

MODULE IV—ENSURING SAFE AND HEALTH FOOD

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Module IV—Ensuring Safe and Health Food

Introductory Remarks

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This session is titled *Ensuring Safe and Healthy Food* and we have already touched upon issues of safety and the healthfulness of food and of diets. Presumably healthy diets and safe food are common goals that everyone would agree upon. There are clearly differences in terms of priorities across the world although some would argue that those priorities are becoming more common. For example, obesity rates—notoriously high in Canada, the United States and in the United Kingdom—are also increasing very dramatically in many lower-middle-income countries. So, for example, the estimate that I saw from the International Food Policy Research Institute (IFPRI) was that the rates of clinical obesity, even in Latin American and Caribbean countries are now at 10% and increasing. Even in some countries of sub-Saharan Africa they are at 5%. So, we are seeing movement towards even more common priorities.

*Health and safety are, as well as scientific constructs, also
social constructs.*

We have talked a lot about causes of food insecurity. The FAO estimates there are 842 million under-nourished people in the world and the number of food-insecure is clearly a lot bigger than that. And we have discussed the reasons, demand-side and supply-side factors—I have to get those words in, being an economist—and where we position biotechnology within that framework; I think that's a very important issue. And another issue that we have hinted upon, which for

me at least is an interesting thing and a good thing, is that health and safety are, as well as scientific constructs, also social constructs. So, what represents healthfulness and safety is not only defined in terms of rates of obesity and in terms of gastrointestinal infections for example, but about how people feel in terms of what is healthy and what is safe. That creates many challenges in terms of dialogue and in terms of communication, but also in terms of setting priorities. What may be regarded as safe and healthy to an Indian consumer may be different from the opinions of a Canadian consumer to some extent.

A few days ago, when thinking about this conference I came across an interview with Hugh Grant, CEO of Monsanto, in the *Financial Times*: “We’ve Bet the Farm On This.” Grant is from a Scottish farming family and in the article the challenge of heading Monsanto, particularly given its history, comes across. It contextualizes some of the discussions we’ve been having here. He asks: “Is a skeptical and frequently cynical audience prepared to listen? The mistake that companies like mine have made, but we’re not exclusive in the mistakes category, is the belief that good science will prevail.” Grant says that much of society doesn’t speak “science.” The debate has to move on and take account of the fact that we are shifting from what Grant calls a “trust-me” to a “show-me” society. A “trust-me” society is a paternalistic society that says, “Don’t worry about it, it’ll be fine, I know best. We have your interests at heart, this will work.” According to Grant, the “show me” society says, “I might not understand the data and that’s okay if I don’t. But I want to know that I can access it at any time and I want to know that my views are relevant to this debate.”

I don’t necessarily agree with everything he says. I’m not sure what the term “good science” means, for example. But, his context and the challenges he articulated are interesting.

Ensuring Safe and Healthy Food has three eminent speakers: Edilberto Redoña, Florence Wambugu, and Suzanne Harris.

Rice Biotechnology for Developing Countries in Asia

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Rice (*Oryza sativa* L.) is the staple food for more than three billion people, over half the world's population. It provides 27% of dietary energy and 20% of dietary protein in the developing world. Rice is cultivated in at least 114, mostly developing, countries and is the primary source of income and employment for more than 100 million households in Asia and Africa (FAO, 2004). Of the 840 million people suffering from chronic hunger, over 50% live in areas dependent on rice production. About 80% of the world's rice is produced on small farms, primarily to meet family needs, and poor rural farmers account for 80% of all rice producers (FAO, 2004). Less than 7% of the world's rice production is traded internationally (Maclean *et al.*, 2002) and with this small marketable surplus, prices fluctuate widely with droughts, floods, and typhoons (Hossain, 1997).

Rice is the dominant crop in Asia where, in many countries, it covers half of the arable land used for agriculture (Cantrell and Hettel, 2004). The Asian continent, host to 56% of humanity including 70% of the world's 1.3 billion poor people, produces and consumes around 92% of the world's rice (Papademetriou, 1999). Nine of the top-ten rice-producing countries in 2003, namely, China, India, Indonesia, Bangladesh, Vietnam, Thailand, Myanmar, the Philippines, and Japan are in Asia. China and India combined account for more than half of the world's rice area, and, along with Indonesia, consume more than three-fourths of the global rice production (Hossain, 1997; Maclean *et al.*, 2002).

In addition to being the world's most popular staple—cultivated for more than 10,000 years—rice provides a symbol of global unity and cultural identity for many countries where its cultivation is intertwined with religious observances, festivals, customs, folklore, and other traditions. Cognizant of this, the United Nations launched the International Year of Rice in 2004 with the theme Rice is Life, the first time a year has been dedicated to a single crop, to underscore the enormous implications of rice for human nutrition, global food security, and alleviation of poverty (FAO, 2004).

THE CHALLENGE TO INCREASE RICE PRODUCTIVITY

Record rice-production increases occurred during the last three decades of the twentieth century, beginning with the Green Revolution. In many Asian countries, yield levels doubled or tripled from the pre-Green Revolution average of 1.9 tons per hectare (t/ha) (Figure 1). Between 1966 and 2000, populations of low-income countries increased by 90%, while rice production increased by 130% from 257 million tons (Mt) in 1966 to 600 Mt in 2000. Average per-capita food availability was 18% higher in 2000 than in 1966 (Khush, 2004). About 84% of the rice-production growth has been attributed to modern farming technologies such as varieties that are semi-dwarf, early maturing, non-photoperiod sensitive (and can, therefore, be planted more than once per year), and responsive to nitrogen (N) fertilizer (Maclean *et al.*, 2002). More than 2,000 modern varieties have been commercially released in twelve countries of South and Southeast Asia over the past 40 years (Cantrell and Hettel, 2004). Gradually, resistances and tolerances to biotic and abiotic stresses were incorporated into many of these varieties, thereby extending their cultivation and productivity potential. As a consequence, rice-production cost per unit output was reduced by 20 to 30%, which translated to reduced rice prices at the consumer level from about US\$450/t unmilled rice in the early 1950s to less than US\$300/t by 1999 (Maclean *et al.*, 2002). Furthermore, these productivity gains have allowed production to more than double and fulfill the demand of a population that grew by 80% in the same period. This has helped to reduce world market rice prices by 80% over the last 20 years (Cantrell and Hettel, 2004).

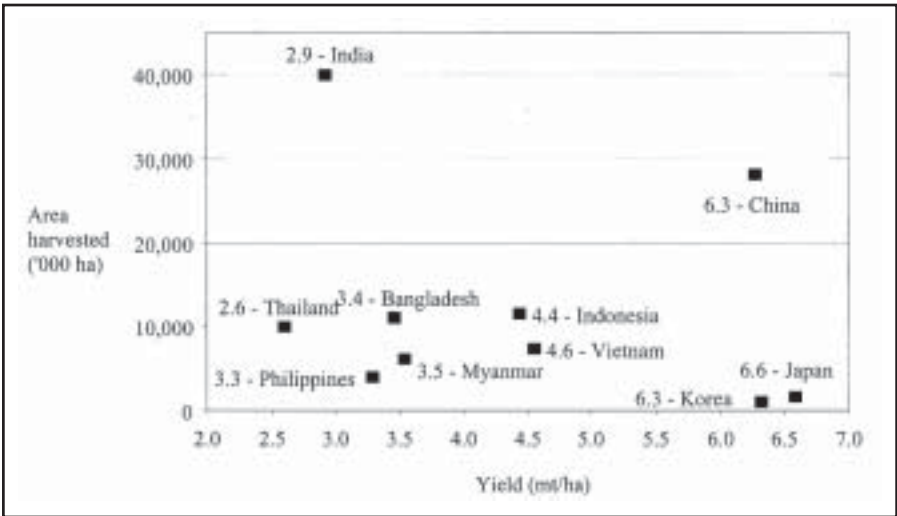


Figure 1. Area harvested and yield levels in major Asian rice-growing countries (FAO, 2004).

There is tremendous pressure, however, to further improve rice productivity in order for it to keep pace with population growth. In Asia, it is projected that demand for rice will increase by 70% over the next 30 years, driven primarily by population growth that, excluding China, is expected to increase by 51% (Hossain, 1997). The Asian population is expected to increase from 3.7 billion in 2000 to 4.6 billion in 2025 (Cantrell and Hettel, 2004). The urban population will nearly double from 1.2 billion to 2.0 billion, as people move from rural areas to the cities in search of employment.

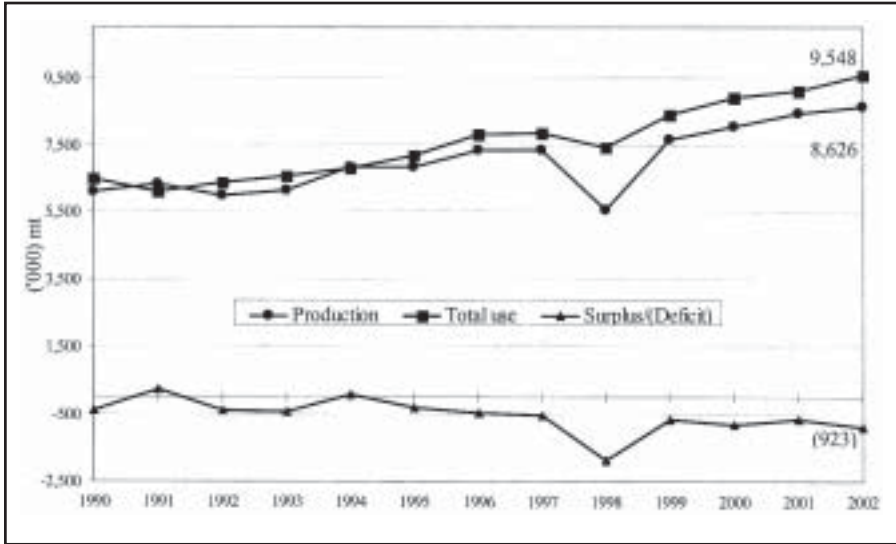


Figure 2. Trends in rice production, utilization, and importation in the Philippines, 1990–2002.

In the Philippines, 65% more rice, relative to present levels, has to be produced by 2025 to keep pace with demand by a projected population of about 107 million, growing by 2.3%/year (Figure 2). To keep up with projected demand, rice-production growth must be sustained at 3%/year, if importation is to be avoided, as espoused by many Asian governments. Given that annual rice-production growth rates have been decelerating to less than 2% per year, and the land frontier—the primary source of growth in recent years—is closing (Table 1), major technological progress has to be achieved in the next two decades for the population demand for rice to be met locally. Against the backdrop of decreasing land, labor, and water that can be devoted to rice production due to increasing competition from non-farming sectors, the challenge to increase rice productivity is indeed enormous.

TABLE I. SOURCES OF GROWTH OF RICE PRODUCTION IN THE PHILIPPINES, 1970-2001.

Source of growth	All		Wet season		Dry season	
	1970-86	1986-01	1970-86	1986-01	1970-86	1986-01
	(%)					
Area	-0.18	0.96	-1.0	-0.89	1.4	2.9
Yield	3.9	0.67	3.9	0.71	3.5	0.66
Production	3.6	1.6	2.9	-0.18	4.9	3.6

CONSTRAINTS IN ASIAN RICE PRODUCTION

Rice productivity and quality are severely compromised by pests, diseases, and physiological and environmental factors. The crop is the world's single largest market for agrochemicals, consuming around US\$3.7 billion annually, with agrochemical costs and crop losses amounting to tens of billions of dollars per year (DFID, 2004). Furthermore, rice cultivation per se is hobbled by resource constraints such as scarcity of water and scarcity of land. Clearly, therefore, technological progress is required in both the biotic and abiotic fronts.

There is a need to increase water productivity of rice.

Scarcity of Water

Rice is a moisture-hungry crop. It consumes twice the water needed to grow corn or wheat. Producing 1 kg of rice requires from 3,000 to 5,000 L of water (Cantrell and Hettel, 2004). In Asia, 90% of the total diverted freshwater is used for irrigated agriculture and, of this, 50% is used to grow rice (IRRI, 2001). By 2025, however, a "physical water scarcity" is expected in Asia's more than 2 million hectares (Mha) of irrigated dry-season rice and 13 Mha of irrigated wet-season rice, and most of Asia's 22 Mha of irrigated dry-season rice will be hampered by "economic water scarcity" (Tuong and Bouman, 2002). As drought is one of the main constraints to high yields also in rainfed-production systems in both the lowlands and the uplands, there is a need to increase water productivity of rice (Cantrell and Hettel, 2004).

Scarcity of Land

Due to competition from non-farming sectors, the land devoted to rice production is decreasing in many Asian countries. In the Philippines, for example, about 10,000 ha of prime rice land is lost annually to the urban and industrial sectors. With water resources becoming limiting and enormous resources required to construct irrigation facilities, there appears to be little room for future expansion of irrigated areas in developing countries. Hence, the contributions of fragile environments such as the rainfed lowlands, uplands, and salinity-prone areas to rice

productivity growth will be increasingly important. Technologies, therefore, will be required not only for increasing rice productivity in these environments, but also for preventing resource and environmental degradation in marginal areas.

Pests and Diseases

Intensive and continuous cultivation makes rice vulnerable to various pests and diseases. Although breeding for resistance, coupled with popularizing integrated pest management, has contributed to managing pest populations and minimizing damage levels in many Asian countries, a wide range of viral, bacterial, and fungal diseases still causes economic losses in farmers' fields. For example, tungro, the most destructive viral disease in Southeast Asia, results in crop losses worth more than US\$1.8 billion annually (DFID, 2004). On the other hand, aside from causing damage by direct feeding, insect pests also act as vectors for various important rice diseases. Among the most important in the Philippines, are tungro, bacterial leaf blight, sheath blight, and rice blast, while the important insect pests are brown planthopper, whiteback planthopper, and green leafhopper, the latter being the vector for the tungro virus.

Constraints and Yield Loss

Yield losses due to biophysical constraints have been extrapolated for Asia by Hossain (1997) and Evenson *et al.* (1996) (Table 2). In the irrigated ecosystem, yield losses due to technical constraints accounted for 20% (962 kg/ha) of the average yield, with soil-related problems being the most significant. On the other hand, yield losses due to technical constraints accounted for 33% of average yield in rainfed lowland and flood-prone ecosystems, with submergence being the most important, while it was more than 40% of the average yield in the upland ecosystem, with drought being the most significant. Overall, all technical constraints caused a total yield loss of about 23% or 833 kg/ha in Asia, with abiotic factors being more important than biotic for all ecosystems. Climate-related constraints like submergence, drought, and cold resulted in yield losses that ranged from 227 kg/ha (20% of average yield) for upland to 429 kg/ha (28% of average yield) for flood-prone ecosystems. Yield losses due to pests and diseases, on the other hand, were most significant in the rainfed ecosystem while those due to weeds were most important for the upland environment.

Tropical Hybrid Rice

In addition to China, a number of countries in tropical Asia, notably, India, Vietnam, the Philippines, Indonesia, Bangladesh, and Sri Lanka have launched national programs aimed at commercializing hybrid rice. These programs aim to exploit the phenomenon of heterosis or hybrid vigor, which provides about 1 to 1.5 t/ha (15 to 20%), higher yields than those obtained using the best inbred varieties under irrigated conditions. The associated seed-production technology that must accompany commercialization promotes the development of seed industries that provide additional rural employment. Already a commercial success in China,

TABLE 2. YIELD LOSS DUE TO TECHNICAL CONSTRAINTS IN THE RICE ECOSYSTEMS OF ASIA (EVENSON ET AL., 1996).

Constraint	Irrigated	Rainfed lowland	Flood-prone	Upland	Average loss for Asia	
					(kg/ha)	(%)
Biotic						
Diseases	69	146	18	70	83	3.1
Insects	108	166	16	65	110	2.3
Other pests	29	88	21	120	52	1.4
Abiotic						
Water	400	288	429	227	358	9.9
Soil	356	75	13	80	229	6.4
Total	962	763	496	563	833	23
Loss of yield (%)	20	33	33	40	23	

In the Philippines, the commercialization of hybrid-rice technology has been embraced as the government's banner program for agriculture.

where 15 Mha (50% of the total rice area) are planted to hybrid rice varieties, about 1 Mha were estimated to be planted to hybrids in tropical Asia in 2003 (Virmani, 2003). In the Philippines, the commercialization of hybrid-rice technology has been embraced as the government's banner program for agriculture, with 200,000 ha planted to seven commercially released hybrids in 2004 (Redoña *et al.*, 2003). Results of the program from 2001 to 2003 showed an average superiority in the yield of hybrids of 1.59 t/ha or 36% over that of modern inbred varieties.

New Plant Type

In the early 1990s, IRRI started developing "new plant type" (NPT) rice that is expected to reach farmers' fields during this decade. With redesigned plant architecture that increases total biomass and harvest index, these "super" varieties—intended for direct seeding—are expected to yield about 20% more than current modern varieties. Several NPT lines with yields >10 t/ha have already been distributed, *e.g.* to Indonesia and the Philippines, for adaptation trials and three NPT varieties have already outyielded popular modern varieties in China by more than 1 t/ha (Cantrell and Hettel, 2004). NPT rices trace their lineage to both the indica and japonica subspecies and are, therefore, also valuable sources of genetic diversity in breeding for higher yield potential and heterosis.

“Aerobic” Rice

To strategically address the projected water scarcity, IRRI has also developed an “aerobic rice” technology that aims to significantly reduce the crop’s water requirement below current levels. Patterned after the rice grown in irrigated upland areas of Brazil, the “aerobic” plant for tropical Asia is expected to yield 6 to 7 t/ha under a crop-management system that will provide only half as much water as rice requires today (Cantrell and Hettel, 2004). In China, where “aerobic” rice has been tested on 190,000 ha, yields of 6 to 7 t/ha have been obtained, while, in the Philippines, several varieties with yield potentials of approximately 6 t/ha have been identified for use under “aerobic” conditions (Bouman, 2003).

Integrated Crop Management

Following the successful promotion of an integrated pest management program across Asia, an even more comprehensive rice-crop management system—designed to close the yield gap—is being piloted in Vietnam, Thailand, Indonesia, and the Philippines, with the support of the United Nations Food and Agriculture Organization (FAO). It is referred to as “rice integrated crop management” (RICM). Similar to the Rice Check system that has been dubbed a major contributor to increases in rice yields in Australia, from 6 t/ha in 1987 to 9.7 t/ha in 2000 (Nguyen, 2002), it provides a platform for the integration of different production technologies and decision-making support tools that should allow farmers to move closer to the practice of real-time precision rice agriculture. In the Philippines, a Rice Check prototype that involves eight key checks throughout the growing season was piloted on-farm beginning in 2004.

Rice-Based Farming Systems

In line with the Asia’s aim to improve the profitability of rice farming, alleviate poverty, and achieve food security at the household level, particularly in marginal or fragile environments where the poorest of Asia’s farmers live, diversified systems that integrate crop, livestock, and fish components are being developed in several countries. In the Philippines, for example, crop relays that result in the highest profits have been identified for the rainfed lowland ecosystem, planting calendars based on agroclimatic data have been formulated for adoption by farmers, and GIS suitability maps have also been developed for use of local government units in the prioritization of agricultural programs.

BEGINNINGS OF BIOTECHNOLOGY IN RICE

In modern parlance, “biotechnology” generally refers to genetic manipulation at the DNA level. However, it is important to note that not all biotechnology involves genetic engineering or recombinant DNA techniques that result in transgenic plants or genetically modified (GM) organisms. In the strictest sense, biotechnology could also refer to specialized fermentation processes, *in-vitro* culture techniques such as embryo rescue and double haploidization, and protein engi-

neering. For the purpose of this paper, however, “biotechnology” will imply manipulations at the level of DNA.

The potential of plant biotechnology to contribute greatly to the world’s fight against hunger and malnutrition, poverty, and environmental degradation—despite claims to the contrary—has already been generally acknowledged. In Asia, agricultural biotechnology has been recognized as having the potential to:

- increase crop and animal productivity,
- improve nutritional quality of food,
- broaden tolerance of crops for drought, salinity, and other abiotic stresses, and
- increase resistance of crops to pests and diseases (ADB, 2001).

Applied to problems of poor farmers, biotechnology holds the greatest promise for increasing yield potential and quality in many crops. This in turn should enhance the attainment of sustainable household and national food security and proper human nutrition, while increasing profits and reducing farming costs, thereby contributing to poverty alleviation, especially in fragile environments, where most of Asia’s poor live.

One of the most comprehensive assessments of the potential that biotechnology holds for a given crop was made for rice by the Rockefeller Foundation (RF) in the process of developing its International Program on Rice Biotechnology (IPRB) (O’Toole *et al.*, 2001). Culminating in the publication *Rice Research in Asia: Progress and Priorities* (Evenson *et al.*, 1996), a series of studies identified the top-twenty priority traits for biotechnology research intervention, balancing research costs *vis-à-vis* the benefits from expected increases in rice productivity or value (Table 3). With clear research priorities in place, in the mid-1980s RF supported a 17-year program that laid the scientific foundation for rice biotechnology as we know it today. At about the same time, national agricultural research systems (NARS) around Asia began building capacity for biotechnology. The salient accomplishments of the IPRB include:

- the generation of the first DNA molecular marker map of rice;
- the transformation and regeneration of rice;
- the use of rice-pest genomic information to understand host-plant resistance;
- discoveries that changed the way rice geneticists view breeding objectives, such as insect resistance, abiotic-stress tolerance, and hybrid rice;
- the discovery of rice’s pivotal genomic position in the evolution of cereal species;
- the transfer of resulting biotechnologies to institutions in rice-producing and -consuming countries; and
- the strengthening of both physical and human resources in cooperation with national and international rice research systems in Asia, Africa, and Latin America (O’ Toole *et al.*, 2001).

TABLE 3. IMPORTANCE OF RICE RESEARCH CHALLENGES MEASURED BY EQUITY-WEIGHTED NET PRESENT VALUE (NPV) AND POTENTIAL OF BIOTECHNOLOGY (BT) TO ADDRESS THE CHALLENGE (HERDT, 1991).

Challenge	NPV worldwide	Weighted NPV x BT potential
Brown planthopper	1,944	1,944
Tungro virus	1,726	6,905
Gall midge	1,292	2,583
Greater lodging resistance	1,228	1,228
Cytoplasmic male sterility	1,161	2,322
Upland drought/blast	1,085	1,962
Yellow stem borer	945	3,781
Submergence (flash flood)	842	1,685
Weeds	718	359
Seedling vigor	540	1,080
Birds	412	206
Cold at seedling	310	310
Drought at anthesis	288	575
Apomixis	275	275
Bacterial blight	274	137
Waterlogged	262	524
Coastal saline/acid	256	256
Sheath blight	168	336
Storage insects	158	158
Ragged stunt virus	155	621

More than 400 rice scientists, primarily from Asia, were trained in advanced laboratories around the world.

The last item involved international collaborative research-cum-training that successfully linked emerging national rice biotechnology efforts directly to advanced research institutes in the United States, Europe, Japan, and Australia, resulting in the training of more than 400 rice scientists, primarily from Asia, in advanced laboratories around the world. At least seventy-three institutions in twelve Asian countries have received research grants and had up to twenty scientists funded for formal training, including: PhD fellowships; dissertation

fellowships; postdoctoral fellowships; visiting-scientist fellowships; biotechnology career fellowships; and technology-transfer fellowships in advanced laboratories and universities in developed countries (Table 4, O'Toole *et al.*, 2001).

TABLE 4. BREAKDOWN OF NUMBER OF INSTITUTIONS BY COUNTRY WHERE FORMAL TRAINING WAS SPONSORED UNDER THE ROCKEFELLER FOUNDATION'S INTERNATIONAL PROGRAM ON RICE BIOTECHNOLOGY (O'TOOLE *ET AL.*, 2001).

Country	Number of institutions according to number of researchers trained ^a						
	>20	15–19	10–14	5–9	3–4	1–2	0
Bangladesh	–	–	–	1	1	–	–
China	–	1	4	4	2	6	5
India	1	1	–	5	7	7	3
Indonesia	–	–	–	1	–	1	–
Malaysia	–	–	–	–	–	1	–
Nepal	–	–	–	1	–	–	2
Pakistan	–	–	–	1	–	–	1
Philippines	–	–	1	1	–	–	–
South Korea	–	–	1	–	–	–	1
Sri Lanka	–	–	–	–	–	–	1
Thailand	–	–	1	1	–	3	1
Vietnam	–	–	1	2	–	3	–
Latin America	–	–	–	–	–	1	3
Total	1	2	8	17	10	22	17

^aColumn headings reflect the number of scientists trained under IPRB sponsorship.

The Asian Rice Biotechnology Network (ARBN) was formed in 1993, with IRRI as coordinator. It facilitated collaborative research amongst several Asian rice-breeding programs with a primary objective of developing disease-resistant varieties through the application of DNA-marker technology (Leung *et al.*, 2004). Among the major Asian R&D institutions involved were the Indonesian Agricultural Biotechnology and Genetic Resources Institute in Bogor, Indonesia; the Central Rice Research Institute in Cuttack, Orissa, India; the Punjab Agricultural University in Ludhiana, Punjab, India; the Philippine Rice Research Institute (PhilRice) in Muñoz, Nueva Ecija, Philippines; the Agricultural Genetics Institute in Hanoi, Vietnam; and the China National Rice Research Institute (CNRRI) in Hangzhou, Zhejiang, China.

PROGRESS IN RICE BIOTECHNOLOGY APPLICATIONS

With increased activities in biotechnology from the mid-1980s, rice gradually became the “model monocot” in molecular genomics research, and eventually was the first food crop to have its genome sequenced. Among the key advantages that rice offered as a model system were its small genome (~430 Mb) (Arumuganathan and Earle, 1991); the development and availability of a complete genome sequence (Komari *et al.*, 1998; Feng *et al.*, 2002; Goff *et al.*, 2002; Sasaki *et al.*, 2002; Yu *et al.*, 2002; The Rice Chromosome 10 Sequencing Consortium, 2003), its diverse germplasm (84,000 accessions at IRRI); and the development of a number of key resources for genomic mapping research (Chen *et al.*, 2002; McCouch *et al.*, 2002; Wu *et al.*, 2002). The progress achieved in biotechnology applications for rice improvement in two major areas—the use of molecular markers for identifying and introgressing favorable genes and gene combinations within the rice species, and the use of transgenic technologies to incorporate traits for herbicide tolerance, biotic-stress resistance, abiotic-stress resistance, and nutritional value into rice—was recently summarized by Coffman *et al.* (2004).

Use of Molecular Markers

The development of the first rice molecular map in the late 1980s (McCouch *et al.*, 1988) sped up molecular genetics research in rice. Among the early molecular marker applications for rice improvement were:

- construction of dense genetic maps using different populations,
- tagging and/or introgression of major genes and those underlying quantitative traits, referred to as quantitative trait loci (QTL),
- high-resolution characterization and fingerprinting of germplasm,
- assessment of the diversity of germplasm pools, and
- map-based gene cloning.

Molecular markers offered great potential for increasing the precision and speed of rice breeding as, among other advantages over phenotypic markers, they provided the ability to screen breeding populations regardless of growth stage; they permitted screening for traits that were extremely difficult, expensive, or time consuming to score phenotypically; and they distinguished the heterozygous condition without need for progeny testing (Coffman *et al.*, 2004). Molecular markers provided geneticists with powerful tools to dissect the inheritance of economically important traits, many of which are quantitatively inherited and complex in nature. Thus, studies dealing with QTLs were carried out on seedling vigor and tolerance to a variety of environmental stresses including drought, submergence, salinity, and mineral deficiencies and toxicities (Champoux *et al.*, 1995; Redoña and Mackill, 1996; Xu and Mackill, 1996; Flowers *et al.*, 2000; Gregorio, 2002; Price *et al.*, 2002). These traits were considered primary targets for molecular marker-aided selection (MAS) as breeding for them using conventional techniques often proved to be difficult.

MAS, or the selection of traits based on the presence or absence of a molecular marker (in lieu of phenotype) has already received a lot of emphasis in rice. The development of simple and less-costly marker systems based on the polymerase chain reaction (PCR) such as the simple sequence repeats or SSRs (McCouch *et al.*, 2002) contributed greatly to the use of MAS in various laboratories in developing countries. For example, at PhilRice—the NARS for rice in the Philippines—MAS studies are conducted to develop varieties resistant to bacterial blight, including the pyramiding of two to three bacterial-blight-resistance genes in a common genetic background, both for inbred and hybrid rice breeding. Gene pyramiding is expected to provide durable resistance against insect pests and diseases; early attempts in this direction were focused on bacterial blight and rice blast diseases and the brown planthopper. Introgressing genes from wild relatives into cultivated rice has also been accomplished with the aid of molecular markers, such as the bacterial-blight-resistance gene from *Oryza longistaminata* (Ronald *et al.*, 1992), and the yield traits from *O. rufipogon* (Thomson *et al.*, 2003). Markers have also been used to minimize the linkage drag that occurs in wide crosses and to obtain the desired recombinants in fewer generations during backcrossing (Blair *et al.*, 2003; Takeuchi *et al.*, 2003). Whole-genome, marker-based selection fosters new opportunities and makes efficient use of genetic variation both in cultivated rice and its wild relatives.

One of the most significant developments aided by the use of molecular markers in rice was the map-based cloning of Xa 21 and its subsequent use in developing varieties with broad-spectrum resistance to bacterial blight (O'Toole *et al.*, 2001). Starting with the genetic mapping, using RFLP markers of the Xa 21 locus in 1990 (Ronald *et al.*, 1992), the gene was cloned using map-based cloning techniques and a bacterial artificial chromosome library was made by 1995 (Song *et al.*, 1995; Wang *et al.*, 1995). By 1997, the gene had been pyramided with other Xa genes using PCR-based MAS (Huang *et al.*, 1997) and, by 1998, Xa 21 had been transformed into elite lines (Zhang *et al.*, 1998); field trials were conducted in China, India, and the Philippines by 1999. By 2000, a hybrid rice parental restorer line had been improved through MAS, resulting in resistant hybrid rices under field conditions (Chen *et al.*, 2000).

The IRRI-coordinated ARBN, supported by the Asian Development Bank (ADB) and the RF, played a key role in developing capacity for marker-aided analyses of pathogens and host-plant resistance in several national breeding programs. This network approach was found essential for the sharing of resources and providing sustained training in the adoption of new biotechnology tools and genetic knowledge in individual breeding programs of various NARS in Asia (Leung *et al.*, 2004). As a result of ARBN activities, elite or commercial rice lines with multiple disease-resistance genes have been developed in several participating countries (Table 5).

TABLE 5. MARKER AIDED SELECTION-IMPROVED VARIETIES AND THEIR CORRESPONDING INCREASES IN YIELD DEVELOPED BY RESEARCH TEAMS FROM ASIAN NARS (LEUNG ET AL., 2004)

Country	Background commercial/ Yield standard	Released (R)/ Near-release(NR)	Yield (t/ha)	Gain over yield standard (%)
Philippines	IR64	AR32-19-3-2 (NR)	5.1	0
	IR64	AR32-19-3-3 (NR)	6.7	31.4
	IR64	AR32-19-3-4 (NR)	6.1	19.6
	BPI Ri10	AR32-4-3-1 (NR)	6.0	17.6
	BPI Ri10	AR32-4-58-2 (NR)	6.5	27.5
	PSB Rc28	Yield standard	5.1	–
Indonesia	IR64	Angke (Bio-1) (R)	5.4	20.0
	IR64	Conde (Bio-2) (R)	5.4	20.0
	IR64	Yield standard	4.5	–
India	PR106	IET17948 (PR106-P2) (NR)	8.2	22.4
	PR106	IET17949 (PR106-P9) (NR)	7.9	17.9
	PR106	Yield standard	6.7	–
China	Zhong 9A/ Zhonghui 218	Hybrid Guofeng No. 2 (NR, R)	7.8	11.4
	II-3A/ Zhonghui 218	Hybrid II You 218 (NR, R)	8.3	18.6
	Zhonghui 218	(NR, R)		
	Shanyou 46	Yield standard	7.0	–

No transgenic rice has yet been commercialized in an Asian country. However, two GM varieties, both with herbicide tolerance, have passed the regulatory approval processes in the United States: the Liberty-Link™ rice of Aventis Crop Science (now Bayer CropScience) and CLEARFIELD™ rice from BASF, Inc.

Use of Transgenic Technologies

No transgenic rice has yet been commercialized in an Asian country. However, two GM varieties, both with herbicide tolerance, have passed the regulatory approval processes in the United States: the Liberty-Link™ rice of Aventis Crop Science (now Bayer CropScience) involving phosphinothricin (PPT) herbicide tolerance, specifically ammonium glufosinate, and CLEARFIELD™ rice involving imidazolinone herbicide tolerance from BASF, Inc. (AgBios, 2004). Ten trials on 11 ha and twelve trials on 45 ha were conducted in 2002 and early 2004, respectively, 90% of which involved Monsanto (Jia *et al.*, 2004). To indirectly gauge the extent of use of GM technology Coffman *et al.* (2004) utilized information on patent applications and classified these into the areas of:

- herbicide tolerance,
- biotic-stress resistance,
- abiotic-stress resistance; and
- nutritional traits.

Up to 2002, 307 patents had been filed in rice biotechnology from 404 different groups (Brookes and Barfoot, 2003). The largest number of patents was held by DuPont/Pioneer (sixty-eight), followed by Monsanto (thirty-three), Syngenta (thirty-two), Bayer (nineteen), public sector institutions in Japan, and Japan Tobacco.

For abiotic-stress tolerance, transgenic rice plants that produce trehalose at three to ten times the normal rate—resulting in tolerance to drought and/or salinity—have been developed by introducing the otsA and otsB genes for trehalose biosynthesis from Escherichia coli.

Amongst various traits, herbicide tolerance has been the major focus for the private sector. In the United States, Monsanto and Bayer were responsible for 80% of GM-rice field trials, primarily addressing herbicide tolerance (Brookes and Barfoot, 2003). Other countries in which herbicide-tolerant GM rice has been field tested include Italy, Brazil, Argentina, and Japan, and possibly China (Coffman *et al.*, 2004). Biotic-stress resistance, on the other hand, has been the primary focus for public-sector research institutions including those in Asia (Brookes and Barfoot, 2003). Specific traits being worked on using GM technologies include resistance to bacterial blight using the Xa21 gene, rice blast, rice hoja blanca virus, rice tungro spherical virus, rice yellow mottle virus, rice ragged stunt virus, the

brown planthopper, and yellow stem borer, the latter—using *Bt* technology—being the closest to commercialization. For abiotic-stress tolerance, transgenic rice plants that produce trehalose at three to ten times the normal rate—resulting in tolerance to drought and/or salinity—have been developed by introducing the *otsA* and *otsB* genes for trehalose biosynthesis from *Escherichia coli* (Garg *et al.*, 2002).

Perhaps one of the most promising, albeit controversial, applications of transgenic technology in rice has been the development of vitamin A-enriched varieties, popularly known as Golden Rice™ due to the slightly yellow color conferred to the endosperm (Potrykus, 2000; Figure 3). Beginning as a collaborative project in the early 1990s between the Swiss Federal Institute of Technology (ETH-Zurich) and the University of Freiburg, Germany, with Ingo Potrykus and Peter Byer, respectively, as lead collaborators, the Golden Rice™ project drew financial support from ETH-Zurich, the European Commission, and the Rockefeller Foundation.

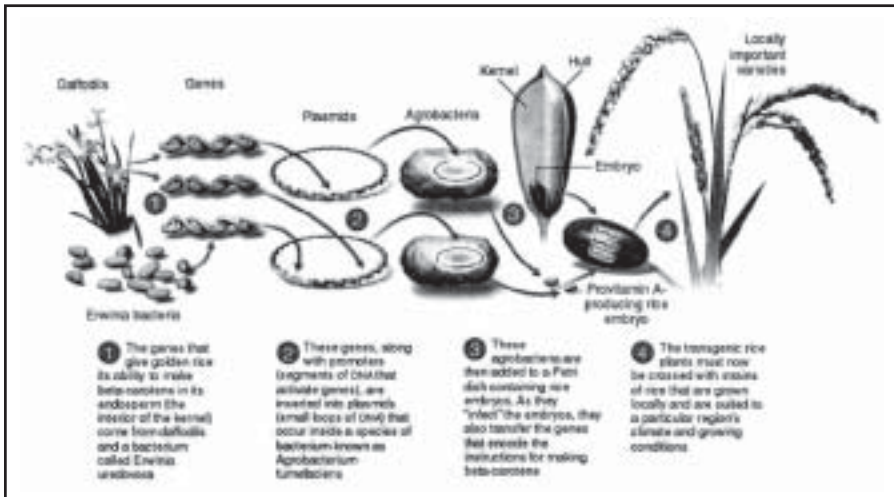


Figure 3. Development of Golden Rice™ (ISAAA, 2004a).

Vitamin A is considered essential for children and women of childbearing age and, worldwide, nearly 134 million children are at risk for diseases related to vitamin-A deficiency (VAD), including some 3.1 million preschoolers who suffer from eye damage, and nearly 2 million under 5 years of age who die each year from diseases linked to persistent VAD. In Southeast Asia alone, 5 million children become at least partially blind every year due to VAD. Golden Rice™ has the potential to improve the supply of vitamin A in the human diet, thereby, alleviating the suffering and death of millions of people, especially those who cannot afford diet diversification (ISAAA, 2004a).

With the proof of concept for rice to produce and accumulate pro-vitamin A (beta-carotene) in the seed endosperm tissue through genetic engineering already demonstrated (Beyer *et al.*, 2002), new vitamin-A enriched materials are now in the pipeline, including several popular Asian indica varieties such as IR64. Some of these new materials are said to contain ten times more pro-vitamin A than the original Golden Rice™ material that was eventually found unsuitable for commercialization as they were in a genetic background (japonica) not grown in most Asian countries. Reported to involve “clean” events, without cross-border transfers or antibiotic markers, the new materials are being readied for backcrossing and stability and field testing in 2004, while vitamin-A absorption and bioavailability tests are underway or planned in the Philippines, China, and the United States (Datta *et al.*, 2003; Coffman *et al.*, 2004; Cantrell and Hettel, 2004).

Another promising use of transgenic technology to improve human nutrition is in combating iron deficiency. One of the most common micronutrient deficiencies, it affects about 3.5 billion people worldwide and causes anemia, heart problems, neurological disorders, *etc.* The ferritin gene from *Phaseolus vulgaris* has been introduced into rice, resulting in doubling to tripling of the iron content in the endosperm, even after polishing the grain (Vasconcelos *et al.*, 2003). To improve the bioavailability of iron, since it is usually complexed with phytic acid, genes from *Aspergillus fumigatus* encoding a thermotolerant phytase protein and a cysteine-rich metallothionein-like protein were also introduced into rice resulting in a seven-fold increase in cysteine level and a 130-fold increase in phytase level (ISAAA, 2004b).

Only the Philippines has so far approved the commercial release of a transgenic food crop: a Bt-enhanced corn.

Many NARS in rice-growing countries of Asia that are endowed with universities and agricultural research institutes with biotechnology research capacity are actively involved in research on transgenic technologies, encouraged by supportive government policies. In a recent study by the International Food Policy Research Institute (Atanassov *et al.*, 2004), 209 transformation events were reported to have already been done in seventy-six scientific institutes in sixteen countries. Of these, 109 (52%) were done in seven Asian countries, namely, China (thirty), Indonesia (twenty-four), India (twenty-one), Philippines (seventeen), Thailand (seven), Pakistan (five), and Malaysia (five). Of these countries, however, only the Philippines has so far approved the commercial release of a transgenic food crop: a Bt-enhanced corn. Although the highest number of transformation events for any crop was reported for rice (18%), followed by potato (11%), maize (8.6%), and papaya (6.2%), a GM rice variety has yet to be commercialized in Asia.

To hasten public acceptance of biotechnology, a massive public-education campaign uses the tri-media as well as various public fora, and involves the government, private, NGO, and religious sectors.

In the Philippines, both IRRI and PhilRice have on-going biotechnology programs employing molecular marker and transgenic technologies, as well as other more conventional techniques such as *in-vitro* culture and wide hybridization. With the Philippine government declaring a supportive policy, the use of biotechnology is embedded as a strategy for achieving the goals set by the irrigated lowland, direct-seeded, rice for fragile environments, and hybrid rice multidisciplinary R&D programs of PhilRice. GM technology, in particular, is being used to improve high-yielding varieties, including NPTs and hybrid parental lines (Aldemita *et al.*, 2004). The Philippine focus is on tungro, sheath blight, blast, and bacterial blight diseases, as well as on insect stem-borer, and tolerance of salinity. Genes procured from laboratories around the world and modified for *Agrobacterium tumefaciens*-mediated transformation, are being used to generate transgenic plants. A number containing chitinase and glucanase genes have already been produced and tested under controlled greenhouse conditions. Moreover, PhilRice has conducted the first and only contained field trials for any GM rice in the Philippines; transgenic IR72 plants containing the Xa21 gene for bacterial-blight resistance showed complete resistance to nine Philippine races of the pathogen. Furthermore, transgenic plants with the pin2 gene are being developed to improve stem-borer resistance, while a coat-protein gene from the rice tungro bacilliform virus is being used in *A. tumefaciens*-mediated transformation. PhilRice, a member of the Golden Rice™ Network, has undertaken backcrossing work on discarded original Golden Rice™ materials. To expedite the availability of vitamin-A enriched rice to consumers, PhilRice hopes to continue its active participation in this network, which involves other Asian countries such as Indonesia, Vietnam, India, Bangladesh, and China, as well as partners in developed countries such as the United States, Germany, the United Kingdom, and Switzerland. Already, guidelines on the national testing of GM rice prior to commercialization are being prepared. To hasten public acceptance of biotechnology in general, and GM rice in particular, PhilRice, along with other Philippine government agencies, has spearheaded a massive public-education campaign using the tri-media as well as various public fora, and involving the government, private, NGO, and religious sectors.

Work in Progress

The availability of the complete rice-genome sequence offers opportunities to further our understanding of natural genetic variation and the effects of alleles and

their interactions, particularly for traits that are of importance in rice breeding, using specific genetic backgrounds and under specific environments. At IRRI, for example, biotechnologists are systematically assessing the array of phenotypes resulting from the disruption of putative gene sequences in mutants, near-isogenic lines, permanent mapping populations, and elite and conserved germplasm through an initiative on functional genomics (Hossain *et al.*, 1997; Leung *et al.*, 2004). However, these gene-discovery and allele-mining efforts require the annotation of the rice genome and the subsequent construction of databases and information resources. The use of information and communication technology and bioinformatics, such as the IRIS (Bruskiewich *et al.*, 2003; <http://www.icis.cgiar.org/>) and GeneFlow (<http://www.geneflow.com>) databases, should make the accumulating information more easily accessible to scientists, especially breeders in rice-growing countries.

Other work in progress includes attempts to transfer the C_4 -photosynthetic pathway and leaf anatomy genes of maize to C_3 rice in order to improve the latter's radiation-use efficiency while reducing transpirational water loss and N-fertilizer requirement, and studies aiming to more thoroughly understand genetic variation for drought tolerance using genomics and bioinformatics tools in order to identify the exact genes involved (Cantrell and Hettel, 2004). Another promising area is the genetic engineering of N_2 -fixation capacity into rice; attempts to engineer the *nif*-regulon into the chloroplast genome have the objective of making rice only partially dependent on external N and able to provide additional N during the grain-filling period to maintain the photosynthetic apparatus for a longer period of time (Potrykus, 2000). Over the medium and long terms, apomixis research, started earlier at IRRI, needs to be vigorously pursued using biotechnology in order to capture—and make available to resource-poor farmers—the benefits of heterosis.

ISSUES, CONCERNS, AND OPPORTUNITIES

Setting Biotechnology R&D Priorities

It may be argued that most of the earlier rice biotechnology activities, particularly in the public sector, and on transgenic technology applications, were more science-driven than attuned to the needs of ordinary farmers. A case in point is the development of Xa 21-enhanced IR72, a variety that, while high-yielding, is of little economic importance to farmers. In this regard, it is important to note that for GM rices to be useful, at least in the short term, and to gain rapid acceptance amongst resource-poor farmers, it is best that they be derived from varieties already widely grown and suited to specific agroenvironments (DFID, 2004). Ranged against the challenges confronting rice cultivation in most Asian rice-growing countries today, it is clear that, trait-wise, to have the greatest impact, international as well as NARS biotechnology research should focus, on one hand on the most important diseases and pests, and physiological and environmental factors

that reduce productivity and quality as discussed earlier, and on the other hand on increasing yield potential. An example of trait prioritization, has been advanced by Hossain *et al.* (1997, Table 6) for achieving the greatest impact on the lives of poor rice farmers and consumers, while being complementary to conventional rice-improvement efforts. Obvious from their analysis is the treatment of biotechnology not as a be-all solution to existing problems but as a tool or strategy complementary to conventional breeding efforts. To ensure relevancy of the biotechnology R&D agenda, a bottom-up approach is needed in the crafting of priorities, with farmers' and other stakeholders' needs and concerns adequately addressed. Such an approach should benefit from the rich indigenous knowledge of local farming communities on specific rice-production constraints, while facilitating public acceptance and ensuring the "trickling down" of benefits from biotechnology-derived products.

*It is incumbent upon the public sector to develop a
"pro-poor" biotechnology R&D agenda.*

Need for More Public Investments

There remains an imbalance in R&D investments in rice biotechnology that tends to favor developed countries, thus impacting on the potential of biotechnology to boost agriculture in the developing world and to alleviate the plight of resource-poor rice farmers. The concentration of biotechnology R&D in developed countries and the limited private-sector effort in developing countries, particularly in Asia, has raised concerns over the economic concentration of biotechnology in favor of developed countries and multinational companies (ADB, 2001). As the private sector is unlikely to undertake rice biotechnology research based primarily on the pressing needs of resource-poor farmers—due to difficulties in recouping costly investments—it is incumbent upon the public sector to develop a "pro-poor" biotechnology R&D agenda. Furthermore, public research products would have to gain similar approval as those developed by the private sector if transgenic research products and their concomitant potential benefits are to reach the poor.

While scientists in Asian countries have demonstrated the capacity to successfully undertake biotechnology R&D relevant to the needs of resource-poor farmers, the desired phenotypes have been few when compared to traits being developed by multinational firms and advanced research institutes in the developed world (Nuffield Council on Bioethics, 2004). One noteworthy aspect, however, has been the case of Thailand, which established the National Center for Genetic Engineering and Biotechnology (BIOTEC) in 1983. BIOTEC has supported biotechnology R&D in six areas, including the improvement of disease resistance in rice, particularly against rice blast. This disease affected 200,000 ha of rice in Thailand in 1993, causing serious economic loss and resulting in government intervention to

TABLE 6. PRIORITIZATION OF TRAITS FOR BIOTECHNOLOGY INTERVENTION IN DIFFERENT RICE-GROWING ENVIRONMENTS (HOSSAIN ET AL., 1997).

Priority traits	Target environment	Available products	Preferred approaches*		
			Conventional breeding	Marker-aided selection	Transgenic
Stress tolerance	Bacterial blight	Genes, markers, transgenic lines	++*	++++	++++
	Sheath blight	Transgenic lines	+	+	++++
	Blast	Markers	+++	+++	+
	Stemborer	Transgenic lines	+	0	++++
	Drought	Under development	++	+	+
Nutritional value	Salinity	Coastal	+++	+	++
	Vitamin A	areas	+	0	++++
	Fe	Gene constructs, transgenic lines	+++	0	+++
Yield enhancement	Zn	Gene constructs	+	0	?
	All ecosystem	Elite lines	++++	++	++

*The more "+" marks, the higher the priority; 0 = not applicable.

With field testing of various transgenic rices in progress since 1998, and with 53 ha planted in 2003, China is poised to becoming the first country in the world to commercialize transgenic rice.

assist stricken farmers, costing about US\$10 million. Since then, BIOTEC has supported research for the molecular genetic characterization of local blast isolates and mapping of blast-resistance genes, with focus on aromatic varieties for Thailand's export rice market. In 1999, BIOTEC also provided US\$3.7 million to fund the "Rice Genome Project Thailand," particularly for the sequencing of rice chromosome 9, which contains a QTL for tolerance of submergence, a very important concern of Thai farmers (Tanticharoen, 1997). Most rice-growing countries in Asia, with the exception of China and India (Atanassov *et al.*, 2004), however, have yet to launch similarly focused government initiatives on rice biotechnology R&D. In China, investments on public-sector biotechnology research have risen dramatically to \$1.2 billion for 2001–2005, a 400% increase over 1996–2000 levels, with about \$120 million allocated for transgenic rice R&D (Jia *et al.*, 2004). With field testing of various transgenic rices in progress since 1998, and with 53 ha planted in 2003, China is poised to becoming the first country in the world to commercialize transgenic rice.

Importance of Collaboration

Given the varying capacities for biotechnology research among rice-growing NARS and the limited resources allocated for biotechnology research in the public sector—unintentionally abetted by the phasing out of the Rockefeller Foundation's IPRB (O'Toole *et al.*, 2001), the constraints in NARS R&D budgetary allocations, and the reduction of funding support for international agricultural research centers (IARCs) including IRRI (Cantrell and Hettel, 2004), the need for biotechnology R&D practitioners to collaborate has become paramount. Collaborations need to be pursued at the individual, institutional, governmental, bilateral, regional, and international levels to ensure not only that the highest returns for R&D investments are attained, but also to facilitate regulatory approvals and biotechnology product commercialization. At the national level, the creation of a coordinating body such as BIOTEC in Thailand (Tanticharoen, 1997) should provide a mechanism for increasing efficiency in the use of limited national R&D budgetary allocations through the avoidance of research duplication and through sharing of in-country research capacity. On the other hand, a regional collaboration approach, as exemplified by the ARBN (Leung *et al.*, 2004), should be able to develop a biotechnology R&D agenda focused on the shared needs of rice farmers in the region and, where possible, pool human, scientific, and financial resources or,

alternatively, parcel out the research portfolio as was done in the rice-genome-sequencing initiative. One type of formal collaboration that is yet to be explored involves bilateral arrangements between countries. In the development of transgenic technologies, such South-to-South collaboration would facilitate learning and sharing of common approaches, genes, germplasm, regulatory trials, and biosafety-related information (Atanassov *et al.*, 2004). Already established broad-based regional cooperative efforts, such as the Association of Southeast Asian Nations (ASEAN) and the Asia Pacific Economic Conference (APEC) should be tapped to support these regional biotechnology undertakings. At the international level, programs that help rice scientists from developing countries to train, further hone their capacities, and maintain ties with advanced laboratories at the IARCs and in developed countries need to be supported.

IARCs and the Private Sector

With many NARS still not fully able to undertake, solely by themselves, activities spanning the whole biotechnology research, development, and commercialization spectrum, IRRI and similar international institutions will continue to contribute as technology and knowledge providers, as well as builders and enhancers of biotechnology capacity. Of particular importance for IRRI is the provision of strategic research outputs that, already, several NARS in Asian countries are capable of transforming into applications and products. These include protocols, gene constructs, and markers for traits relevant to local problems, but prohibitively expensive for NARS to develop single-handedly. Alternatively, IRRI should be able to complement its strategic research program with a product-development thrust, focusing on biotechnology-derived advanced breeding lines and varieties, with traits commonly of high relevance amongst Asian countries. The product-development portfolio includes varieties that are tolerant of drought, of high nutritional value, and are resistant to major diseases such as tungro and bacterial blight. The role of IRRI as facilitator in the transfer of useful technology and products amongst NARS through the sharing of hardware, knowledge, and experience needs to be strengthened. Equally important is its role in facilitating the formation of effective NARS/public-sector and private-sector collaborations, so that NARS may access private-sector-held intellectual property (IP) on rice biotechnology and products. IRRI can also serve as a clearinghouse for IP-protected technologies from both the public and private sectors to facilitate access by NARS scientists. Training support by IRRI and similar institutions for NARS should now include those designed to advance NARS capacity on the science and management of biotechnology, IP rights, biosafety and food-safety regulations, and international negotiations. As Cantrell and Hettel (2004) argued, with IRRI's strengths, it can serve as the unbiased broker and facilitator amongst the rice NARS, advanced research institutions, and the private sector.

Other international organizations, such as the FAO, can help expedite progress in rice biotechnology in Asia by promoting and supporting networking mecha-

nisms such as the South-to-South cooperation model. They can also help in developing and supporting infrastructure for public-good agricultural research, providing knowledge and training to NARS researchers, enabling interactions amongst stakeholders through dialogue and similar fora, facilitating access to relevant IP, sensitizing policymakers on biotechnology-related issues, and assisting governments in the crafting of biotechnology-related policies. As the primary source of GM crops continues to be the private sector, technology transfer between the private and public sectors—in terms of products as well as experience in regulation, commercial development, and release of GM crops—would greatly benefit NARS. This technology transfer could be facilitated by private foundations such as the International Service for the Acquisition of Agri-Biotech Applications (ISAAA).

In total, seventy intellectual and technical property rights belonging to thirty-two companies and universities were used in product development and for which “freedom-to-operate” situations had to be applied for in order for NARS to begin using Golden Rice™ in further breeding and in de-novo transformation activities using locally adapted varieties

Intellectual Property Rights

The impact of IP rights on biotechnology research is often imbedded in discussions on public- and private-sector partnerships. There is a need to balance the fact that, on one hand public-sector institutions, due to limited resources, cannot fully avoid accessing private-sector-held IP during the development of their own products and, on the other hand, the private sector has to avail itself of IP rights protection to be able to safeguard its investments and commercial interests and to enable sharing of its IP with other sectors without fear of exploitation. The development of Golden Rice™ is a case in point. In total, seventy IP rights and technical property (TP) rights belonging to thirty-two companies and universities were used in product development and for which “freedom-to-operate” situations had to be applied for in order for NARS to begin using Golden Rice™ in further breeding and in *de-novo* transformation activities using locally adapted varieties (Potrykus, 2000). Several modalities, however, are still open to the public sector, providing access to genes and technologies from the private sector. These include licensing, the fact that patents have time limits, confidentiality agreements, and the purchase of genes for incorporation into local germplasm. New types of IP agreements

Compliance costs for regulatory approval could be prohibitive for many developing-country institutions.

have also evolved, such as the donation of IP facilities and “humanitarian”-use type agreements as were done with Golden Rice™, with the threshold for humanitarian versus commercial use being a \$10,000 income from the technology. As the issue of IP rights becomes increasingly important, strengthening of capacities of governments and science sectors of many developing countries will be needed to understand, deploy, and negotiate regarding biotechnology. Rice biotechnology practitioners in Asia need to be trained on the intricacies of modern IP rights systems and on negotiating with institutions and companies for the purpose of accessing IP, and applying for IP protection. Alternatively, research institutions could establish IP units, not only for negotiating with other institutions and sectors, but also for registration of their own biotechnology processes and products.

Regulatory Requirements

National biosafety committees in developing countries have made impressive progress in the drafting and implementation of biosafety regulations for the importation and testing of transgenic crops; regulations for field tests are already in place in rice-growing countries such as China, India, Thailand, and the Philippines (Atanassov *et al.*, 2004). A looming issue, however, revolves around the compliance costs for regulatory approval: they could be prohibitive for many developing-country institutions. In the various studies cited by Atanassov *et al.* (2004), annual compliance costs, including those for initial greenhouse and field screening, field testing for environmental impact, and food safety, but excluding technology development costs, ranged from US\$140,000 for a virus-resistant papaya in Brazil to US\$830,000 for a virus-resistant potato in South Africa. For rice, an annual regulatory compliance cost of US\$680,000 was estimated for a virus-resistant variety in Costa Rica (Sittenfeld, 2002) covering tests on molecular characterization and epidemiology, transgenic field trials, biosafety, IP rights, food-safety deployment, and gene flow. Given reduced NARS budgets, this could pose a major hurdle in the commercialization of rice biotechnology products from the public sector. It is hoped, however, that as knowledge and experience are gained by regulatory agencies, approval costs may decrease, both by reducing the number of required tests, and by shortening the length of experimentation. The latter would also avoid the risk of biotechnology products becoming irrelevant to farmers’ needs due to long delays in approval (Atanassov *et al.*, 2004). In this regard, continuous training of personnel in regulatory bodies of developing countries on new biotechnology developments and approaches is necessary for them to make

educated recommendations, as is envisioned in the Cartagena Biosafety Protocol (CBD, 2000). A well functioning regulatory system can hasten acceptance of biotechnology products by instilling public confidence that risk assessments are carefully done, science-based, and, therefore, reliable.

Biosafety and Food Safety

The benefits that biotechnology confers upon the environment include reduction in the use of agrochemicals and preservation of presently uncultivated and marginal lands and concomitantly of biodiversity due to increases in productivity in currently used arable lands. To sustain the rice agriculture resource base and avoid environmental disturbance, it is important to match new genes and biotechnology-derived varieties to the target environments (Atanassov *et al.*, 2004). In 2003, GM crops commercialized in the developing world were largely limited to insect-protected cotton in Argentina, China, India, Mexico, and South Africa (James, 2003, Figure 4); experience remains limited on safety assessments of GM food crops such as rice. Among developing countries, only four have approved a single transgenic event in a food crop (soybean in Brazil, the Czech Republic and Uruguay; and maize in the Philippines), two have approved two events (soybean and tomato in Mexico; soybean and maize in South Africa) and one (Korea) has approved three events (one in soybean and two in maize) (Atanassov *et al.*, 2004). Therefore, the sharing of experiences and knowledge from food-safety assessments done in these countries should be valuable for developing countries with rice-biotechnology products in the pre-commercialization stages. As rice is a food,

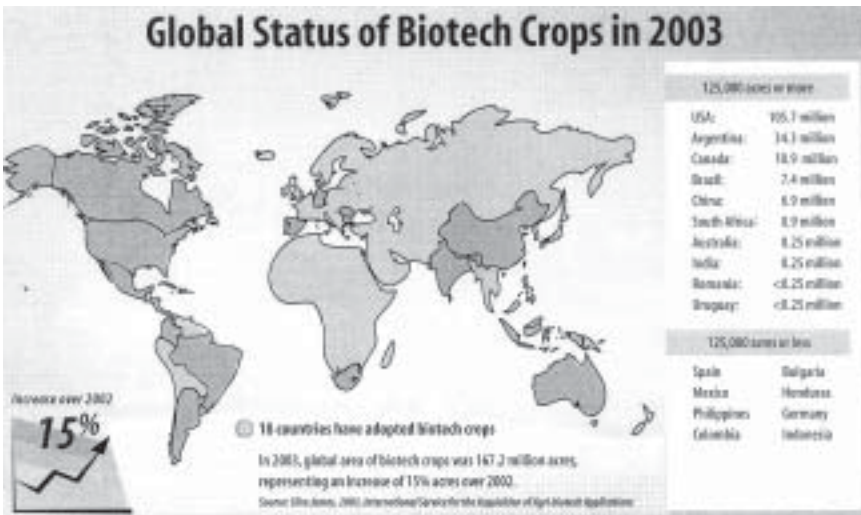


Figure 4. Global status of biotech crops in 2003 (James, 2003).

and *per-capita* consumption varies both within and among countries—from less than 100 kg/yr in China and India to over a 200 kg/year in Myanmar (Maclean *et al.*, 2002)—careful food-safety experimentation must be done in the case of nutrient-enhanced GM rice to remove any potential health dangers related to over-dosages; alternatively, effective GM-rice deployment strategies need to be developed.

Given all of these issues and challenges, lessons can be learned from the saga of Golden Rice™, as to the confluence of factors necessary for a rice-biotechnology product to be developed and commercialized for maximum impact. As detailed by Potrykus (2000), the Golden Rice™ project was made possible because of enabling factors such as:

- an environment supportive of independent research,
- strong institutional collaborative research partnerships,
- availability of the needed genes,
- support from donor institutions for strategic research for developing countries, and
- a highly motivated team of scientists willing to work on a pro-poor R&D agenda.

Potrykus further noted that the Golden Rice™ experience should:

- facilitate greater public acceptance of GM technology,
- encourage research investments in projects without guarantees of success,
- motivate research to be more food security- and less industry-focused,
- encourage free licensing for enabling technologies if used for humanitarian purposes, and
- motivate scientists to undertake projects relevant to the poor.

Rice production in Asia must increase from its current level of 545 Mt to 700 Mt by 2025 in order to feed an additional 650 million consumers while ensuring profitability for countless resource-poor farmers. Biotechnology—which has progressed rapidly to a point where transgenic rices are about to be commercialized—can help address these major challenges of guaranteeing food security while alleviating poverty in Asia.

CONCLUSION

Rice production in Asia must increase from its current level of 545 Mt to 700 Mt by 2025 in order to feed an additional 650 million consumers while ensuring profitability for countless resource-poor farmers. Biotechnology—which has progressed rapidly to a point where transgenic rices are about to be commercialized—can help address these major challenges of guaranteeing food security while alleviating poverty in Asia. New processes and second- and third-generation products of greater relevancy are also in the pipeline, expected to gain rapid acceptance both by farmers and the rice-consuming public. It is important to note, however, that biotechnology is not a panacea for achieving food security and sustainability of rice-based agricultural systems in Asia. The technology must address the existing and projected problems of small rice-farming communities and, at the same time, the dietary and health needs of more than half of the world's population. Furthermore, products must be designed so that they complement rather than replace existing practices, and enrich rather than disrupt the agroenvironments for which they are targeted for deployment.

The tasks ahead are gargantuan and the future—particularly for transgenic rice in Asia—remains uncertain. Full engagement of and dialogue amongst all stakeholders are needed at all levels, in the public, private, NGO, and other relevant sectors of society. New modalities of collaboration need to be explored. Asia must draw its lessons from cumulative experience in the developed world. Programs that stimulate open discussions and enable concerted and cooperative efforts to be made on the safe and relevant use of rice biotechnologies must be supported. Only then can the impact of science in general, and biotechnology in particular, be maximized for the benefit of the poor in Asia, through the attainment of stable and sustainable rice-based agriculture and household food and economic security.

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With 20 years experience in rice research, Redoña's foremost interests include the application of molecular markers and biotechnology in breeding, and development of hybrid rices. His contributions in these endeavors garnered him the Outstanding Young Scientist Award from the Philippine National Academy of Science and Technology, and the Outstanding Researcher and Best Research Awards from the Philippine Department of Agriculture. He leads the commercialization of hybrid rice technology, the Philippine government's banner program for agriculture.

Africa's New Focus in Establishing Food Security

FLORENCE M. WAMBUGU

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Africa Harvest is the latest member of the biotechnology family. It's an international foundation based in Africa with an African focus but also with a global vision, realizing that biotechnology cannot be done in isolation; it needs the cooperation of all stakeholders. We are a nonprofit foundation with a mission to use science and technology—including the tools of biotechnology—to achieve sustainable agricultural development. We realize that biotechnology is broader than genetic engineering and includes use of molecular markers, tissue culture and many other tools, but we also recognize the power of biotech in terms of genetic engineering.

Although we started just 3 years ago, we are making rapid progress. Two of our board members are here: Kanayo Nwanze and Mary Mackey. We are making various international contributions, including participation in the United Nations Millennium Hunger Task Force, which was started by Kofi Annan after the world summit in Johannesburg, and we provide input to the science board of the Bill Gates Foundation. Across Africa we are involved in the New Partnership for Africa's Development (NEPAD) and the Forum for Agricultural Research in Africa (FARA). With Dr. Nwanze, we are also in the Pan Africa Network, trying to see how we can help our continent. We have been involved by the African Union to talk about how science and technology can be used for economic empowerment of women in Africa in the twenty-first century. But most important are the national programs in which we demonstrate the impact of biotechnology for the poor. When all is said and done, we believe we have to touch people; our national downstream networks are fundamentally important.

In the big picture, according to United Nations standards, 800 million people are classified as hungry of which 200 million are in Sub-Saharan Africa. Africa is the only continent where hunger and poverty are projected to increase by the Food and Agriculture Organization.

The African food-security challenge is that 60% live in absolute poverty—it is estimated at between 60 and 70%—with 40% deemed food secure. There is a direct link between hunger and poverty in that, on average, Africans spend 80% of their income on food. This applies also to city dwellers; much urban poverty results from relatively high expenditure on food.

CHALLENGES

Africa's development challenges may be summed up as follows:

- investment in human development: nutrition, health, education, water, sanitation;
- increasing agricultural productivity by smallholder farmers;
- attaining an adequate threshold of infrastructure: roads, railroads, energy, ports, communications
- gaining access to global markets and fair trade.

In February 2003, I attended an FAO meeting in Johannesburg for discussion of the trade issues that emerged from the Cancun Meetings in Mexico. At the conclusion, President Mbeki of South Africa stated, in a strong speech, that scientists cannot solve Africa's problems alone; political intervention will be necessary especially to address unfair trade. Farmers in Africa who grow coffee, tea or cocoa, get less than 10% of the profit. Most of the money is made by the people who do the processing. It would be a delusion to think that by increasing production, scientists are going to solve the problems of Africa. There has to be political intervention because some of the policies set during the colonial era still apply. Tropical countries are still producing raw material for export and that issue is bigger than science can handle.

Investments are needed in urban infrastructure to establish industries to produce goods for export because young Africans don't want to be farmers. They want to live in the cities, yet jobs are not being created.

Another issue is empowering the poor, especially women, through democratic governance and human rights. We must protect and enhance natural and human-dominated ecosystems, including the urban environment. Urban poverty is destructive to development. Obviously, biotechnology is not going to solve all this; however, although there are bigger issues, that doesn't mean we cannot make significant contributions.

Another challenge facing us is to make smallholder farmers more productive. Population is growing and families are becoming larger, yet family farms are not growing in area. Children orphaned as a result of HIV are taken in by relatives. A family that would otherwise have been composed of husband, wife and five children may now be composed of ten or more. So we have to make each unit of land produce more, not only to provide basic nutrition but to help the family shift from subsistence to income generation.

INITIATIVES

There have been global initiatives to find solutions for Africa, including small-holder agricultural development and food-based safety net programs of the FAO, and the United Nations Hunger Task Force—we are playing a role in the UN Task Force with Pedro Sanchez—making markets work for the poor. Other initiatives have involved the Canadian International Development Agency (CIDA), the International Development Research Council (IDRC, Canada), the US Agency for International Development (USAID), the international centers of the Consultative Group on International Agricultural Research (CGIAR), national agricultural research institutes (NARIs) and non-governmental organization (NGO) programs.

African efforts to reduce hunger and poverty include the Pan African Initiative and this is why I see what I call a new awakening, a new paradigm, a new thinking-through. I see new strong political leadership under NEPAD and the African Union. I see Africans themselves taking political leadership roles in solving their own problems, in contrast to thinking that the World Bank, the International Monetary Fund or another external agency will sort things out. I see also strong science-based leadership; FARA—composed of forty-two African countries—is saying, “We need to identify what we can do as Africans and where we need help. After choosing good leadership, we will look for partners and participate in networks.”

African leaders in NEPAD resolved to put 10% of African GDP into agriculture research.

In a significant development in April, 2004, at a meeting in Maputo, Mozambique, African leaders in NEPAD resolved to put 10% of African GDP into agriculture research. In view of the fact that many African countries have traditionally invested less than 5% in agriculture, and in some cases 0%, this is a major initiative. This commitment is now being followed up: rather than depending wholly on donors, investment in our own agriculture can be used as leverage to attract wise investment externally. With investment of our own funds we have tighter control of the research, otherwise research direction is controlled by those who provide funds.

Another new initiative is NEPAD's Comprehensive African Agricultural Development Program (CAADP), which has identified “scaling up success modules” as the best way to progress. Three projects are in progress:

- New Rice for Africa (NERICA).
- Tissue-culture (TC) banana.
- Cassava.

Regarding NERICA—New Rice for Africa—we must recognize the leadership of Kanayo Nwanze; for the first time Africa was nominated for the World Food Prize. Monty Jones is the first African to be a joint winner for his work on NERICA at the Africa Rice Center (WARDA) in the Ivory Coast. NERICA rice has been chosen by NEPAD as a success model to be duplicated in the rest of Africa. Another is tissue-culture banana—which we have been working on—and the cassava program; others will be included in due course. The point is: instead of always starting new projects, we identify those that have worked and scale them up to provide immediate intervention for hunger. Of course, this approach does not preclude continuance of research to identify novel approaches.

Networking within Africa is on the increase, involving national programs, NGOs, universities, and farmer groups. In the past, certain organizations worked with one another, groups within Canada or within the United States of America, whereas networking is now occurring within Africa—sharing information, sharing resources—which I think is the way forward.

GENETIC ENGINEERING

The potential exists for genetic engineering technology to contribute to hunger abatement. There are opportunities in biofortification—Golden Rice™ is a good example; we hope to be able to similarly fortify NERICA rice. In the future, we may have fortified sorghum, and so on. *Bt* cotton has had a significant impact in South Africa. Genetically modified (GM) crops have met with success globally and this will apply also to African countries. The fact that the technology is within the seed ensures its delivery to, and use by, smallholder farmers. Packages of information with technologies such as chemical sprays have not worked. Biotechnology is skill-neutral.

*The controversial issue of GM-food aid—resulting largely
from strictures espoused by European NGOs—
must be addressed.*

GM FOODS

The controversial issue of GM-food aid—resulting largely from strictures espoused by European NGOs—must be addressed. According to FAO, twenty-four African countries currently face hunger, and deficits have been met with GM food from the United States and Canada. However, Zambia and Angola recently declared that they will not accept GM-food aid, which raises complex issues of trade between America and Europe in which Africa is likely to become embroiled. On my way here, I attended the annual conference of the Biotechnology Industry Organization (BIO). One seminar addressed the question, “What does the Cartagena

Protocol mean to us?” This is something that we should be concerned about: the Protocol—heavy in its demands—was negotiated under the assumption that all GM products would come from multinational private-sector companies. It does not consider products from universities and other public-research entities. In my opinion, its objective is to “freeze” big companies. It deals with issues of devising formal agreements, liability, compensation, *etc.* If the costs of regulation are to be minimized, the Cartagena Protocol must be addressed. And on the issue of risk, very few African countries have operational national biosafety committees.

Africa's food-security problems will be solved not with maize, soybean and canola, but by working on African food crops: banana, cassava, sorghum and rice.

We cannot claim that Africa's poor have benefited from GM technology, partly because there is such limited opportunity to access possible benefits. There is no question that the technology has potential, but, of the four major GM crops—maize, soybean, cotton, canola—only *Bt* cotton has shown tangible benefits, in South Africa. Africa's food-security problems will be solved not with maize, soybean and canola, but by working on African food crops: banana, cassava, sorghum and rice.

Challenges to be faced in the introduction of GM-technology include:

- limited human and infrastructural capacity,
- biosafety regulations, particularly in terms of the demands of the Cartagena Protocol,
- public acceptance—pro-biotech funding is limited compared to money being spent to fight biotechnology,
- available products are all from the private sector; public-sector products will promote acceptance.

THE WAY FORWARD

African Leadership

Increasing African leadership in project design and implementation is an important new trend. As already stated, in the past, projects have been unduly influenced by the sources of funding. True North/South partnerships are emerging between organizations in Africa and organizations abroad, as well as very profitable South/South partnerships: Africa working with India, China and Argentina. And public/private partnerships must continue because the private sector has the intellectual property rights that we need, as well as technical know-how.

National Funding

Increased national government funding will be essential. We cannot make progress without our governments providing money or, at least, incentives. Funding of scientific consortia will encourage networking within Africa with sharing of resources and expertise.

Safety Policy Development

Biosafety policy development will be essential. Only five or six African countries have such regulatory capacity. Information outreach is very important; biotechnology information availability in Africa has been very limited. The ISAAA briefs provide global figures and statistics, but the average person needs to understand local applicability. Data for China, India or Canada may have little relevance to a national program in Africa. And again, access to markets and fair trade are essential.

Sweet Potato Case Study

Work on GM sweet potato was started in 1991. Part of the problem of bringing improved cultivars to the market is the dearth of organizations in Africa that can do this kind of work. They exist in South Africa and Egypt and in some CGIAR centers, but most national programs do not have the capacity. The scientific staff may possess the necessary knowledge but lack the infrastructure.

For our GM work in sweet potato, we had two years of training and capacity building before the GM product was developed. GM trials are on-going. When we started this work in 1991 there was no transformation system for sweet potato, so we started by developing that system. We are in the process of developing a second-generation product, tailor-made for Kenya.

Whether GM or non-GM, largely the same issues apply in terms of the poor accessing improved plant types.

Emergence from Poverty

In South Africa, *Bt* cotton has generated much excitement. This Monsanto product is the only GM crop we have. *Bt* white maize is under development. Tissue culture banana is not GM, but it exemplifies the challenge of getting a novel technology to the poor. Whether GM or non-GM, largely the same issues apply in terms of the poor accessing improved plant types. Having an improved product through science is not enough. Microcredits to access the technology, good soil fertility, water, and access to good extension services and markets, must be available.

We are working with sigatoka, a fungal disease of banana. Success in transferring GM technology starts with the farmers, bottom up. Again, whether it is GM

or non-GM, the issues are the same. You must communicate and have discussions and involve farmers in the generation of information. Otherwise there will be public-acceptance issues. The process must be consultative; it must start with the farmers. Panama weevil spreads the fungus and farmers transplant suckers that already have the disease. We are making lab-produced fungus-free plantlets available. We have successfully used similar approaches with pyrethrum, sugar cane and even with trees. When we started this work in Kenya, only four labs were operational, producing flowers for export to Europe. Kenya and Israel each has a big market share in flower production. When we approached these laboratories to assist in plantlet production, they refused because local crops were viewed as commercially risky. We had to plead with them to work on banana. So, even where laboratories exist, inducing work on local crops is likely to be another challenge because people in business want big markets and even in Africa the private sector must make a profit.

*Farmers participate in our field trials; they serve as our
best extension workers.*

Farmers participate in our field trials; they serve as our best extension workers. Building confidence with farmers is fundamentally important. No longer do we go to the farmer wearing a lab coat and say, “I’m Dr. So-and-so, you must listen to me.” We have to literally work together.

Management is also important. The way to get maximum value from a product is via management—desuckering, integrated pest management, *etc.*—new skills may need to be imparted to farmers.

Finally, the product must prove itself. No matter what it is, it must be better than what it replaced. It has to have a proven performance. And with this simple technology, not only good quality is necessary but high standards. If there has been no shedding, then all the bananas come at the same time and you have a small unit of business.

Farmers themselves become distributors. They learn very fast. Even with just a small profit margin, other products can then be considered. Chickens, for example, may be produced from profits from bananas. With some entrepreneurial spirit, the small-scale farmer can obtain greater profit with appropriate handling and packaging of the bananas. By making banana crisps, wine or starch, even more profit is possible from the same product.

*A farmer needs only sixty-five tissue-culture banana
plants to get out of poverty.*

The whole value chain must be considered, with donors encouraged to fund technology-transfer, market development and entrepreneurship to create job opportunities and build prosperity for everyone.

A farmer needs only sixty-five tissue-culture banana plants to get out of poverty. Once the farmer gets credit, (s)he breaks even the first year and thereafter profit accrues every 6 months. After paying back the loan, other money-making projects may be considered.

The TC-banana project is a major success; a half-million small-scale farmers are participating and the number is expanding. The demand for plantlets is great; obtaining credit is the major limitation to continued expansion.

Most importantly, whether dealing with a local GM or non-GM crop: you don't introduce the technology and leave it there. You must work it through to the market, exploring all means of maximizing value. When we started working with donors several years back, they declared that they would fund only research. From 1994 to 1996 no donor in Kenya funded anything beyond research. I asked what happens after the research is done? Things have changed. FARA is now funding market development. We had a major marketing conference in April, 2004, to encourage entrepreneurship among small-scale farmers, e.g. turning bananas into juice, into wine or into starch. In so doing, jobs are created for young people who thus learn that farming is not such a bad means of earning a living: in the process, it is possible to become a businessman, an entrepreneur.

The whole value chain must be considered, with donors encouraged to fund technology-transfer, market development and entrepreneurship to create job opportunities and build prosperity for everyone.



FLORENCE WAMBUGU is a plant pathologist with specialization in genetic engineering for crop protection against viral diseases. Her postdoctoral work involved production of transgenic virus-resistant sweet potato currently being tested in Kenya, which has paved the way for training of African scientists in gene technology.

Dr. Wambugu has been awarded “Woman of the Year” recognition by the American Biographical Institute. Under

her leadership, the Biotech Tissue Banana Project won the World Bank Global Development Network Award.

She is a member of the Private Sector Committee (PSC) of CGIAR, DuPont Biotech Advisory Panel-USA, the Board of Trustees IPGRI and she serves as the Vice-Chair of the African Biotechnology Stakeholders Forum (ABSF). She also participates in the Bill and Melinda Gates Foundation as well as the United Nations Hunger Task Force (UN-HTF).

She is a strong believer in the power of biotechnology to boost food production. She has participated in many international forums in support of biotechnology for developing countries. She has (co)authored about sixty papers in local and international journals and publications, and is the author and publisher of the book *Modifying Africa: How Biotechnology Can Benefit the Poor and the Hungry: A Case Study from Kenya* (www.modifyingafrica.com, winner of the 2002–2003 Golden Web Award).

The Goal Is Nutritionally Adequate Diets: How Do We Get There?

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Biotechnology has been held up as a critical key to solving the world's nutrition problems. Recent worldwide media coverage of "Golden Rice™" fueled the view that changing a few foods would alleviate world hunger. Unfortunately, this is not likely to be reality. Biotechnology can be an important tool in the world's effort to address malnutrition when used in combination with other important tools.

WORLDWIDE NUTRITION PROBLEMS

An important initial step in realizing the benefit of biotechnology is to fully understand the nature of malnutrition in the world today. Undernutrition (*i.e.*, protein-calorie malnutrition and micronutrient deficiencies) remains an important public-health issue in the developing world. The Food and Agriculture Organization of the United Nations estimates using food-supply data that 17% of the populations in the developing world are undernourished (FAO, 2003). Table 1 provides selected examples of undernutrition and current prevalence figures. Undernutrition has a significant impact on development capacity because it reduces education attainment and worker productivity.

**TABLE 1. PREVALENCE OF NUTRITION-RELATED HEALTH INDICATORS
FOR CHILDREN IN DEVELOPING COUNTRIES.**

Nutrition Related Health Problem	Prevalence Estimates in 2005
Underweight children (0–5 years old)	126.5 million (22.7 %)¹
Stunted children (0–5 years old)	147.5 million (26.5 %)¹
Vitamin A deficient children (0–5 years old)	127.3 million (25.3 %)²
Low birth weight infants	17% of live births³
Iron deficient anemic children (0–5 years old)	45%⁴
Overweight children (0–5 years old)	18.5 million (3.4%)¹

¹SCN (2004). ²2002 figure (West, 2002). ³2004 figure (UNICEF, 2004). ⁴UNICEF/MI (2004).

As important as undernutrition is, overnutrition is now taking over the spotlight as the world's primary nutrition problem.

As important as undernutrition is, overnutrition is now taking over the spotlight as the world's primary nutrition problem. The number of overweight and obese individuals is now greater worldwide than the number underweight. This is the first time in human history that such a statement could be made. Unfortunately, the health sequelae of obesity are just as serious as those from undernutrition, and the rising cost of healthcare to manage obese individuals with diabetes and cardiovascular disease is rapidly becoming a significant economic burden in many countries. Many developing countries are seeing both over- and under-nutrition in their populations and are ill equipped to deal with either.

In September 2000, 189 members of the United Nations adopted a series of Millennium Development Goals (MDGs) aimed at reducing poverty and hunger. Nutritional status is an indicator for poverty and hunger in several of the eight goals to be met by 2015 (Table 2).

**TABLE 2. UN MILLENNIUM DEVELOPMENT GOALS
(UN GENERAL ASSEMBLY, 2001)**

Eradicate extreme poverty and hunger
Achieve universal primary education
Promote gender equality and empower women
Reduce child mortality
Improve maternal health
Combat HIV/AIDS, malaria and other diseases
Ensure environmental sustainability
Develop a global partnership for development

Various strategies are available to improve nutritional status, including:

- poverty reduction through food-assistance programs, education and training,
- improved food availability through increased production and enhanced trade,
- enhanced food quality through biofortification, fortification and improved food processing,
- dietary diversification through education and improved food-preparation skills.

These strategies are interrelated and must involve broad segments of the population to ensure their sustainability. Those individuals around the world who are suffering from malnutrition—either under- or over-nutrition—require:

- adequate nutrients and other bioactive compounds,
- adequate quantities of food year-round,
- safe, clean food and water,
- enough—but not too many—calories.

LESSONS FROM ILSI WORKSHOPS

The International Life Sciences Institute (ILSI) has been working for more than 25 years to improve the health of people worldwide. Nutrition is one of our primary areas of interest. ILSI is a nonprofit, worldwide foundation that brings together scientists from academia, government, and industry to solve problems with broad implications for the well-being of the general public. Its funding comes from industry, governments and foundations. Additional information is available at <http://www.ilsi.org>.

The potential of biotechnology to help alleviate malnutrition has been a focus within ILSI, using a variety of approaches including international workshops, creation of databases and development of technical guidance. ILSI has also been involved for some time in developing the science base for safety assessment of food derived from biotechnology and providing training seminars for scientists in government, academia, and industry in developing countries. More information about these activities is available on the ILSI Web-site.

In 2002, ILSI, working with the Joint Institute for Food Safety and Applied Nutrition (JIFSAN) at the University of Maryland and with the Institute for Food Policy Research, sponsored a workshop in Cancun, Mexico, on *Biotechnology-Derived Nutritious Foods for Developing Countries: Needs, Opportunities, and Barriers*. Scientists with expertise in nutrition or plant breeding from developing countries in Asia, Africa, of Latin America were invited to participate in a series of plenary sessions and small-group discussions. The objective was to engender innovative thinking about the nutrition problems faced in these countries and feasible solutions to address them.

The workshop format was particularly important to fostering the innovative thinking needed to develop solutions. The important components of the format were:

- the majority of participants were scientists from developing countries,
- participants were evenly divided in expertise between nutrition and plant breeding,
- there was a mix of plenary presentations and small-group discussions.

The proceedings were published in the *Food and Nutrition Bulletin* (Bouis *et al.*, 2002). The small-group discussions generated ideas that the whole group endorsed. These ideas can be segregated into those that relate (i) to the science of

improving nutritional status in developing countries and (ii) to the process of utilizing the science base.

The group described modern biotechnology as an array of tools that provide flexibility and new approaches to improving crops. They strongly recommended a total food-systems approach to addressing nutritional problems, rather than focusing on a single crop or nutrient. Biotechnology should be considered along with traditional breeding practices in finding ways to enhance nutrient content.

The answer will not always involve the transfer of genes. Biotechnology offers the ability to quickly screen cultivars for higher nutrient content or needed agronomic traits, such as resistance to drought or pests. Tissue culture, diagnostics, and trait markers are all part of the biotechnology tool kit. Gene transfer is another valuable tool, but should not be the exclusive focus. The output of such research could be an entirely new crop or a locally used crop that has been adapted in a novel way.

The return on an investment of \$42 million in conventional breeding would be \$4.9 billion over 10 years in improved nutrition and higher agricultural production. Biotechnology could increase this return by speeding the selection process.

Bouis (2002) simulated the cost effectiveness of biofortification using data from India and Bangladesh for iron- and zinc-enhanced varieties of rice and wheat. Using conservative assumptions in his simulations, he demonstrated that the return on an investment of \$42 million in conventional breeding would be \$4.9 billion over 10 years in improved nutrition and higher agricultural production. Biotechnology could increase this return by speeding the selection process.

The group of experts expressed interest in finding ways to increase the use of indigenous crops that are currently underutilized. The nutritional quality of these crops could be enhanced, agronomic traits could be improved thereby increasing yields, or improvements could be made to enhance food safety. Specific examples given at this and a follow-up workshop held in Bali, Indonesia, in early 2004, included:

- increased lysine and tryptophan in maize,
- increased beta-carotene in sweet potato,
- increased protein, iron and folic acid in cassava,
- improved disease resistance for papaya and cocoa,
- increased iron and zinc in wheat.

All of these examples focus on undernutrition, but there is a need also to identify approaches to modifying the food supply to address growing obesity worldwide.

Of equal importance to these scientific issues in the minds of the participants were those related to exchange of knowledge about biotechnology. It was readily apparent from the workshop that nutrition experts and plant breeders in developing countries do not often interact. Fostering multidisciplinary exchange is essential to improving nutrient availability. Support for so-called “South-South” exchange—scientists in developing countries exchanging practical scientific knowledge—is vital. There is a real need to develop sustainable networks among interested scientists to facilitate knowledge-exchange.

The workshop participants also acknowledged the need in developing countries to continue to foster broader dialogue about biotechnology—what it is and what it is not—with farmers, food processors, consumers and policymakers. Having specific success stories, *e.g.*, increased profits for local farmers and increased availability of affordable, nutritious foods for consumers, is very helpful in building this dialogue.

ILSI followed up on these recommendations by holding the second workshop, in Bali, Indonesia. *Biotechnology-Derived Nutritious Foods—Challenges and Opportunities in Asia* was cosponsored by the Institut Pertanian Bogor in Indonesia and JIFSAN. Participants were primarily from Asian countries and were again a mixture of experts in nutrition and plant breeding. Rice was a major focus of discussion. Need for sustained dialogue within developing countries was again pointed to as an important requirement for progress.

ILSI CROP COMPOSITION DATABASE

ILSI has developed two additional tools to help to improve nutrient content of the world's food. The first is the Crop Composition Database, which is comprehensive, up-to-date, globally accessible and searchable (www.cropcomposition.org). It was developed by the ILSI International Food Biotechnology Committee (IFBiC) (Ridley *et al.*, 2004). One of the challenges in understanding nutrient composition is to develop valid estimates for natural variation in concentration. Using data from conventional crops grown for comparison purposes, the IFBiC has compiled composition ranges for nutrients and other bio-active compounds for corn, soybean and cotton. More data will be added as they become available.

With more than 70,000 data points, each linked to the validated, analytical method used to generate it, this database complements existing food and nutrient databases, such as the US Department of Agriculture's National Nutrient Database and the Food and Agriculture Organization's INFOODS database. The IFBiC database provides individual measurements (sample from a single plot at one location) as well as summary data including minimum, maximum and average values. The data are from multiple worldwide locations, collected from 1995 to the present.

Specific requests can be made for comprehensive data—all proximates for all years and all locations—or more refined data, for example, a single amino acid in

a particular geography in a single year. Data are available for the whole plant and its parts expressed in terms of fresh and dry weights.

FRAMEWORK FOR NUTRITIONAL AND SAFETY ASSESSMENT OF BIOTECHNOLOGY-DERIVED FOODS

ILSI, through IFBiC, has also published a framework for *Nutritional and Safety Assessments of Foods and Feeds Nutritionally Improved through Biotechnology* (ILSI, 2004). This document discusses scientific approaches and methods needed for such evaluations and provides scientific underpinnings and recommendations. The framework was developed by an expert working group comprised of international academic experts. Their draft was externally reviewed by a larger group of international experts and presented for comment at an international workshop in Paris in December 2003. The revised document was then published.

The key conclusion presented is that existing comprehensive safety and nutritional assessment processes used for agronomic traits are also appropriate for improved nutritional traits. On a case-by-case basis, additional studies may be needed, such as metabolite analysis or nutrient bioavailability and efficacy data. Comparative assessment provides the framework for identifying similarities and differences between a new food and its conventional counterpart. The identified differences become the focus of additional scientific studies.

ILSI will continue to use these tools in training workshops worldwide to transfer scientific knowledge about biotechnology and its safe use to improve the nutritional adequacy of diets. These efforts, combined with those of many others, generate new ideas and share existing scientific knowledge. More research, which will require more resources—financial and human—will be needed as will the continued involvement of the broader community in areas where diets are not nutritionally adequate.

Biotechnology offers significant potential for enhancing nutritional quality of foods and for improving agronomic characteristics to increase food availability.

CONCLUSIONS

Biotechnology offers significant potential for enhancing nutritional quality of foods and for improving agronomic characteristics to increase food availability. Coupled with adequate public-health guidance on scientifically sound dietary patterns and other strategies, real progress can be made toward eliminating malnutrition.

The challenge to make this potential a reality is large, but the benefit is even greater in terms of improving the lives of millions worldwide.

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In January 2004, **SUZANNE HARRIS** assumed the role of executive director for the International Life Sciences Institute, a nonprofit, worldwide foundation established in 1978 to advance the understanding of scientific issues relating to nutrition, food safety, toxicology, risk assessment, and the environment by bringing together scientists from academia, government, industry, and the public sector. She is also executive director of the Human Nutrition Institute



(HNI) of the ILSI's Research Foundation, a position she has held since 1989. HNI is the arm of ILSI responsible for implementing long-term nutrition research programs.

Prior to joining ILSI, Harris was the Deputy Assistant Secretary of Agriculture for Food and Consumer Services from 1985 to 1989. While with the USDA, she assisted in the development of national nutrition and consumer policies, as well as in the oversight of the Food and Nutrition Service, the Human Nutrition Information Service, and the Office of Consumer Advisor.

Prior to joining the USDA, she held faculty positions at the University of Alabama at Birmingham where her primary research interest was in vitamin A and bone formation. She holds a PhD in biochemistry from the University of Alabama at Birmingham and a BA in chemistry from Vanderbilt University.

Module IV—Ensuring Safe and Healthy Food

Q&A

MODERATOR: SPENCER HENSON

*University of Guelph
Guelph, ON*

Ann Oaks [University of Guelph (retired), Guelph, ON]: Dr. Wambugu, I really appreciated your talk. I haven't seen such a good overview of the situation in Africa. You mentioned a population increase in Africa, whereas from what I've been reading, HIV/AIDS is causing a decline in numbers. My other comment has to do with nutrition. There are two ways to approach this, one being via agbiotech, the subject of this conference, for vitamin-A deficiency for example. But from my reading, NGOs like CARE and Oxfam are emphasizing small mixed garden plots to encourage families to grow a variety of foods. Sometimes we have a misperception in North America that one food is going to solve all the problems. We want a mixture. Carrots, for example, would supply vitamin A. Is that an alternative to Golden Rice™ and an easier alternative to handle?

You said something about subsistence agriculture and I have a feeling in North America we think that's bad. But really it's food for the people and it should be the first priority. In addition we need a cash crop and you stressed that. Bananas may be the cash crop; each country needs subsistence and cash crops. We don't want importation of food. We want to grow as much as possible. But each country—particularly in the South—have something to export: bananas or coffee or cocoa. I think that this is something that people in developed countries—America and Europe—do not appreciate and it needs to be addressed by the World Trade Organization, International Monetary Fund, *etc.* I wish Dr. Wambugu had brought her book along; I want to buy one. I want to buy ten. Thank you very much for a good talk.

Florence Wambugu: Thank you very much for that compliment. I share it with the rest of the people in Africa Harvest and many others working in Africa. The interesting bit about HIV is certainly there is population decrease, but at the same time it doesn't help because a lot of resources are being used on people who soon die. But, they don't just die in a day. Before they die, a lot of family income is consumed with medicine purchases, or whatever. Thus, poverty is increased by HIV. A large part of the problem is that the children are left. The high-risk population—many of them have several children who are left without anybody. Some people take them on board, so families are increased in size, which exacerbates hunger and poverty. Also those who live in poverty and are undernourished are more likely to succumb to HIV. They are less likely to respond even when retroviral drugs are available. I can't say that there is documented data, but it is very clear that good nutrition helps people who are taking anti-viral drugs.

I am in agreement that—whether it is banana, rice or whatever—there have to be products not only for eating but for generating some income to help the poor emerge from this vicious cycle. The North American countries now are big economies, but they started where we are. You started by farming and then by producing more, people moved to cities. Agriculture is the wheel that generates income that creates urbanization. Without producing surplus you don't have the wheel that drives industrialization.

Edilberto Redoña: Golden Rice™ has been mentioned. However, many rice farmers in Asia in particular, don't have the capacity or the access right now, or can't afford diversification. To cite an example in my country, most farmers plant rice and nothing else, so unless rice farming is profitable it is impossible to diversify. In Myanmar, for example, many people eat over 200 kilos of rice every year: breakfast, lunch, dinner and snacks in between. So while it's a good suggestion and needs to be explored you have also to consider the economies of these countries and access.

Manish Raizada (University of Guelph, Guelph, ON): A quick comment and then a question. To help some of our students and ourselves appreciate some of the realities in Africa or in Asia, I suggest listening to live-stream radio stations on the Internet. A radio station in Ghana called Joy-FM held a contest, and the prize was a sack of rice. When you hear that, it really hits home what the challenges are. I'm a molecular biologist and I would like my lab to assist in the training of future scientists in, lets say, Africa. but I'm also afraid of increasing the brain drain by doing that. Do you have any advice?

Wambugu: Well I don't think I have the answer, but I can offer some comments. It's a difficult issue because of the economies in Africa. It's good to come and take a degree here in Canada, but then the person may be trained with the mentality that the Canadian way is the only way to make things work back in Africa. So,

they go back home and they prepare a budget and are grieved to learn that it equals the budget for the whole organization. The people who are needed in Africa are those who will actually generate jobs, those who can use what they have learned here and are able to step it down and be innovative and take pride in their home situation and generate some kind of income or generate some kind of product. And so, sometimes you don't want to bring people to Canada or the United States. I don't have an answer to that.

Kanayo Nwanze (Africa Rice Center, Abidjan, Ivory Coast): There are many ways in which you can help students in Africa. There are programs for student training in biotechnology—affiliated with universities in Africa—and I can help you with that. Rockefeller offers training for young biotechnology scientists. We just had a case where two of those scientists returned to the Africa Rice Center as postdocs. But then you have to obtain funding for employment as postdocs. The budget is about \$40,000 a year, including benefits. I mentioned in my presentation a biosciences facility at the International Livestock Research Institute (ILRI). Is John McDermott here? Yes, that is another possibility for you to assist young African scientists—training at the facility in ILRI. And then we have exchange programs with which you can assist young already-qualified African scientists with on-the-job training in techniques and methodologies to enhance their research capacity. This could be summer training, or a specific training course, at the University of Guelph, for example.

Wambugu: I fully support that. Even in our own situation having the biotransformation laboratory in Kenya for GM sweet potato—has helped to bring back a number of people—although we still have some who haven't come back. Again I agree, but there has to be some infrastructure.

Joel Cohen (International Food Policy Research Institute, Washington, DC): A question for Dr. Redoña and a follow-up for Dr. Wambugu. Why has the Philippines been successful in approving and advancing GM food crops in Asia where China and India have not? Second question: I've heard that a well functioning biosafety system is now being looked at in parallel by a UNEP-GEF [United Nations Environment Program Global Environment Facility] effort under the Protocol; why are we examining another system when one is working fairly well? And Dr. Wambugu: the same question to you on food crops—why isn't it in all of Africa? Is South Africa is the only country that has approved food crops for use by its people?

Redoña: This is a very difficult question for me to answer given my perspective, which is pushing and pushing biotech products. The Philippines is considered to have among the strictest biosafety regulations in Asia and it has been successful probably because of strong support at the highest level. I'm referring to the level

of the president, enabling commercialization of certain crops. Otherwise it would not have been possible because of the strong NGO position. You say also that China has recently obtained support at the highest level, so I think the situation will change in China. I cannot say why we need to come up with another round of review—it was decided by the Department of Science and Technology. One thing that is good in the Philippines is that biosafety and the regulatory process is not under the wing of government that is generating all the outputs—the Department of Agriculture and the universities. It's done by a separate—like what was referred to earlier—arms-length regulation with NGOs in that case being regulators.

Wambugu: I think John McDermott has an answer to this question. I can only give indicators as to why only South Africa has commercialized GM crops. Let me start by saying that South Africa has 42% of all Africa's GDP. It's the richest country in Africa—42% of all the African wealth is in South Africa. And that's why almost all the companies we have are represented in South Africa because it has ability to purchase, there is money to pay for products. Like China, it has population with purchasing ability, so big companies are there. Now, all the products in South Africa are from the private sector so that doesn't make a difference with other countries, although local universities are also participating in terms of trials, *etc.* Also, before private-sector companies came on board, South Africa had its own scientific expertise in GM technology—people like Professor Jennifer Thompson—who demanded the protocol. It was internally driven. The GMO Act in South Africa was actually initiated by scientists in the country saying they needed such an act because they were already handling plasmids, they were handling DNA, they were handling GM issues. Because it was internally driven and the country already had capacity in biotech, things could be put in place very quickly. It was demand-driven. Then it was easy for companies to come on board with their products because the country had the infrastructure, and they had finances; it's a country that is developing very rapidly.

As far as other countries are concerned, it is necessary to develop regulatory capacity. Biosafety policy cannot develop in a vacuum. The legacy of so many biosector workshops is that they have not produced capacity. Workshops, conferences, do not develop capacity. They help in networking. But, a lot of people who came to Africa thought the way to fix biosafety was to have lectures. People moved from one lecture to another, but it didn't translate to a regulatory setup. The only countries that are making progress in this regard are those with GM expertise. Kenya's was driven by the GM sweet potato. Egypt has been partnering and networking with the North and has developed quickly; they are going to commercialize *Bt* cotton. Kenya will commercialize *Bt* cotton soon; the license has been issued for field-testing. I believe Zimbabwe has conducted some pre-commercialization trials. Nigeria has a protocol. Again, in a nutshell, policy cannot develop in a vacuum. There has to be local capacity on which to build and the country must have the ability to attract significant private investment.