalent exposure to eating 14 kg of soil (Table A3.1). Under more likely concentrations of Cry protein of 10-100-fold less (that is, amounts in nature and not in a fermenter), the equivalent amount of soil would be over 1 metric ton. Cry toxin reaches concentrations as high as 115 μg/g in commercial GM corn (Table A3.2). At this concentration, the corn component of a normal

[3] In a survey of 19 families, the average daily intake of soil varied from 37-207 mg for children, to 23-625 mg for adults.

Table A3.1: Kilograms of soil that would need to be eaten for equivalent Cry exposures from Bt maize[1]

μg Cry/g seed	estimated amounts (ng) of Cry/g soil			
	0.02	**0.05**	**0.2**	**0.7**
0.29 (MON810)	500	200	50	14
1.4 (BT11)	2,500	1,000	250	71
20	36,000	14,400	3,600	1,030
40	72,000	28,800	7,200	2,060
115	207,000	82,800	20,700	5,910

[1] Based on average American consumption of corn; see Table A3.2.

Table A3.2[1]: Soil and transgenic corn mass equivalents of Cry toxin

Plant	Toxin in μg/g seed (range)	Consumed Cry (μg/day)[2]	New global Cry load in human food[3]	Equivalent necessary soil mass[4]
BT11	1.4	50	2.7×10^3 metric tons	3.9×10^{12} metric tons[4]
MON810	0.29 (0.19-0.39)	10		
cry1F (Herculex?)	93 (71-115)	3,300		
MON863	67.5 (49-86)	2,400		
Average	40.5	1,500		

[1] Clark et al. (2005). [2] Based on FAOSTAT, 2003 annual consumption data (36g/day USA) and product as sole source. [3] Based on an average of 40.5μg Cry/g seed, 4.41 metric tons of grain/ha[5] and 15 million ha of *B. thuringiensis* corn in 2004 (Clark et al., 2005). [4] Assuming 1,000 spores/g soil and 7×10^{-7}μg Cry/spore.

American diet could contain up to 4,140 μg of Cry protein. This translates into an equivalent soil consumption of 6-600 metric tons per person per day. 600 tons of soil is the amount carried by approximately 10 standard-sized railroad boxcars.

Mexicans and Africans eat significantly more maize per capita than do Americans and New Zealanders (Table 4.5). The proportion of daily protein from maize for an African is 40 times that for New Zealanders. Some individual statistics are even more profound. In Malawi 55% of daily protein comes from maize whereas New Zealanders get only

4 Based on figures from Heinemann and Traavik (2004), this amount of soil would fill a train 60 billion standard US boxcars long.

5 http://www.fas.usda.gov/wap/circular/2005/05-09/Wap%2009-05.pdf

0.5% of their daily protein from maize (FAOSTAT, 2008). If all the maize consumed in Malawi and New Zealand were Bt, then those in Malawi would be exposed to 15 times more Bt on average from ingestion, and potentially far more from inhalation. A protein or amino acid-based food hazard is a quantitatively different risk for Mexicans and Africans than it is for Americans and New Zealanders because of different exposures.

Pre-market acute toxicity studies are not the same as chronic studies and do not anticipate the safety of new varieties, toxins and novel forms of toxins.

> The introduction of new varieties and toxin mixtures, such as those derived from recombinant techniques, should not be assumed safe on the basis of previous work and should be carefully evaluated (Drobniewski, 1994, p. 106).

Where previous studies may match most closely, such as in the concentrations of toxin or bacteria used, they still differ in that they use only a very select group of strains and toxins and each is produced under conditions that differ from exposures that might arise outside of the laboratory.

Moreover, I am unaware of any commercial Bt crop that has been subjected to allergenicity testing using inhalation exposure, the way humans are expected to be exposed when they handle flours for cooking or breathe in pollen. A study from 1959 found no evidence of disease in 18 human volunteers who inhaled *B. thuringiensis* spores, but later studies could not exclude disease in three people exposed to aerial spraying (NPTN, 2000). Chronic exposures to *B. thuringiensis* and its toxins could easily be overlooked without concerted efforts to monitor them. Disease could also be more likely among the immunocompromised, which, because of both AIDS and malaria (Drobniewski, 1994), is an increasingly common predisposition.

When testing rats for an immune response to a variety of Bt rice, researchers found low or no response from oral exposure, but a high response from inhalation exposure. The route of exposure was even capable of eliciting an immune response in control groups kept in the same room but not fed the experimental rice. The control animals developed anti-Cry antibodies (Kroghsbo et al., 2008).

> Surprisingly, an antigen-specific antibody response was also detected in the control groups kept in the same room in both the 28- and 90-day study with Bt toxin and PHA-E lectin. As the nasal and bronchial mucosal sites are potent sites for induction of an immune response, the results may be explained by inhalation of particles from the powder-like non-pelleted diet containing PHA-E lectin or Bt toxin, thereby inducing an anti-PHA-E or anti-Bt response (Kroghsbo et al., 2008, p. 31).

In summary, there is a conspicuous absence of research on Cry protein toxins as either toxins or allergens in human food plants, both on the unique ways that they may be expressed in plants and on the unique context and concentration in which we are exposed to them through food (see an extended discussion on the effects of cooking in Chapter Four).

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Appendix Four

Legal Remedies: Case Studies

FARMERS who adopt GM products may be the target of liability claims. These farmers and also consumers and competitors may be the source of claims against seed producers. Economic damages in the event of contamination will depend on the GM tolerance threshold in place in the country concerned. However, non-GM and organic farmers catering to zero-tolerance private markets will have their business compromised by any level of GM contamination.

Switzerland: Pioneer Hi-Bred corn

In May 1999, non-GM corn varieties from Pioneer Hi-Bred were found in Switzerland to contain novel Bt genes. Ulrich Schmidt, Pioneer managing director in Germany, stated that the contamination was likely to be from "stray pollen during the growing season" (Furst, 1999, p. 629). About 200 hectares of the corn had been planted by the time the contamination was found. As Switzerland had a "no tolerance" standard for genetic purity, sowing the seed was illegal under environment law. This meant that these crops had to be destroyed, and compensation payments had to be made to farmers (Smyth et al., 2002). Schmidt admitted that Pioneer Hi-Bred and other seed biotechnology companies would not be able to guarantee that their non-GM seed was pure, with Novartis spokesman Rainer Linneweber affirming that "100% [technical] purity for conventional seed is utopian" (Furst, 1999, p. 629).

United States: Aventis StarLink corn

In the StarLink corn case, GM corn was grown to be marketed as animal feed in the US. The GM feed corn contaminated approximately 10% of corn meal designated for human food products despite the fact that less than 1% of corn acreage was planted in StarLink (Lin et al., 2001). The producer has had to pledge over US$1 billion to address the contamination situation – withdrawing the product and compensating producers and food manufacturers who have had to recall their products (Smyth et al., 2002).

Furthermore, a class-action lawsuit was filed by consumers who claimed that they inadvertently consumed food unfit for human consumption, because StarLink was not approved as a human food product. The lawsuit ended with a settlement against the corn's developer, Aventis. This suggests that consumers may have grounds for compensation, at least in the US, even if their health is not affected by the transgenic crop (Kershen, 2004).

Canada: Percy Schmeiser

In 1998, Canadian farmer Percy Schmeiser was prosecuted by Monsanto Canada after GM canola was found growing on his farm. Although the courts acknowledged that this was the result of wind-based seed contamination, the mitigating circumstances were deemed insignificant defence for the patent infringement case. Schmeiser found 60% of the crop survived after spraying with Roundup herbicide, confirming his suspicions that Roundup Ready canola was present in his crop. He harvested and stored the seed from the area he had sprayed, using this seed in 1998 for his new crop. Despite the innocent origins of the seed, the court found that Schmeiser "knew or should have known that he was planting Roundup Ready canola", with his behaviour disqualifying him from "innocent grower" status (Kershen, 2004, p. 462). The legal impact of Schmeiser having knowledge of the contamination was left ambiguous at the time, because "[t]he court left undecided whether Monsanto would have an infringement claim against a truly innocent grower" (Kershen, 2004, p. 462). However, the irrelevance of the cause of contamination – whether through pollen drift, seed dispersal from transportation, or potentially even covert planting from an outside farmer or supplier – highlights the need for increased vigilance, monitoring and quality legal advice for all farmers, regardless of whether they choose to enter into an agreement with a supplier.

Patent thickets (Thomas, 2005)

Intellectual property protection includes particular genes and plant varieties as well as techniques for creating transgenic plants and product ideas, such as the use of Bt-sourced Cry toxins as a plant-expressed insecticide. *"A company that has the rights to a species of Bt toxin protein can still be subject to another company's broad patent rights on Bt toxin technology"* (ISB News, 2005). Determining who owns such transgenes is critical because multiple companies market versions of Bt toxins in cotton, soybean, maize and possibly other products in the future. Both public and private institutions that are developing GM crops are thus likely to stumble into a patent thicket: described as a network of intellectual property claims that make achieving a licensing agreement difficult if not impossible.

In 2002, Syngenta claimed that Monsanto, DeKalb Genetics (a subsidiary of Monsanto), Pioneer Hi-Bred International, Dow Agrosciences LLC, and Mycogen Seeds (a subsidiary of Dow) infringed on patents owned by Syngenta that describe synthetic transgenes based on *cry* genes. However, in 2004 a US Federal judge ruled that Mycogen Seeds invented Cry1F, a gene product based on an insect toxin first isolated from the bacterium *B. thuringiensis*. Syngenta and Pioneer reached an out-of-court licensing arrangement. Monsanto and Dow prevailed in court. Subsequently, the US Patent and Trademark Office eliminated 12 of 14 claims in a Mycogen patent because it determined that Monsanto had prior ownership. That ruling was then disputed by Mycogen. A flurry of other lawsuits were filed over ownership of *cry*-based transgenes. In parallel, there is similar legal wrangling over herbicide tolerance transgenes (ISB News, 2005).

These and other (e.g., Jones, 2006) cases illustrate the seriousness of intellectual property issues among developers. The issues are so central, there is speculation that they are the primary reason for mergers in an industry that is decreasing its number of primary players (Thomas, 2005). Companies with complementary intellectual property reduce the complexity of the patent thicket by collapsing the number of competing companies. The cases also illustrate the vast legal resources of the industry.

Monsanto vs. US farmers

A report published by the Center for Food Safety (CFS) in 2005 chronicled the impact of material transfer agreements (MTAs) between Monsanto and US farmers. According to CFS, "[f]armers who discontinue their use of Monsanto's genetically engineered seed face patent infringement allegations in the event that some of that seed from the previous year sprouts 'volunteers' in fields converted to conventional varieties" (Center for Food Safety, 2005, p. 20). This liability may extend also to farmers who purposefully save seed (for update, see Barlett and Steele, 2008). The MTA between Monsanto and the grower states that the grower accepts the terms of the licensing agreement "by signing this Agreement and/or opening a bag of seed containing Monsanto Technology".[1] If Monsanto considers that a grower has infringed on its patents, the grower may be liable for restitution including Monsanto's court and legal fees. Growers are required to answer claims exclusively in the US District Court of Missouri or the Circuit Court of the County of St. Louis, near Monsanto headquarters. CFS reports that Monsanto has 75 employees and devotes US$10 million annually for the purpose of investigating farmers, including its former customers. CFS provided evidence of between 475-600 investigations by Monsanto annually, with settlements estimated in the millions of dollars. CFS found that Monsanto has filed 90 lawsuits across 25 US states. The largest judgment in favour of Monsanto is reportedly just over US$3 million, with a cumulative total of US$15 million (Center for Food Safety, 2005).

Monsanto reportedly estimates that without MTAs, as much as a quarter of their royalties on Roundup Ready crops would be lost to unregistered use and with the MTAs, they estimate losses of 10% (Smyth et al., 2002).

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[1] 2006 Monsanto Technology/Stewardship Agreement

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hope *not* hype

Can we feed the world in the year 2050? If we can, will it be at the price of more distant futures of food insecurity? 21st-century Earth is still trying to find a way to feed its people. Despite global food surpluses, we have malnutrition, hunger and starvation. We also have mass obesity in the same societies. Both of these phenomena are a symptom of the same central problem: a dominating single agri*culture* coming from industrialized countries responding to perverse and artificial market signals. It neither produces sustainable surpluses of balanced and tasty diets nor does it use food production to increase social and economic equity, increase the food security of the poorest, and pamper the planet back into health.

This book is about a revolution in agriculture envisioned by the International Assessment of Agricultural Knowledge, Science and Technology for Development (IAASTD), a five-year multi-million-dollar research exercise supervised by the United Nations and World Bank that charts sustainable solutions. The solutions are of course not purely technological, but technology will be a part of the solution.

Which technology? Whose technology?

Hope Not Hype is written for people who farm, but especially for people who eat. It takes a hard look at traditional, modern (e.g., genetic engineering) and emerging (e.g., agroecological) biotechnologies and sorts them on the basis of delivering food without undermining the capacity to make more food. It cuts through the endless promises made by agrochemical corporations that leverage the public and private investment in agriculture innovation. Here the case is made for the right biotechnology rather than the "one size fits all" biotechnology on offer. This book provides governments and their citizens with the sound science in plain language to articulate their case for an agriculture of their own – one that works for them.

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