Food Biotechnology:

European and North American Regulatory Approaches and Public Acceptance—A Traveling Workshop

Summary Report for Policy-Makers

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Frontispiece: Inset: Vo-Tong Xuan (Vietnam) and R.A. Hautea (ISAAA, Philippines) (photo: David Alvarez,

ISAAA). From left to right: Ruben L. Villareal (the Philippines), Joko Budianto (Indonesia),

Rogelio A. Panlasigui (the Philippines), Hassan Bin Mat Daud (Malaysia), Anatole Krattiger (ISAAA, Switzerland), Sakarindr Bhumiratana (Thailand).

Note that Vo-Tong Xuan was not present on that day. (photo: Amy K. Flatten, National Science

& Technology Council, Executive Office of the President).

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Preface

The stakes of the agri-biotech revolution are enormous, particularly for developing countries. Eager to provide an inclusive outlet for science-based critical analysis, the International Service for the Acquisition of Agribiotech Applications (ISAAA) invited representatives from developing countries to join in an open forum for discussion. We hope that this Traveling Workshop serves as an important step toward the examination of views from all sides, thus spurring informed action concerning this critical topic.

Six senior policy-makers responsible for food biotechnology crops in ISAAA's client countries in Southeast Asia participated in a twoweek Traveling Workshop in Europe and North America (Canada and USA). This Study Group comprised Dr. Joko Budianto, Director General of the Agency for Agricultural Research and Development (AARD) in Indonesia; Dr. Hassan Bin Mat Daud, Director of the Malaysian Agricultural Research and Development Institute's (MARDI) Biotechnology Center; Dr. Rogelio A. Panlasigui, Undersecretary of Science and Technology in the Philippines; Dr. Sakarindr Bhumiratana, then Director of the National Center of Genetic Engineering and Biotechnology (BIOTEC) in Thailand; Dr. Ruben L. Villareal, then Chancellor of the University of the Philippines Los Baños and now Director of SEAMEO-SEARCA (Regional Center for Graduate Study and Research in Agriculture) in Los Baños, the Philippines; and Prof. Dr. Vo-Tong Xuan, Vice-Rector of the University of Cantho, Vietnam and Rector of An Giang University, Long Xuyen City, Vietnam.

The objective of the Traveling Workshop was to provide these leaders with an opportunity to meet with prominent figures from the public and private sectors of agri-biotech in industrialized countries as well as to meet face-to-face among themselves. A vigorous exchange of views ensued. Meeting with representatives from organizations embodying a broad spectrum of views—ranging from DuPont and Novartis to Greenpeace and The Union of Concerned Scientists—the Workshop's primary participants carefully considered both the purported benefits and potential risks of food biotechnology crops. Through these meetings, it was hoped that the Traveling Workshop participants would gain a better understanding of the current global situation of agricultural biotechnology, in particular the policy issues that have facilitated the adoption of genetically manipulated (GM) crops in the USA and Canada, but hindered their adoption in Europe. The spotlight was focused on the following issues:

- biosafety and food safety regulations;
- benefits derived by growers from food biotechnology crops;
- risks posed by such crops;
- the relationship between public awareness and acceptance of agribiotech; and
- the respective roles of government and the private sector in the development, dissemination, and use of food biotechnology.

Of particular interest to Workshop participants was probing the events of Europe and North America, and using these experiences to

develop policies for their own nations with the goal of safe, responsible, efficient optimization of their urgent food security needs.

Members of the Study Group met with more than 100 individuals from a host of organizations during the 5–16 September 1999 tour. The tour began in the Netherlands and included visits to Belgium and the UK, culminating in North America with visits to Canada and Washington, D.C., in the USA. In an effort

to facilitate a frank exchange of ideas, small-group discussions were the norm, with topics chosen by those present. Organizations contributing to the discourse spanned the public and private sectors, including associations of farmers, consumers, and environmentalists; as well as members of various nongovernmental organizations (NGO), government regulatory agencies, scientific and development/donor communities (including universities), and trade agencies.

1. Overview and Major Conclusions

The Traveling Workshop organized by ISAAA in Europe and North America was well received and considered very timely and useful by the participating senior Asian policy makers, who reported open and informative meetings with representatives of companies, government agencies, universities, and NGOs. The Study Group gained experience and knowledge about methods worth emulating and about those to be avoided. Moreover, in addition to obtaining state-of-the-art information about food biotechnology, the participants were able to establish personal contacts with representatives from a variety of organizations.

Those assembled considered the program to be a rousing success, unanimously believing that other policy makers and scientists from developing countries would similarly benefit enormously from such an experience. Because developing countries encounter comparable obstacles regarding the adoption of food biotechnology crops, those gathered suggested that a visit to one or more of the four developing countries with commercialized food biotechnology crops would strengthen a future Workshop. As they noted, biotechnology, like many other new technologies, must be locally adapted. In particular, the technology must be geared towards the needs of local customers. For example, insufficient attention to consumers in Europe has contributed to the backlash against food biotechnology in those markets. Finally, all participants agreed that there is no substitute for face-to-face exchanges on a subject of such critical importance to developing countries.

The Traveling Workshop sought to address the urgent requests by developing countries for beneficial biotechnology applications. Their needs—and the capacity of agribiotech to meet them-deserve careful consideration through scientific and socioeconomic research. Of course, any such analysis must be a two-way street. Although developing countries have much knowledge to reap from industrialized nations regarding crop biotechnology, the inhabitants of developing countries deserve a voice in the adoption of these technologies. Indeed, the Workshop was guided by the principle of choice of adoption vs. stasis, on a countryby-country basis. All public and private parties concerned must openly debate the application of food biotechnology and its consequences in society.

As the Nuffield Council on Bioethics Report from the UK has clearly and thoughtfully articulated, real dialogue is essential if food biotechnology is going to play its part in contributing to the alleviation of global hunger and poverty. The discussion meetings of the Traveling Workshop, which encompassed both the concerns of entities such as Monsanto and Greenpeace, were partly guided by the recommendations of this Report. (see the Nuffield Foundation's website for more information at www.nuffieldfoundation.org/bioethics).

In developed countries, farmers have adopted biotechnology more quickly than any other agricultural technology. In 1999, a total of 40 million hectares were planted, mainly in North America (USA had 72% and Canada 10% of the world acreage of GM crops), Argentina (17%), and China; followed by Australia, South Africa, Mexico, Spain, France, Portugal, Romania, and Ukraine. Between 1998 and 1999, planting of these crops increased in area 1.4-fold in industrialized countries and 1.6-fold in developing countries, with the vast majority of the acreage (82%) occurring in industrialized countries. Planting for the year 2000 is still ongoing, but there appear to be significant increases in cotton, squash, and papaya; and a slight increase in corn, cotton, and soybeans. Overall, the increase in acreage from 1999 to 2000 was not as great as the prior year, largely because of European uncertainty surrounding agricultural biotechnology. Usage in developing countries, however, is expected to increase significantly in the future, particularly in China where biotech crops are already commercialized, particularly insect resistant cotton.

As these numbers suggest, growers perceive great value from the superior characteristics of these crops, which provide higher yields, require less pesticide usage, foster more efficient management practices, and contribute to sustainable farming systems. In those countries where agri-biotech has succeeded, proactive governments provided regulatory frameworks establishing credibility and public trust in the biosafety and nutritional safety of food biotechnology products.

Developing nations may use—and improve upon—the successful models supported by such governments, thus saving time and scarce resources as they develop their own

regulations. Furthermore, international cooperation helps harmonize food and biosafety regulations, which will increase trade and global prosperity.

With the exception of 1.3 million small farmers growing Bt cotton in China, smallscale farmers in Asia have not yet benefited from the promises of biotechnology. For a staple crop like rice, realistic plant breeding goals include increased yield, lowered pesticide usage, adaptation to marginal lands, and quality improvement (e.g., enhancement of fragrance and in Vitamin A content through GoldenRice™). None of these should be denied to the developing world. Asia is home to approximately 700 million of the world's 1.4 billion poor people, around 500 million of whom live in absolute poverty. Moreover, a significant number continue to suffer from micronutrient deficiencies in iodine, vitamin A, and iron. The region has high agricultural productivity potential and can benefit from several types of agri-biotech. However, ineffective or nonexistent agri-biotechrelated governmental policies hamper the implementation of the significant biotech research capacity that is in place. To compound the problem, no significant institutional arrangements assist the development and commercialization of improved products for small-scale, resource-poor farmers. The Traveling Workshop sought to promote the development of such institutional infrastructures in order to open this conduit of new food biotechnologies to the poor.

During their tour of Europe and North America, Workshop participants engaged in open and frank discussions about the needs, concerns, and interests of the countries they represented. Overall, Asian policy makers concluded that the scarcity of current authoritative information and knowledge regarding food biotechnology crops represents a major deficiency in developing countries—a deficiency that denies policy makers and scientists access to the vital knowledge needed to make well-informed decisions. Some general conclusions and recommendations include the following:

- Consumers are generally ill informed regarding agri-biotech crops and food.
 Anti-biotech groups mounting aggressive campaigns, initially in Europe and now globally, erode public confidence in several areas: food biotechnology, scientists, regulators, and indeed the entire industry that provides new crops and novel food products. Ironically negating their initial goal to promote consumer choice, the current aspiration of the anti-biotech contingent is to eliminate food biotechnology crops from the marketplace.
- Claiming their rightfully authoritative positions, the global science community, government regulators, and the agribiotech industry must instill public knowledge and confidence through

- credible educational initiatives. Full awareness of the benefits, constraints, and attributes associated with food biotechnology crops belongs in the hands of developing nations—who stand to gain, or lose, the most.
- To date, developing countries have been eclipsed in the dialogue on food biotechnology crops. Totaling more than 80% of the global population, the people of the Southern Hemisphere should be adequately represented in this critical global debate. Instead, vocal and affluent activists from the North-on both sides of the dispute—have dominated, sometimes taking a patronizing attitude toward their southern neighbors and generally not addressing the urgent needs of resource-poor, subsistence farmers in developing nations. The Traveling Workshop was a modest step forward in remedying this situation.
- Developing countries lack current and authoritative agri-biotech information.
 The Study Group recommended that ISAAA move quickly to implement its Global Knowledge Center on Crop Biotechnology. Great benefit will come from the consistent and focused distribution of knowledge in plain language through ISAAA's global network.

2. Summary of Discussions, Views and Recommendations

While touring Europe and North America, the six members of the Study Group exchanged views with representatives of diverse organizations, some opposing and some favoring the genetic manipulation of crops. With opinion varying among individuals within organizations and across groups representing a similar interest, the primary participants saw merit in chronicling the views of the different factions and making recommendations where appropriate. The following is a compilation of views and recommendations, categorized by group or subject matter.

2.1 Farmers

Crop breeding has been practiced for centuries. Farmers generally view food biotechnology as merely a step along this continuum, with their experience in conventional breeding leading them to consider agri-biotech as a natural process to improve crops. Acknowledging the public-opinion impact of scientific and regulatory counsel, concern abounds within the farming community that well-founded and even-handed guidance may not prevail.

The problem stems, in part, from a misinformed debate about the risk of food biotechnology crops. Risk is an accepted element of innovation—or lack of innovation. In biology, as indeed in any science, probability governs risk levels; thus, zero risk is unachievable—nothing is 100% certain. Accordingly, the demand to with-

draw food biotechnology crops from the marketplace because of inherent nonzero risk is neither realistic nor reasonable. The relative benefits and risks associated with any new product should determine product approval or rejection. In this context, it is critical to point out that food biotechnology in agriculture replaces other technologies, such as toxic conventional pesticides, which themselves carry a certain risk to the environment and the farmers who apply them.

2.1.1 The European Scene

Due to the poor regulatory response to mad cow disease in the UK and to dioxin contamination of food in continental Europe, a growing mistrust of government and science has strengthened the specter of risk. With the consequent erosion of public confidence in European food safety standards, the volume of the European Union debate on food biotechnology crops has risen to a fevered pitch. Caught in the middle of the maelstrom, European farmers and their respective associations must move more cautiously than their North American counterparts, while concurrently in full recognition of the agronomic and economic value of the new technologies. Public fear influences regulation as much as scientific rigor, leaving farmers limited in their ability to enhance productivity and increase the sustainability of agriculture.

2.2 Regulatory Systems

In contrast to those in industrialized countries, farmers in the developing world overwhelmingly operate on small scales. Still embedded in an agrarian economy, these farmers represent a significant percentage of both the population and the consumer community. In developing countries, the foremost concern of small-scale, resourcepoor farmers is to grow enough food to eat. Hunger and malnutrition continue to stalk much of the globe, with demographic studies alarmingly indicating that 680 million people in developing countries—mainly in Asia and Africa—will suffer from malnutrition in the year 2025. Despite the forecasted doubling of grain trade, it is expected that 90% of food will continue to be consumed within its country of origin. Accordingly, although improved distribution can contribute to food security, developing countries do not view this as a complete solution. Instead, this complex problem requires an integrated, multiple-thrust strategy that prominently includes the key element of food biotechnology.

To the greatest possible extent, farmers in developing countries must optimize their production of food to maximize national food self-sufficiency. Labor-intensive production of food staples, in both the public and private sector, waits to be streamlined by the initiation of national programs and by local farming efforts. Governmental oversight ensuring adherence to international standards of biosafety and food safety is imperative, yet insufficient incentives or institutions are currently in place to realize this goal.

All European and North American countries have approval systems in place to evaluate new entrants to the agri-biotech scene. European countries have promulgated new legislative Acts that focus on the process of GM food production. In contrast, the United States and Canada have relied on several existing Acts to achieve the same goal, with the *product* as the center of attention. Evaluating an end-product orientation toward regulation/deregulation as superior, the Traveling Workshop concluded that the more progressive North American approach should be emulated by developing countries.

Both Europe and North America deal with submissions on a case-by-case basis. Europe continues to rely on regulation, North America pursues deregulation, which was implemented in 1993 and has seen more than 1,000 applications within the first five years approved upon through a notification system. In contrast, only 23 applications required permits during the same period. In North America, novel foods, which include food biotechnology crops, are subject to stringent regulation. A 1992 inquiry recommended a focus on premarket approval with special emphasis on marker genes, allergenicity (with examination of every transformed protein), and labeling. All such information is freely available to the public under the Freedom of Information Act.

Indeed, transparency of information is key to a credible regulatory system. The most effective way to achieve transparency is to leverage the Internet and post all information on regulatory-agency websites. Experience has shown that when the regulatory system is transparent, legal challenges contribute to, rather than detract from its credibility. Based on accumulated wisdom, regulatory systems are increasingly launching networks to optimize public visibility of information. Furthermore, long-standing regulatory committees are awarded the highest level of credibility, having benefited from more extensive experience and garnering a broader consultation base and involvement from all stakeholder groups.

Although all regulatory committees ground their decisions in scientific data, Europeans are also swayed by vocal public concern. Noting that biosafety and food safety are handled by different committees, the participants in the Study Group stressed the need for intercommittee collaboration. Poor communication produces inconsistency and confusion on the part of the public, as well as inefficiency for those subject to the resultant regulations. Toward this end, Canada may provide training courses in both biosafety and food safety, including the integration of all elements.

In North America, food safety is a broad concept encompassing all aspects of food production (e.g., the impact of pesticides), including the use of GM crops. Alternatively, GM crops themselves have served as the lightning rod that trigger safety concerns in Europe. This dichotomy of viewpoints is consistent with the process-vs. product-oriented approaches of Europe and North America, respectively. Overall, the

participants of the Traveling Workshop agreed that the regulatory system in the USA and Canada offers more advantages than the EU system.

Food labeling represents an additional avenue toward agri-biotech information transparency. Despite the recognition that informed consumer choice and access to information regarding food specifications are principles not to be compromised, no policy consensus has emerged regarding labeling—options presently range from voluntary to mandatory. Representative of current practices, yet confounding the situation further, the labeling debate ignores the predicament faced by developing nations: not only are most foods unpackaged in these countries, but illiteracy also renders labeling ineffective. Other methods exist to inform the public regarding food products.

The segregation of GM and non-GM commodities and foods is one suggested remedy. Nevertheless, this is predicated on the following three conditions:

- 1. segregation is feasible,
- 2. diagnostics are available to verify the specification of the product, and
- 3. thresholds exist to implement the scheme.

It remains unclear who will bear the costs associated with each aspect of segregation, yet any implementation would indisputably impact World Trade Organization (WTO) and Biosafety Protocol policies and practices.

As the WTO negotiates global trade regulations concerning food biotechnology crops—producing factions including the Miami group, the EU, the G7, and Africasome are concerned that anti-biotech groups will aggressively lobby the divided multinational body. Moreover, the small voice of the developing world remains a concern, particularly if critical countries are excluded from deliberations on the Biosafety Protocol. Accordingly, the participants in the Traveling Workshop recommended the establishment of a WTO-based supranational authority for arbitration, as well as the establishment of an overall authority in the EU, similar to the U.S. Food and Drug Administration (FDA).

Finally, the members of the Study Group were not current with China's regulatory system. With China as the first to deploy large areas of GM crops, this Asian model was identified as a high priority for further study.

2.3 Industry

With the enormous investments in food biotechnology crops, the innovative contributions by the life sciences industry dominate the landscape. These companies have spent billions of dollars in the last few decades in agri-biotech research and development (R&D). However, over the past several years, the industry has rapidly consolidated, leaving few participants in the race to significantly penetrate the market. Currently, more than 85% of all agri-biotech activities are concentrated in five or six

multinational companies. Some view this as a necessity; others consider it a threat; while still others view it as an opportunity. Increased development costs, the synergy stemming from combined patent rights, and competition for market share conferred advantage to corporate mergers. This bundling of power, however, frightens anticapitalist groups, who fear that multinational corporations are gaining a stranglehold on the world's food supply. Those with extremist views have occasionally resorted to vandalizing scientists' research efforts, but their greatest sabotage has been the pollution of the public debate (and arguably the public's mind) about food biotechnology. Whereas some NGOs have fostered consumer awareness by responsibly furthering the democratic process through informed discussion and decision making, the public forum has too often been littered by errors parading as facts in an atmosphere of global conspiracy and fear of the unknown.

Against this backdrop, industry has become more aware of its social responsibility to consumers—both in developed and developing countries. Agri-biotech corporations increasingly recognize that shareholders' value and institutional continuity are insufficient baselines of business success. Indeed, deliberate focus should be brought to bear on broad issues, including the treatment of consumers, the poor, and the environment. The willingness to provide scientific and technological assistance to developing countries and a commitment to good stewardship of the environment are now seen as industry responsibilities.

In short, a new sustainable model is required that features both commercial viability and socioeconomic equity. Although global cooperation is expected to contribute to social good, developing countries deserve to be supported according to their particular needs, most notably the increase of yields on shrinking acreages and better crops for planting on marginal land. ISAAA was promoted as a model for reaching out to the poor farmer. Seeking increased corporate responsibility, some Workshop participants argued for industry to encourage the participation of small farmers in the market economy in an effort to improve the economic standing of those in greatest need. Concretely, industry could seek to create win-win situations in technology transfer, explore partnerships for the royalty-free donation of appropriate technology, and assist in the training of scientists to build capacity in developing countries.

Corporate entities also hold a stake in improved communication and public awareness regarding food biotechnology crops, and they would do well to assign high priority to efforts in these directions. The establishment of global networks would help consolidate and disseminate authoritative databases about food biotechnology crops, with information gathered from both the public and private sectors. Public-sector NGOs that were mentioned by those in the Workshop include NABC and IFIC, along with private-sector organizations such as BIO, BIOTECanada, and EuropaBio.

For global adoption, the benefits of agribiotech products must be made evident to both farmers and consumers. This can be achieved by complementing the current input "agronomic" traits with output "quality" traits. Whereas quality is universally valuable for such traits as high oleic acid content, high vitamin A content, and low phosphate in animal feed, for developing countries, input traits retain crucial importance due to inadequate agricultural capacity.

The participants of the Traveling Workshop recommended that an organization such as ISAAA establish Information/Knowledge Centers on food biotechnology crops to serve the urgent needs of developing countries. Adding additional utility, a conflict resolution dialogue (similar to the successful Keystone Dialogue on Genetic Resources) to advance understanding and international cooperation regarding food biotechnology crops should be initiated.

Some of the lessons—both positive and negative—that industry has recently learned include the following:

- the positive response to food biotechnology from growers in the United States, Canada, Argentina, China, South Africa, Brazil, and Mexico;
- the reduced use of chemicals in U.S. agriculture, along with correspondingly lower production costs;
- confusion still reigns in the regulatory environment where a lack of authoritative decision making is distressingly frequent;
- the lack of benefits, as yet, to the consumer (exception: Zeneca tomato paste);
- the low level of consumer understanding;

- the devastating influence on public opinion of the tabloid press in Europe;
- the need for instant communication globally—science-based, clear, simple, and consistent;
- the use of modern communication methods, including Internet list servers, e-mail, press releases, interviews, and flyers in supermarkets;
- the critical need for coalitions, including strong cooperation between corporations and public-sector scientific institutions in addressing issues of interest and concern to the public.

The Traveling Workshop further emphasized the positive potential of strong, clear attempts to counter erroneous information about food biotechnology:

- there is no evidence to support a moratorium on the commercial introduction of agri-biotech products;
- there is no evidence to support the claim that biotech products are unsafe;
- governments must take an objective stand, be transparent, and invoke deregulation when appropriate;
- the regulatory framework must be transparent, effective, and authoritative;
- industry should take more responsibility for social good, equity for the poor, and stewardship of the environment.

Behind these recommendations is the working assumption that increased communication efforts should include all stakeholders—industry, producers, public science, environ-

mentalists, and ethical groups—leading to opinions reflecting greater balance and more careful consideration. Furthermore, the public has the right to expect the facts, both pros and cons, about agri-biotech crops. For the public to construct reasoned judgments, these should be clearly portrayed.

Overall, the members of the Study Group concluded that industry and science have largely obscured the facts, contributing to the public's current anxieties about agri-biotech. Finally, the Group contended that the responsible use of food biotechnology within effective biosafety and food safety regulatory systems warrants greater attention than it now receives.

2.4 Governments

Governments' adoptive role in the agribiotech challenge has been based in the promotion of science and regulation. With regulation as a prerequisite for the deployment of biotechnology in the market place, regulatory bodies for biosafety and food safety must be in place to promote local product development. Whereas biosafety regulations require country-specific environmental adaptation, food safety regulations lend themselves more easily to international harmonization. It was noted that the Codex and the Biosafety Protocol are important for international trade in the framework of the WTO, resting on the establishment of fair trade rules. To accomplish this, more input is needed from developing countries.

As was the case with industry, many Workshop participants thought that greater effort is appropriate on the part of governments toward information transparency. Government-mediated forums for stakeholders could promote informed discussion, with special attention given to the establishment of information/knowledge centers. The World Wide Web presents an ideal medium to disseminate information and encourage continuous dialogue. Effective use of modern telecommunications technology escalates in importance with the anticipated exponential increase in information. Together, the need for capable systems and the potential widening of the digital divide represent challenges for the coming decade.

Workshop participants learned that expert studies must be implemented with a focus on environmental impact and food safety. Greater credibility accompanies regulations underpinned by such studies, which simultaneously support socioeconomic predictions regarding varied topics, including trade in novel products, requirements of consumers for special foods, and the acceptance of agri-biotech crops by diverse cultures. Along with an intensified independent assessment of crop biotechnology farming experiences, the suggested safety studies would provide valuable information to fuel a more objective dialogue.

The availability of skilled regulators is a special concern, particularly within developing countries. Subjected to demanding international standards, but with minimal access to the necessary resources, those

seeking to feed the majority of the world's population find themselves at a disadvantage compared to developed countries.

With this in mind, the complexity of the labeling issue was recognized. Apart from country-by-country needs, a global approach for labeling is necessary, yet it is not evident that labeling should be the way to inform consumers in developing countries. Alternative methods to provide adequate information to the public warrant exploration. Careful monitoring should accompany the U.S. Department of Agriculture (USDA) deliberations on the possibility of a Balance Act for segregated products.

Furthermore, governments have an important role to play vis-à-vis R&D funding. Investments in science should be encouraged to meet community needs. By closely monitoring the use of biotechnology with staple crops, optimal advantage of new developments may be leveraged in this highly strategic arena. For rice, important technologies include vitamin A enhancement to produce enriched GoldenRice™, enhancement of iron for anemia, Bt for stemborer resistance, resistance to fungal disease, control of bacterial leaf blight, and development of herbicide-tolerant rice, which is expected to be ready for deployment in the United States by 2001; abiotic stress tolerance is expected in the longer term. It was also noted that initiatives in developing countries should focus on orphan crops, such as sweet potato, papaya, banana, and cassava.

Finally, the encouragement of private-public partnerships should occur at the interna-

tional and national levels to facilitate the transfer of biotechnology applications for the benefit of farmers in both industrial and developing countries. This could also prevent governments from wasting vital resources by "reinventing the wheel." Moreover, the indigenous private sector in developing countries shoulders the important responsibility of ensuring that new and improved technologies are efficiently distributed.

2.5 Consumers

Consumers unanimously demand a right to be involved in decision making regarding GM foods. Strongly advocating the right to choose, they stress the importance of labels appearing on products found in the marketplace.

Consumers also perceive an information void concerning food biotechnology crops. The International Food Information Council (IFIC) has developed a schedule of ten communication steps for the introduction of a novel product, and the Workshop participants recommended that these steps be implemented in developing countries when introducing agri-biotech crops.

For popular acceptance of agri-biotech foods, benefits must be readily apparent to consumers. The needs of developing and developed countries differ markedly in this respect. Obviously, enhanced yields leading to diminished hunger encourage its use in the Southern Hemisphere, whereas consumers in the North have yet to experience comparable tangible benefits.

2.6 Opposition

A large number of "green" organizations express concern about the potential long-term effect of the spread of transgenes in nature. Some greens brand food developed through agri-biotech as unnatural and suspect that there are dangers to human health when such food is consumed. Furthermore, many opposition groups are of the opinion that multinationals will use agribiotech to control the world's food supply.

The extremist opposition uses pseudoscientific information to influence public perception. Denigrating terminology like "Frankenfood" is part of an attempt to deliberately raise fears in the public. Greenpeace openly declared to the Workshop participants their intention to achieve a moratorium on the use of food biotechnology products. Their principal argument appeals to the unknown long-term effects of agri-biotech crops, while concomitantly claiming that these products should carry zero risk—something impracticable for any type of technology. Greenpeace further indicated that it would exploit the lack of European public acceptance to deny developing countries the opportunity to export agri-biotech products to that region. However, Greenpeace acknowledged no responsibility for the negative impact of its actions on the economies of the developing world.

The Study Group members advocated continued dialogue with industrialized countries to remain abreast of contrarian views on food biotechnology crops. Indeed, participants were pleased to be able to hear

and probe first hand the criticisms offered by opposition groups. Overall, the Group held to the view that, compared to outside opinion makers who try to override the decision-making process of nations in the South, indigenous national bodies are best situated to express balanced judgements about the value of biotechnology for their own communities.

Of particular interest to Workshop participants were issues related to the conservation of biodiversity. They found it noteworthy that internationally recognized ecologists share the opinion that biotechnology can be used to prevent the destruction of habitat by deforestation, to protect less competitive populations in fragile ecosystems, to reinforce valuable land races through the incorporation of transgenic resistance to biotic stresses, and to facilitate the conservation of natural resources. Similarly, the potential negative effects resulting from the flow of transgenes to neighboring species is considered low: most transgenes will not survive in new genomes and will be eradicated through selection pressure within a few generations. Thus, biosafety research should focus on exceptions to this general rule.

2.7 Education

Participants considered the science community lax in asserting its views about food biotechnology. The public has not heard the positive and generally balanced views of scientists in regards to agri-biotech crops. Effective expression of their fact-based opinions is often met with difficulty, since

the message is not sensational, and is therefore considered unworthy for exposure in the tabloid press. Yet, ultimately, the failure of the scientific community to educate the public about agri-biotech fears will lead to policy makers decreasing or eliminating funding for novel crop R&D.

Similarly, educational institutions have not taken up the challenge to properly inform students about the pros and cons of the food biotechnology crop debate. The Workshop participants recommended that Ministers of Education be alerted to this deficiency of knowledge, which may be remedied through curriculum updates (at all educational levels) and the inclusion of the significant new knowledgebase relevant to this class of crops.

2.8 Donors

Participants learned that donor agencies are generally more interested in broad goals, such as poverty alleviation, rather than in biotechnology—despite the latter's effective role in reaching this goal. Donors favor programs that deliver a quick and visible impact, ignoring the fact that a sustainable solution to a chronic problem may well be absent.

Public opinion also greatly influences donor policies; in Europe this has resulted in significant underfunding for biotechnology. Donors find it uncomfortable to rationalize support for a biotech program in developing countries, when domestic risk-justified moratoria are in place—this would suggest a

double standard, with developing countries being used as guinea pigs. This is another reason for scientists in Europe to voice facts about food biotechnology.

The World Bank also plays a role in agribiotech funding, using the willingness of national programs to assign high priority to food security and agriculture as a measure of commitment, which in turn influences lending by the bank in areas such as biotechnology. The Bank supports work in Intellectual Property Rights, food biotechnology crops, the Biosafety Protocol, and the role of NGOs. The goals of World Bank projects focus on poverty alleviation, food security, economic growth, and the sustainable management of natural resources.

2.9 Recommendations to ISAAA

Overall, the participants of the Traveling Workshop considered the undertaking an exciting, innovative approach to bringing together a team of national policy-makers from Southeast Asia and exposing them to all the major policy issues on agricultural biotechnology. The participants valued the knowledge and real-world experience gained as they exchanged views with the various stakeholders in the realm of agri-biotech.

Members of the Workshop Study Group expressed the hope that ISAAA would continue to organize such efforts to better inform policy-makers and scientists from developing countries about the current developments in the fast-moving world of food biotechnology crops. Everyone agreed that no substitute

exists for a face-to-face exchange of opinion when seeking a true understanding of the issues, as well as the philosophy and motives underpinning them.

Because of group dynamics, traveling as a unit was particularly useful for all participants, including the resource staff from ISAAA. Given the value of the people met by the participants, some Workshop members wished that a larger group of Southeast Asians had been invited. Other suggestions included the following:

- Prior to commencing the Traveling Workshop, a deeper level of background information on host institutions and individuals would have been valuable.
- ISAAA should urgently initiate an Information/Knowledge Center on food biotechnology crops and should network the knowledge to developing countries with a priority need for this information.
- A visit to a field trial with transgenic crops should be included in the Workshop, so that the procedures and precautionary practices can be viewed first hand.
- A visit to China, which was originally planned for the Traveling Workshop, would have been an ideal complement to the visits in Europe and North America. The China visit would uniquely offer a developing country's experience in Asia.

3. Program of the Traveling Workshop

MONDAY 6 SEPTEMBER 1999 THE HAGUE, NETHERLANDS

Arrival from Southeast Asia in Amsterdam, the Netherlands.

MONDAY 6 SEPTEMBER 1999 THE HAGUE, NETHERLANDS

Ministry of the Environment

Ir Jasper E. Van Zanten Vice Chair, ISAAA Welcome and Briefing

Dr. Piet J. van der Meer

Ministry of Environment, The Hague Law and regulations applied

Dr. J.E.N. (Hans) Bergmans

Secretary, Regulatory Committee on Genetic Modification in the Netherlands, COGEM Cases, key decisions, and systems implemented by COGEM

Agricultural University of Wageningen and Industry

Dr. Niels Louwaers

Institute of Plant Science, Agricultural University of Wageningen

Prof. Eric Houwink

Groningen University, replaced by Jasper E. Van Zanten

Basic concepts in society in relation to public acceptance of biotechnology

Dr. Cees Noome

ADVANTA, Director, Public Affairs

The seed industry and the public in Holland

Mr. Rob Baan

Manager, Marketing Pacific Rim, Novartis Seeds The seed industry and public acceptance in South and East Asia

TUESDAY 7 SEPTEMBER 1999 LE MANOIR DU LAC, GENVAL BRUSSELS, BELGIUM

Farmers, Consumers, Scientists and Environmentalists

Ms. Gwenn Strasburger

Public Affairs, European Community of Consumer Cooperatives, Eurocoop Application of genetically modified food and ingredients, precautions required

Dr. Stephaine Reinard

Secretary, European Farmers' Associations COPA-COGEVA,

and

Dr. Euros Jones

Secretary General, European Young Farmers' Association CEJA GM varieties in agriculture

Dr. Doug Parr

Campaign Coordinator and Scientific Advisor, Greenpeace, London, UK

The role of GMO's in industrialized and in developing countries

Prof. Klaus Ammann

Chairman, Europlant Specialist Group of the International Union for the Conservation of Nature IUCN, and Director, Botanical Garden, University of Bern, Switzerland *The role of GMO's in Bioconservation*

Dr. Dick A. Toet

Head, Public Affairs, Nestlé Vevey, Switzerland Participant in the discussions

Ms. Elisabeth Vallet

School education project leader, European Young Farmers' Association CEJA Biotechnology education for young students

Dr. Hans Blankestijn

Foreign Department, and **Dr Jos Geerligs**, System Development, Foundation for Educator Training in Agricultural Sciences, STOAS, Wageningen, The Netherlands Education

WEDNESDAY 8 SEPTEMBER 1999 BRUSSELS, BELGIUM

EuropaBio

Mr. Anthony F. M. Arke

Secretary General, European Biotech Industry Association, EuropaBio
The contribution of European industry to the public debate

Dr. Simon Barber

Director, Plant Biotechnology Unit, European Biotech Industry Association EuropaBio

EuropCommerce

Henrik Kroner

Secretary General

Monsanto Europe

Marco Thyssen

Director of Industrial Relations

University of Ghent

Prof. Marc van Montagu

Prof. Plant Molecular Sciences
University of Ghent, Belgium
Science capacity building in developing
countries

THURSDAY 9 SEPTEMBER 1999 LONDON, UK

Round-Table Discussion with
The Nuffield Council on Bioethics,
Greenpeace, and Industry

Dr. Sandy Thomas

Director, Nuffield Council on Bioethics, London, UK

Prof. Mike Gale

Director, John Innes Centre, Norwich, UK

Prof. Roger Hull

Emeritus Research Fellow, John Innes Centre, UK, – Sessions Chair Welcome and briefing

Prof. Michael Lipton

Poverty Research Unit, University of Sussex, Brighton

Mr. Andrew Sims

Senior Researcher, Christian Aid, London

Karen Oon-Buffin

Desk-Officer, Southern Asia, Christian Aid, London

Ethical and social issues in the third world

Mark Griffiths

Natural Law Party, Winchester

Dr. Julian Kinderlehrer

Assistant Director, Sheffield Institute of Biotechnical Law & Ethics, Sheffield

Lord Peter Melchett

Executive Director, Greenpeace UK, London Risks and benefits, public perceptions

FRIDAY 10 SEPTEMBER 1999 LONDON, UK

Industry, Consumer Groups, Donors, and Universities

Dr. Colin Meritt

Technical Manager, Monsanto UK, Cambridge

Ms. Camilla Beech

Biotechnogy Regulatory Affairs Manager, Zeneca Plant Science

Dr. Judith Irwin

Research Scientist, John Innes Centre, Norwich, UK Science and industry calling for transparency in communication

Catherine Fookes

Campaign Manager, The Soil Association, Bristol

John Lampitt

Biotechnology Working Group, British National Farmers' Union, Charlecote, Warwickshire

Sue Davies

Principal Policy Researcher, Consumer Association, London The need for GM crops and foods, pros and cons

Dr. John Tarbit

Head, Natural Resources Research Department, Dept for International Development DFID, London

Michael Pattison

The Gatsby Charitable Foundation, London Views of the donor community

Prof. Alan Gray

Director, Institute of Terrestrial Ecology, Wareham, Dorset

John McLeod

Recently retired Director, National Institute of Agricultural Botany, Cambridge Biosafety risk assessment

SATURDAY 11 SEPTEMBER 1999 BRACKNELL, UK

<u>Visit to Zeneca Plant Science, Jealott's</u> <u>Hill Research Station, UK</u>

Ms. Camilla Beech

Biotechnology Regulatory Affairs Manager, Zeneca Plant Science

Dr. Adrian Dubock

Commercial manager, Zeneca Biotechnology Group

Zeneca biotechnology strategy

Dr. John Hawtree

Technical Manager, Asian Region Zeneca in Asia

Travel to Ottawa, Canada.

SUNDAY, 12 SEPTEMBER 1999 OTTAWA, CANADA

BIOTECanada

Joyce Groote

President, BIOTECanada

Paul T. Hough

Vice President, BIOTECanada

Overview of the Canadian biotechnology

industry and Canadian infrastructure

John McCully

Executive Director Governmental and Regulatory Affairs, Dow AgroSciences, Participant in the discussions

Chris Warfield

Manager, Government Affairs, AgrEvo The Canadian regulatory system: an industry perspective

R.G. (Bob) Ingratta

Director, Government Regulatory Affairs, Monsanto Key issues regarding labeling

Health Canada

Paul R. Mayers

Acting Director, Bureau of Microbial Hazards, Agency CFIA Inspection, support, and development of safety measures

Karen McIntyre

Assistant Head, Office of Biotechnology, Bureau of Microbial Hazards, Evaluation Division, of Health Canada Capacity building, training courses for developing regions

MONDAY, 13 SEPTEMBER 1999 OTTAWA, CANADA

Canadian Food Inspection Agency

André Gravel

Vice President, Programs, Canadian Food Inspection Agency CFIA Welcome, overview of CFIA activity

Margaret Kenny

Acting Director, Office of Biotechnology, CFIA

Ag Biotech and regulation: public awareness, communication, and public participation

Bart Bilmer, CFIA

Labeling of food in Canada and the Codex WG

Stephen Yarrow

Chief Plant Biotechnology Office, CFIA Regulating environmental release

Phil Macdonald

Plant Biotechnology Office, CFIA Regulating environmental release

M. Prud'homme

Plant Health Risk Assessment Unit, CFIA

Catherine Italiano

Toxicologist, Feeds, CFIA

D. Blair

Fertilizers, CFIA

G. Gifford

Veterinary Biologics, CFIA, Food Directorate, Health Protection Branch, of Health Canada

Primal Silva

Veterinary Biologics, CFIA

Manjeet Sethi

Veterinary Biologics, CFIA

Luc Bonbonnière

Seed Section, CFIA

D. Fournier

Consumer Protection & Food Policy Coordination, CFIA

P. Haddow

International Affairs, CFIA

Participating in the discussions

Nora Nishikawa

Biotechnology Communications Manager, Office of Biotechnology, CFIA Visit coordination

Travel to Washington DC.

TUESDAY 14 SEPTEMBER 1999 WASHINGTON DC, USA

DuPont

Terry L. Medley

Vice President, Biotechnology Regulatory & External Affairs, DuPont Nutritional & Health Agricultural Enterprise Dupont and the global society: past and future position

Celeste D. (Clete) Boykin

Manager, Government Affairs, External Affairs, DuPont Participating in exchanges of views

Quentin Kubicek

DuPont

The Dupont plant biotechnology research program and its relations to regulatory institutions

Dr. Amy K. Flatten, National Science & Technology Council, Executive Office of the President, Office of Science & Technology Policy

The Government's policy towards biotech legislation

<u>Biotechnology Industry Organization</u> (BIO)

Carl Feldbaum

President, Biotechnology Industry Organization BIO

L. Val Giddings

Vice President, Food & Agriculture, BIO *Industry and public: a global approach*

Carol Bolan

President, Food & Agriculture, Pioneer Hybrid Seed Company

Jorge Fenyvesi

President, DNA Plant Technology Corporation

Dr. Sally Van Wert

Head, Regulatory Affairs/Biotechnology North America, AgrEvo USA Bio Board members' discussion with Southeast Asian visitors

Office of Science and Technology,

Cliff Gabriel

The White House

Head, Office of Science and Technology, The White House

World Bank

Eugene Terry

Advisor, Agricultural Research & Environmentally Sustainable Development

Gesa Horstkotte-Wesseler

Junior Professional Officer, Agricultural Research & Extension Group

M. Uma Lele

Adviser, Rural Development Department

WEDNESDAY 15 SEPTEMBER 1999 WASHINGTON DC, USA

Pioneer Hi-Bred International

Carol Bolan, President, Food & Agriculture, Pioneer Hybrid Seed Company Breakfast meeting

Food & Drugs Administration

Nega Beru

Industrial Coordinator for GM Food, Team Leader, Regulatory Policy Branch, Division of Product Policy, Office of Pre-Market Approval, FDA Regulatory policies in the US

<u>United States Department of Agriculture</u> (USDA)

Patrick M. Steel, Associate Administrator, Foreign Agricultural Service, USDA

Rebecca Fecitt

Food Safety and Technical Services Division, International Trade Policy, USDA

Beverly J. Simmons

Assistant Deputy Administrator Responsibilities and concerns of the administration

Animal and Plant Health Inspection Services (APHIS)

Richard L. Dunkle

Deputy Administrator, Agricultural Plant Health Inspection Service, US Department of Agriculture

Subhash C. Gupta

Biotechnologist
Introduction to APHIS

Monsanto

Jack H. Watson

Chief Legal Strategist

Monsanto's contribution to agri-biotech

acceptance

Gerard Barry

Co-Director, Rice Fellow Perspectives of Rice breeding

Judith Chambers

Director, International Government Affairs Small holder farmers development program

Bob Harness

Biosafety Protocol

Steve Englebert

Senior Vice President on Government Affairs Lessons learned in the European Union

Patricia Ward

Manager, Public Policy Program

Lisa Watson

Public Affairs

Information and contact to growers, consumers and the general public

Janet Collins

Manager, Applied Nutrition *The Codex*

THURSDAY 16 SEPTEMBER 1999 WASHINGTON DC, USA

The Grocery Manufacturers of America (GMA)

Karil L. Kochenderfer

Director, International Trade & Environmental Affairs, GMA

International Food Policy Research

Institute (IFPRI)

Per Pinstru-Andersen

Director General and IP Expert

Union of Concerned Scientists

Margareth Mellon

Program Director, Agriculture and Biotech-

nology Program

Jane Rissler

Senior Scientist, Agriculture and Biotechnol-

ogy Program

FRIDAY 17 SEPTEMBER 1999 WASHINGTON DC, USA

International Food Information Council

Sylvia Rowe

President, International Food Information

Council IFIC

Andy Benson

Director of International Outreach

David Schmidt

Senior Vice-President, Food Safety

Return to Southeast Asia.

Acknowledgments

This report represents the observations, views, and conclusions of the participants in the Traveling Workshop, as compiled by ISAAA's Vice Chairman, Jasper E. Van Zanten, and Anatole F. Krattiger, based on notes taken by the participants and the authors of this *ISAAA Briefs*. The Study Group held several evaluation sessions and agreed that their generic views would be written-up. Therefore, no individual opinions may be extracted from the report, nor can any of the Traveling Workshop members be held responsible individually for the statements made in this report.

The six participants must be recognized for making quality time available for this Traveling Workshop. It is gratifying to note that they felt their time was well spent and that others from the region should be given an opportunity to participate in future Traveling Workshops. As one of them noted: "I felt it was very balanced, and timely and accurate information is so important. Any policy maker should take the opportunity to do something like this. I would always recommend an ISAAA sponsored trip to anyone."

All hosts showed a remarkable willingness to cooperate in the Traveling Workshop. In the Netherlands, Dr. Piet van der Meer of the Ministry of Environment provided both space and information. The Workshop organizers and participants recognize the strong encouragement and information given by Mr. F.H. Vigeveno, Senior Vice

President of Unilever. Dr. Sandy Thomas and Ms. Julia Fox of the Nuffield Council on Bioethics made extremely valuable contributions to the success of the meetings in the UK, which were chaired by Prof. Roger Hull. Ms. Camilla Beech of Zeneca Plant Science hosted the Group to discuss and evaluate their trip.

The highly efficient organizational work in Canada by Dr. Joyce Groote of BIOTECanada and by the Canadian Food Inspection Agency was very much appreciated. Finally, acknowledgement is made of the reception in Washington, D.C., by DuPont, by the Board of BIO of the USA, the White House Office of Science and Technology, the World Bank, the American Grocery Manufacturers, the American Food Information Council, Monsanto, and the Union of Concerned Scientists.

ISAAA appreciates the contributions of several of its officers and board members for organizing the Study Group Tour: Dr. Randy Hautea, Director of the ISAAA SEAsiaCenter for bringing the participants together, Dr. Clive James, Chair, for his foresight of the timeliness and value of face-to-face information/knowledge supply to Southeast Asian policy makers, David Alvarez, Director of Administration at the ISAAA AmeriCenter for editing this document, and Patricia Brand and Fely Almasan for making all the travel arrangements.