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 *Nichomachean 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

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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

[1]The 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 1. 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).

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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).

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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.

References

Edgar A (1998) Quality of life indicators. In: Encyclopedia of Applied Ethics (Chadwick R Ed) San Diego: Academic Press 759–776

Food Ethics Council (1999) Beyond Nuffield. Brighton: Food Ethics Council.

Food Ethics Council (2003) Engineering Nutrition. Brighton: Food Ethics Council.

Glover J (1977) Causing Death and Saving Lives. Harmondsworth: Penguin

Nuffield Council on Bioethics (1999) Genetically Modified Crops: the Ethical and Social Issues London: Nuffield Council on Bioethics.

Nuffield Council on Bioethics (2004) The Use of Genetically Modified Crops in Developing Countries. London: Nuffield Council on Bioethics

Nussbaum MC (2000) Women and Human Development: The Capabilities Approach. Cambridge: Cambridge University Press.

O'Neill O (2000) Bounds of Justice. Cambridge: Cambridge University Press.

Rathenau Institute (2003) Genes for Your Food: Food for Your Genes: Societal Issues and Dilemmas in Food Genomics (Working Document 92). The Hague: Rathenau Institute.

Sen A (1988) On Ethics and Economics. Oxford: Blackwell.

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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

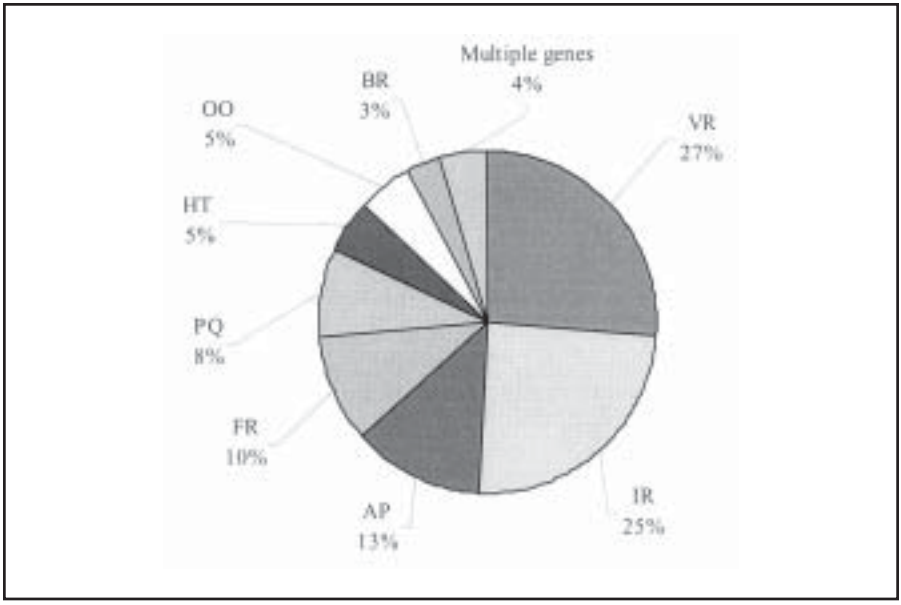

Figure 1. Phenotypic distribution and percent of total events (Atanassov *et al.*, 2004).
AP–Agronomic properties; BR–Bacterial resistance; FR–Fungal resistance; HT–Herbicide tolerance; IR–Insect resistance; OO–Other; PQ–Product quality; VR–Virus resistance.

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.

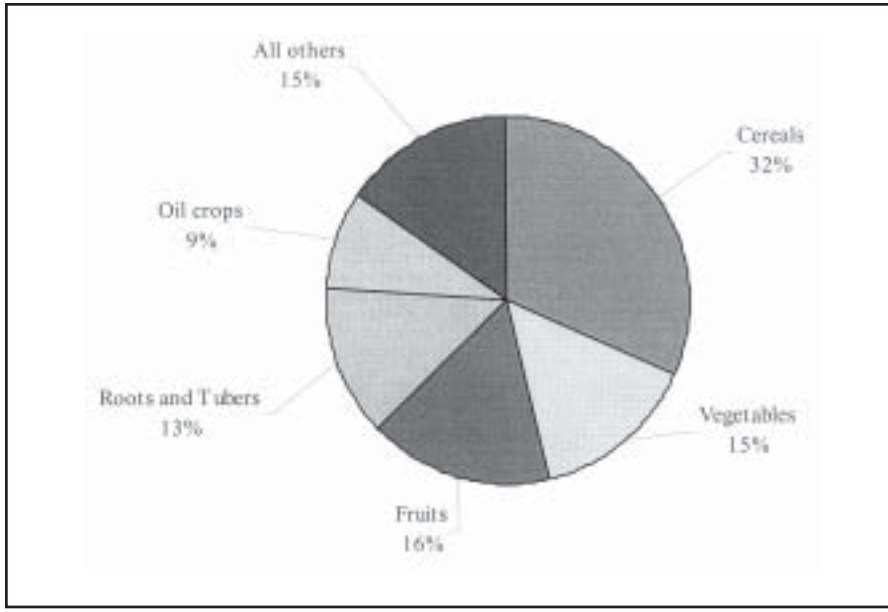

Figure 2. Percent transformation events by crop group (Atanassov *et al.*, 2004).

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 Framework[1] (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 policies[2]. 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.

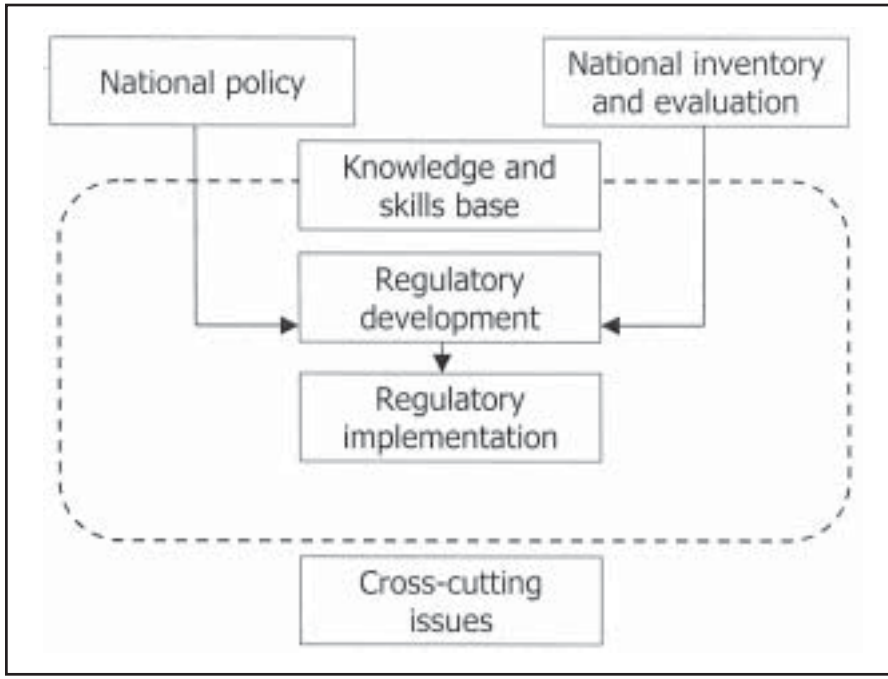

Figure 3. Basic elements of a Conceptual Framework for implementing biosafety frameworks and their interconnections (McLean *et al.*, 2002).

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

[2]Major 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).

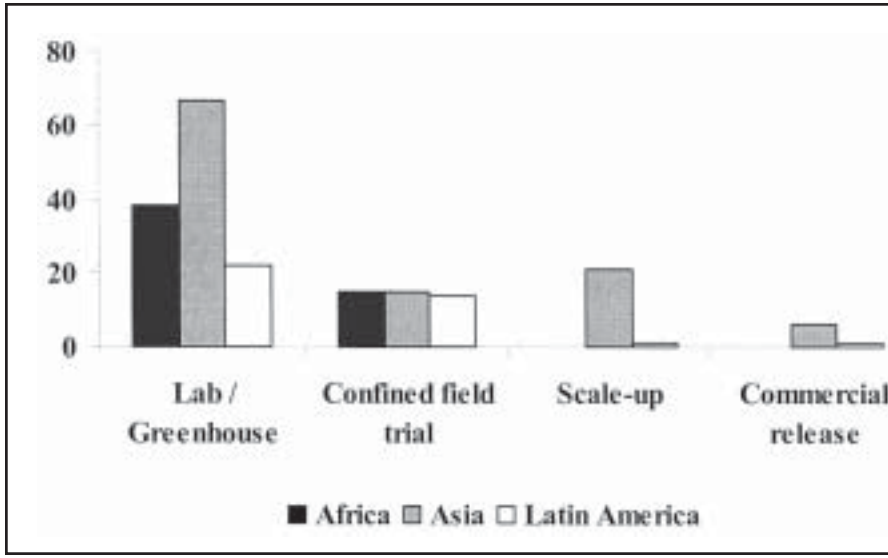

Figure 4. Public events classified by regulatory stage and region (Atanassov *et al.*, 2004)
Note: Eight transformation events for Bulgaria are not included, as the regulatory stages were not disclosed at the time of survey.

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 processes[3] 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

[3]Interim 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.

[4]PBS 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.

References

Alhassan, W.S. (2003) Agrobiotechnology Application in West and Central Africa (2002 Survey Outcome). Ibadan: IITA.

Asian Development Bank (ADB) (2001). Agricultural Biotechnology, Poverty Reduction, and Food Security. Working Paper. Manila: Asian Development Bank.

Atanassov AA *et al*. (2004) To Reach the Poor. Results from the ISNAR-IFPRI Next Harvest Study on Genetically Modified Crops, Public Research, and Policy Implications. EPTD Discussion Paper 116. Washington, DC: International Food Policy Research Institute. http://www.ifpri.org/divs/eptd/dp/eptdp116.htm.

Briggs, C. (2001) Planning for the Development of Nearly 100 National Biosafety Frameworks. Paper presented at the international consultation A Framework for Biosafety Implementation – A Tool for Capacity Building, organized by the International Service for National Agricultural Research (ISNAR) and Virginia Polytechnic and State University, Washington, DC, July 23–26.

Cohen JI (2005) Poorer nations turn to publicly developed GM crops. Nature Biotechnology 23 27–33.

Cohen JI and Paarlberg R (2004) Unlocking crop biotechnology in developing countries – a report from the field. World Development 32(9): 1563-1577.

Convention on Biological Diversity (CBD) (2004) The Cartagena Biosafety Protocol. http://www.biodiv.org/biosafety/signinglist.aspx?sts=rtf&ord=dt.

Evenson RE and Gollin D (2003) Assessing the impact of the green revolution, 1960 to 2000. Science 300: 758–762.

Food and Agriculture Organization of the United Nations (FAO). (2004) The State of Food and Agriculture 2003-04. Rome: FAO.

Hopper WD (1987) An interlude with Indian development. In: Policy and Practice: Essays in Honour of Sir John Crawford (Evans LT Miller JDB Eds), Sidney: Australian National University Press.

Hopper WD (1999) Introduction, The Future: Social Research. Pages 1-4. New School for Social Research in association with The Gale Group and LookSmart.

Independent Science Panel (ISP) (2003) The Case for A GM-Free Sustainable World. http://indsp.org/ISPreportSummary.php.

James, C. (2003) Preview: Global Status of Commercialized Transgenic Crops. International Service for the Acquisition of Agri-biotech Applications (ISAAA).

McLean MA *et al*. (2002) A Conceptual Framework for Implementing Biosafety: Policy, Capacity and Regulation. ISNAR Briefing Paper 47. The Hague: The Netherlands.

Nuffield Council on Bioethics. (2004) The Use of Genetically Modified Crops in Developing Countries. London: Nuffield Council.

Oxfam (1999) Biotechnology in Crops: Issues for the developing world A report compiled for Oxfam GB by Laura Spinney. http://www.oxfam.org.uk/what_we_do/issues/livelihoods/biotech_gm.htm.

Pinstrup-Andersen P Schioler E (2000) Seeds of Contention. World Hunger and the Global Controversy over GM Crops. Baltimore: Johns Hopkins University Press.
Sharma AB (2004) Demand for Bt cotton takes root. The Financial Express (India) May 12.
United Nations Economic Commission for Africa (UN ECA) (2002) Economic Report on Africa 2002. Tracking Performance and Progress.
United Nations Environment Program Global Environment Facility (UNEP-GEF) (2004) Project on Biosafety. http://www.unep.ch/biosafety.
Vogel D (2001) Ships Passing in the Night: The Changing Politics of Risk Regulation in Europe and the United States. EUI Working Papers RSC No. 2001/16. San Domenico, Italy: European University Institute.

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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.

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 Gueph, 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 Mepham, 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 meali-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 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.