

MODULE III—IMPROVING QUALITY OF LIFE

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Module III—Improving Quality of Life

Introductory Remarks

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The title of this session, *Improving Quality of Life*, implies optimism. A similar optimism was expressed in the title of Module II, *Diminishing the Ecological Footprint*. The speakers in that module presented some challenging and mixed assessments of optimism that are certain to make us think long and hard about the implications of biotechnology and the eco-footprint. Quality of life is certainly related to the other topics—ecological footprint and food safety—but, as we've seen so far in this conference, food is a major component of the quality of life for many people in the world and is a less significant component for others. Also, problems related to food distribution have been discussed, as have the challenges associated with incorporation of appropriate cultural practices to enable people in developing nations to utilize and produce food.

This session's distinguished group of speakers will address the relationships people have with food, the way it's produced and distributed and the larger implications for both industrialized and developing nations: Tom Remington, Ruth Chadwick, and Joel Cohen.

How Might NGOs Handle Genetically Modified Seeds for Small Farmers in Africa?

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Catholic Relief Services (CRS) works through partners throughout the developing world to help farm families recover from disaster and increase incomes and resilience, and collaborates with international and national research institutions to facilitate farmer access to seeds of new and promising varieties. It supports farmer evaluation of new materials, the multiplication of farmer-selected varieties and their subsequent promotion and dissemination. CRS expects that genetically modified (GM) varieties will soon be available, and is articulating guidance for Country Program and Partners on how to handle these materials in our technology-transfer work with farm communities.

AGRICULTURE IN DEVELOPING COUNTRIES

A report by the United Nations Food and Agriculture Organization recently discussed the potential benefits of biotechnology for resource-poor farm families in developing countries (FAO, 2004). It surveyed the current state of agricultural biotechnology, its potential use by smallholder farmers in the developing world, possible risks, and the status of biosafety regulation. The report stated that agriculture is faced with many difficult challenges as the world population expands and agricultural production falls behind consumption for the fourth year in a row. There will be an additional two billion customers for agricultural products within 30 years. At present, 384 million people are chronically food insecure, most resid-

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ing in rural areas of the least developed countries. Many more suffer from nutritional deficiencies due to poor food quality and lack of diet diversity. Although the global need for food aid has declined in the past 15 years, the need continues in Africa, where thirty-eight of the forty-three countries were found to be in need of assistance in 2003. Seven of the eight countries in the CRS East Africa region were declared food emergencies in 2004.

COMPARING AND CONTRASTING THE GREEN AND THE “GENE” REVOLUTIONS

The contribution of technological innovation to sustained growth in food production and to reduced poverty and hunger in developing countries was also recently reviewed (FAO, 2004). The Green Revolution was compared and contrasted with the “gene” revolution since both are encapsulated in the seeds of new improved varieties. The successful dissemination and exploitation of the Green Revolution varieties was dependent on the availability of international public goods and sufficient national agricultural research capacity to adapt new varieties to local conditions. The majority of this research was done by public institutions and was freely transferred. The Green Revolution initiated a major international plant-breeding effort and the development of germplasm-exchange mechanisms which are still important for the crops grown by smallholder farmers in Africa. It established a model for public international cooperation in plant breeding, germplasm evaluation and variety testing still present in conventional crop improvement today. While the approach to agricultural development initiated with the Green Revolution has made substantial improvements in productivity in Asia, its impact on resource-poor farmers in Africa remains disappointing.

The “gene revolution,” with its reliance on products of biotechnology such as GM plants, has a different approach. The majority of the research products are being developed by the private sector for commercial purposes. The focus has been on traits that are of value to farmers in developed country, such as herbicide tolerance and insect resistance. Because this research has not been done in the public sector, there is no easy spillover of the technology to crops and traits of

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greater value to developing-country farmers. The private cost of biotechnology research, development, and the approval processes is much greater than with the conventional approach. Consequently, the products of biotechnology are held under restricted access with patents and exclusive licenses. This restricted access, and the increased cost of regulation, will impact the ability of NGOs to promote GM crops as part of the development package for smallholder farmers in Africa.

HIGH COST OF BIOSAFETY REGULATION

The development of biosafety regulations and the approval and release of specific GM products has taken more than a decade in the United States and Canada (CBI, 2004). These regulatory processes are elaborate, complex and expensive, involving a number of regulatory agencies and procedures at various stages of the approval process. The cost of regulation can be in the range of \$50–300 million and require 6 to 12 years. It is a high-risk venture with only a 0.4% probability of any gene or trait making it to the market. In developed countries, the development and commercialization of a GM variety is recovered in the price and volume of its seed sales. In developing countries, who will pay the cost of this technology? Smallholder farmers are not likely to bear the high cost of seed or purchase the required volumes. The exception in Africa is cotton, a vertically integrated cash crop.

The majority of developing countries do not have a regulatory system for GM plants. Tawanda Zidenga (2003), reporting on the status of biosafety regulation in Africa, identified four issues where African countries differ from developed countries:

- the prevalence of farmer seed saving,
- the importance of informal seed exchange to variety dispersal,
- the introduction of GM products as food aid, and
- weak scientific and technical capacity.

Despite these constraints, there has been progress in biosafety. Two countries, South Africa and Zimbabwe, have GM legislation and a functioning biosafety framework. Seven other countries are formulating legislation, while forty-three countries are in the UN Environment Programme-Global Environment Facility (UNEP-GEF) biosafety development process. In South Africa, GM plants are being grown under a general release permit.

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It is clear that delivery of GM products to smallholder farmers in Africa will be expensive. For example, it is estimated that the regulatory costs alone will be \$10 million for each new transgenic product.

CURRENT SUPPORT FOR AGRICULTURE IN AFRICA

The trend in donor assistance for agriculture continues downward. This decline has been most severe in Africa where assistance per agricultural worker is now only 25% of the peak 1982 level. Compounding this reduction in support is evidence that the assistance is not reaching the countries most in need. External assistance is significantly higher in countries where undernourishment is the lowest (over \$25/worker in countries with <5% undernourishment, but less than \$10/worker in countries with >35% undernourishment).

Clearly, in the competition for declining funding, the poor are neglected. FAO (2004), recognizing the role that NGOs play in advocating for the poor, suggested that they should advocate for increased funding for agriculture research, both conventional and biotechnological. They went further, recommending that specific advocacy groups be developed to lobby for public biotechnology research funding for the poor, and that this should include purchasing the right to use private-sector technology on behalf of the poor. This should raise the alarm that increased funding for biotechnology will come at the expense of conventional research technology transfer and that the benefits will be captured by more advanced developing countries and by larger and richer farmers.

CURRENT SUPPORT FOR GM CROPS IN AFRICA

Currently, a number of institutions in Africa are focused on developing and promoting biotechnology for farmers (CBI, 2003). A search of the Internet presents a plethora of Web-sites dedicated to biotechnology for Africa. Foundations, international organizations (including NGOs), and national governments are promoting the potential benefits of biotechnology in addressing the critical need to increase food production in Africa. Several research networks have been established to

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promote biotechnology research in crops such as cassava, sweet potato, and cowpea that can benefit the poorest farmers in Africa. Donor initiatives are promoting research and development of biotechnology products with public/private-sector partnerships, and donor and international organization initiatives will strengthen biosafety-regulation and technical expertise in developing countries to enhance the application of biotechnology products. The United States and Germany are funding projects to enhance biosafety research, policy, and the scientific/technical capacity for African countries in biosafety and to help countries develop laws and regulatory structures to ensure that GM crops pose no threat to human or environmental health. Currently, one regional body in southern Africa and eight countries are involved in regulation of GM food (especially food aid) and seeds (Organic Consumers Association, 2003).

PERCEIVED BENEFITS OF BIOTECHNOLOGY FOR RESOURCE-POOR FARMERS

The FAO (2004) survey concluded that biotechnology has potential benefits, but only if the technologies are appropriate for poor farmers in poor countries and there is access on sustained and profitable terms. This means that research and development of biotechnology products needs to be part of a well funded comprehensive program, with public and private sector investment. Regulation should be strong and rationalized with transparent, predictable, and science-based evidence. While the FAO report provided a comprehensive review of the role of research and development in the application of biotechnology, technology transfer and dissemination aspects were assumed to be of secondary importance. However, the report (page 87) apparently contradicted this in stating that “the paradigm for research and technology delivery that made the Green Revolution possible has broken down.” Technology transfer is critical, complex and expensive. To the extent that it continues to function, NGOs have assumed a lead role. Effective biotechnology transfer will require increased commitment, capacity and donor support for NGOs. These should not be assumed.

While African countries are open to the potential benefits of biotechnologies for their farmers, there is consensus that improving food security and agriculture will require more than technology. Rosset (2000) concluded that it is not a lack of technology that limits productivity and keeps farmers in poverty. Rather, the persistent injustices and inequalities in access to resources, such as land, credit,

markets, and anti-poor policy biases are responsible. Therefore, farmers do need greater resources targeted to research, development, and dissemination of pro-poor technologies in order to overcome diseconomies of scale, such as agroecology and farmer organization. In addition, an agro-enterprise approach is needed that enables farmers to access and benefit from market opportunities.

ROLE OF NGOS IN TECHNOLOGY TRANSFER

NGOs, such as CRS, have a long history of transferring new technologies to poor farmers. Agricultural recovery from disaster programs have typically included the delivery of “seed and tools” packages. When available, this has been of commercial seed of new varieties. These same packages have been promoted in development contexts, often combined with training programs on new farming methods such as row planting, animal traction, and other “improved farming system options.” The main objective of these programs has been increased productivity and production. They have been supported by technical assistance from international and national research programs. A range of approaches has been used, including farmer-evaluation plots, demonstration plots, and more recently, mother-baby trials and farmer field schools.

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These activities are important opportunities to transfer new technologies to smallholder farmers to contribute to reducing poverty. Similar programs will enhance the adoption of GM products. The strength of these partnerships with NGOs has been their established presence in the community and their logistical capacity to deliver the seeds and conduct the trials. However, NGOs have significant weaknesses including:

- lack of capacity to conduct scientifically sound testing programs,
- rapid staff turnover,
- short-term nature of programming and funding, and
- diverse social and cultural objectives contributing to low priority assigned to agricultural development.

Although NGO-based technical transfer is feasible, it requires effective research support for training, activity design, implementation, data collection, analysis, reporting and follow up. These requirements are needed even more for the testing and delivery of GM varieties with which there are biosafety concerns.

ASSESSING AND ACCEPTING GM-CROP-ASSOCIATED RISK

CRS supports farmer evaluation of a wide range of crops including maize, pearl millet, sorghum, chickpea, pigeon pea, cassava, bean, sweet potato, rice, sesame and groundnut. All of the available varieties come from public institutions, either directly from the International Agricultural Research Centers (IARCs) or through national agricultural research system (NARS) programs and have been tested over a period of years in regional or international trials. These tests are done as part of larger research programs, and potential productivity and stability of specific traits are determined prior to decisions to proceed with farmer evaluations. This process has resulted in high probability of farmer acceptance. Risk is rarely explicitly assessed in the technology-transfer process. Rather, it is assumed that it will be considered by farmers themselves prior to adoption. Risks—nutritional, human health, environmental, agronomic, marketability, *etc.*—are inherent in all breeding programs. However, there is increased risk with GM crops because of:

- possible transmission of transgenes to other varieties or to wild relatives,
- possible health implications,
- social and ethical acceptability, and
- market acceptability due to these same concerns on the part of the consumer.

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The questions for CRS and other NGOs will be who should assess and who should accept the risk: the developer of the technology, the international and national research programs, the NGOs, or the farmers? These questions, not asked in traditional technology transfer, must be addressed in GM-crop programs.

The FAO (2004) report reviewed the status of risk to human and environmental health from GM crops and raised these key questions:

- Who bears the risk and who stands to benefit?
- Who evaluates the harm?
- Who decides what risks are acceptable?

Risk is a product of the hazard, its probability, and its consequence. There are a number of direct and indirect food-safety concerns with GM crops, the assessment of which is based on the precautionary principles of risk assessment, risk management, and risk communication. The principles of risk assessment state that the food derived from GM plants should be compared with its conventional

counterpart. It states that the risk-management measures should be proportional to the risk. Risk communications are based on the ideal that they are effective and transparent. Participatory process should be used to communicate at all phases of the risk analysis. The risk analysis of GM crops for farmers in Africa needs to be carefully considered on a case-by-case basis depending upon the particular species, trait, and agro-ecosystem.

The assessment of risk can be based on various sources of data and on various assumed uses. In addition, assessment of traditional food-use risk will need to be addressed, including home-use preference as well as human-health concerns. The marketability of GM commodities will also need to be assessed within local markets for local food uses. The overall impact of the introduction of the GM crop to the complex agroecology of traditional farming systems will need to be assessed, especially as it relates to the intercropping systems used by farmers. These assessments will be needed prior to the introduction of a GM crop to farmers or there is a risk that the trials will be used as local seed sources, as was the case for *Bt* cotton in Gujarat, India. As with evaluation of conventional varieties, farmers will grow and save seed prior to official release. This would be a significant risk for NGOs when testing GM varieties that are still in the development stage. Formal approval and release will be needed, therefore, before initiation of testing and promotional programs in conjunction with farmers.

The increased risk and cost involved in the development and release of GM varieties, and the need for a mechanism and institutions to insure that farmers have long-term sustained access to these products, will impede their distribution to poorer farmers. In order to ensure that these increased costs and regulations are worthwhile, economic studies will be needed to measure the value of these varieties to farmers versus the cost, including the cost of risk. The process of release and promotion needs to address environmental concerns, health concerns, cultural concerns, economic concerns, and long-term sustainability concerns. The cultural concerns include questions of who will access the technology, how will they access it, how will seed be exchanged and how will seed be regulated. Economic concerns include the cost:benefit aspects of the technology in comparison with alternative options, impact of the adoption of the technology on trade or market potential and the impact of the adoption on credit burden. The long-term sustainability issues include predictable access to seed and to markets and impact on crop and variety diversity.

Risk has been addressed through international conventions and agreements. The Convention on Biological Diversity deals with the management of risk to biodiversity from the introduction of GM crops. It protects and promotes the conservation of the local biodiversity, and led to the Biosafety Protocol. The crops currently grown by poor farmers in Africa are covered by this Convention, which obligates signatory countries to develop legislation to protect and conserve biodiversity. These same countries have agreed to follow general rules laid out in the Biosafety Protocol for development of regulations within their countries for

the introduction, testing and release of the products of biotechnology. To date, these regulations have been established in very few of the least-developed countries of the world.

The Biosafety Protocol, ratified in September 2003, is an agreement on rules that govern international trade in GM organisms. It allows developing countries to control the importation of GM crops and their products. A number of issues impact the promotion and dissemination of GM crops by NGOs (Christian Aid, 2004). One of the main issues is that social and economic concerns should be explicitly included in risk analysis, in particular the impact on the livelihoods and food security of smallholder farmers. A second issue is that only GM seed is covered by the Protocol and not their products, for advanced informed consent. This is a concern because GM products could be used for seed as well as for food and/or feed. There is a third issue of liability for damages and labeling. These regulations are necessary to ensure that any risk to environmental and human health is avoided or minimized. Strategies to manage risk can be developed, but these need to be adhered to and considered prior to product release. All of this requires research and testing. Adherence requires enforcement of government regulations. The absence of enforcement of regulations increases risk and compromises farmer recourse. It is possible that farmers would find themselves assuming all the risk and NGOs would find themselves assuming responsibility for enforcing regulations post-release; the developer of the research products, research institutions and government would bear little of the risk.

THE COST OF TECHNOLOGY TRANSFER

The products of conventional breeding programs are the result of a process that begins with early-generation testing, usually on-station. In the final years of testing, the varieties' overall productivity, adaptation and stability are evaluated at multiple locations, including farmers' fields, often with NGO assistance. The final stage of testing occurs when the value of the variety has been determined, but its acceptability to farmers and the market is not yet certain. The cost of most of this process is borne by the IARCs and national programs. This testing, which can be expensive, results in the identification of recommendation domains.

The testing of a GM variety has additional steps due to concerns over risk to environmental and human health.

The testing of a GM variety has additional steps due to concerns over risk to environmental and human health. This includes stricter field-testing protocols, more extensive testing for human-health issues, and assessment of risk of transfer of the transgene(s) to other varieties, wild relatives, or other organisms in the environment. This results in greater cost and time to make the GM products avail-

able for testing by farmers. The cost of this testing will have to be borne by the developer since it requires greater control and stricter guidelines, regardless if the developer is a private company, IARC, or a national program. The broader testing and promotion that occurs with the partnership of the NGOs cannot be undertaken until environmental and human health risks have been assessed and determined to be minimal and manageable. Post-release strategies to manage risk will need to be considered in partnership with the NGOs to ensure that they can be adhered to by resource-poor farmers. This may include consumer-acceptability and market analyses. Clearly, one of the major constraints to the release of GM crops to farmers by NGOs is the increased costs involved. Thus, benefits from these new varieties will need to significantly outweigh their increased cost and risk.

Commercial seed companies are compelled to apply measures to prevent or discourage seed-saving by farmers.

SEED ISSUES

The private-sector profit on investment in conventional and GM varietal development comes from recurrent seed sales. This is not a significant issue with hybrids, with which farmer seed saving comes at a cost of reduced performance. However, this is not the case for other crops in Africa, most of which are either self-pollinated or vegetatively propagated. For these crops, commercial seed companies are compelled to apply measures to prevent or discourage seed-saving by farmers. These include use of a terminator gene, a patent and legal injunction, and misinformation (e.g. an unsubstantiated claim of loss of performance with seed saving). Based on the Catholic Social Teaching principle of the universal destination of good, CRS opposes these three measures (Warner, 2001). Terminator genes are harmful to smallholder farmers in Africa. Punitive legal injunctions are difficult and costly to apply. Misinforming growers results not so much in farmer decisions to purchase seed annually as in loss of credibility for NGOs and other information brokers. In addition, CRS opposes the appropriation of the responsibility for seed production by commercial seed companies, when farmer seed production is both effective and efficient. This is counter to the Catholic Social Teaching principle of subsidiarity.

Farmers continually experiment with new varieties, obtained from relatives, neighbors, the local market or from development projects. They adopt a new variety when they have determined it is of value to the household. Adoption does not always imply abandonment; they may grow new varieties and continue to plant their own landrace varieties, because of different uses in the home or in the cropping system. Once obtained, farmers in traditional cropping systems in Africa depend on home-saved seed for future needs.

In many cases, lack of access to seed of new varieties is a constraint to technology adoption in the remote, rural areas of Africa. It is a concern of many agricultural recovery programs implemented by NGOs. Continuous movement of seed into and out of the home is referred to as seed flow. Production of own seed can result in the transfer of genes from other varieties of the crops grown by the household with cross-pollination. The pollen from the farmers' variety can also cross with wild relatives in the field or adjacent areas. This is referred to as gene flow. This practice can result in the incorporation of new genes from other varieties, including new improved GM varieties. The consequences of traditional seed saving and seed exchange are an additional risk with GM varieties and will need to be considered in the release and promotion of GM seeds to smallholder farmers.

The responsibility for regulating the use of GM seed by farmers and the need to meet their need for affordable seed will have to be clarified before NGOs consider the promotion of these varieties.

Seed flow in the farmer-seed system is very informal and can be used to disseminate new varieties where formal seed systems do not exist. This is the case for most of the crops (maize is an exception) grown by poor farmers in Africa. Although discouraged for the new publicly available varieties, farmers have not found affordable reliable options for access to these varieties while being able to retain their traditional approaches. The release and promotion of new varieties with legal protection will add a new complication to this issue. Farmers might be restricted from saving seed and told to obtain new seed each year. This restriction on seed saving will be compounded by the higher cost of GM seed. The responsibility for regulating the use of GM seed by farmers and the need to meet their need for affordable seed will have to be clarified before NGOs consider the promotion of these varieties.

ISSUES FOR CRS

The promotion of the products of biotechnology is an opportunity to introduce and assist farmers to grow crops that will contribute to poverty alleviation through enhanced agricultural development in Africa. The GM plant is a technological innovation that carries new challenges in introduction, evaluation, adoption, and sustained use. The potential benefits of this new technology are great, but so also are the costs and risks. NGOs must confront the following opportunities, risks and challenges to ensure that smallholder farmers, benefit.

Farmer and NGO Participation in Decision-Making

Farmers and NGOs need to be involved in policy and donor-fund allocation discussions that affect them. The tendency to first make a decision to invest in biotechnology and to allocate funding and then bring in farmer and NGO stakeholders needs to be reversed. The costs of investing in biotechnology need to be compared with costs of investing in alternative means of agricultural development.

Biosafety

National and international regulations to ensure environmental and human health, and to address cultural, economic, and sustainability issues need to be in place before technologies are recommended to farmers. Varieties made available to NGOs must have all the necessary assessments to ensure their safe use by farmers. The need for risk management of these GM crops, such as refuges, will need to be developed and training programs for farmers developed and implemented.

Benefits from GM Crops for Resource-Poor Farmers

There is a need for clear evidence that the improvements offered in these biotechnology products outweigh the risk of their introduction and use. There needs to be a clear, transparent assessment of the risk, including factors that are unique to traditional tropical cropping systems. Farmers need to have redress options for any damage to environmental or human health or their economic well-being caused by GM crops.

Freedom to Save and Exchange Seed

The issues of long-term access to affordable seed and planting material need to be addressed. The farmer seed system is of vital importance to African agriculture. As is the case with the products of formal breeding, farmers must have the right to save and multiply seed for further planting. Furthermore, research must support NGOs and farmers to improve the effectiveness of seed saving.

The focus of the IARCs on the science of the problem and the focus of CRS on the delivery of the solution can lead to conflicts and disappointments. Transparent partnerships are required that place value on both research and development. Partnerships with the private sector will be new and require new mechanisms of interaction and funding.

Partnerships and Capacity Strengthening

NGOs will need strong partnerships to effectively deliver this biotechnology to farmers. They need access to technical expertise from the national programs, IARCs, and the private sector on biosafety concerns, intellectual property and license agreements, and risk management. CRS currently has partnerships with IARCs and national programs to deliver new varieties and other improvements. These partnerships have constraints, such as the need to claim success to attract donor funds, which result in conflicts on equitable sharing of credit and costs. The focus of the IARCs on the science of the problem and the focus of CRS on the delivery of the solution can lead to conflicts and disappointments. Transparent partnerships are required that place value on both research and development. Partnerships with the private sector will be new and require new mechanisms of interaction and funding.

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Dr. Remington has served as agriculture advisor with Catholic Relief Services (CRS) since 1994. Currently he is responsible for Eritrea, Ethiopia, Sudan, Uganda, Tanzania, Kenya, Rwanda, and Burundi. He has helped CRS articulate a comprehensive agriculture strategy consisting of innovative means of recovery from disaster; increasing farm-family income and resilience; facilitating farmer access to new technologies through linkage with national and international research institutions; integrating domestic and productive uses of water; and improving nutrition through biofortification.

He collaborates with international research centers on farmer evaluation of new crop varieties, including the International Potato Center (Peru, sweet potato), the International Institute of Tropical Agriculture (Nigeria, cassava), the International Center for Crop Research in the Semi-Arid Tropics (India, chickpea, groundnut, and pigeon pea), the International Center for Tropical Agriculture (Colombia, common bean), the International Maize and Wheat Improvement Center (Mexico, maize) and the Africa Rice Center (Ivory Coast, rice).

Agricultural Biotechnology and Quality of Life: What Counts as Quality?

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Every act and every inquiry, and similarly every action and pursuit, is thought to aim at some good; and for this reason the good has rightly been declared to be that at which all things aim.

—Aristotle

Aristotle began the *Nicomachean Ethics* with the statement that there is some good at which all things aim, and proceeded to delineate the good for man. His teleological view included two versions of the “good for man,” in his term “*eudaimonia*” which is commonly expressed as “flourishing”—the moral life and the life of contemplation. For Aristotle, however, certain things could be taken for granted, like the meeting of the basic physical necessities of life, and indeed slaves to cater for the needs of Athenian citizens. Nevertheless, the teleological aspects of his ethical thought continue to be very influential in thinking about quality of life. Andrew Edgar, in his article on quality of life indicators, suggested that “it may not be an exaggeration to suggest that talk of one’s quality of life makes an implicit appeal to the degree to which one’s life approaches one’s personal image of an Aristotelian good life” (Edgar, 1998). If we can agree that human beings have a *telos*, then it should facilitate further agreement on what the elements of that are and the instrumental steps towards it.

Barriers to agreement about this derive from competing conceptions of human nature, or disagreements as to whether there is such a thing as a universal human nature. I shall argue that quality-of-life arguments are inevitably going to be beset by pluralism, but that this is not necessarily a bad thing. In particular, some accounts of quality of life may be described as “end state” conceptions: others as “process” accounts. By an “end state” conception I mean an account of quality of life that depends on an assessment of the impact of a particular development on a group or population: by a “process” account I mean an account that includes an

Achieving food security is a necessary condition of quality of life, and improvements in this may at the same time constitute an improvement in quality of life, but they are not sufficient. Quality of life, which is distinguishable from “standard of living,” cannot be reduced to food security or to discussions of wealth and poverty. Even on a well-being account of quality of life, there are other factors to consider.

assessment of, for example, how much control they had over the process of getting to that state. Arguably, between the different accounts I shall consider, there will be some consensus, e.g. on the desirability of food security, defined by the FAO as freedom from hunger and fear of starvation. Achieving food security is a necessary condition of quality of life, and improvements in this may at the same time constitute an improvement in quality of life, but they are not sufficient. Quality of life, which is distinguishable from “standard of living,” cannot be reduced to food security or to discussions of wealth and poverty. Even on a well-being account of quality of life, there are other factors to consider. It is interesting to note, however that recent discussions of “quality time” and “time poverty” in rich societies have themselves used the language of poverty.

My aim in this paper is to discuss the link between agri-biotech and quality of life, with a view to informing the debate about the likely success of different strategies for improving quality of life. I want to stress that while it may appear that the disagreement between proponents and opponents of agri-biotech is about the relevant means to achieve food security, an end on which they agree, on the contrary there are deeper disagreements about what counts as quality of life, disagreements that may not always be recognized. The question of the likely contribution of agri-biotech to food security does not settle the question of its significance for quality of life.

QUALITY OF LIFE, FOOD AND HEALTH

As Andrew Edgar noted, in ordinary language usage “quality of life” suggests the general satisfaction that one has with one’s life, and it will thus depend on factors such as housing, the environment in which one lives and works, and social relationships, but the concept of “quality” remains difficult to elucidate (Edgar, 1998). Related concepts include that of a life worth living, which Jonathan Glover explored in *Causing Death and Saving Lives* (1977). Having thought about trying to draw up a list of elements of a life worth living, however, he gave up the task,

coming to the conclusion that a person's wish to go on living was good *evidence* for their having a life that is worth living. I mention this point for two reasons. First, Glover's conclusion is an instance of a more general point that stresses the importance of the perspective of the person or persons whose [quality of] life is at issue; secondly, because Glover was writing primarily about the medical context, but I would argue that there are insights to be drawn from that context for the agri-biotech context. Food and health are closely connected and in the biotech sphere growing closer with the introduction of functional foods and nutrigenomics.

*. . . three main approaches to quality of life in relation to
agri-biotech, the well-being approach, the capabilities
approach and the justice approach.*

Alongside the attempts to explain the ordinary language use of “quality of life” there are attempts to develop tools of measurement to compare the impact of various interventions on quality of life of individuals or populations. One of the best-known instances of a quantifiable version of this is in the health-care context, the quality-adjusted life year, or QALY. Though the aim might be to produce a neutral tool of measurement, any given tool will inevitably be supported by some value perspective so it is important to examine the presuppositions on which they depend. For example, critics of the QALY have pointed out that things look rather different to those who are suffering from a condition as opposed to those who are not. Some of these elements are included in what I regard as the three main approaches to quality of life in relation to agri-biotech, the well-being approach, the capabilities approach and the justice approach. The capabilities approach, for example, is presented not only as an account of the meaning of quality of life, but also as a means of comparison. I want to set my account, however, in the context of that provided by the UK Food Ethics Council (2003) in its recent report *Engineering Nutrition*, so I shall begin by saying something about that.¹

Engineering Nutrition takes as an example for discussion Golden Rice™, and questions the ways in which the issues are framed by scientific experts. They point out that the proponents of GM crops are no longer portraying them as *the* answer to world hunger as in the discredited example we saw in the 1990s. Their target is a subtler version of the argument that holds that GM crops have the *potential* to help increase food security, given appropriate conditions. Their objections to the framing assumptions and to the argument that greater investment should be put into GM crops include the fact that the framing assumptions built

¹The author is a member of the Food Ethics Council.

into the decision-making processes in rich countries are not commensurate with the values of society at large in those countries most affected, specifically:

- they take no account of social risks in the risk-assessment process,
- they overlook the importance of assessing food-security strategies for their effect on the whole diet, taking into account social dimensions of food insecurity, rather than concentrating on single nutrient solutions such as Golden Rice™,
- utilitarian considerations are given primacy over considerations of justice,
- consumer “choice” comes in too late in the research and development process.

The report is right to point out the importance of framing assumptions, but it does not itself discuss the different framings of the notion of quality of life itself. Quality of life as a term is mentioned in the “ethical matrix” (Table 1) around which previous reports of the Food Ethics Council have been structured, including their earlier report on GM foods, *Beyond Nuffield* (1999). The ethical matrix is a structured approach to a pluralistic method of decision-making, including the ethical principles of well-being, autonomy and justice. A similar principled approach, but not the matrix itself, was employed by the first report of the Nuffield Council on Bioethics (1999) on GM crops. Designed by Ben Mepham, it addresses technological developments by assessing their impacts on different groups of stakeholders with reference to these three principles. The point to which I want to draw attention is that in the ethical matrix as illustrated in *Engineering Nutrition* “quality of life” only appears in connection with the *well-being* principle as applied to consumers. This is what I call an “end state” account of quality of life. Mepham understands well-being in the matrix to be based on the utilitarian tradition and so the judgment of quality of life here will be based on some assessment of the utility status of those affected. While *Engineering Nutrition* does not limit itself to a utilitarian outlook—far from it—it is instructive that the other principles are not *explicitly* related to quality-of-life issues.

TABLE I. THE ETHICAL MATRIX DEVELOPED BY BEN MEPHAM.

Respect for	Well-being (Health and welfare)	Autonomy (Freedom/choice)	Justice (Fairness)
Farm animals	Animal welfare	Behavioral freedom	Intrinsic nature
Agricultural and food industries	Satisfactory income and work	Freedom to adopt or not to adopt	Fair treatment in trade and law
Citizens	Availability of safe food. Quality of life	Respect for democratic, informed choice	Availability of affordable food
The ecosystem	Conservation of the biota	Maintenance of biodiversity	Sustainability

In many instances, the improvements that can be achieved through GM crops may reduce much of the effort required in subsistence agriculture.

As far as well-being is concerned, the Nuffield Report (2004) makes the following claim:

Poverty has many causes...Poor efficiency of agriculture is one of them. It is also clear that the efficiency of agriculture has considerable impact on the standard of living of people involved in work on small-scale farms in developing countries. This is most notable in Africa, where the majority of the population lives and works in small farms in rural areas...Moreover, it is particularly true with respect to improving the situation of women, who make up the majority of the world's resource-poor farmers...In many instances, the improvements that can be achieved through GM crops may reduce much of the effort required in subsistence agriculture.

In disagreeing with Nuffield, *Engineering Nutrition* accepts that proponents such as Nuffield recognize that the first generation of GM crops has been for the benefit not of such communities but of rich companies in developed countries. Both sides also accept that sweeping generalizations about *all* instances of GM can be unhelpful. Nevertheless, the Food Ethics Council regards the call for a case-by-case approach as potentially harmful because it can overlook cumulative effects on well-being.

AUTONOMY, AND THE CAPABILITIES APPROACH

The autonomy column as Mepham developed it incorporates a cluster of notions such as freedom, rights and dignity, including the freedom to pursue a natural telos. Although *Engineering Nutrition* addressed the issue of freedom of choice, it is arguably others who come closest to explicitly relating such notions to quality of life. An example would be the capabilities approach of Amartya Sen and Martha Nussbaum. From this perspective, what is important in assessing quality life is not what people have but what they can do.

For Sen, well-being and agency are not to be regarded as independent. He argued that “to judge the well-being of a person exclusively in the metric of happiness or desire-fulfilment has some obvious limitations....It can be argued that advantage may be better represented by the freedom the person has, and not by...what the person achieves—in well-being or in terms of agency—on the basis of that freedom. This type of consideration will take us in the direction of rights, liberties and opportunities” (Sen, 1988). Like Sen, Martha Nussbaum used the notion of capabilities to develop a space of comparison in which to compare nations, as a

rival to other types of measurement such as *per capita* GDP, but wanted to go further and use the approach as the philosophical basis for fundamental constitutional principles establishing a social minimum or threshold. The idea of a basic social minimum is focused on human capabilities, central human functions that could form the basis of agreement.

To what extent is it right to include autonomy and capability considerations in accounts of quality of life? And to what extent does agri-biotech impact on autonomy? These are not easy questions. It is fair to say that autonomy, and choice, have been paraded as primary considerations both in applied ethics and in policy in recent years. As *Engineering Nutrition* pointed out, however, the “choice” has been largely construed as being that of the consumer to buy the product, not only a very limited but also a westernised interpretation. A report of the Rathenau Institute is also critical of this notion. Asking “Where is the autonomous consumer?” they say: “A somewhat slow consumer is ‘activated’ with difficulty and is typically a less interested, less involved, conversation partner. . . . However, the ever-critical and oh-so-autonomous consumer is very hard to remove from the discussions on technology development and thus obstructs the creation of a more realistic image” (Rathenau Institute, 2003).

*In the context of GM crops . . . the relevant choices are
about styles of life rather than choices of products
Thus they are about global life choices rather than
local life choices.*

In the context of GM crops, however, much more than this is at stake. The relevant choices are about styles of life rather than choices of products, and about the extent to which interventions facilitate the pursuit of the human telos, the good life mediated through the perspective of those affected. Thus they are about global life choices rather than local life choices. Whereas a local life choice might be “Do I want this product now?” a global life choice is “What sort of life do I want to lead?”

Martha Nussbaum’s development of the capabilities approach has been particularly focused on the position of women (Nussbaum, 2000). The ethical matrix has not explicitly included the perspective of feminist ethics, which has been critical of a ‘principles’ approach such as that represented by autonomy, well-being and justice. It would not be sufficient, on this perspective, simply to subdivide by gender the “consumer” row of stakeholders. From the perspective of feminist ethics, it is important to look at power relations and the extent to which certain interventions or developments will differentially affect vulnerable groups. Insofar

as autonomy is an important principle to apply, the relevant question is not whether the idealized autonomous consumer can take an informed decision, but the extent to which vulnerable groups have a voice. Attention to the ways in which power relations are relevant to quality of life, however, is connected with consideration of the third principle, and column in the matrix, that of justice.

JUSTICE

A significant problem with addressing questions of justice in this area lies in the fact that these questions do not arise within states, or between states. Onora O'Neill has pointed to the "messiness" of trying to develop principles in what she calls "transnational" justice: to whom are they to be addressed—who are the agents of change? Nevertheless it is impossible to avoid asking the question.

O'Neill made the following points, relevant to quality of life: "One of the more promising strategies concedes that a full account of transnational economic justice might require a complete account of human needs, but claims that less is needed for a discussion that considers basic economic rights. It is not controversial that human beings need adequate food, shelter and clothing appropriate to their climate, clean water and sanitation, and some parental and health care, without which they become ill and die prematurely. These *basic needs* may provide a basis for arguing for *basic rights*. It is controversial whether human beings need companionship, family life, education, politics, or food for the spirit....But these issues do not have to be completely settled for a discussion of hunger and destitution to proceed" (O'Neill, 2000).

O'Neill argued that there are severe difficulties with both utilitarian and rights-based approaches to transnational justice. Specifically, on the right to food, she said that "if the claimants of supposed 'rights' to food or development cannot find where to lodge their claims, these are empty 'manifesto' rights." She argued for a Kantian-inspired account based on obligations, which assumes a picture of human life in which agents with "limited capacities and varied vulnerabilities" interact. A picture of justice has to take account not of idealized autonomous agents, but of the real situations of oppression in which people find themselves. So she argued for a picture of transnational justice that does not depend on the agreement of ideal abstract agents as in the Rawlsian original position, nor upon what people actually would consent to in the real world, which ignores power relations, but on what people *could* consent to. This is abstraction without idealization. In thinking about how this would work in practice, we might "ask to what extent the variable aspects of any arrangements that structure vulnerable lives can be refused or renegotiated by those whom they actually constrain" (O'Neill, 2000). She argued that, in fact, the poor cannot refuse or renegotiate their role in economic structures: Debtors who need further loans for survival cannot make much fuss about the terms creditors offer for purchasing their crops; the most dependent women...are acutely vulnerable both to market factors and to more powerful kin.

. . . stakeholder participation needs to be involved in setting the research agenda and not only at the stage of accepting particular crops or foods, and a greater proportion of research funding be directed towards alternatives.

This account of transnational justice is at odds, then, with arguments about justice in the agri-biotech debate that emphasize the moral urgency of trying to help poor farmers through agri-biotech, albeit on a case-by-case basis. Such arguments, which focus on well-being or even autonomy, frequently fail to take account of the real conditions of choice and in particular leave the entry of “choice”—in other words, areas over which people *have* a choice—to a late stage. In *Engineering Nutrition*, the Food Ethics Council argued that stakeholder participation needs to be involved in setting the research agenda and not only at the stage of accepting particular crops or foods, and that a greater proportion of research funding be directed towards alternatives. If this is not the case, then the stakeholders have no effective possibilities of refusal or renegotiation. In this sense, they are implicitly at least in line with O’Neill’s account.

Food security is a richer concept than the individual right to food, as it is good for society as a whole. Knowledge is said to be an archetypal public good, and genomics as a type of knowledge is in principle therefore, arguably, a global public good.

OWNERSHIP AND GLOBAL PUBLIC GOODS

Being treated justly is clearly highly relevant to an assessment of quality of life, and this applies both to individuals and population groups. Another aspect of justice, however, which is germane to the present context, is sharing of the benefits, and this is where issues of private and public goods become relevant.

Food security is considered by the United Nations Development Programme to be a global public good, defined as a good that is enjoyable by all without detriment to others; it is non-rivalrous and non-exclusive. Food security is a richer concept than the individual *right* to food, as it is good for society as a whole. Knowledge is said to be an archetypal public good, and genomics as a type of

knowledge is in principle therefore, arguably, a global public good. But whether or not knowledge is a public good is not independent of social and political arrangements. *Engineering Nutrition* however pointed out that the proponents of “pro-poor” agri-biotech have argued for public-private partnerships as the way forward, and are highly critical of this: “We question whether a science that depends on privatising public goods to sell at premium prices can make a realistic promise to generate food security, which depends on public goods (Food Ethics Council, 2003).

Rice is one of five crops constituting 75% of food in developing countries, and 70% of the patents for modification of these crops are owned by five biotechnology companies.

The report also highlighted the concern that poor countries are being “bullied” into abiding by patent rules that do not apply to them. This worry again is consistent with the concept of transnational justice developed by O’Neill. Rice is one of five crops constituting 75% of food in developing countries, and 70% of the patents for modification of these crops are owned by five biotechnology companies (Rathenau Institute, 2003). The Rathenau Institute suggested that research should be encouraged into so-called “orphan” crops that are not seen as commercially interesting. The way towards global sustainable food security must, therefore, proceed through the local varieties from the Third World, otherwise the Third World countries will only get on their plates the “crumbs” from production in the west.

The Food Ethics Council recommends that research should be directed to public-good projects. In the present context, it is difficult to accept the argument that genomics is a public good, but the deployment of the public-good argument may be regarded as a useful strategy towards improvement of quality of life.

Our understanding of what counts as quality of life must be pluralistic.

CONCLUSION

Our understanding of what counts as quality of life must be pluralistic. Even if we can establish a global “telos” for human beings, this must be mediated through local understandings. In other words, there will be a plurality of ways of pursuing

it. Food security is a necessary condition of quality of life, but not sufficient. Thus the debate over the extent to which agri-biotech helps to answer food security problems does not settle the question of its relevance to quality of life.

Different perspectives on ethics emphasize different aspects of quality: well-being, living autonomously, and being treated justly. In ethics and political philosophy, the debate about the priority of liberty and equality is an issue, but I have not attempted to settle that question here. Rather it has been my intention to demonstrate the different contributions of the different principles to making judgments about what constitutes quality of life and means to improving it. There is a considerable amount of consensus in the debate that well-being is insufficient, at least insofar as consequentialist or utilitarian interpretations of well-being are concerned. Process is arguably at least as important as the end state. An expanded notion of well-being, to include meaningful choice, has more support, but choice itself has tended frequently to be interpreted in an impoverished way, in terms of the ideal autonomous consumer. Attention at least to global dimensions of choice is required. This is not unconnected with justice, which directs our attention to both power relations and distribution of benefits. It has been shown that choice is relevant here too insofar as there are issues about the relevant bargaining power of the parties. In terms of courses of action for improving the situation, two things stand out: moving stakeholder involvement upstream in the research-priority-setting process, and encouraging fair and equitable sharing of benefits through appropriate infrastructure and ownership arrangements. Thus the concept of global public goods remains an important strategy in addressing the issues concerning improvement of quality of life.

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How Much is the Quality of Life Being Regulated?

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Worldwide, genetically modified (GM) crops comprise mainly four species in five countries (James, 2003), produced with GM technologies that have been developed mostly by the private sector in the developed world. Although an active public sector in the developing world is engaged in crop biotechnology (Atanassov *et al.*, 2004), little so far has reached smallholder farmers. Thus, when we discuss biotechnology in the developing world, we can only speak of “potential.” Many of the technologies under development have the potential to generate agronomic and environmental benefits or to enhance the nutrition of people in the developing world and to increase income and improve overall well-being. Most of the evaluations of benefits from GM crops in the developing world have been based on *ex-post* data for insect-resistant cotton, which has been approved for use in several countries.

Genetically modified food crops have not met with general acceptance, contrasting sharply with the widespread adoption of high-yielding varieties during the Green Revolution that were regulated under seed- and plant-protection laws still in place today. In the mid-1970s in India, despite a “paralysis that beset the public servants and politicians” (Hopper, 1987, 1999), farmers accessed, traded and sold the goods of the Green Revolution. The impact and longer-term effects of these high-yielding varieties have been studied (Evenson and Gollin, 2003), and their debatable qualities are being modified, some through biotechnology.

Genetically modified cotton and soybean—two of the four major crops grown—have had similar “farmer-first” adoption in developing countries as had the high-yielding varieties of the 1970s. Farmers sought and obtained access to *Bt* cotton before the Indian regulatory system had officially approved it, and interest is increasing in areas where cultivation of GM crops is not yet approved (Sharma, 2004). In fact, approval came months after the GM cotton had been harvested. In Brazil, a similar situation occurred with the planting of an estimated 4 million acres of GM herbicide-tolerant soybean that had not been approved for planting.

Safety standards for crops, as for all food and agricultural products, should not be compromised. However, GM crops now have new regulatory regimes or require additional scrutiny beyond those of conventional crops. The need to identify/evaluate long-term health or environmental effects of GM crops arises in part because the transgenes are new to agricultural systems. Although they function the same as genes introduced through plant breeding, hybridization, introgression, and wide crosses, they are treated differently in terms of management, monitoring and evaluation.

Regulatory decisions on GM crops have been made with varying familiarity as to crop and trait, and with varying uncertainty with respect to risk. So far, they have been deemed safe in a number of global reports (FAO, 2004; Nuffield, 2004), have few negative environmental or health effects, and in certain environments have been proven efficacious.

Regulatory decision making is done country by country and on a case-by-case basis, with little sharing of knowledge, delaying the regulatory and hence adoption process. Additionally, countries adhering to the Cartagena Biosafety Protocol have the option to deny approval for import or use of GM crops by using the precautionary approach, if generally not satisfied with existing scientific knowledge.

These complexities translate to the delaying the approval of GM crops, even in cases where quality-of-life improvements are anticipated. Such improvements potentially include:

- reduction in pesticide use that could benefit farmers and their communities not only for the direct effect of decreasing expenditure in this input, but also by reducing overall health and environmental risks associated with their use,
- increase in yields that can boost local production of food, benefiting local economies and reducing reliance on imports or food shipments,
- implementation of promising technologies that minimize the effects of biotic or abiotic stresses on crop development, such as salt resistance and drought tolerance that are major constraints on marginal lands where many poor farmers are localized,
- delivery of alternative compositions and forms of carbohydrates and fats,
- improved provision of vitamins, with new avenues of reaching the poor.

Timeframes for realizing such benefits from GM food crops may be from 5 to 15 years. Like conventionally developed crops, those considered as genetically modified must pass agronomic and safety evaluations. Field evaluations begin with confined trials, often conducted at experiment stations or commercial research facilities, where environmental risk and exposure are minimized, and where seed production/collection can be controlled. Promising lines are advanced to more-open evaluations and multi-location trials and, eventually, are released to farmers.

Safety assessments are inherent to risk assessment and biosafety. Whether these reviews are carried out through a coordinated framework using existing regulatory agencies, through specially created agencies for GM crops, or through national biosafety committees, the same questions arise as to safety and risk. Therefore, it is essential that regulators in neighboring countries facilitate exchange of data, understand where areas of uncertainty and perceived risk exist, and are cognizant of potential benefits.

However, safety considerations generally do not take into account potential benefits including life-enhancing possibilities.

However, safety considerations generally do not take into account potential benefits including life-enhancing possibilities. Commercial entities and public research institutes in developing countries are often ill-equipped to ensure adequate risk assessment. A consequence of research devoted to regulatory requirements is the additional cost, which means that only a few traits are researched and developed, and even fewer reach confined testing in developing countries. Countries may also decide to set multiple regulatory requirements to avoid a decision, rather than approve an unfamiliar trait where risk is uncertain. If 100% confidence in risk assessment is not achieved, the precautionary approach may result in cessation of the approval process.

PURPOSE OF THIS PAPER

The purpose of this paper is to review GM crops under development and their regulation, potential benefits and cost of lost opportunities, and the social implications of biosafety. The study of GM crops focuses on potential quality-of-life traits under research by the public rather than private sector in developing countries. Regulatory necessities for GM crops are considered, comparisons with prior crop developments are made, the current state of regulation among developing countries is conveyed, and a Conceptual Framework for biosafety systems is introduced. Alternative sources for helping rural communities are interjected, and specific concerns regarding the GM approach are discussed. Suggestions are made for achieving new models for regulation with benefits for public, as well as private, research. Difficulties encountered within a regulatory system, as well as those external to it are described, and aspects of opportunity, costs, benefits and risk are discussed.

CAN PUBLIC GM RESEARCH PRODUCE CROPS WITH QUALITY-OF-LIFE BENEFITS?

Currently, for-profit industry is the most successful provider of GM crops in developed and developing countries alike. For this reason, such production is a significant concern in developing countries. Using only commercially derived GM crops may result in inability to save seed, loss of control over costs and other unwanted effects of monopoly control. Arguments have been made for developing countries to consider biotechnology as part of their public-sector agricultural research agenda (Pinstrup-Andersen and Schioler, 2000). This research could provide the foundation for alternative sources of GM crops free of strong commercial control. However, until recently, no reliable data were available regarding such public research or its regulation.

A recent study (Atanassov, 2004; Cohen, 2005) indicated that public research on GM crops has targeted species and traits of importance to developing countries; it identified forty-six successfully transformed crops being tested in developing countries (Table 1). The percentages of these transformation events—distributed by phenotype—are presented in Figure 1. Over half of the 209 events involved single genes that confer either viral or insect resistance. In eleven events, multiple (stacked) genes are being tested for phenotypic combinations, such as insect resistance with herbicide tolerance.

TABLE 1. NUMBER OF TRANSFORMATIONS
(ATANASSOV *ET AL.*, 2004).

Region	Country	Number	Sub-total of events
Africa	Egypt	17	
	Kenya	4	
	South Africa	28	
	Zimbabwe	5	54
Asia	China	30	
	India	21	
	Indonesia	24	
	Malaysia	5	
	Pakistan	5	
	Philippines	17	
	Thailand	7	109
Eastern Europe	Bulgaria	8	8
Latin America	Argentina	21	
	Brazil	9	
	Costa Rica	5	
	Mexico	3	38
All			209

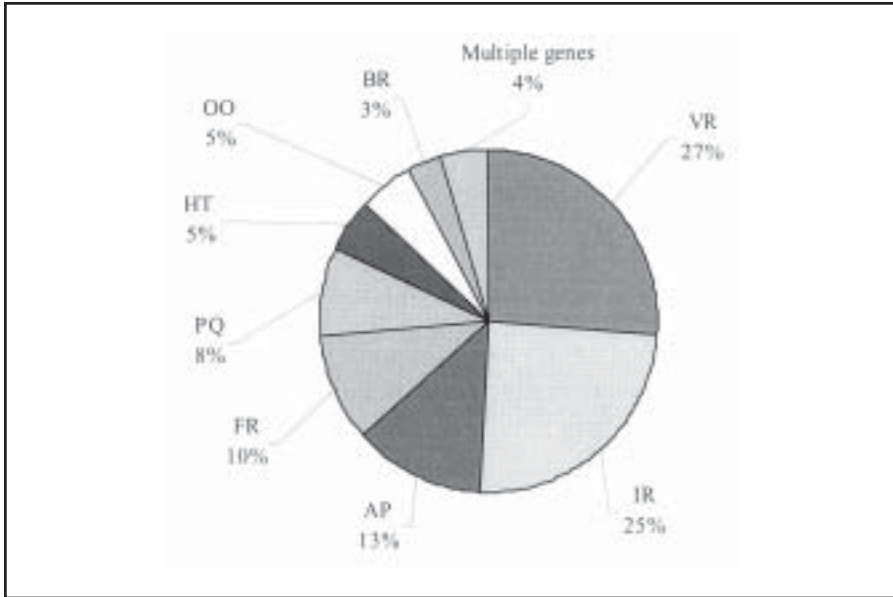


Figure 1. Phenotypic distribution and percent of total events (Atanassov *et al.*, 2004).

AP–Agronomic properties; BR–Bacterial resistance; FR–Fungal resistance; HT–Herbicide tolerance; IR–Insect resistance; OO–Other; PQ–Product quality; VR–Virus resistance.

Transformation events grouped by crop type are shown in Figure 2. Although cereals predominate, significant numbers of fruits, roots and tubers, and vegetables are represented, with each group containing diverse species. Progress in transforming indigenous crops is also significant. Although almost half of all transformation events are for rice, potato, maize, papaya, and tomato, the other half are spread over forty-one other crops, most of them indigenous, including pearl millet, papaya, mung bean, common bean, chickpea, cowpea, lupin, cacao, and coffee.

These combinations of crops and traits have great potential in areas not reached by the Green Revolution and in cases where such crops have been affected by new types of pests, water shortages, and/or where crops better suited to environmental constraints are needed. Benefits for poor farmers are directly related to the degree to which such cultivars can substitute for chemical inputs. Furthermore, the products of public research carry the advantage of being free of restrictive proprietary controls set by commercial providers.

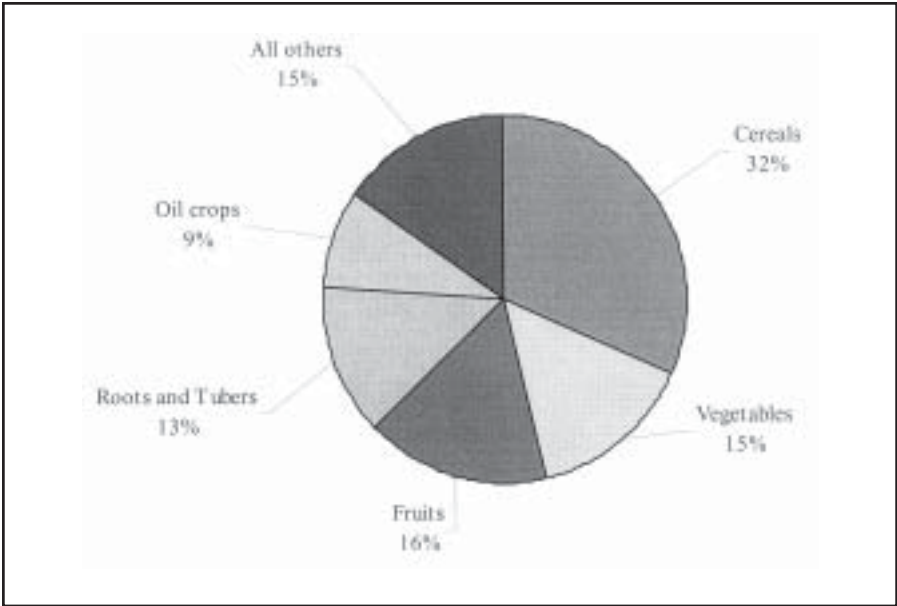


Figure 2. Percent transformation events by crop group (Atanassov *et al.*, 2004).

Many of these GM crops under development target very specific quality-of-life priorities in the countries where they are being developed. In Table 2 we included only those crops that have the greatest potential to improve people's well-being. Strictly we could broaden this to all events, as all the technologies under development by the public sector have at least an indirect effect on producers' or consumers' well-being, which is the purpose of all public research. For example, all fifty-one insect-resistance events under development will have an effect on farmers' quality of life, but we included only the thirty-five specifically developed for lepidoptera as they will have the greatest effect in reducing the impact of insecticide use.

The crops under development are in various stages of regulatory review in their respective countries. The total number of events decreases as lines are cut that do not convey sufficient agronomic efficacy, or if safety requirements cannot be met.

Despite this progress, the primary source of GM crops continues to be the private sector. Multinational companies have invested significant resources in guiding technologies through regulatory processes to production. With the exception of China, public-research products lag behind, eliciting concern because private funds are not being invested in countries, crops, traits or technologies that are most relevant to small-scale, resource-poor farmers.

TABLE 2. QUALITY-OF-LIFE RELATED EVENTS (COHEN, 2005)

Category 1	Category 2	No.	Subtotal
Insect-pest resistance	Lepidoptera	35	35
Disease resistance	Bacteria	8	84
	Fungi	21	
	Viruses	55	
Abiotic-stress tolerance	Drought	7	11
	Salinity	4	
Quality improvement	Nutritional and other	9	15
	Enhancing shelf-life	6	
Other	Vaccines	9	9
Subtotal		154	154
All events			209
% Subtotal over all			74

It is clear that Asia in particular has made a significant commitment to GM-crop research (ADB, 2001). This region contains the largest number of countries engaged in such research as well as the highest percentage of events in the testing phase. Africa, with the exception of South Africa, is seriously lacking in capabilities and resources to consider such research (Alhassan, 2003; UN ECA, 2002); many countries are exploring implications and are considering whether to invest in research on, or importation of, GM crops. Research capacity and potential markets are evolving (e.g. for insect-resistant cotton), albeit subject to uncertainties regarding the use of, and trade in, GM crops.

Developing countries are reacting in a precautionary manner regarding approvals of GM food crops, and justifying this approach by referring to the options articulated in the Convention for Biological Diversity and the Cartagena Protocol on Biosafety.

PUBLIC GM RESEARCH AND REGULATORY CONSIDERATIONS

Developing countries are reacting in a precautionary manner regarding approvals of GM food crops, and justifying this approach by referring to the options articulated in the Convention for Biological Diversity (CBD, 2004) and the Cartagena Protocol on Biosafety (Cohen and Paarlberg, 2004). Approaches to regulation that are consistent with the Cartagena Protocol are supported through the United Nations Environment Program Global Environment Facility (UNEP-GEF) pro-

gram on biosafety, which provides training in regulatory policy, frameworks, legislation and capacity building (Briggs, 2001; UNEP-GEF 2004). While significant progress has been made in building regulatory capacity and developing guidelines, biosafety decision-making remains complicated, lacking transparency.

A Conceptual Framework¹ (McLean *et al.*, 2002) has been developed to bring together regulatory policy, procedures and capacity (Figure 3). It starts by acknowledging that no single biosafety regulatory system fits the needs of all countries. This is shown as countries adopt different approaches for implementing biosafety systems, regulations and policies². Individual countries have different capacities and needs for biosafety regulation. One of these needs is to become compliant with the articles of the Cartagena Biosafety Protocol that one-hundred and ten countries have ratified.

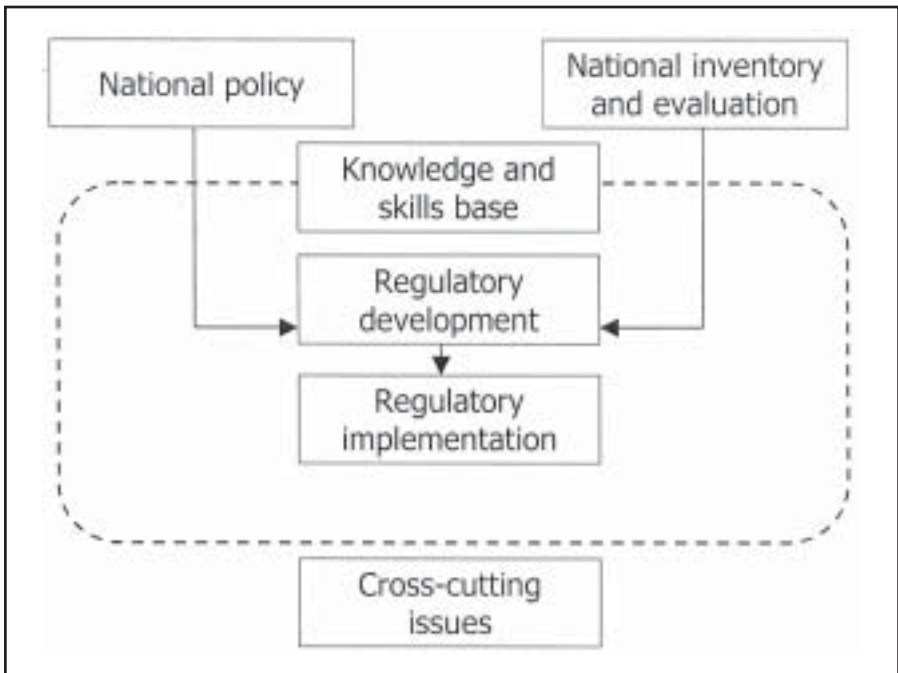


Figure 3. Basic elements of a Conceptual Framework for implementing biosafety frameworks and their interconnections (McLean *et al.*, 2002).

¹The Conceptual Framework recognizes five elements central to a regulatory system: policy, national inventory, knowledge and skills base, regulatory development, and regulatory implementation.

²Major differences between countries are explained by overall economic development level, available human and technical resources, governments' implicit or explicit perspective on biotechnology and genetically modified organisms (GMOs), and whether policies governing the use of GMOs are promotional, permissive, precautionary or preventive.

The Cartagena Protocol on Biosafety speaks both to risk management and to risk assessment (Article 16, and Annex II and III) by which regulators can assess safety, but also consider (explicitly or not) the levels of risk they are willing or able to tolerate. Little data are available to help regulators balance risk analysis and risk perception with the advantages of releasing a promising new technology, and with analysis of cost of regulation. In addition, the Protocol does not specify the different requirements for confined or limited testing versus approvals for commercial release. This tends to confuse both the scientists and the regulators as per the type of trial requested.

For this reason, regulatory stage categories were defined and used to group each transformation event recorded in the study of public sector GM-crop research. Respondents were asked to indicate the stage of regulation for their respective events. Those in the experimental stage contain stable research products derived from multiple generations, beginning in the laboratory and moving to the greenhouse. In this stage, the stable expression of the gene of interest is confirmed.

Fifteen traits remain stable in small-scale, single or multi-location confined trials. These trials are contained to prevent any environmental damage, thus the regulatory standards are different from those established for subsequent stages.

The scale-up stage occurs when products advance from confined to pre-commercial trials, requiring the ability to increase seed amounts and larger areas for testing purposes. These tests may be conducted for environmental safety purposes or to examine agronomic efficacy, or both. Finally, products are made available to farmers after commercial release, through privately or publicly owned seed companies or other institutional mechanisms. The data show a total of 127 events at the experimental stage, forty-four are in confined trials, twenty-two are in scale-up testing (mostly in China), and seven are at the commercial release stage (Figure 4).

Events at the stage of confined testing represent the most promising public research on GM crops. These forty-four events will decline in number during their evaluation. Of those listed, only five countries have five or more such trials in place. However, the public sector must go beyond confined trials for safety and efficacy. It must also guarantee seed supplies to evaluate product performance on a large scale, and include experiments designed specifically for safety evaluation. However, many of the events recorded have been in multiple years of testing and now await approvals for scale-up or pre-commercial trials.

For these crops, regulatory decision-making is needed for advancement and approval. To efficiently review public GM crops, it is necessary to first analyze and then strengthen regulatory decision-making. This necessitates actions internal and external to the biosafety system itself as described in the Conceptual Framework. Efficient processes essential for timely application review can be neutralized by external factors, including political, trade and activist positions, and, especially, difficulties when encountering European markets that are essentially closed to GM imports or use (Cohen and Paarlberg, 2004).

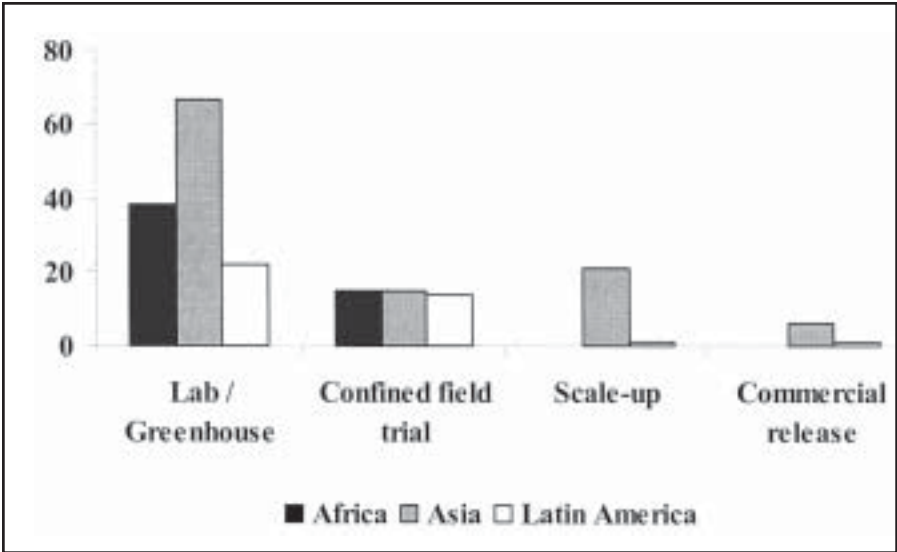


Figure 4. Public events classified by regulatory stage and region
(Atanassov *et al.*, 2004)

Note: Eight transformation events for Bulgaria are not included, as the regulatory stages were not disclosed at the time of survey.

No uniform roadmap is available for working externally, facing political, trade, environmental concerns, anti-GM lobbies, moratoriums, and non-governmental or activist influence.

Developing actions that will impact on advocacy voices external to the regulatory system is difficult. No uniform roadmap is available for working externally, facing political, trade, environmental concerns, anti-GM lobbies, moratoriums, and non-governmental or activist influence. Informed discussion regarding biotechnology's benefits and potential risks is needed—in the context of specific GM crop examples, political governance and advocacy concerns, and including farmer perspectives.

SOCIAL AND OPPORTUNITY COSTS FOR BIOSAFETY SYSTEMS

There are at least three consequences for countries using alternative paths to implement biosafety systems. First is the potential for lack of coordination between neighboring countries, creating a patchwork of regulatory systems that hinders trade and discourages technology transfer. Second is the potential for duplication of effort coupled with resource depletion. Third is the potential for jurisdictional arbitrage to seek those countries with the least stringent environmental regulations. Therefore regional regulatory approaches offer the possibility of creating greater efficiency and safety. Even the most dissimilar of biosafety systems will have in common the need for scientific expertise; ability to distinguish confined from open trials, communications infrastructure, appropriate facilities, and suitably educated personnel.

The challenge is to ensure safety while facilitating new opportunities for farmers. Such an outcome recognizes that there is a real social cost for not having efficient biosafety regulatory systems in place.

Regulatory systems are required that, while addressing safety, take account of national agricultural objectives, implications of international treaties [WTO-Sanitary and Phytosanitary (SPS) Agreement and the Cartagena Protocol on Biosafety], and potential to facilitate regional harmonization. On a more technical level, using a country's own interim processes³ can keep the regulatory process moving, particularly for authorization of confined/experimental field-testing.

A new initiative addressing these matters—the Program for Biosafety Systems (PBS)⁴—will use regionally focused discussions regarding specific commodities, knowledge of existing regulatory systems, and a sub-set of multi-sector issues for analysis. This will explore trade-offs between options and decisions involved in the design of a biosafety regulatory process from a multi-country perspective, identify specific areas where data and regulatory approval can be shared, and guide the development of these areas over the life of the project. This analysis will ultimately help shape new models for biosafety regulatory systems that take into account likely opportunity costs and variations of the risk-benefit-cost calculation. The ideas discussed look for participatory development of new models for biosafety systems to be implemented in a local context of expertise, resources, regulations, political and social realities, and trade constraints.

Policymakers will have an opportunity to examine the consequences of having a biosafety process that is too lengthy or expensive, to look at how this can reduce opportunities for domestic companies and public-sector R&D institutes to reach

³Interim processes can be defined as steps that allow countries to manage issues of immediacy while providing policymakers with experience that can be used to guide the development of a rational statutory process under either new or adapted legislation.

⁴PBS management is based at the International Food Policy Research Institute. Further details in its policy approach to regulation are under development. <http://www.ifpri.org/themes/pbs/pbs.htm>.

the farmers' hands, and to examine how this can bias the system toward multinational firms. The use of interim processes offers one way of achieving a new model for regulatory implementation. These processes offer a way to reduce lag time for the introduction of biotechnologies, while formal legislation is being formulated.

Two philosophies about risk assessment and management currently prevail in relation to transgenic organisms: the benefit-cost approach, and the precautionary principle.

ASSESSING RISK AND LOSS CALCULATIONS

Two philosophies about risk assessment and management currently prevail in relation to transgenic organisms: the benefit-cost approach, and the precautionary principle, as used by the European Union (Vogel, 2001) and by the Cartagena Biosafety Protocol. However, both these approaches have generally agreed on the same scientific criteria to be used in risk decision-making for transgenic organisms. The PBS will analyze the implications of these different approaches and develop decision models using a new methodology that integrates benefit-cost and risk analysis. Under this approach, the EU's precautionary approach becomes a special case with zero or negligible risk.

The development of new decision models for PBS involves integrated quantitative risk assessments and benefit-cost analyses. These two approaches are used in a complementary manner, providing different information about decisions to release transgenic organisms. Integration of both approaches is needed to assess where to implement costly regulations for small benefit in terms of reduced risk.

The analysis will be conducted around a series of country case studies of crop-trait combinations and will involve an assessment of the costs, benefits and risk of these combinations under the regulatory conditions existing within each country. The country-specific biosafety regulations will affect the costs (opportunity, timing, etc.) incurred and the level of risk assumed.

Therefore, changes to the regulatory environment can be assessed as far as they impact the receipt of benefits, or the increase in costs and various potential risks.

CAN QUALITY OF LIFE COME FROM ELSEWHERE?

GM research requires human, institutional and financial resources. Each country determines if it is able to make and sustain such commitments in the face of competing claims for funding. Such funds could otherwise be invested in irrigation, organic production methods, clean water development, or human disease prevention and eradication.

Furthermore, GM-free zones are being widely advocated or forced on countries by trade agreements. Consequently, at this time, GM-crop production may not be timely; rather it may be more advisable for countries to focus on enhancing food distribution, infrastructure and markets (Oxfam, 1999).

One industry developer has seen its regulatory costs reach between \$10 million and \$20 million for each crop event. These costs have grown substantially since the developer began GM research in the early 1980s.

Safety is key for the deregulation of GM crops. However, one industry developer has seen its regulatory costs reach between \$10 million and \$20 million for each crop event. These costs have grown substantially since the developer began GM research in the early 1980s. Overall, this means that crop research using GM technologies is *a priori* severely limited and such production costs can be justified only with crops with the highest potential profit. The same considerations apply to public research; ways must be found to meet the costs of addressing safety and regulation.

Another issue is whether a GM approach should even be considered, as it may be naively seen as a panacea for increasing national food security or productivity. Such a philosophy dictates that GM approaches be dropped as they may result in precipitous development and adoption of GM crops, avoiding full appraisal of potential or presumed risks (ISP, 2003).

CLOSING STATEMENT

Safety is a foremost concern while we develop a track record of familiarity with GM crops and traits. However, the Cartagena Biosafety Protocol presents a precautionary approach when science is new. Among concerns over process, procedures, compliance, and trade, quality-of-life benefits can be unclear. While many farmers benefited immediately from Green Revolution varieties and, more recently, from insect-resistant GM cotton, their voices within regulatory circles and in the Conference of the Parties for the Cartagena Protocol on Biosafety have been otherwise absent.

All of the research and regulatory issues ahead leave developing countries at a difficult juncture, as complexities exist to approve either confined or larger trials. This complexity means that, presently, there is little chance of public GM food crops reaching the farmer. Without such access, determining if quality of life can be more than just a “potential” is not possible. Without such impact, many will argue that there are more certain and successful alternatives to improve quality of life or livelihoods than agricultural biotechnology.

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Dr. Cohen recently authored papers on the public production of genetically modified (GM) crops in sixteen developing countries and their regulatory implications; the policy setting for food-safety assessments in the developing world; regulatory concerns and GM crops; and, realities/possibilities for crop biotechnology to mitigate or cope with effects of climate change.

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Prior to joining ISNAR, Cohen worked for the US Agency for International Development as senior biotechnology specialist in the Office

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Module III—Improving Quality of Life

Q&A

MODERATOR: NANCY COX

*University of Kentucky
Lexington, KY*

Alan Wildeman (University of Guelph, Guelph, ON): A question for Dr. Chadwick. Is the matrix you talked about equally applicable in Africa and the United States or the United Kingdom or Canada for example? Or does the matrix need to be prioritized in different situations?

Ruth Chadwick: Ben Mephram, who developed the matrix, recognizes that it has drawbacks. However, it can be a useful way of structuring a discussion and looking at the different ethical dimensions of a problem. However, I think that it is true that the three principles, well-being, autonomy and justice, are principles of western ethical traditions and so it may very well be the case that it omits a lot of important considerations. Well, I mentioned one important consideration that it does omit and that's the perspective of feminist ethics, for example. And so yes it may very well need to be adjusted. If you think that that type of approach is useful it may very well need to be adjusted for different cultural contexts.

John McDermott (International Livestock Research Center, Nairobi, Kenya): I want to raise some issues regarding public and private goods—how they are developed and disseminated. First of all, in the general area of biotechnology most of the work we do in public research institutions doesn't lead to GM crops, for example. It leads to conventional breeding solutions sometimes or to other solutions. The second thing is: the nature of the goods. They are usually a mixture of public and private. For example, a new vaccine for animals could have important implications as a public good in terms of control or even eradication of disease for a whole country. It could have important social equity aspects. But it could also be used by individual farmers as a private good for safeguarding the health of their

animals. Another issue we struggle with is—as a public research institute—we are not very good at the final stages of vaccine release. A lot of proprietary technology expertise with regulatory mechanisms is held in the private sector. So, my issues are how do we mix these public/private-good goals? One of our approaches has been to safeguard, as much as possible, the intellectual property in the public sector. But, my biggest problem as a research director is not that we safeguard intellectual property, but that we don't get products to farmers in a way that helps them; the research actually doesn't produce anything at the end of the day. We actually need some kind of private-sector collaboration.

Chadwick: Yes, that is very interesting. Certainly the distinction between public and private is much more complicated than it might appear. But, I was trying to outline the position of the Food Ethics Council, which is very concerned about proposals—what needs to happen in this area is more public/private partnerships. They see the way forward as encouraging more public-good projects. Not just in terms of thinking about products, but in thinking about genomics itself as a public good in terms of knowledge and development of infrastructure to enable people in developing countries to take advantage of that knowledge and develop their own projects. It's important to find ownership arrangements that do make that possible. That's the main point: ownership- and benefit-sharing arrangements are needed to facilitate that kind of development.

Joel Cohen: John, let me add that I didn't have the opportunity to present data on partnerships that we also collected in this sampling of public research. Over 60% of these institutions are working without any partnerships. Another 23% are working public to public and less than 10% are working with some kind of collaboration with the private sector, as follows:

PUBLIC-SECTOR PARTNER	NUMBER OF EVENTS	%
No partner	129	62
Foundation/Private	1	0.5
Private	13	6.2
Private/Public	5	2.4
Foundation	1	0.5
Foundation/Public	8	3.8
IARC	3	1.4
Public	49	23

It's a real indication that while that need is there—it's argued for, it may exist—there is virtually no experience with it now in the developing world. Institutions working alone are at a great disadvantage because they don't get the global expertise and knowledge that could help with their research.

Allan Eaglesham (NABC, Ithaca, NY): Dr. Remington may have an inside track on this. I'm referring to a situation that prevailed in Zambia recently. Although there was hunger—possibly even starvation—aid from the United States in the form of corn was declined because it was genetically modified.

Tom Remington: Fortunately I don't cover Zambia. But, it's a very interesting point. CRS was caught between a rock and a hard place. In particular, the Zambian Catholic Conference of Bishops came down very strongly in opposition to GMOs. There is a Social Peace and Justice Commission in Zambia that is very strong and very active and doing excellent work, headed by Peter Henriot. He has taken Catholic Social Teaching farther than anybody. However, I think he made a mistake in not focusing on the social justice issues. In trying to address the health issues—the issues of compromising exports to Europe, *etc.*—they, CRS, came down behind the Zambian Bishops on this one. I think that was a mistake. I think there was an undercurrent that Europeans were making suggestions that this could compromise exports to Europe. I never could figure out where the beef exports from Zambia to Europe were coming from; clearly they are not smallholders. So what's the big deal? Are these large South African farmers? I never figured that one out. So, it's a complex issue. We, CRS, are the largest mover of US-food aid. The US government refuses to label whether it is genetically modified or not. Why not? They don't want to because essentially all the maize and soy is GM. So the assumption is it's all genetically modified. It's a big issue and it's an issue that we don't know how to deal with. One last point: I heard the Minister of Agriculture being confronted by the BBC on how he could do this and put his people at risk. The point was made that Americans eat GM corn all the time with no health affects. The Minister said, "Look—they eat a bowl of corn flakes once a week, we eat meal-meal three times a day." I thought that was compelling logic from his point of view, so I don't have an answer. But, based in part on that experience, I try to concentrate on where I think NGOs—and CRS in particular—should be focusing and leave the health and environmental issues to those people who are better placed.

Audience Member: We've heard a lot about the precautionary principle. That doesn't sit very well in Canada as a useful standard. Certainly we support a precautionary approach. We look at Europe and it seems to be a bureaucratic quagmire where things get lost for years and years intentionally. Good scientists say that biotechnology is safe; we've done the testing, other countries have done the testing. But there doesn't seem to be any harmonization globally—that point has been made today. How do you respond to the comment that this is just a bureaucratic way of protecting the domestic market that it's basically a trade issue in a lot of ways—a non-tariff trade barrier?

Chadwick: I am involved in the regulatory system in the United Kingdom—at least I sit on the Advisory Committee on Novel Foods and Processes, which looks at safety and assesses the applications to put novel foods on the market. Yes, we do apply the precautionary principle. We also have the risk-assessment process that is based on purely scientific evidence. As a participant in that process, I don't have any sense of it being as you described. But then, I suppose you could argue that since I'm implicated in the system I would say that. Wouldn't I?

Audience Member: Especially in the UK there is a great deal of bias to protect the organic industry and this seems to be sacrosanct, from what I've read or observed. Organic is regarded as the ideal; everything has somehow to meet that standard. That seems to be politically motivated, perhaps because of Prince Charles. But not everybody worships organic food—there's a great deal of risk there as well.

Chadwick: Well, yes. You may be right that Prince Charles does have some influence, but he's not as great an influence as you might think. In my opinion, the present government is very pro-GM. I don't see it as supporting the organic movement in particular.

Kanayo Nwanze (Africa Rice Center, Abidjan, Ivory Coast): My question is for Tom Remington. If I heard you correctly, you indicated that the task of biosafety risk assessment will fall on the NGOs who have only a weak capacity to analyze data. Why does this responsibility fall on the NGOs and not on national systems in the countries that you referred to?

Remington: I wonder why also. It's just that there is a creative tension between those sorts of research and, in this case, the NGOs who are doing the extension work. I'll give you an example. The research institutions came up with a wonderful paradigm called “mother and baby” trials. I must admit that they took me in. It sounded really nifty: an on-farm multi-location trial involving hundreds of babies, fully replicated and statistically analyzable. Well, we were tasked to do this, to collect all the data. We failed miserably, to the great consternation and disappointment of our research partners. I said, “What we need to learn from this is that we don't have the quantitative capacity.” If we want to do mother and baby trials—conventional varietal work—you need to come a lot farther down to our level and help us with it. Partnership yes, but you need to get closer to the field. We discovered the limit of our capacity and of our partner's capacity. Speaking of biosafety I must admit I'm a bit ignorant: how long does biosafety monitoring continue at the farm level? Does it continue? Or once a GM variety is released, once it's in the hands of the farmer, is there need for continued monitoring? If that's the case, then my concern is less.

Nwanze: Okay. The last part of your answer pacifies me. I was worried when you said that NGOs would take responsibility for risk assessment. How would GM plants come into a country if the national system does not officially provide clearance? This emphasizes what you said regarding the weak capacity for NGOs to do that. We need to be very cautious. If I may say so, the issue at stake here is that we should assist national programs or systems to increase capability, to assume the necessary responsibility to do the job. Otherwise, it will fall to institutions such as NGOs, albeit of weak capacity, to do what national systems themselves should be doing.

Remington: In their recent paper, the FAO actually suggested that NGOs should actively support the GM process and should actively advocate for increased funding for GM crops, which got me wondering and worrying about what else NGOs would be tasked with doing. But, again, we won't be bringing GM plants into the country. It would be at the point when it reaches the farmer. At that stage, the farmer is usually involved in participatory evaluation. As Joel mentioned, that's the point at which farmers are coming over and grabbing hold of the product and saying thank you very much, I think this is good stuff. I don't see how you can have an on-farm pre-release without that being a *de facto* release, if the stuff is good.

Marc Saner (Institute on Governance, Ottawa, ON): I feel compelled to clarify the use of the precautionary principle in Canada. In a previous question it was said that few people in Canada are interested in it. Historically Canada was quite important in the design of the Convention on Biological Diversity and previous Prime Minister Brian Mulroney was the first one to sign it. So Principle 15 was endorsed by Canada. It entered legislation in Canada. It's in the Canadian Environmental Protection Act and also in the Oceans Act under two different names. In one case as "precautionary principle" and in other case as "precautionary approach." And I also believe it's in the newest version of the Pest Control Products Act. And finally our Privy Council Office, which is the central agency that ensures consistency of decision-making and policy-making has written up a guideline on how to use the precautionary principle after a very lengthy interdepartmental exercise. So, there is plenty of usage in Canada of the precautionary principle.

John Radin (USDA, Washington, DC): Dr. Cohen, I'd like to commend you for identifying some things that could be done and should be done fairly quickly regarding regulatory aspects in the less-developed countries. Are you aware of movement to try to initiate collaboration to simplify the highly segmented process?

Cohen: That is something that we are doing now. We are trying to reengage that process. Unfortunately, there have been scattered attempts before that have not come to fruition. It's difficult because the initiative comes from the agricultural sector through regional bodies that do not include regulators. So, we are trying to build regional and national consortia to look at that. Our entry points are modest—it's a long-term hope.

Ann Oaks [University of Guelph (retired), Guelph, ON]: In Canada, the Wheat Board tests the quality of wheat that comes from different farmers. It's a public enterprise, and it's something that industry south of the border complains about constantly. Is this the way we should be thinking, regarding the issue of testing being done by NGOs? There is distrust of industry because of its track record—the tobacco industry, for example. And there is secrecy because of patents. I think that testing and setting standards have to be at the public level, but sufficiently organized and sophisticated so that people can believe in it.

Remington: Obviously, quality assurance is very important. In East Africa, seed certification—originally intended to protect consumers—has been perverted; it's used really to protect commercial seed companies. It's now a barrier to entry by farmer seed entrepreneurs and small seed companies. So, I would agree with you in principle, but in practice quality assurance can be perverted and fail to serve the intended purpose. I can see I didn't answer your question.

Oaks: It seems to me that there needs to be a central place where the testing can be done, whether it's for quality or safety or whatever.

Tony Shelton (Cornell University, Geneva, NY): I'd like to get a point of clarification from Dr. Chadwick. The council of which you are a member, that makes these decisions: you said that you use the precautionary principle and then also a risk/benefit analysis. Can you clarify that? As Dr. Cohen explained it, there was really much more of a separation between the two.

Chadwick: Well, in making decisions about whether to allow something onto the market, the only thing we are allowed to look at is safety, really. It's based on a scientific assessment of whether there are any concerns about safety. It's not a risk/benefit analysis in that sense because we're not really looking at benefits. It's not within our remit to look, for example, at whether a functional food that claims health benefits has any benefits or whether it's likely to be effective.

Shelton: Or a crop that is insect resistant, whether that really has any benefit, your council focuses on the risk but not the benefit?

Chadwick: That's right.

Shelton: Okay. I just wanted that clarified. Although the principles that you outlined would be the same, or should be the same, throughout the world, in a developing country would you find that you would emphasize some of the principles more than others? That is to say, would you be more inclined to look at risk/benefit analysis in a developing country versus the United Kingdom or Europe where hunger is not a major concern?

Chadwick: We need to be clear about different spheres of operation here. The Advisory Committee of Novel Foods and Processes is purely part of the regulatory process in the United Kingdom and there are clear lines within which we can operate. When I'm talking about the principles in the ethical matrix, then that is within the sphere of general ethics. Although the Food Ethics Council has used that matrix, it doesn't have any regulatory status; it's an independent body that thinks about ethical issues in foods and agriculture. It was asked earlier whether the principles in that have global application, well this is a discussion in theoretical ethics because some people argue that they do have global application because everyone everywhere ascribes to the importance of well-being, choice and justice although they might interpret them differently. So, I'm not sure that one could say that any particular principle has greater priority in a particular part of the world. There is an ongoing debate about the priority of liberty as opposed to equality, and liberty and well-being, so I guess in certain conditions it would be more important to put an emphasis on basic needs rather than, say, on liberty.

Shelton: Right. I wonder if cultural aspects would profoundly influence the principles that you have listed there though? I don't know the answer to that, but I wonder if that would occur and what the ramifications would be for putting GM crops into developing countries that way.

Chadwick: Well, discussions I have had with bioethicists in China, for example, have led to the idea that although there might be pragmatic agreement on some of these principles, the underlying reasons that people might have for agreeing with them might be rather different because of different traditions. So, yes, I think there are important cultural differences to take into account.

