AGERI & ABSP

WORKSHOP SERIES

BIOSAFETY

INTELLECTUAL PROPERTY RIGHTS

PROJECT EVALUATION

JANUARY 24 - 31, 1994

FORTE GRAND PYRAMIDS HOTEL

CAIRO, EGYPT

UNDER THE AUSPICES OF:

H.E. PROF. DR. YOUSSUF WALLY

DEPUTY PRIME MINISTER & MINISTER
OF AGRICULTURE, ANIMAL WEALTH, FISHERIES
AND LAND RECLAMATION, EGYPT

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TABLE OF CONTENTS

Page ... Topic

4 .... SECTION 1: INTRODUCTION

4 .... Acknowledgments

4 .... Preface

5 .... Foreword
John H. Dodds

6 .... SECTION 2: BIOSAFETY

6 .... The Safe Application of Biotechnology: A Need for Regulation in Egypt and Worldwide
Michael F. Ghaly and Patricia L. Traynor

9 .... ABSTRACTS from the AGERI/ABSP Biosafety Workshop, January 26th & 27th, 1994

9 .... PART I: Biosafety Policy Development Considerations

9 .... Current Status of Biosafety in Africa and The Middle East
Prof. Dr. Adel El-Beltagy

9 .... Legal Aspects of Biosafety
John H. Barton

10 ... Environmental Assessment of Genetically Engineered Crops
Susanne L. Huttner

10 ... Safety Assessment of FLAVR SAVR™ Tomato and kan^r/APH(3')II
Keith Redenbaugh

11 ... Social Consequences Concerning Biosafety
Paul B. Thompson

11 ... The Economics of Biosafety
Mywish K. Maredia

12 ... PART II: Building the Biosafety Regulatory Framework

12 ... International Approaches to Biotechnology Regulations: An ICGEB/UNIDO Perspective
George Tzotzos

12 ... An Overview of the Regulatory System for Testing Transgenic Plants in Mexico
Ariel Alvarez-Morales

Page ... Topic

13 ... The Safe Use of Biotechnology in Egypt
Michael Francis Ghaly

13 ... ISAAA's Biosafety Initiative
Eppie Zandvoort

13 ... Results of the African Regional Conference for International Cooperation on Safety in Biotechnology
Bert Visser

14 ... PART III: Tools and Models for Evaluating Risks/Benefits of Biotechnology

14 ... The National Biological Impact Assessment Program (NBIAP): An Important Part of the U.S. Biosafety System
Patricia L. Traynor

14 ... Regulation of Contained Use and Release of Modified Organisms Within the European Union
Julian Kinderlerer

15 ... Biosafety Research and Assessment of Technology Impacts in Switzerland (BATS): Objective and Programme
Othmar Käppeli

15 ... Risk Assessment for Commercialization of Transgenic Crops
Jane Rissler

15 ... Safe Deployment of Transgenic Plants Expressing a B.t. Gene in Agricultural Systems
Roy L. Fuchs

16 ... PART IV: Laboratory, Greenhouse and Field Testing of Transgenic Germplasm

16 ... Biosafety Regulations and Guidelines in the United States
Patricia L. Traynor

16 ... A Critical Review of Field Test Results Using Genectically Engineered Crop Plants
Philip J. Dale

Page ... Topic

17 ... Regulatory Requirements in the Production and Testing of Transgenic Corn
Martin Wilson

17 ... Field Testing of Transgenic Cucurbits Resistant to Viruses
Hector Quemada

17 ... Greenhouse and Field Testing of Transgenic Potatoes
David S. Douches

18 ... SECTION 3: INTELLECTUAL PROPERTY RIGHTS

18 ... Intellectual Property Rights and Biotechnology in Developing Countries
Atef Mohamed El-Azab and John H. Barton

20 ... ABSTRACTS from the AGERI/ABSP Intellectual Property Rights Workshop, January 24th & 25th, 1994

20 ... Patent Protection in Biotechnology
Rebecca S. Eisenberg

21 ... Intellectual Property and Plant Breeders' Rights
John H. Barton

Page ... Topic

22 ... Intellectual Property and Licensing Agreements
Frederic Erbisch

22 ... SECTION 4: RESEARCH AND NETWORKING: Project Evaluation Workshop, January 30th & 31st, 1994

22 ... Research Accomplishments in the First Year of the AGERI/ABSP Collaboration
Magdy Madkour, Claude Fauquet, Rebecca Grumet, David Douches and Mariam Sticklen

26 ... AGERI/ABSP Networking: Enhancing Communication Within the Global Biotechnology Community
Karim Maredia and Bruce Bedford

27 ... BioComputing and Networks Unit at AGERI
Raef Bishara and Eman Atef El-Azab

28 ... SECTION 5 WORKSHOP PARTICIPANTS

28 ... Participants from Egypt

29 ... AGERI Participants

30 ... International Participants

30 ... U.S. Participants

Participants of the 1994 AGERI/ABSP Project Evaluation Workshop

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SECTION 1 INTRODUCTION

ACKNOWLEDGMENTS

It is difficult to describe the monumental effort required in bringing together over one hundred forty scientists from around the world to engage in meaningful discussion about such a broad area as agricultural biotechnology and such complex issues as intellectual property rights and biosafety. Even more difficult, perhaps impossible, is the task of giving proper recognition to all those who made this workshop series possible.

Under the auspices of H.E. Prof. Dr. Youssuf Wally, Deputy Prime Minister and Minister of Agriculture, Animal Wealth, Fisheries and Land Reclamation, the government and people of Egypt acted as excellent hosts and participants. Prof. Dr. Adel El-Beltagy, Director General of the National Agricultural Research Project (NARP), and Chairman of the Board of the Agricultural Research Center, gave his steadfast support and encouragement. The energy and vision of Prof. Dr. Magdy Madkour, Director of the Agricultural Genetic Engineering Research Institute (AGERI), provided the catalyst for smooth operation and an environment of enlightenment and intellectual challenge. Deep gratitude is due the directors and officers of USAID/Cairo, particularly Mr. Nasr Rohaiem, AGERI/ABSP Project Officer, the new initiatives staff of the National Agricultural Research Project and the many programs within the Agricultural Research Center for their support and the encouragement they provided to their representatives who were in attendance.

Dr. John Dodds, Managing Director of the Agricultural Biotechnology for Sustainable Productivity (ABSP) project at Michigan State University, enthusiastically worked hand-in-hand with Dr. Madkour and gave meaningful direction to the process of imparting important knowledge to workshop participants. The form and depth of the subject matter presented were proposed and reviewed by Prof. John H. Barton, Stanford Law School (Intellectual Property Rights), Dr. Sivramiah Shantharam, USDA/APHIS/BBEP (Biosafety), and Dr. Mariam Sticklen, Research Director for the ABSP project (Project Evaluation).

Thanks are given to UNIDO/UNEP and ISAAA for providing funding for some of the speakers and workshop participants from Africa and to the international centers (CIP and ICARDA) for their representation. The speakers represented a wide range of organizations and they are given thanks for being an integral part of the learning process.

Finally, the diligence and service of the administrative and network offices of AGERI and ABSP touched every part of the workshops, from travel to accommodations, material development, conference arrangements, speaker invitation, secretarial support . . . the list is endless. Many thanks to the undauntable.

PREFACE

This report contains five major sections. The first section contains introductory notes (acknowledgments, preface and foreword). The second section addresses biosafety in two parts: the first is an article which gives an overview of the need for regulation and the many issues involved in the development of national policy and a regulatory framework, briefly citing Egypt as a relevant example, and the second is a collection of abstracts from the biosafety workshop presentations which address those issues in a more specific manner.

The third section delves into the subject of intellectual property rights (IPR). The first part is an article which provides a context for thinking about IPR and its importance to developing countries who endeavor to develop or use the products of biotechnology research, again using Egypt as an example. The second part is a collection of abstracts from the IPR workshop speakers providing more specific information about IPR. It is important to remember that the biosafety and IPR workshop abstracts reflect the views of the abstract author and are not necessarily those of the ABSP project.

The fourth section contains three articles about the AGERI/ABSP project which you will find very interesting. The first is a summary of research accomplishments in the first year of the project, arranged by commodity (maize, potato, cucurbits and tomato). The second is a brief report on the activities of the networking office at ABSP. The third is a description of the BioComputing and Networks Unit at AGERI.

The fifth section should be very useful to anyone interested in the topics of biosafety, IPR or the AGERI/ABSP collaboration; it is simply a list of participants. It is certain that any of the workshop speakers would welcome further contact or inquiry regarding their presentations. This report will provide a slightly different perspective for your consideration of these very important issues. As always, comments are welcomed.

FOREWORD

John H. Dodds, Managing Director
Agricultural Biotechnology for Sustainable Productivity Project
Michigan State University, USA

This report summarizes an intense eight days of workshops held in Cairo, Egypt, in late January 1994. Initially, many people were daunted by the idea of holding three consecutive workshops (biosafety, intellectual property rights and project evaluation); however, at the end of the events, it was clear that significant synergistic benefit was derived from bringing together a critical mass of ABSP cooperators and other international participants to discuss a wide range of topics. These workshops were indeed a unique set of activities and tremendously strengthened the interaction between scientists from Egypt, the region, the United States and Europe.

Wide Ranging Participation

One hallmark of the Agricultural Biotechnology for Sustainable Productivity (ABSP) program is its integrated approach to agricultural biotechnology. In the context of the workshops, participants could grasp the entire spectrum of project activities from basic to applied "product-oriented" research, to policy issues, to networking, to promoting cooperation with institutions involved in the commercialization of the end products of research.

The three workshops concentrated on research and policy and brought together both individual and institutional cooperators from Egypt, the region, the United States and Europe. ABSP, together with the Agricultural Genetic Engineering Research Institute (AGERI), interacted closely with Egypt's National Agricultural Research Project (NARP) and the Agricultural Research Center (ARC), through many of its commodity programs, to design workshops which could relate directly to challenges in biotechnology research and development in Egypt and the North Africa and Middle East region. International programs such as the International Potato Center (CIP), International Center for Agricultural Research in the Dry Areas (ICARDA), and International Service for the Acquisition of Agri-Biotech Applications (ISAAA) were represented at the workshop. Several members of the donor community participated, including representatives from ODA (United Kingdom), DGIS (The Netherlands), UNIDO and UNEP (Austria), in addition to the U.S. Agency for International Development (USAID), the principal donor. The private sector was well represented by Asgrow Seeds (Upjohn), ICI Seeds, Inc., Monsanto and Calgene from the United States, in addition to Danton, a private agribusiness firm based in Cairo.

The Importance of AGERI/ABSP

Both in general and in its cooperation with AGERI, ABSP has focused on a limited number of crops and a limited number of technologies. The crops are chosen on the basis of nutritional or economic value and the technologies are carefully chosen to attack problems often associated with practices which result in environmental degradation, such as high levels of chemical pesticide usage. In the case of North Africa, Egypt in particular, the environmental conditions are ideal for the destruction of plant material by insects either during production or storage.

The use of pesticides in Egypt is currently at a very high level, risking health problems and environmental degradation and reducing biological diversity; at some point, innovative alternatives must stop the pesticide treadmill. The potential impact of the AGERI/ABSP program on Egyptian and U.S. agriculture is astounding. New areas of research involved in the program, will help to reduce pesticide usage and alleviate the associated risks.

...at some point, innovative alternatives must stop the pesticide treadmill.

The research, management and network teams on all sides of the collaboration have been dynamic. In an extremely short time, significant progress has been made on a wide range of research and policy fronts. There also have been real advances in human resources development through short- and medium-term training programs which have covered areas within biotechnology research, biosafety and intellectual property rights.

Success to date has been dramatic because all parties are working hard for the delivery of the longer-term objectives and goals of an improved and sustainable agriculture within Egypt and the subsequent benefits to farmers and consumers in Egypt and the United States. The research and the infrastructure building currently underway will keep Egypt in a leading role within the region and help to maintain the current process of technology transfer by the Egyptian research community to its surrounding country partners.

As plans are made for the future, several new partners are expected to join the AGERI/ABSP consortium. Genetic Resources Communications Systems (GRCS), publishers of DIVERSITY magazine, will organize a workshop in June 1994, to review the situation of genetic resources in Egypt and in the region. This will lead to a special issue of DIVERSITY, to be published in English and Arabic. Following the interactions of Asgrow Seeds and ICI Seeds, Inc. in the workshops, it is hopeful that AGERI and ABSP will develop cooperative research with those two commercial partners in the near future on cucurbits and maize.

With its wide range of issues, the various perspectives from which they are seen and their relevance to Egypt and the region, it is hoped that you will find this report very interesting and useful reading.

The Safe Application of Biotechnology: A Need for Regulation in Egypt and Worldwide

Michael F. Ghaly, Research Associate,
Agricultural Genetic Engineering Research Institute, Giza, Egypt

Patricia L. Traynor, National Biological Impact Assessment Program (NBIAP) Coordinator, Michigan State University, USA

In both developed and developing countries, the safe application of biotechnology to problems of agricultural productivity requires an appropriate biosafety system that encompasses both policy and regulations. Developing countries seeking to use the new technology to address limitations in food and fiber production are being pressured from within as well as by outside forces to formulate biosafety systems. Countries lacking mechanisms for review and oversight of biotechnology products risk being used as a testing ground for materials deemed too risky to test in a developed country. At the same time, companies seeking to produce genetically engineered crops tailored for developing country needs are reluctant to operate in the absence of a regulatory structure.

The Principles Behind Biosafety Policy

A well-designed biosafety policy will ensure the safety of human health and the environment without restricting innovation or stifling incentives for product development. The policy should embody two basic principles. The first principle states that the risks of introducing a genetically modified organism (GMO) into the environment derive from the nature of the organism and the environment into which it is introduced, rather than from the process by which it was developed. The second principle states that the degree of oversight applied to a GMO in the environment should be commensurate with the degree of risk it presents.

Biosafety policy should address national priorities in agriculture, food safety and environmental protection, and should establish the scope and intent of guidelines or regulations. In addition to issues of science and technology, a well-designed biosafety policy will also address the attendant social, economic and legal issues. These aspects of agricultural biotechnology are not generally codified in regulations but merit consideration during the formulation of policy.

Social Aspects

Foremost among social issues is the question of how to achieve a proper balance between risks and benefits of biotechnology and ensure fair and equitable distribution of both.

- Who decides what is an acceptable level of risk?
- How can decisions be made in the face of uncertainty about potential risks?
- What are the risks of not using the technology?
- What role should the public have in setting a research agenda and deciding which products should be developed?
- How will the public have access to information?

Ideally, input from social scientists and community leaders should be sought in the early stages of biosafety policy development.

Economic Issues

Economic issues will also shape biosafety policy. During the development, testing and marketing of biotechnology products, biosafety regulations add costs by, for example, slowing research and diverting human and physical resources into risk assessment and oversight procedures. A biosafety system affords benefits by reducing risks to human health and the environment and by encouraging investment in the technology.

- How much money should be spent to reduce risk to an acceptable level?
- Should the costs imposed by biosafety regulations be borne by those developing biotechnology products or by those who will use the products?

Although the economic costs and benefits are ultimately shared by all sectors of society, how they are allocated among producers, consumers and society at large is determined by policy decisions.

The Regulatory Structure

Legal issues of intellectual property rights and international trade law must also be considered in the design of biosafety policy. The accompanying article in this report by Atef Mohamed El-Azab and John H. Barton discusses the importance of intellectual property rights for the continuing advancement of agricultural biotechnology in developing nations.

A well-designed biosafety policy will ensure the safety of human health and the environment without restricting innovation or stifling incentives for product development.

Biosafety regulations address the scientific and technical issues of GMOs and describe procedures and practices for safe handling of genetically engineered materials in the laboratory, the greenhouse, and in the field. Biotechnology regulations need to be compatible with existing laws; for example, rules for importing GMOs should be consistent with plant and animal quarantine statutes. Coordination is needed among various national authorities for public health, food safety, natural resources, etc.

The regulatory structure needs to be flexible and responsive to new information relevant to risk assessment. It should be implemented in a way that will allow rules to evolve as initially identified risks are shown to be negligible or only narrowly relevant and as unanticipated risks become apparent. For developing nations that may lack sufficient expertise for risk assessment, international resources are available to provide guidance and training as well as data. Among these are UNIDO's Biosafety Information Network and Advisory Service (BINAS) and USDA's National Biological Impact Assessment Program (NBIAP) databases.

Many information resources were available to Biosafety Workshop participants.

The regulatory structure needs to be flexible and responsive to new information relevant to risk assessment. It should be implemented in a way that will allow rules to evolve as initially identified risks are shown to be negligible or only narrowly relevant and as unanticipated risks become apparent.

Relating Technical Issues to Risk Assessment

Scientific and technical biosafety issues associated with GMOs concern the consequences of releasing transgenic materials outside the laboratory and impacts on human health. Potential deleterious effects on natural or managed ecosystems need to be considered for small scale field tests and become even more important when transgenic crops are grown for commercial production. Responsible environmental risk assessment should address the following questions:

1. Does the newly engineered trait confer "weediness" on the genetically modified crop? Traits such as drought or salt tolerance may confer enhanced fitness, allowing the transgenic species to invade and become established in previously unsuitable environments. Such spread could lead to displacement or replacement of other species occurring naturally in the ecosystem.

2. Are transgenically expressed pesticidal or pharmaceutical compounds toxic to non-target organisms? Where plants producing these compounds are grown on a commercial scale, what are the potential short- and long-term effects on animals, microbes, and other plants in the area?

3. Will the widespread deployment of plants engineered to express pesticidal proteins hasten the development of resistance in target pest species? Insect populations can respond quickly to the selection pressure imposed by large scale and prolonged application of conventional pesticides. Use of only a few genes, such as those encoding delta endotoxins in *Bacillus thuringiensis*, to transform numerous crop species is poor pest management practice with potentially serious implications. The same argument can be raised with respect to genes for resistance to bacterial and fungal pathogens.

4. What is the potential for gene flow, in which a trait genetically engineered into a crop species is inadvertently transferred to sexually compatible species via pollen from the transgenic plant? Such "escape" of introduced genes could lead to the contamination of wild germplasm and a subsequent loss of genetic diversity.

5. Most importantly, for a particular GMO introduced into a particular environment, what interactions between the biology of the organism and ecology of the site present unique concerns for biosafety?

Human health issues associated with agricultural biotechnology are primarily concerns about the safety of food and food additives. Public acceptance of the new technology will be directly linked to consumer perceptions that foods derived from biotechnology are safe to eat. Genetically engineered food products should be evaluated for potential toxicity or allergenicity of new expressed proteins, increased levels of known toxicants, or significantly altered nutritional qualities. Clear and consistent policy must be developed regarding labeling of genetically engineered foods, keeping in mind the purpose and intent of other food labeling statutes.

In Egypt, as in other developing nations, a national biosafety system will ensure the safe development of biotechnology products and facilitate collaborative research activities with other countries.

The Progress Toward Biosafety Regulation in Egypt

One approach to developing a biosafety system can be illustrated by the activities currently underway in Egypt. The population of Egypt is expected to grow to about 70 million by the year 2000, and swell to 110 million by the year 2025. The Egyptian government is faced with the task of bridging the food gap and fulfilling the goal of self-reliance. Simply placing more land under cultivation will not solve this problem. Increasing the agricultural land base from the present 7.4 million to 14 million feddans would satisfy only half the land requirement for the current population of 60 million. Modern biotechnology research methods offer new approaches to agricultural sustainability that will meet human requirements and enhance the environment.

The Agricultural Genetic Engineering Research Institute (AGERI), within the Agricultural Research Center (ARC) of the Ministry of Agriculture, is the primary institute that deals with biotechnology in Egypt. AGERI's research projects have now reached the stage of evaluating genetically modified organisms in a containment greenhouse that is being constructed in 1994, as part of an AGERI/ABSP agreement with the University of Arizona. Existing regulations in Egypt do not include guidelines for handling transgenic materials under contained conditions nor do they cover the release of GMOs into the environment. Thus, there is a critical need for the Egyptian government to build a national biosafety policy that could regulate such articles.

Recently, a National Biosafety Committee (NBC) was formed, consisting of representatives from the Ministries of Agriculture, Health, Industry, Education, Sectors of Environmental Affairs and Scientific Research. The NBC also includes members from the private sector, non-technical members that represent community interests, and policy makers. To formulate a biosafety system for Egypt, the first step is gathering from different nations information on their regulations, guidelines, and system designs. A draft document, entitled "The Establishment of a National Biosafety System in Egypt: Regulations and Guidelines", will be submitted to the NBC in the near future. The draft incorporates information on the structure, composition and activities of both national and institutional biosafety committees.

In Egypt, as in other developing nations, a national biosafety system will ensure the safe development of biotechnology products and facilitate collaborative research activities with other countries.

Participants of the 1994 AGERI/ABSP Biosafety Workshop

ABSTRACTS

From the AGERI/ABSP Biosafety Workshop, January 26th & 27th, 1994

PART I: BIOSAFETY POLICY DEVELOPMENT CONSIDERATIONS

Current Status of Biosafety in Africa and The Middle East

Prof. Dr. Adel El-Beltagy, Director General, National Agricultural Research Project, and Chairman of the Board,
Agricultural Research Center, Egypt

Biotechnology offers significant opportunities to enhance agricultural productivity in Africa and the Middle East region. The deployment and use of new technologies, however, have raised a number of regulatory issues related to risk/benefit analysis associated with genetic diversity, the environment, and human and animal health. There is a critical need for a regulatory framework in African and Middle Eastern countries to ensure safe use of new technologies and importation of biotechnology products. A regulatory framework in these countries will not only allow the scientists to develop and test transgenic materials in the local environments but also will help safeguard the environment, attract private sector investments and facilitate commercialization and trade with the international community.

Currently, most countries in Africa and the Middle East lack guidelines or regulations for biotechnology products. Many countries depend on the government departments or statutory bodies such as National Councils for Science and Technology to institute mechanisms for regulating the use and release of genetically modified organisms (GMOs). There is a great need, therefore, to revise existing legislation to incorporate provisions that address safety issues in biotechnology.

Positive steps must be taken in building a biosafety regulatory framework for GMOs. As an example, Egypt has recently established the National Biosafety Committee which has put together a draft set of guidelines that are pending approval of the Plant and Animal Quarantine Authority. Zimbabwe has also prepared a draft of biosafety guidelines and regulations that are pending approval of the Research Council of Zimbabwe. Kenya is in the process of developing guidelines based on the Indian model.

International activities such as the AGERI/ABSP project in Egypt, funded by USAID/Cairo, and the Special Programme for Biotechnology in the Dutch Ministry of Foreign Affairs have conducted regional workshops to enhance cooperation and harmonization in the safe use of biotechnology. The ABSP project has sponsored internship programs in biosafety to develop the human resources in Kenya, Egypt, Indonesia and other developing countries. There have been discussions at the regional workshops of developing Regional Biosafety Networks and Committees. In this way, the countries in Africa and the Middle East are making progress in building a regulatory framework that would enable them to use and manage biotechnology in an environmentally safe way.

Legal Aspects of Biosafety

John H. Barton, George E. Osborne Professor of Law
Stanford Law School, USA

In the United States, biosafety regulation goes back to the NIHRAC (National Institutes of Health Recombinant DNA Advisory Committee), which was created shortly after scientists, meeting at Asilomar, California, first raised questions about the safety of genetic engineering. During the 1980s, the NIHRAC was supplemented by the "matrix" under which responsibilities for monitoring biosafety were divided among a number of different agencies, based on their existing statutory authority. In all cases, however, the agency or committee acts on the basis of a protocol that has been prepared by the applicant; it is up to the applicant to conduct the testing and assemble the information necessary to show that the agency's safety standards are met.

Other nations have systems that differ substantially in procedure, depending on their administrative law tradition — although the effective standards are often quite similar from nation to nation. For developing-nation application, biosafety review is required under USAID contracts, and, in certain cases, under NIHRAC rules. There are also codes of conduct at the international level, one negotiated by a number of United Nations agencies (the United Nations Environment Program, the United Nations Industrial Development Organization, the World Health Organization, and the Food and Agriculture Organization) and one by the Organization for Economic Cooperation and Development. The new Biodiversity Convention contemplates consideration of a new international agreement in the area; if this agreement does go forward, it will probably include an advance informed agreement procedure under which exporting nations will require agreement of recipient nations before transgenic materials can be exported.

In complying with these requirements, help is available from a number of sources, including the Stockholm Environment Institute, the United Nations Industrial Development Organization, and the United States Department of Agriculture's Animal and Plant Health Inspection Service (USDA/APHIS). In planning projects, the requirement of biosafety review and of preparing for it should be taken into account. Most of all, it is crucial to ensure public participation in the process.

Environmental Assessment of Genetically Engineered Crops

Susanne L. Huttner, Director, Systemwide Biotechnology Research and Education Program, University of California, USA

Two principles guide effective risk assessment: (1) assumptions about the nature, magnitude, and distribution of risks must be scientifically defensible; and (2) if requirements and costs for risk management are to be imposed upon innovation and commercial development, they should be commensurate with risk. The validity of risk assumptions determines the integrity of the risk management process. If the assumptions are flawed, risks are left unchecked and resources are wasted without improving public safety.

International scientific and policy organizations conclude that risk is a function of the characteristics of the plant and the environment into which it is to be introduced, and not of the genetic modification process. Past experience with crop research can guide risk assessment to consider traits known or suspected to be related to risk, {e.g., invasiveness; weediness; undesirable substances (e.g., toxins); and transfer of genes that could confer a selective advantage to nearby wild plants}. Similarly, plant breeding experience dictates that breeders should generate sufficiently large numbers of new plants and discard unwanted phenotypes and genotypes (e.g., considering new traits, selectable marker effects, gene copy number and position effects, expression pattern and stability, pleiotropic effects, and somaclonal variation, etc.).

Scientifically sound risk assumptions have not been consistently applied by regulatory agencies. Field research has generally been more heavily burdened with special research design and reporting requirements than are necessary to identify and mitigate risks. Such regulations reflect cultural values and product development costs acceptable to those societies.

Safety Assessment of FLAVR SAVR™ Tomato and kan^r/APH(3')II

Keith Redenbaugh, Manager, Regulatory Affairs, Calgene, Inc., USA

In 1989, Calgene began consultation with the FDA on safety assessment of the FLAVR SAVR™ tomato. This product was engineered to contain an antisense copy of the tomato polygalacturonase gene and the selectable kanamycin-resistance marker gene (kan^r gene). The following conclusions were reached after extensive consultations with the U.S. Food and Drug Administration (FDA). The safety of FLAVR SAVR™ tomatoes has been shown by a thorough evaluation and demonstration of equivalence: the FLAVR SAVR™ tomato does not differ from other tomato varieties except for the specific, intended effects of the inserted genes. All data–molecular analyses, biochemical analyses, nutritional levels, horticultural traits, genetic analyses, field trial results, plant pest risk evaluation, and safety studies–support this conclusion. No data indicate or suggest any safety risk.

Calgene also conducted a thorough review and analysis of the use of the kan^r gene and gene product, APH(3')II (aminoglycoside 3'-phosphotransferase II), for use as a selectable marker in FLAVR SAVR™ tomatoes (as well as in transgenic cotton and rapeseed). The data generated support the conclusions that APH(3')II is not a toxin or allergen, that the kan^r gene is highly unlikely to move from the plant genome into microorganisms via horizontal gene transfer, that if such a transfer could occur the impact would be minimal, and that APH(3')II in transgenic plants will not compromise antibiotic use in humans or animals.

The APH(3')II data are currently under review by the U.S. FDA as a Food Additive Petition (FAP 3A4346) for the use of APH(3')II in transgenic plants. The FDA is considering the safety of the FLAVR SAVR™ tomato as a Request for Advisory Opinion (Docket #91A-0330/API). Calgene anticipates FDA approval in early 1994, at which time it will begin commercial sales in the United States.

Dr. Magdy Madkour, Director of the Agricultural Genetic Engineering Research Institute, led a large number of workshop participants on a tour of facilities and shared the many complex issues involved in directing AGERI.

Social Consequences Concerning Biosafety

Paul B. Thompson, Director, Center for Biotechnology Policy and Ethics, Texas A&M University, USA

Social consequences of agricultural technology can become relevant in two ways. First, some have argued that the concept of biosafety should cover all unintended or unwanted but predictable consequences of researching, developing, or adopting a technology. If this broad definition is used, then social consequences are a part of biosafety. Second, even if biosafety is limited to human, plant, animal, and ecosystem health consequences, the attempt to implement an effective biosafety program will be complicated by interest groups seeking essentially social objectives. This will particularly be the case in a public policy environment such as the United States, where no agency of government has the authority to monitor or regulate technology based upon social consequences. Lacking an outlet for their frustrations, groups seeking remediation of social consequences will politicize the regulatory process for biosafety.

Social consequences are associated with all agricultural technologies. Some consequences, such as the elimination of hand labor jobs, may be intentional. Some technologies are too costly for food producers, but can give large or wealthy farmers significant advantages over the poor. The economic structure of agriculture in both developed and developing countries means that aggressive early adopting farmers derive short-term benefits from producing enhancing technology, but that the ultimate beneficiaries are food consumers. Although agricultural biotechnologies may be less susceptible to a farm size bias than are mechanical and chemical technologies, it is reasonable to think that many poor producers will be unable to compete with richer competitors as a direct result of biotechnology.

Strategies for redressing social consequences include the following:

- Mitigate the effects of farm loss with adequate programs of education, unemployment benefits, relocation assistance and interim health care.
- Compensate losers from technological change with social entitlements or income transfers.
- Restrict or plan technology development to match an explicitly designed pattern of development for rural communities.
- Monitor consequences and intervene when benefits to consumers do not compensate for losses to poor farmers.
- Adjust the research agenda to emphasize technologies that minimize unwanted social consequences.

All presuppose economic and sociologic assessment of social consequences likely to be associated with biotechnology.

The Economics of Biosafety

Mywish K. Maredia, Department of Agricultural Economics, Michigan State University, USA and CIMMYT, Mexico

Biosafety is gaining importance as many countries seek to benefit from agricultural biotechnologies without endangering public health and environmental safety. There are, however, many complex economic issues that need to be addressed in designing an efficient biosafety policy. Biosafety represents a mechanism of transferring costs of possible “accidents” (externalities) to be incurred by farmers and consumers to the research institutes and present generation citizens. In the process of transferring these costs, biosafety will generate benefits and costs to the society.

The benefits of biosafety include: reduced risks of biotechnology products and “accident” costs to the society; increased predictability about the expected time and money to get a new product on the market; increased accessibility of biotechnology products to a country; and, increased certainty and stability to the social framework, necessary for the development of biotechnology research industry. These potential benefits should be compared to the tangible costs of biosafety. To a research firm, biosafety represents both the time and opportunity cost; it will increase the research lag, production costs, transaction costs and marketing costs. Given the scarcity of human and physical resources, setting up and implementing a biosafety system also poses opportunity costs to the society.

The following issues need careful examination in designing a biosafety policy: 1) the goal of biosafety policy (whether it is to minimize “accident” costs or the sum of “accident” and “accident”- prevention costs); 2) the appropriate means of controlling risk (ex ante regulation, ex post liability or a combination of both); 3) the impact of regulations on science, research investments and the international transfer of technology and trade; 4) the incidence of biosafety costs; and 5) the size of biosafety system. In designing a biosafety policy, developing countries should emphasize the safe use of biotechnology rather than safety in biotechnology. This is particularly important in the climate of shrinking resources for agricultural research. The growing pressure for developing biosafety regulations should not lead developing countries into a situation that can best be characterized as “elephantiasis of biosafety and atrophy of biotechnology research.”

International Approaches to Biotechnology Regulations: An ICGEB/UNIDO Perspective

George Tzotzos, Science Coordinator, ICGEB/UNIDO, Austria

The manifest variance in international regulatory approaches is the result of country level considerations on:

- the competitive advantage of biotechnology over other conventional technologies
- public perception of biotechnology
- regulatory capability.

For as long as these continue to vary from country to country it is unlikely to have one unique set of regulations accepted globally. Nevertheless, it is reasonable to expect a certain convergence in what constitutes the scope of regulations. We are already observing a shift from technology-based to product - or risk-based regulations. The trend will be to focus on the safety, quality and efficacy characteristics of a given product rather than on the method by means of which it is derived. Until now, in many countries, the production method has been the trigger of regulatory oversight.

In addition, the case-by-case risk assessment approach is already giving way to fast-track approaches in which risk is evaluated on the basis of grouping products in given categories. Whereas the latter approaches are certainly practical they may eventually lead to exclusion of regulations of (a) certain types of manipulations (e.g. single-gene manipulations involving non-coding or non-expressed nucleotide sequences) (b) transgenic products for which there is no information indicating potential risks.

The wisdom of such exclusions can be challenged, particularly in the case of developing countries where a large number of ecological parameters are ill-defined and/or studied. In the majority of these countries, the advocacy of adopting guidelines and not regulations and of adapting existing legislation to cover biotechnology are likewise questionable on grounds of institutional capability and legislative history.

In view of the above considerations, UNIDO has established a Biosafety Information Network and Advisory Service (BINAS) which is aimed at strengthening national and institutional biosafety committees in member countries through:

- information support (e.g., remote access to relevant databases)
- human resource development (e.g., training courses)
- expert advice

An Overview of the Regulatory System for Testing Transgenic Plants in Mexico

Ariel Alvarez-Morales, Director, CINVESTAV, IPN., Unidad Irapuato, Mexico

In Mexico, the first application to carry out a field trial with transgenic material took place in 1987, and came from a biotechnology company in the United States. At this time, the government did not have a procedure to review applications for such field releases and therefore a committee was implemented.

This first committee included government officials from the Secretary of Health, the Secretary of Social Development and Ecology, the Secretary of Agriculture and Water Resources (SARH), the Office of Plant Health, many research institutes and agricultural colleges, etc.

The committee solved the initial problem posed by the pending application; however, it was very clear soon after that a large committee which included several high-ranking government officials was not appropriate simply because of the difficulties in getting all the people together and because of the wide range of opinions, many of which were not fully substantiated on social, technical or scientific principles.

Soon after this experience, it was decided that SARH should be in charge of the approval, supervision and regulation of the field trials. The SARH then decided that this matter should fall under the Office of Plant Health (DGSV) which then formally established the Committee for Agricultural Biosafety (CBA).

The CBA is headed by an official from DGSV and includes representatives from the Office of Agricultural Policies, the National Institute of Agriculture, Forestry and Livestock Research (INIFAP) which is the research branch of SARH. It also includes three members of the scientific community: The Postgraduate College of Agriculture, The Institute of Biotechnology of the National Autonomous University, and CINVESTAV, Irapuato.

Because Mexico, Canada and the United States of America were negotiating the North American Free Trade Agreement (NAFTA), it was necessary to insure to the three countries that the testing and release of transgenic plants would follow similar rules and guidelines so that biosafety of the region rather than a single country could be assured.

At the present moment, the requirements for testing and releasing transgenic plants is considered under the law, and there is a set of guidelines and procedures to implement this law. These guidelines are similar in all three member countries of NAFTA, with some differences to accommodate specific requirements or needs of each country.

The Safe Use of Biotechnology in Egypt

Michael Francis Ghaly, Research Associate, Agricultural Genetic Engineering Research Institute (AGERI), Giza, Egypt

Genetic engineering is considered one of the most promising tools of biotechnology in this era. The release of the products of genetic engineering research into the environment raises concern on accompanied risks to human health and to the environment.

The Egyptian government, realizing the necessity of establishing a national policy system to regulate such research, had already formed an Egyptian National Biosafety Committee (NBC) that comprises members from the Ministries of Agriculture, Health, Industry, Education, Sector of Environmental Affairs, and Scientific Research. The committee also includes members from the private sector, non-technical members that represent the community interest, policy makers and designers.

The activities of the National Biosafety Committee will cover:

- Formulation, implementation and update of safety codes
- Risk assessment and license issuance
- Training and expert advice
- Coordination with national and international organizations
- Reporting to governmental authorities

The NBC has agreed on gathering all the existing regulations and guidelines from different nations that have biosafety systems and to develop a draft for an Egyptian biosafety structure, including regulations and guidelines adapted to Egyptian conditions. The draft will be submitted to the NBC in the near future, accessing information to the structure, composition and activities of national and institutional committees, also the regulations and guidelines for laboratory, containment greenhouse and small scale field trials.

ISAAA's Biosafety Initiative

Eppie Zandvoort, EuroCenter Director, International Service for the Acquisition of Agri-Biotech Applications (ISAAA), John Innes Centre, Norwich, United Kingdom

In the past, developing countries have had the privilege of freely accessing non-proprietary traditional technology from the public sector. With the advent of new biotechnology applications, this situation is changing. The new applications are increasingly proprietary, owned primarily by private sector corporations in industrial countries, and generally not accessible to most developing countries.

The specific objective of ISAAA, the International Service for the Acquisition of Agri-Biotech Applications, is to develop new mechanisms to facilitate the sharing and transfer of, particularly proprietary, agricultural biotechnology applications from the industrial countries for the benefit of the developing countries. Brokered projects involve only near-term technologies with a high probability of success, using tissue culture, disease diagnostics, and transgenic plants.

ISAAA recognizes the urgent need to assist emerging countries in building a regulatory infrastructure for overseeing the correct and safe development and implementation of recombinant products, particularly transgenic plants, and ISAAA will only broker technology transfer projects that involve recombinant DNA products if they are developed, tested, and introduced in a safe way. Accordingly, we give top priority to assisting client countries to build their institutional capacity in biosafety regulation. This is achieved by sharing the biosafety experience of Australia and other countries of the Asian Pacific Rim, the USA, Canada, and Europe with nationals from developing countries.

In addition to individual training, ISAAA organized in 1992-93, three workshops, attended by nationals of 13 developing countries. ISAAA's unique approach is to remain neutral on specific regulatory policy which is the sovereign decision of each country.

Results of the African Regional Conference for International Cooperation on Safety in Biotechnology

Bert Visser, Special Programme Biotechnology and Development Cooperation, Ministry of Foreign Affairs, The Netherlands

In October 1993, the African Regional Conference for International Cooperation on Safety in Biotechnology was held in Harare, Zimbabwe. Participants came from Botswana, Kenya, Malawi, Mozambique, Namibia, South Africa, Swaziland, Tanzania, Uganda, Zambia and Zimbabwe. The aim of the conference was to contribute to the establishment of national biosafety procedures in each of the countries in the region. The conference discussed the international status of biotechnology, the international status of biosafety regulations, the assessment of regional needs and a priority setting for the establishment of biosafety procedures.

As a result of the conference, it was decided to establish a standing committee between countries in the region to facilitate regional cooperation. Regional cooperation may include the sharing of expertise, exchange of information on procedures, decision making and activities. A follow-up meeting has been planned for late 1994. In addition, a regional newsletter will be published through the standing committee.

Specific attention will be paid to current legislation in related areas, available infrastructure and expertise in the region, and ecological aspects of Eastern and Southern Africa.

PART III: TOOLS AND MODELS FOR EVALUATING RISKS/BENEFITS OF BIOTECHNOLOGY

The National Biological Impact Assessment Program (NBIAP): An Important Part of the U.S. Biosafety System

Patricia L. Traynor, NBIAP Coordinator,
Michigan State University, USA

Regulations and guidelines are key structural components of a biosafety system. To be fully functional, however, the system should include a mechanism to promote the exchange of information among all participants. In the U.S., the National Biological Impact Assessment Program (NBIAP) provides information resources to the agricultural and environmental biotechnology community, including academic and corporate research scientists, federal and state regulators, policy makers, administrators and the interested public.

NBIAP operates an electronic bulletin board that supports text files of relevant documents and searchable databases pertaining to biotechnology, biosafety, and field releases of genetically modified organisms. NBIAP also publishes a monthly News Report that contains timely information on biotechnology related developments in Washington, DC, advances in plant, animal, and microbial biotechnology research, patents and commentary. NBIAP conducts training workshops for Institutional Biosafety Committees on field testing and risk analysis, to support local committees in their oversight responsibilities and help ensure that field tests are conducted safely and in compliance with applicable laws.

Together, these activities foster communication within the biotechnology community at large, so that policy makers and regulators are kept informed of new data that address biosafety concerns, scientists are kept informed of new changes in the regulatory structure, and the public has full access to all available information. In this way, NBIAP serves an essential role in the biosafety system instituted in the United States.

Regulation of Contained Use and Release of Modified Organisms Within the European Union

Julian Kinderlerer, University of Sheffield, United Kingdom

In Europe, there are three Community Directives which govern the use of genetically modified organisms. The control of the use of biological agents, modified or not, is intended to protect workers from the risks resulting from exposure to biological agents, and identifies the containment required when handling biological material.

Unlike the U.S., the contained use of modified microorganisms is formally regulated (Directive EC 90/219). Organisms are classified as being either in Group I or Group II. Group I organisms are essentially those not pathogenic to humans; Group II are all others. The handling of organisms relates to the group and to a risk assessment which is largely related to human health and safety, but taking into account environmental issues in the event of accidental or incidental release of the contained organism.

Risk analysis in the U.K. involves taking access (measure of probability that the modified microorganism will be able to enter the human body and survive); damage (likelihood of harm resulting from exposure); and expression (anticipated or known level of the inserted gene product). These parameters allow an estimation of containment required for the use of the organism.

The release of modified organisms is regulated on a case by case basis. A large number of questions are asked of an applicant which allows an estimate of risk. These relate to the characteristics of the organism, vector and the modified organism. Questions are also asked about the site of release and the interaction of organism and the environment, including potential environmental impact and characteristics affecting the survival of the organism within the environment. Applicants are required to indicate emergency plans. As knowledge is gained, fast track procedures are to be introduced.

Biosafety Research and Assessment of Technology Impacts in Switzerland (BATS): Objective and Programme

Othmar Käppeli, Agency BATS, Basel, Switzerland

The activities of BATS comprise the documentation and the transfer of relevant knowledge concerning biosafety research and technology impact assessment issues. The analysis of biotechnology impacts and the elaboration of science and technology communication concepts are in the focus of BATS. The actual objectives are:

- establishment of a specialist database by monitoring and evaluation of
  - international biosafety research and scientific literature
  - international meeting reports
  - international regulatory activities and
  - technology impact assessment studies

- communication of knowledge by
  - providing the necessary scientific tools for safety assessment (derived from scientific papers, guidelines, legislation, research projects)
  - in-depth studies on particular issues of safety assessment
  - teaching and training
  - support in organizing national biosafety research
  - organization of meetings

Relevant information will be stored in a database which will be made available to scientists, authorities, industry and other interested users. The database subjects will focus on biological, ecological and technical aspects. An expansion on ethical, sociological and economic impacts of biotechnology is considered. A subject catalogue for the database has been designed. The content of the database is gradually expanded in collaboration with potential users in order to establish a database adapted to user needs. In order to achieve a contribution to the international information network, a coordination is initiated with other databases and institutions, e. g., in Europe and the USA, offering data on related areas.

Risk Assessment for Commercialization of Transgenic Crops

Jane Rissler, Biotechnology Specialist,
Union of Concerned Scientists, USA

Developing countries have an opportunity to consider the experiences of the United States as they prepare regulatory oversight of small scale and commercial applications of transgenic crops. In the United States, companies are ready to commercialize transgenic crops. Some transgenic crops will present ecological risks — risks of weediness and flow of new genes to wild plants–including those in centers of crop diversity. The U.S. federal government has not developed a strong regulatory program to assess and control risks. Moreover, the 1,000 field tests that have been conducted were designed to gather agronomic data. There have been few experiments designed to examine ecological risks.

The Union of Concerned Scientists, in a recent report Perils Amidst the Promise, has proposed a scheme for assessing weediness and gene flow before commercialization. The scheme relies on both existing data and the generation of new data on transgenic plants — both the transgenic crop and wild plants that receive the new genes. The center of the proposal is the use of population replacement capacity as a predictor of weediness.

Population replacement capacity is determined by two components: population replacement rate and seed bank persistence. The ecological experiments can be conducted concomitantly with small scale experiments to determine agronomic traits.

The Union of Concerned Scientists recommends that commercialization be halted in the United States until the federal government develops a strong regulatory program to control the risks. That program should also take in to account threats to centers of diversity around the world. Developing countries may want to consider adding ecological risk assessments to small scale tests of transgenic crops as a way of preparing for the eventual large scale release of engineered crops.

Safe Deployment of Transgenic Plants Expressing a B.t. Gene in Agricultural Systems

Roy L. Fuchs, Regulatory Science Consultant,
Monsanto Company, USA

After more than a decade of research and over 1,000 field tests with plant varieties developed via biotechnology, the first products are poised for market introduction, pending appropriate regulatory approvals. One of these products is a new cotton variety that is protected against damage and yield loss caused by the lepidopteran insect pests.

Monsanto has completed an extensive food, feed and environmental safety assessment of this product, addressing the questions and concerns raised by the three U. S. regulatory agencies (USDA, FDA and EPA) as well as by the public. The safety assessment focused on two essential questions: 1) Are the introduced proteins safe for food, feed and environmental uses? and 2) Is the insect protected cotton variety "substantially equivalent" to the current commercial varieties in terms of compositional and nutritional quality?

The results of this safety assessment show that there are no food, feed or environmental safety concerns identified for the two introduced proteins (*Bacillus thuringiensis* var. kurstaki and neomycin phosphotransferase). The insect-protected cotton variety was also shown to be "substantially equivalent" to commercial cotton varieties in terms of: outcrossing, competitiveness, aggressiveness, composition of macronutrients (oil, protein, carbohydrate, ash), individual fatty acids, as a feed for rodents and birds, and in the levels of the endogenous toxicants (gossypol, aflatoxin and cyclopropenoid fatty acids).

These studies have established that there are no food, feed or environmental concerns raised after extensive safety assessment of the insect-protected cotton variety and that this variety is equivalent in composition and nutrition to the varieties currently commercialized.

PART IV: LABORATORY, GREENHOUSE AND FIELD TESTING OF TRANSGENIC GERMPLASM

Biosafety Regulations and Guidelines in the United States

Patricia L. Traynor, NBIAP Coordinator, Michigan State University, USA

The regulation of biotechnology research and its products comes under the authority of several federal agencies. The National Institutes of Health (NIH), the U.S. Department of Agriculture (USDA), the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA), have primary responsibility for ensuring the safety of human health and the environment with respect to genetically modified organisms and their products. In cases where more than one agency has jurisdiction, a lead agency is designated.

Laboratory research is subject to the NIH Guidelines for Research Involving Recombinant DNA Molecules. These guidelines prescribe four levels of containment for experiments that pose different levels of risk. Revised guidelines, completed but not yet approved, contain new sections for experiments with GMOs conducted in greenhouses and animal facilities.

USDA's Animal and Plant Health Inspection Service (APHIS) regulates the importation, interstate movement, and release into the environment of transgenic plants and animals. A permit is required for all such introductions, except those that meet a specified set of eligibility criteria and performance standards. This latter group requires only notification of the agency prior to introduction. As products move toward commercialization, companies may petition for a determination of regulatory status, which provides a means for APHIS to find that a product is no longer subject to their regulation.

EPA regulates the environmental release of microorganisms and GMOs having pesticidal properties. At present, final EPA rules for biotechnology applications are not yet in place.

The FDA is responsible for ensuring the safety and effectiveness of genetically engineered products such as food and feed, food additives, drugs, and biologics. Thus, FDA oversight applies to products that have moved beyond laboratory development and field testing and are ready to enter the marketplace.

A Critical Review of Field Test Results Using Genetically Engineered Crop Plants

Philip J. Dale, Brassica and Oil Seeds Research Department, Cambridge Laboratory, John Innes Centre, Norwich, United Kingdom

Worldwide there have been about 1,000 field releases of transgenic crop plants in more than twenty countries, in 30 or more crop species, over a period of 8 years. The purposes of the releases have included academic and commercial research, to understand how genes are regulated, to assess stability of expression through development and inheritance and to address questions relevant to risk assessment.

Considerable variation is observed between plants transformed with the same gene construct. This can result from differences in transgene copy number, from transgene position effects, pleiotropic effects and somaclonal variation. Field experiments aimed at measuring the extent of cross pollination between transgenic and non-transgenic plants have provided data on the distance pollen can travel and on the sexual compatibility between crop plants and their related species. This information is being used by the regulatory authorities to define isolation procedures for the evaluation of novel transgenic plants.

Other release experiments have involved planting a range of the currently available transgenic plants into natural habitats to determine their impact compared with non-transgenic control plants. So far, transgenic plants have not been grown in natural habitats where they would display a selective advantage.

AGERI/ABSP Maize team members Dr. Mohamed Soliman and Ms. Shireen Assem of AGERI interact with Dr. Heng Zhong at Michigan State University during a scientific exchange visit to MSU.

Regulatory Requirements in the Production and Testing of Transgenic Corn

Martin Wilson, Cell Biologist/Project Leader,
ICI Seeds, Inc., Slater, Iowa, USA

Regulatory requirements for working with transgenic corn are best considered under the headings of: (a) laboratory, (b) greenhouse and (c) field.

(a) Laboratory
Insect and rodent control measures must be taken. One easy way to address this issue is to engage the services of a company which specializes in insect and rodent control. All media and disposables which come into contact with transgenic materials have to be autoclaved prior to disposal. Appropriately marked and autoclavable bags to collect media (agar) and plastic are required.

(b) Greenhouse
Soil can be processed in small quantities by autoclaving. In larger quantities steam sterilization in a large (150 gallon) container is a more practical option. Plant parts have to be processed through the autoclave in biohazard bags.

(c) Field
Measures to contain transgenic plants in the field include the planting of hybrid corn around the experimental plots to dilute any movement of transgenic pollen (research shows that this expedient effectively limits pollen movement to 15 feet), maintaining a distance of at least 660 feet between the transgenic plants and any open pollinated foundation seed fields and ensuring that any seed produced on the transgenic plants as a result of an unplanned pollination is not used for replanting or for seed.

ICI Seeds works closely with USDA–APHIS in the testing of transgenic corn. The burden of permit application preparation has been considerably lightened with the introduction by APHIS of a notification system for field experiments with transgenic corn. Testing is now moving into multi-site yield trials as transgenic lines progress to commercialization.

Field Testing of Transgenic Cucurbits Resistant to Viruses

Hector Quemada, Associate Director,
Vegetable Biotechnology, Asgrow Seed Company/Upjohn Co., USA

Much progress has been made in recent years in the development of virus resistant cucurbits through traditional breeding, both in the United States and in Egypt. The Asgrow Seed Company's vegetable biotechnology group assists our breeders in the development of virus resistant cucurbits by offering an alternative means of obtaining this resistance. There are two strategic reasons for this: 1) the use of molecular constructs for multiple virus resistance can increase a breeder's efficiency by enabling him to move the virus resistance as a single dominant locus, and 2) the range of strains against which the transgenes offer resistance might differ from that of the traditionally bred resistance, therefore offering the opportunity for more broad and durable resistance.

Field testing has been an important component of our development process. Standard test conditions for these trials, particularly with respect to genetic isolation standards, have been developed through consultation with an authority in the field of cucurbit pollination biology, the recommendations arrived through the experience of breeders, and through published literature. Subsequent confirmation of the validity of these test conditions — by us and others — have shown that in this case, information from the existing body of knowledge can provide good predictions about the behavior of a transgenic organism.

Through field testing, a commercially useful transgenic line of squash has been developed. Our experience with several lines of transgenic squash in the field, particularly with respect to the identical behavior (with the exception of the virus resistance) of transgenic lines and the original lines from which they were derived, led us to conclude that our transgenic line showed no plant pest characteristics and that it no longer should be regulated as a plant pest. We have subsequently been involved in discussions with USDA/APHIS in order to provide them with additional substantiation of this conclusion. These additional data have strengthened our original petition for deregulation of this line.

Greenhouse and Field Testing of Transgenic Potatoes

David S. Douches, Assistant Professor, Department of Crop and Soil Sciences, Michigan State University, USA

Being a plant breeder with a primary objective to develop and release improved potato cultivars, I am involved with the field testing of transgenic potatoes. The breeding program is divided into varietal development and germplasm enhancement. I classify the transformation of cultivars with agronomically useful genes as a form of germplasm enhancement, therefore, the transformation process is another means to introduce genes into the cultivated gene pool. My breeding program at MSU has the facilities to produce transgenic potatoes, thus, my role is to acquire useful genes, transform desirable genotypes, greenhouse and field test these transgenic plants and, if valuable genotypes are identified, follow the avenues to commercialization.

The model I use for my decision making involves the consideration of the crop, the gene and the location. Being at the applied end of the process of handling transgenic plants, I do not get involved with untested genes. The genes I am using (B.t. toxin gene, viral coat protein genes and starch gene) pose little risk to the environment in small field tests or have negligible food safety issues. In Michigan, the cultivated potato has no wild relative that it can cross to, therefore, there is no risk of transferring genes outside the potato field. In conclusion, I make the decision to work with genes that have agronomic value and pose little or no risk to their deployment in a potato research plot.

SECTION 3

INTELLECTUAL PROPERTY RIGHTS

Intellectual Property Rights and Biotechnology in Developing Countries

Atef Mohamed El-Azab, Counsel, Academy of Scientific Research and Technology and Ex-Vice President of the Council of State, Egypt

John H. Barton, George E. Osborne Professor of Law, Stanford Law School, USA

Intellectual property rights are important for biotechnology in Egypt and other nations with substantial biotechnology programs because they can provide incentives for local researchers and firms, they have come to be required by international law, and they can assist in the international transfer of technology.

The intended purpose of an intellectual property system is to create incentives for research by giving the successful researcher an opportunity to protect its market against imitators for a reasonable term of protection. Thus, with a plant breeders' rights system, the breeder can keep others from selling its variety without its permission.

Protection of a variety in this way or through the regular patent system is an important part of encouraging the evolution of a private seed industry. If private firms are able to breed their own varieties, they clearly need protection against copying. Even if they simply buy varieties produced by the government, the possibility of exclusive rights permits them to be more confident in such desirable marketing expenditures as providing training to farmers or conducting additional tests to ensure that a variety is adapted to a particular region.

As a nation moves toward genetic engineering, it needs to ensure that the developer of a novel gene can obtain appropriate protection and thus needs more than plant breeders' rights. The major research effort in this form of biotechnology is in identifying the gene and in learning how to insert it into crop plants. If another breeder can simply transfer the gene to another variety, as through backcrossing, the genetic engineer loses the benefit of its research investment.

IPR Workshop Speakers: (left to right)
Prof. Rebecca Eisenberg, University of Michigan Law School,
Prof. John Barton, Stanford Law School, and
Dr. Frederic Erbisch, Michigan State University

Thus, if the private sector (local or international) is to do genetic engineering oriented to the nation's needs, it must be able to patent the use of a gene identified and transferred through biotechnology. Not only is an intellectual property system likely to be useful to the nation, it is also becoming required by international law. The new Uruguay Round "Agreement on Trade-related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods," defines minimum standards for intellectual property law in a number of areas including biotechnology. In particular, it requires that patents be available in all fields of technology. This is clearly meant to include pharmaceuticals and agricultural chemicals; it covers genes as well.

Intellectual property rights are important for biotechnology, they can provide incentives for local researchers and firms, they have come to be required by international law, and they can assist in the international transfer of technology.

The agreement goes on to say that plants and animals (except for microorganisms) and essentially biological processes for their production can be excluded from patentability, but that there must be protection for plant varieties, either through patents or through a sui generis system such as plant breeders' rights.

These obligations, however, can be substantially postponed. A developing nation need not enact the patent law changes for 5 years or certain of the product patent law changes for 10 years (and the provisions on plants and animals are to be reviewed four years after the agreement enters into force). The least-developed nations have another 10 years.

As a nation moves toward genetic engineering, it needs to ensure that the developer of a novel gene can obtain appropriate protection.

Egypt is already moving to strengthen its laws.

Egypt is already moving to strengthen its laws. Under its old law, Law No. 132 of 1949 on patents, there is no food or pharmaceutical product protection, but only a possibility of 10-year process protection. According to the law's explanatory memorandum, food products are excluded on the ground that they do not constitute an invention and that a monopoly over producing such products is harmful to the public's health.

Under a new draft law, agriculture, foodstuffs, medical drugs, pharmaceutical compounds, plant and animal species, and microbiological organisms and products are included as patentable subject matter. This is a significant strengthening from the current law and brings Egypt in line with international standards as set forth in the GATT text discussed above.

In other provisions, the new draft increases the patent term to the new international norm of 20 years from filing. It includes a pipeline provision stating that, for a one-year period from the effective date of the law, a firm will be able to obtain protection for a medical drug, pharmaceutical, agricultural, or chemical product that was not protectable under the old law if (a) the product has not been marketed in Egypt prior to the effective date of the new patent law, and (b) the product is the subject of an unexpired patent elsewhere. In such a case, the term of protection will be equal to the term remaining in the other country.

Egypt will have to confront further issues in a world that is both privatizing and looking more to intellectual property. It is already exploring technolog y transfer questions and plant variety protection.

Mr. Ismail Abdel-Hamid of AGERI, gains hands on experience in potato transformation techniques at Dr. David Douches laboratory, Michigan State University

Under a new draft law, agriculture, foodstuffs, medical drugs, pharmaceutical compounds, plant and animal species, and microbiological organisms and products are included as patentable subject matter.

The draft also deletes a provision in existing law that permits the government to expropriate patents for public utility and instead permits only compulsory licenses, in certain cases, with fair remuneration. It widens the rights of employers vis-a-vis employees and creates a new utility model provision permitting coverage of innovations that are not great enough to be patentable, such as a new shape or composition for a tool or implement.

New law such as this, and expanded understanding of intellectual property, should assist Egypt to acquire technology more readily and to enter into more effective scientific strategic alliances that will help in developing new technologies and in strengthening local research capabilities. Agreements, for example, between a developed world university and an Egyptian research center such as AGERI are becoming increasingly complex, as they have to consider issues such as inventions made cooperatively, the expense of filing patent applications, the allocation of decision-making with respect to future inventions and the participation of international and possibly of national firms in the research.

Looking into the future, Egypt will have to confront further issues in a world that is both privatizing and looking more to intellectual property. It is already exploring technology transfer questions and plant variety protection. As AGERI completes new transgenic varieties and as a private seed industry evolves in Egypt, it will have to consider the terms and procedures for the release of the new varieties to the private sector and, with the Biodiversity Convention now in force, it will have to define appropriate terms and provisions for the transfer of genetic

Patent Protection in Biotechnology

material newly identified within the nation.

Rebecca S. Eisenberg, Professor of Law, University of Michigan, USA

Patent rights are typically justified as a means of encouraging investment in research and development that might not be profitable if firms that had not shared in the initial risk and cost were free to copy successful new inventions. A patent confers the right to exclude others from making, using and selling the invention within the territory of the nation granting the patent for a limited term — 17 years from the date the patent issues under U.S. law, and 20 years from the date the application is filed in many other countries. In some circumstances, a patent on a process also confers a right to exclude sales within the nation of a product manufactured abroad through the use of the patented process. In order to obtain a patent, the inventor must file an application that includes a full description of the invention and of how to make and use it. In Europe and Japan, this disclosure is made public 18 months after the application is filed; in the U.S., it is made public as soon as the patent is issued. The extent to which patent systems achieve their goals of inducing the development of new inventions and promoting disclosure to the public is an empirical question with no clear answers. Patent systems involve certain costs that must be weighed against their benefits, including increased prices and reduced supply of products covered by patents as well as administrative costs.

The basic requirements for patent protection are novelty, utility or industrial applicability, and nonobviousness or inventive step. Determining whether an invention is new and nonobvious requires searching through certain categories of prior art, including prior patents, publications, and public uses of inventions, to determine the state of knowledge in the field at the time the invention was made or the patent application filed. An invention that already existed in the prior art is unpatentable for lack of novelty. A new invention might still be unpatentable if it would have been obvious to a person of ordinary skill in the field in light of prior art. The utility requirement limits patent protection to inventions with practical applications.

The range of biotechnology inventions qualifying for patent protection has expanded tremendously in the past 15 years, particularly in the U.S. In 1980, the U.S. Supreme Court upheld the patentability of a living, genetically-engineered microorganism. Since that time the U.S. utility patents have been issued on plants, animals, and DNA sequences. Claims to such inventions must be carefully drafted so as to distinguish them from any naturally occurring products. The range of biotechnology inventions falling within patentable subject matter is somewhat more restricted outside the U.S.

The commercial value and significance of a patent depends on the scope of the patent claims, which in turn depends on the breadth of the disclosure in the patent specification. The disclosure must be adequate to enable a skilled person reading the patent application to make and use the invention as broadly as it is claimed without undue experimentation. This determination varies according to the background knowledge of other skilled people working in the field at the time of the disclosure and is specific to the facts of a particular case. U.S. courts have used the enabling disclosure to hold invalid broad claims in a number of recent biotechnology patent cases. At other times the U.S. Patent and Trademark Office has issued biotechnology patents of extremely broad scope.

The technological scope of a patent monopoly is determined by the language of the patent claims. Ordinarily, if the defendant's product or process includes each of the elements of a patent claim, infringement will be found. Sometimes a court will find infringement even though the defendant's product or process fails outside the literal scope of a patent claim under the doctrine of equivalents, if the defendant's device does the same work in substantially the same way to accomplish substantially the same result as the patented product or process.

Participants of the 1994 AGERI/ABSP Intellectual Property Rights Workshop

The doctrine of prosecution history estoppel limits the doctrine of equivalents by holding that a patent owner may not use the doctrine of equivalents so as to recapture subject matter deliberately surrendered in response to a rejection of broad claims by the patent office in light of prior art.

Defenses to a patent infringement action include invalidity of the patent, inequitable conduct or fraud during patent prosecution, misuse of a patent to violate antitrust laws, experimental use of the invention and unreasonable delays in bringing suit. Remedies for proven infringement include preliminary and permanent injunction, compensatory damages in the amount of lost profits, established royalty or reasonable royalty, increased damages up to treble the amount of compensatory damages in the discretion of the court for willful infringement, interest and attorneys fees.

The Paris Convention for the Protection of Industrial Property requires that signatory nations allow nationals of any country in the Union the same rights that they extend to their own nationals under their patent laws. The Patent Cooperation Treaty streamlines filing procedures where an applicant seeks patent protection in multiple countries that are parties to that treaty.

John H. Barton, George E. Osborne Professor of Law, Stanford Law School, USA

Intellectual Property and Plant Breeders' Rights

In addition to patents, plant breeders' rights are often available and provide an intellectual property system designed specifically for breeders. Under this system, a farmer is, in general, able to reuse harvested crop from a protected variety as seed; this is probably not the case for a variety protected under the regular patent law. Moreover, a breeder can freely use another's protected variety in breeding. This freedom is slightly restricted in a new international version of plant breeders' rights under which a breeder may not market a variety that is "essentially derived" from another's variety. Typical examples include a variety in which one gene is changed, as by genetic engineering or backcrossing.

In general, for conventional breeding, plant variety protection is adequate. For biotechnology-based breeding, however, the right to protect a gene under the regular patent system is essential; otherwise, the benefit of protection can be lost to another breeder who breeds the inserted gene into his or her varieties.

In understanding the implications of a regular patent, it is important to distinguish the specification, which describes and discloses the invention, from the claims, which define the actual legal monopoly. In a patent of a gene, for instance, the specification will give the sequence of the gene or otherwise describe how to obtain it. The claim will typically cover an isolated DNA fragment containing the sequence, a plasmid containing it, a plant that has been transformed with it, and the seeds or progeny of such a plant that contain the relevant gene. Thus, the patent does not cover conventional breeding with the gene as found in its natural background, because such breeding never isolates the DNA or creates a plasmid or transformed plant. In addition to gene patents, some in the United States have patented varieties under the regular patent system, presumably to provide stronger protection. There are also a variety of process patents relevant to biotechnology, e.g., the original Cohen-Boyer patent on the process of genetic engineering.

A number of important international treaties create a framework for intellectual property systems. Traditionally, the most important were the Paris Convention, governing regular patents and UPOV (International Union for the Protection of New Varieties of Plants) governing breeders' rights. The Paris Convention has an international secretariat called WIPO (World Intellectual Property Organization) in Geneva, Switzerland. The UPOV secretariat is also called UPOV and is located in Geneva. Recently, intellectual property has become coupled with trade. The result has been not only a number of international disputes about the use of unilateral trade sanctions in the intellectual property area but also a new Uruguay Round agreement on intellectual property. This agreement requires protection of pharmaceuticals and genes; it does permit exclusion of living plants and animals from patentability, but requires use of a sui generis system such as plant breeders' rights for plants. These obligations, however, need not be enacted into law (save for certain pipeline provisions) for 10 years for a developing nation that does not currently protect such products and for 20 years for the least developed nations.

Entities license intellectual property and materials for a number of reasons. They license out technology in order to market it; the Agricultural Genetic Engineering Research Institute (AGERI) in Egypt, for example, may soon be able to license the technology contained in a new seed to an Egyptian firm for distribution to the farmer. They license in technology that they may not have themselves or as part of a cooperative development process, such as that between AGERI and Michigan State University. In these agreements, it is important to describe the technology (and to deal with the issue of technologies that may be derived from the transferred technology or material) or technology for research or commercial purposes and, in appropriate cases, to define royalty obligations. Agreements will typically, also, have provisions governing such issues as liabilities in the event that a patent is invalid, obligations and liabilities respecting biosafety and arrangements for dispute settlement and termination. With the new Biodiversity Convention, the global community has recognized the sovereign rights of source nations over genetic materials located within their boundaries; transfers of these materials will probably be under new forms of license or material transfer agreements still to be negotiated.

Intellectual Property and Licensing Agreements

Frederic Erbisch, Director, Office of Intellectual Property, Michigan State University, USA

Two basic points were evaluated. The first dealt with the importance of establishing an institutional intellectual properties policy and the other with the components of a typical license agreement.

An institutional intellectual properties policy describes how these properties are handled and, most importantly, who owns them. Establishing ownership is very important in patenting and licensing of inventions. Without clear ownership, patenting may be impossible and licensing very difficult. The policy also provides the researcher with guidance in the handling of his/her inventions and what reward can be expected for inventing.

Three terms or components a license agreement need considerable attention. One is the definition of the licensed materials or process. This definition includes the concerned patents and/or pending patent applications and know-how. It must also include a complete description of the biological material which is being licensed. The other two components are Grant of License and Royalties. Both need considerable review and study to determine the appropriate terms for each. For example, for the particular material or process being licensed it may be best to do this under a non-exclusive or exclusive license or a variation of an exclusive license. Also, the royalty rate determination depends on a number factors including sponsor of the research, stage of development and cost of commercialization. Most of the other components of a license can be handled routinely.

SECTION 4 RESEARCH AND NETWORKING

Project Evaluation Workshop, January 30th & 31st, 1994

Research Accomplishments in the First Year of the AGERI/ABSP Collaboration

Magdy Madkour/AGERI, Claude Fauquet/ILTAB-Scripps, Rebecca Grumet/MSU, David Douches/MSU and Mariam Sticklen/MSU

Egypt is facing the challenge of increasing agricultural productivity to feed its growing population while simultaneously protecting the environment and conserving its natural resources. To meet this challenge, Egypt is looking for alternatives to the traditional systems of food production. Biotechnology offers significant opportunities to maximize productivity in the agricultural sector in an environmentally responsible way. In this context, the USAID Agricultural Biotechnology for Sustainable Productivity (ABSP) project, through a new cooperative agreement with USAID/Cairo, has become a partner with Egypt's agricultural research community.

Initiated in October 1992, this cooperative project involves the Agricultural Genetic Engineering Research Institute (AGERI) of the Agricultural Research Center (ARC) in Egypt and several institutions in the U.S., bringing together scientists, regulatory and legal consultants from AGERI, Michigan State University (MSU), Cornell University, ILTAB at The Scripps Research Institute, University of Arizona, USDA-APHIS, Stanford Law School and the International Potato Center (CIP-Egypt). The AGERI/ABSP project encompasses the research, policy, networking and management aspects of biotechnology.

An Integrated Approach

The AGERI/ABSP project takes an integrated approach to the development of specific research products. The project's goal is to mutually enhance both Egyptian and U.S. institutional capacity for the use and management of biotechnology research to develop environmentally compatible, improved germplasm. Along with its product-oriented research focus, the project also examines issues such as appropriate technology transfer, biosafety (to protect Egypt's environment and human health), intellectual property rights (IPR) to exploit the knowledge, human resource development and linkages between the public and private sectors in both countries.

Research Focus

Multidisciplinary commodity teams have been established which include plant breeders, entomologists, virologists, microbiologists, molecular biologists, agronomists, social scientists, et al, a key component in novel product development and deployment. Research focuses on two constraints to productivity — virus and insect pests — in a limited number of very important food crops in Egypt (maize, potato, cucurbits and tomato).

The goal for the maize team is the development of *Bacillus thuringiensis* (B.t.) transgenic maize germplasm for resistance to stem borers, a major limiting factor to maize production in Egypt. The potato team focuses on the development of B.t. transgenic potato germplasm for resistance to the potato tuber moth, a serious pest of the potato in Egypt and North Africa. The cucurbits team aims to develop potyvirus resistant cucurbits crops using coat protein genes via genetic engineering, which builds on many years of work done through conventional breeding. The tomato team is working to produce tomato yellow leaf-curl virus resistant germplasm using coat protein genes through an *Agrobacterium*-based transformation system.

Resistance to Stem Borers *in Maize*

Egypt grows approximately 750,000 hectares of maize. Stem borers are the major constraint to maize production in Egypt and worldwide. In Egypt, three species of stem borers attack maize of which the *Sesamia cretica* is the most serious pest. The major thrust of the maize research is to clone and characterize insect resistance genes and transfer these genes into Egyptian maize for resistance to maize stem borers. To this end, collaboration has been established between breeders, molecular biologists and entomologists located at AGERI and MSU. The key collaborators are Drs. Hanaiya El-Itriby, Ebtissam Hussein, Yehia Osman, Mohamed Soliman and Mamdouh Idris from AGERI and Dr. Mariam Sticklen at MSU.

Interactions and progress during the first year of the project have been very good. Dr. Sticklen visited Egypt in January 1993, to implement the collaboration and Drs. El-Itriby, Hussein, Taymour, Soliman and Ms. Shireen Assem have visited MSU to facilitate the technology transfer

The AGERI/ABSP maize team: Dr. Mohamed Soliman (AGERI), Dr. Karim Maredia, (ABSP Network Specialist), Dr. Ebtissam Hussein (AGERI), Dr. Mamdouh Idris (AGERI): Dr. Mariam Sticklen (ABSP), Dr. Hanaiya El-Itriby (AGERI) and Dr. Yehia Osman (AGERI).

to Egypt.
Transformation of maize, as with other members of the Gramineae family, is very difficult and also requires specific regulatory sequences to obtain a sufficient level of foreign gene expression in transgenic plants. For example, Cauliflower Mosaic Virus 35S promoter has been demonstrated to be incapable of controlling gene expression as well as it normally does in dicotyledoneous plants. The presence of an intron from a Gramineae plant (i.e., maize Adh intron, rice Act1 intron, etc.) has been shown to increase the foreign gene expression in gramineous plants. As a result, collaborators have initiated the construction of appropriate mini-genes.

Recent reports indicate that insects are developing resistance to B.t. and AGERI/ABSP scientists plan to deploy strategies that would prevent or delay the development of that resistance. One such strategy uses a combination of genes with different modes of action (pyramidal effect); the use of a codon-modified B.t. gene along with a GC rich plant chitinase gene is being considered.

The AGERI/ABSP research team finds it important to produce the genes to be used in their studies as much as possible. This issue becomes very important in the training of scientists in gene cloning and characterization, but it is also important in the context of intellectual property rights, since it is hoped that the transgenic plants will eventually be commercialized. AGERI has isolated several clones of the Egyptian strains of B.t. with promising results that have indicated a few of these clones encode the full length genes. Sequencing has been completed for one gene and work is in progress to design and codon optimize this gene.
A GC rich chitinase gene isolated and characterized in Dr. Sticklen's laboratory is to be expressed in *E. coli* and the recombinant product evaluated with and without B.t. protein and/or proteinase inhibitor II against maize stem borers by AGERI scientists in Egypt.

Dr. David Wright of ODA, United Kingdom, discusses potato production in Egypt with Dr. Ramzy El-Bedewy of the International Potato Center (CIP) research station in Kafr El-Zayat

The major thrust of the maize research is to clone and characterize insect resistance genes and transfer these genes into Egyptian maize for resistance to maize stem borers.

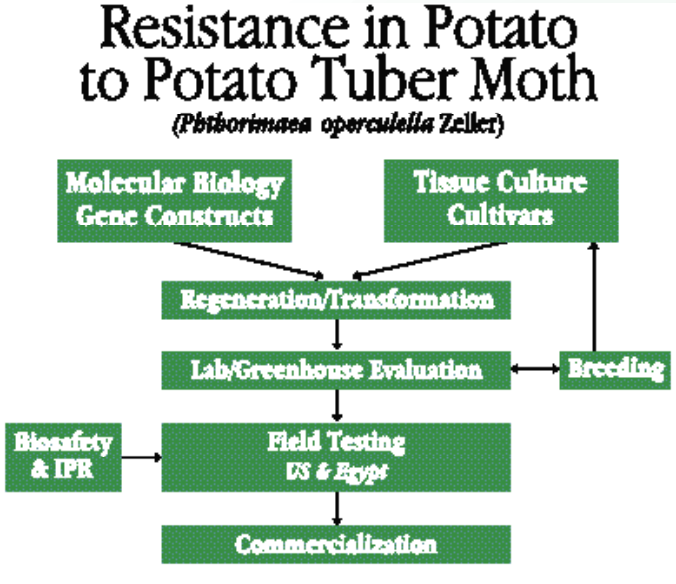
A plasmid containing Dr. Sticklen's chitinase gene driven by a rice actin promoter and intron was constructed by Dr. Soliman during his visit to MSU. In addition, a plasmid construction prepared by Dr. Ray Wu's group (Cornell University), containing the bar gene regulated by rice actin 1 5' sequences and a Nos terminator, will be used in a 4:1 ratio (plasmid containing the bar gene to plasmid containing the B.t.k. gene) to co-transform maize for selection. A plasmid containing the potato proteinase inhibitor II gene controlled by rice actin 1 5' sequences was also developed in Dr. Wu's laboratory.

The possibility of transforming maize genotypes via the shoot multiplication system developed in Dr. Sticklens's laboratory is being examined. Egyptian genotypes of maize have been used via the novel regeneration system, as well as immature embryo culture, for transformation studies. Both systems have proven successful. The shoot multiplication system has produced over 1,000 chemically-selected shoots. The immature embryo system has yielded R_0 transgenic maize (U.S. variety).

Potato Tuber Moth Resistance *in Potato*

The cultivated potato is an important export and local market crop in Egypt where eighty-six thousand hectares of land is used for potato production. Potatoes are planted three times per year and harvested in fall (December - January), winter (February - April) and summer (May - June). Egypt imports almost all of its seed potato from Europe. Imported seed is planted during the December/February planting and seed produced from this planting is stored and used for the fall or winter planting.

The major insect pest affecting Egyptian potato production is the Lepidopteran insect, the potato tuber moth (PTM) (*Phthorimaea operculella* Zeller). The potato tuber moth is destructive in its larval stage; it mines the foliage and tubers in the field, reducing yields by 30% and is even more destructive in storage where 50% infestation occurs. As larvae tunnel through the tubers they fill the tunnels with frass and webbing. These tunnels allow for secondary infection,



rendering the tubers unfit for market or seed use.

To help solve the PTM problem, a collaboration has been established between plant breeders, molecular biologists and entomologists located at AGERI and MSU to develop PTM-resistant transgenic potato germplasm for Egypt. The collaborating scientists include: Drs. Taymour Nasr-Eldin, Walid El-Yassaki and Mamdouh Idris at AGERI and Drs. David Douches, Edward Grafius and Walter Pett at MSU.

In the first year of the project, improved transformation and regeneration systems for various potato cultivars have been developed in the laboratory of Dr. Douches at MSU. Dr. Nasr-Eldin, Mr. Ismail Abdel-Hamid and Dr. El-Yassaki from AGERI have visited MSU to facilitate the technology transfer to Egypt. Transgenic potato plants previously developed in the Sticklen laboratory using a wild-type B.t. gene were tested at the field level at MSU facilities by Drs. Douches and Grafius. This test was to evaluate the level of resistance against the Lepidopteran *Manduca sexta* as a test insect and the agronomic qualities of transgenic plants. Laboratory cultures of PTM have been established in the laboratory of Dr. Grafius to provide a ready source of insects for testing newly transformed plants.

During the second year of the project, emphasis will be placed on the transformation of FL1607, Spunta, and Desiree potato cultivars with the Syn-B.t. gene developed by ICI Seeds, Inc. and with B.t. strains isolated in Egypt. Field tests of transgenic potatoes, both in the U.S. and in Egypt, to evaluate the levels of resistance and the agronomic qualities of these cultivars will have a high priority. Preliminary field tests will be conducted in the U.S. during the 1994 field season; thereafter, field studies will be conducted in both Egypt and the US. The incorporation of existing PTM resistant breeding lines with the transgenic lines will be emphasized in the development of a long-term resistance management strategy. Traditional breeding practices will be used to produce crosses between transformed and non-transgenic lines which will be evaluated for B.t. protein expression and resistance levels.

Potyvirus Resistance *in Cucurbits*

Approximately 75,000 hectares are planted to high-value cucurbit crops in Egypt each year. Cucurbit crops such as cucumbers, squashes, melons and watermelons are subject to severe losses due to virus infection. Cucumber mosaic virus (CMV) and the potyviruses zucchini yellow mosaic virus (ZYMV), watermelon mosaic virus (WMV) and the watermelon strain of papaya ringspot virus (PRV-W) can result in yield losses of 50-100%. These viruses cause problems throughout the world and have been particularly devastating in the Middle East.

The AGERI/ABSP cucurbits research team uses a combination of conventional breeding and molecular genetic approaches in its effort to develop virus-resistant cultivars of cucurbit crops that are well adapted for Egyptian agriculture. Collaborations have been established between breeders, molecular geneticists and virologists located at AGERI and the Horticultural Research Institute (HRI) in Egypt, and at MSU and Cornell University in the United States. Key participants in the scientific team include: Dr. Ahmed Abou-Salha (AGERI, tissue culture), Dr. Hamdy El-Doweny (HRI, plant breeding), Dr. Rebecca Grumet (MSU, molecular genetics, virology), Dr. Molly Kyle (Cornell, plant breeding, molecular genetics), Dr. Henry Munger (Cornell, plant breeding), Dr. Rosario Provvidenti (Cornell, virology), Dr. Mahmoud Rifaat (AGERI, molecular genetics, virology) and Dr. Abdel-Hamid Sabek (Plant Pathology Research Institute/ARC).

The cucurbits project has made good progress in the first year; Drs. Grumet, Munger and Provvidenti have visited Egypt to establish collaboration and observe research progress and Dr. Abou-Salha, Dr. Rifaat and Mr. Mohamed Saleh from AGERI have visited MSU and Cornell University, as well as several other institutions in the U.S., to facilitate technology transfer. Multiple-virus resistant cucumber, melon and squash materials resulting from many years of breeding effort have

Members of the cucurbits research team in attendance at the 1994 AGERI/ABSP Project Evaluation Workshop: Dr. Rosario Provvidenti, Dr. Hamdy El-Doweny, Dr. Abdel-Hamid Sabek, Dr. Ahmed Abou-Salha, Dr. Mahmoud Rifaat and Dr. R.C. Yadav

The major insect pest affecting Egyptian potato production is the Lepidopteran insect, the potato tuber moth (PTM) (Phthorimaea operculella Zeller).

been exchanged between the breeding programs at Cornell and the HRI in Egypt.
The ABSP project was able to utilize a ZYMV coat protein (CP) gene clone and transgenic melons that had been produced in Dr. Grumet's laboratory at MSU. Greenhouse trials indicate that this gene appears to confer a high level of resistance to both U.S. and Egyptian strains of ZYMV. Commercially important Egyptian melon cultivars were provided to Dr. Grumet's program and transgenic shoots transformed with the ZYMV-CP gene now have been obtained for one of those cultivars.

Transgenic ZYMV coat protein-expressing melon plants (right) are protected from infection by the Egyptian strain of ZYMV. Control plant (left).

In all, there have been fruitful interactions and successful collaboration among the participating research groups. During the second year of the project, materials supplied by breeding programs will be field tested and the transgenic melon cultivars that have been engineered for ZYMV will be developed further.

Tomato Resistance to Geminiviruses

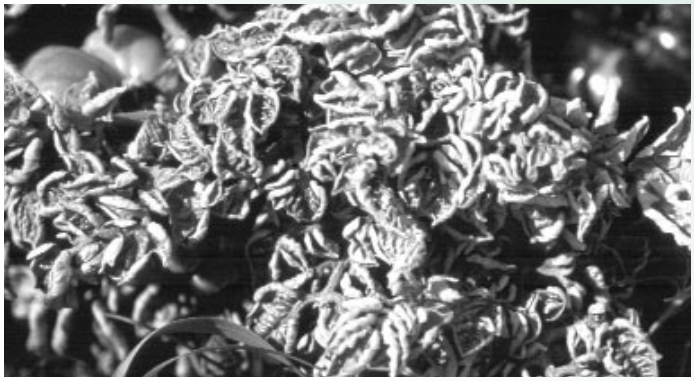
Egypt cultivates approximately 500,000 hectares of tomatoes. The tomato yellow leaf curl (TYLCV) is a serious viral disease problem in Egypt, the Middle East, Africa and Southeast Asia. In Egypt, yield losses of up to 35% have been reported from this disease. White flies serve as a vector and there are virtually no efficient control methods available to prevent the development of disease. There are no resistant varieties available and no effective treatments against either the vector or virus.

The goal of the tomato research team is to produce transgenic tomatoes resistant to the Egyptian strain of TYLCV. Collaboration has been established between breeders, molecular biologists and virologists located at AGERI in Egypt and at ILTAB/The Scripps Research Institute in the United States. Key collaborators are; Drs. Naglaa Abdallah, Nagwa Aref and Ahmed El-Bakry from AGERI and Drs. Roger Beachy, Claude Fauquet and Malla Padidam from ILTAB. To accomplish the research goal, the tomato team is investigating the molecular biology of the virus and establishing a molecular strategy to control the virus and transfer the viral genes involved in this strategy into Egyptian tomato varieties.

Significant progress has been made in the first year. Dr. Claude Fauquet visited Egypt in January 1993, to establish the collaboration while Dr. Nagwa Aref, Dr. Ahmed El-Bakry, Mr. Mohamed Abdel-Wahed from AGERI have visited ILTAB to facilitate technology transfer.

Part of the AGERI/ABSP tomato research team met with tomato producers in Ismailia, Egypt, during the Project Evaluation Workshop. From left to right; tomato farmer, Dr. Malla Padidam (ILTAB), Dr. El-Bakry (AGERI), K. Essam (AGERI), K. Ashem (AGERI), M.A. Hamada, (Egyptian Agricultural Consultations Office).

In order to properly identify the geminivirus(es) involved in the disease, the team has established a quantitative taxonomic classification of geminiviruses in order to recognize the virus strains from the virus species and determine if this disease is caused by more than one virus strain or virus species. From these findings, a diagnostic kit using primers has been established. An isolate of the virus (TYLCV-Egypt) has been sequenced and the corresponding antibodies have been produced in Egypt. In order to perform tomato transformation, many chimeric constructs have been made using different viral genes of the TYLCV and are used for tomato transformation. At the same time, protocols of regeneration of local Egyptian varieties have been established and are being optimized for transformation. Transformation of an American variety of tomato has been achieved and the TYLCV-Egypt constructs are now used to produce more transgenic tomatoes.



Atypical symptoms of tomato yellow leaf curl virus (TYLCV) observed in Ismailia, Egypt.

During the second year of the project, the study of virus(es) will be continued to determine whether there is more than one virus involved in this disease. Studies will be done using the diagnostic kit of primers developed in the first year of the project. More serological tools will be produced to be used for detecting the expression of the transgenic plants.

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The viral gene constructs made in the first year will be integrated into an American tomato variety to find the appropriate control strategy for this type of virus. The transgenic plants will be challenged against the virus using the natural vector *Bemisia tabaci* and the particle gun as well. From the results obtained, the best technique will be chosen and the corresponding gene will be used to transform Egyptian tomato cultivars. After the optimization of the regeneration protocols, the transformation technology will be transferred to Egyptian varieties and protocols to challenge the transgenic plants will be established.

Long-term Goals

The AGERI/ABSP cooperative project has made significant progress and hopes to help Egypt move closer to meeting the challenges of producing more food on a sustained basis while improving the quality of its environment through reductions in the use of toxic chemical pesticides. These steps will help improve the quality of life for both subsistence and commercial farmers, enhancing in the long-term the sustainability of Egypt's agroecosystems.

AGERI / ABSP Networking: Enhancing Communication Within the Global Biotechnology Community

Karim Maredia and Bruce Bedford
ABSP Network Specialists, Michigan State University, USA

The integrated management approach of the USAID/Cairo funded AGERI/ABSP project encompasses the research, policy, networking and management aspects of biotechnology. Networking activities foster communication and facilitate information flow to Egyptian scientists, policy makers and administrators through the quarterly newsletter, Bio*Link*, and other publications, project posters and computer networking. In addition, the networking activities help build linkages and promote interactions among institutions and individuals by organizing local and regional workshops and seminars, facilitating scientific exchange via short-term visits, conducting internship programs and participating in global biotechnology meetings and workshops.

Through the AGERI/ABSP collaboration, AGERI has become a member of the Biotechnology Industry Organization (BIO), the world's largest biotechnology trade association. The project's integrated approach encourages maintaining relationships with crop commodity programs in Egypt, the private sector in the U.S., international agricultural research centers, and other international agricultural biotechnology programs.

Institution and Team Building

The AGERI/ABSP project was implemented at a workshop held at AGERI in January 1993. Twelve scientists from the collaborating U.S. institutions traveled to Egypt and the interactions which took place with AGERI scientists provided significant momentum to the project as various teams began developing comprehensive work plans. Since then, research teams at AGERI and collaborating institutions in the U.S. have been actively working to achieve the project's research goals. Fifteen Egyptian scientists have visited the laboratories of the cooperating institutions in the U.S, greatly benefiting them in acquiring new knowledge, facilitating technology transfer and sharpening research skills in the transformation of maize, potato, tomato and cucurbits, and in the areas of biocomputing and computer networking.

Three Egyptian scientists and policy makers have participated in a four-week internship program in intellectual property rights (IPR) at Stanford Law School and are currently assisting the Egyptian government in providing the language to address biotechnology-related IPR issues in the existing patent right laws. Two other Egyptian scientists have participated in an eight-week internship program in biosafety at Michigan State University (MSU), interacting with various state and federal regulatory agencies in the U.S. They will play an active role in the development of an institutional biosafety protocol for AGERI and a national regulatory framework in Egypt which will allow Egyptian scientists to test genetically engineered plants in the field.
In collaboration with the University of Arizona, the ABSP project is working with AGERI to construct a modern biosafety containment facility in Giza, Egypt.

Institutional leaders from Egypt and other developing countries participated in an ABSP-sponsored industrial seminar series.
The seminars provided participants with opportunities to interact with technical and business personnel at three U.S private biotechnology companies: ICI Seeds America, Ecogen and DNA Plant Technology.
The seminars were instrumental in opening lines of communication between Egyptian and other countries' leaders and host companies.

In January 1994, three consecutive workshops–intellectual property rights (IPR), biosafety and project evaluation–were held in Egypt.
The IPR workshop involved government officials and scientists from Egypt and addressed patent issues related to the materials generated and used in many cooperative biotechnology projects. The biosafety workshop was held in cooperation with the United Nations Industrial Development Organization (UNIDO). Over fifty participants from Egypt and ten other countries in Africa, Europe and the Americas attended the biosafety workshop which addressed policy issues, risk assessment and field testing aspects that surround the management and safe use of genetically engineered plants in the environment.

The project evaluation workshop brought the AGERI/ABSP research, policy, networking and management teams together and reviewed the progress made in the first year of the project. During the evaluation workshop, comprehensive work plans for the second year of the project were developed and preliminary discussions were held to develop long-term objectives for future cooperation. Representatives of USAID/Cairo, USDA/OICD and NARP also participated in the workshop and conducted a review of the project.

Future cooperation between AGERI and ABSP will involve field testing and commercialization of genetically engineered transgenic germplasm in Egypt. Active participation and linkages with the private sector are envisioned. In addition, as the products of biotechnology move into farmers' fields in Egypt, the issues of long-term sustainability of transgenic germplasm, environmental impacts and socioeconomic impacts on producers and consumers will be examined and analyzed.

BioComputing and Networks Unit at AGERI

Raef Bishara and Eman Atef El-Azab,
BioComputing and Networks Unit, AGERI, Egypt

Realizing that effective handling of information is necessary for research and innovation, AGERI has employed the BioComputing and Networks Unit. The basic goals of the unit are to provide researchers with rapid and efficient access to data and information located within and outside Egypt, and to provide computational assistance to molecular biologists in analyzing protein and nucleic acid sequences.

These services are provided through worldwide communication and networking capabilities. AGERI is now connected to both Internet and Bitnet which facilitate on-line database searches and information retrieval from many servers internationally. Using this system, AGERI can FTP and TELNET to servers located internationally, access Gopher servers and bulletin boards. Through the networking unit, AGERI scientists can send and receive E-mail messages and participate in scientific group discussions.

The unit also provides electronic literature search and retrieval capabilities. Over the network, AGERI receives over 30 journal TOCs from Springer Verlag in Germany, 4-6 weeks before the hard copy is published. The unit receives the CCOD which covers bibliographic data and abstracts of over 900 leading agricultural journals, and also receives the ASM Journals on CD-ROM which contain complete listings of articles published in Microbiology Review, Journal of Virology, Molecular and Cellular Biology, Applied Environmental Microbiology and Journal of Bacteriology.

The BioComputing and Networks Unit maintains a wide variety of BioComputing software including commercial packages from leading companies (Intelligenetics), and software downloaded from the network. It receives regular updates of the EMBL and Swiss-Prot data banks on CD ROM and maintains a software library consistent with the diverse needs of AGERI's computing. This includes advanced statistical applications and programs that can process text and graphics to meet AGERI's publishing needs. The unit also offers software consulting and a training facility for its services. In 1993, the unit produced a brochure covering the activities of AGERI.

Expanding BioComputing and Networking Services at AGERI

In order to help expand the range and scope of BioComputing and Networking services at AGERI, Mr. Raef Bishara from the AGERI networking unit visited the Computer Science Department at Michigan State University for four months and received training in networking, expert systems and database management. In the area of networking, he learned the basics of TCP/IP-based networking and gained hands-on experience by installing TCP/IP networking software on three PCs, connecting the three PCs to a local area network, and using the networking software to communicate with other systems on the MSU Computer Science Networks, and other systems on the Internet. Mr. Bishara has become familiar with existing networking utilities at MSU and has formulated a plan of action for improving AGERI's networking services through installing a local area network.

At MSU, Mr. Bishara was also introduced to the application of expert systems, including its utilities and benefits to agriculture in Egypt and gained experience in the use of database technology for biological information systems and the access and maintenance of genomic databases including GenBank and Maize dB developed by USDA.

The BioComputing and Networks Unit provides efficient access to information, data analysis and connectivity to the rest of the world for AGERI scientists.

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