Socio-economic, Ecological and Policy Impacts Assessment in the Introduction of a Transgenic Staple Crop Variety to the Developing World – the Insect Resistant Maize for Africa (IRMA) Project, Kenya

Abstract

In Kenya, as throughout most of East and Southern Africa, maize represents the primary staple. However, the country is yet to become self-sufficient in the crop and current increases in productivity fall short of population growth. Throughout the region, pre-harvest losses due to stem borers are estimated by farmers to range around 15%. The identification of maize varieties with seed-based insect tolerance has been an ongoing focus of the Kenyan Agricultural Research Institute (KARI) since its inception in 1979. The Insect Resistant Maize for Africa (IRMA) Project, a partnership between CIMMYT and KARI, and funded by the Novartis Foundation for Sustainable Development, was initiated in 1999. Its aim was to increase maize production and food security through the development and deployment of insect resistant maize, both through conventional breeding and through the use of lines transformed with toxin genes from the entomopathogenic bacteria *Bacillus thuringiensis* (Bt). Whereas genetically modified insect resistant maize has been grown widely in the US since 1996, controversy, public opposition, and regulatory confusion have characterized the history of Bt maize in Europe. Although Kenya is ahead of most African nations in the adoption of the technology (with the third GM crop currently undergoing assessment prior to the import of germplasm), policies on biosafety and biotechnology in general are still in the early stages of development, and public awareness is minimal. Through the provision of practical experience, workshops, and continuous dialogue with stakeholders, the IRMA project aims to raise public awareness of the issues surrounding the technology and to build capacity among

local institutions in biosafety and biotechnology policy as encapsulated in Article 22 of the Cartagena Protocol on Biosafety.

IRMA represents the first case in Kenya where non-target effects, genetic erosion, and insect resistance management, are all to be assessed prior to the release of the crop. The project is also unique in its incorporation of socio-economic studies in the assessment of the technology, addressing equity, market demand, and intellectual property-rights (IPR) issues to equip Kenyan scientists, administrators, and policy makers with the full range of tools required for technology assessment. This paper analyses the approaches used to assess the impacts of Bt maize in the ecological and socio-economic realms, and IRMA's subsequent impacts on Kenyan biotechnology policy and public awareness, especially relating to GMOs.

Whereas previous attempts at project impacts assessment may have been retrospective, coinciding with or following interventions, IRMA's prognostic impacts assessment work will determine whether a release policy is to be pursued and, if so, will continue after commercialization. This predictive and monitoring approach is especially vital with the introduction of a new technology that is under intense scrutiny from national and international observers. This case study provides a model for projects dealing with the introduction of biotechnology products in the developing world.

Introduction

The global acreage of insect resistant transgenic maize carrying genes from the entomopathogenic bacteria *Bacillus thuringiensis* grew from none in 1995 to over 10 million ha in 2000[1], the most rapid expansion of an agricultural technology in history. The vast majority of this area is made up of seed purchased from the private sector and planted on large-scale farms in North America and Argentina. Large amounts of impact assessment research have been carried out by governmental and academic institutions in the United States and Canada on Bt maize. Nations in sub-Saharan Africa have been slower to adopt the technology, largely due to uncertainties over the impact that such crops might have on the countries' environments, economies and consumer health. Investigation of such impacts is often beyond the capacity (both in terms of capital and expertise) of many of the regions' governments. For private corporations targetting the largest and most lucrative markets, the investment required to conduct such investigations is unfeasible, and thus impact assessment for Bt maize in Africa has been severely lacking.

The Insect Resistant Maize for Africa (IRMA) project is a collaboration between CIMMYT and the Kenya Agricultural Research Institute (KARI), which seeks to enhance insect resistance in tropical maize, specifically for Kenyan and East African conditions, both through conventional and transgenic (Bt) techniques. Financial assistance for the project is derived from the Syngenta Foundation for Sustainable Agriculture. A major focus of the IRMA project is the assessment of both environmental and socio-economic impacts of the introduction of insect-resistant maize to Kenya. Recent years have seen an increasingly polarised debate, especially in the developed world, over the potential benefits and hazards associated with the use of genetically modified crops as a tool for promoting food security. Much of this discourse, however, has been carried out on hypothetical grounds, with little empirical evidence on which to base specific claims. The Insect Resistant Maize for Africa

[1] James (2001) Global Review of Transgenic Crops, ISAAA Briefs, Ithaca

Project hopes to advance this debate by amassing some of the various data needed to evaluate the appropriateness and likely efficacy of Bt maize in Kenyan farming systems.

This paper represents a discussion of the impact assessment work carried out by the IRMA project to date. After introducing the background to the IRMA project, it will review the impact assessment findings, evaluate their significance and examine problems faced in their production. We conclude by considering the strengths and weaknesses of the IRMA approach as a model for future introductions of biotechnology products to the developing world by the public sector.

Background

Maize production in Kenya

Maize is the primary staple crop throughout Eastern and Southern Africa. Over the last three years (1998-2000) Kenya produced on average 2.3 million tons of maize, on an area of 1.5 million ha (2 seasons)[2]. This production has remained fairly constant over the last 10 years. During the same period, the population has increasing by 2.9% per year, reaching 28.7 million in 1999[3]. Average production per capita is therefore estimated at 81 kg/capita, while consumption is estimated at 103 kg/per capita[4]. As most of the land suitable for agriculture in Kenya is already under cultivation, enhanced production must result either from more efficient farming practises or from further adoption of agricultural inputs or technologies. Maize research, especially the introductin of hybrid varieties, was highly successful in 1960s till 1980s. Since then, however, very few new varieties have been introduced, and even fewer were widely adopted.

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[2] Ministry of Agriculture, unpublished data
[3] Central Bureau of Statistics. 2001. 1999 Population and Housing Census. Counting Our People for Development. Volume I Population distribution by administrative areas and urban centres. Nairobi (Kenya): Ministry of Finance and Planning.

In Kenya, six major agroecological zones for maize production can be identified[5] (see map). Moving from east to west, there are the Lowland Tropics (LT) on the coast, followed by the Dry Midaltitudes and Dry Transitional zones around Machakos. These three zones are characterized by low yields (less than 1.5 t/ha); although they cover 29% of maize area in Kenya, they only produce 11% of the country's maize. In Central and Western Kenya, we find the Highland Tropics (HT), bordered on the west and east by the Moist Transitional (MT) zone (transitional between midaltitudes and highlands). These zones have high yields (more than 2.5 t/ha) and produce 80% of the maize in Kenya on 30% of the area (see Table 1). Finally, around Lake Victoria, is the Moist Midaltitude (MM) zone, which produces moderate yields (1.44 t/ha), covers 22% of the area and produces 9% of maize in the country.

The most important species of stem borers are the spotted stem borer *Chilo partellus* (Swinhoe), found in the warmer and lower areas around the coast and Lake Victoria, and *Busseola fusca* Fuller, found in the cooler and higher altitudes[6]. A third, less important species is *Sesamia calamistis* Hampson, found at elevations up to 2600 m. For the first two species, four major areas of distribution can be distinguished[7]. The first area is situated in the southeast , where *C. partellus* is important, and it covers the lowland tropics and most of the dry areas. The second area covers the highlands and the eastern moist transitional zone and is distinguished by *C. partellus* below an altitude of 1500 m, and *B. fusca* above that. The third area, around Lake Victoria, has a mixture of the two species, and covers the moist

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[4] Pingali P.L. (ed.) (2001) CIMMYT 1999-2000 World Maize Facts and Trends. Meeting World Maize Needs: Technological Opportunities and Priorities for the Public Sector. Mexico, D.F.: CIMMYT. 60 pp.
[5] Hassan, R.M. (ed.). (1998) Maize technology development and transfer: A GIS application for research planning in Kenya. Wallingford (United Kingdom): CAB International/CIMMYT/KARI. 230 pp.
[6] Mulaa M. A. (1995) Evaluation of factors leading to rational pesticide use for the control of the maize stalk borer *Buseola fusca* in Trans-Nzoia district, Kenya. PhD thesis, University of Wales, Cardiff.
[7] William Overholt (pers. comm.)

midaltitudes and the southwest of the moist transitional zone. The fourth area covers the northwest corner of the highlands and moist transitional zones and is dominated by *B. fusca*.

The identification of maize varieties with seed-based insect tolerance and conventional breeding of resistant cultivars has been an ongoing focus of the Kenyan Agricultural Research Institute (KARI). CIMMYT has been involved in maize breeding research in Kenya since 1997, using conventional breeding and more recently marker assisted selection (MAS) to produce stem-borer-resistant lines.

Status of biotechnology in Kenya

The Kenyan biotechnology sector is small and consists primarily of collaborative research activities between national and international research institutions. The country's policies towards genetically modified crops have been described as *precautionary* in the areas of biosafety (for example deliberate release), in trade regulations (import), in public investment in R&D and also in terms of legal protection for intellectual property holders[8]. Concurrent with this analysis is the fact that national regulators have only considered the import of three crop species of genetically modified germplasm to date. Moreover, no commercial releases of genetically modified organisms (including maize), have so far been approved by the Kenyan authorities. It is possible, however, that some of the maize donated as food aid from North America and Europe since 1997 was transgenic in origin and could have been planted in areas worst hit by droughts.

Under the Kenyan system, imports and deliberate releases of GMO's and LMO's are first assessed by the institutional biosafety committee of the establishment wishing to conduct work on the organisms. After institutional approval, the dossier is passed to the National

Biosafety Committee, a multi-disciplinary group made up of stakeholders drawn from various government, NGO, national or international institutions, acting under the auspices of the National Council for Science and Technology, which finally delivers its approval or rejection of the application.

Overview of Impact Assessment within the IRMA Project

IRMA was developed as a pilot project to enhance the use of biotechnology for agricultural research in Africa. Hence since the beginning of the project in 1999 impact assessment was given a lot of consideration, with a full-time CIMMYT economist based in Kenya and a socio-economic working group made up of economists and sociologists from CIMMYT and KARI. At the project planning meeting in Mombassa, the objectives of the working group were defined as advising the project in the choice of germplasm (seed, plant, and consumption characteristics), evaluation of the new varieties by farmers under farmers' conditions, policy analysis and cost/benefit analysis.

The working group kept an open spirit, and scientists and students from the University of Nairobi and Egerton University were included as well as independent consultants. Activities for the first two years included:

- Assessing farmers' preferences and demand for new varieties, using Participatory Rural Appraisals (PRAs)
- Maize sector study: study constraints in maize production, marketing, and inputs
- Study the institutional framework and Intellectual Properties Regulations (IPR) in which the new varieties are being developed
- ex ante impact assessment, including crop loss, health effects, equity concerns

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[8] Paarlberg, R. L. (2001) The Politics of Precaution, p. 149 IFPRI

- Development of methodology for participatory variety selection (to do ex post later)
- Communicate the developments within the project to a scientific and general audience

The scope of ecological impact assessments were also determined by discussions carried out at this meeting. KARI ecologists, supported by experts from CIMMYT, would focus on the areas of:

- impacts on non-target organisms
- possible development of insect resistance to Bt toxins
- the likelihood and characteristics of possible gene flow between transgenic maize and other cultivated and/or wild species.

Where such research was outside current capacity, training would be offered and strategic alliances with other institutions adopted.

Socio-economic Impacts

Assessing farmers' preferences and demand for new varieties - PRAs

The key objective of the working group was to assess farmers' demand for new varieties. This study was initiated with Participatory Rural Appraisals in all major maize production zones of Kenya, organized in 2000, using secondary data, key informants and group interviews in a representative sample of villages from all agro-ecological zones, 43 in total[9].

Farmers made a list of the varieties they grew, and how many farmers grew them. The results show that, over all zones, most farmers plant local varieties. Local varieties particularly dominate in the low-potential areas such as the lowlands, the moist mid-altitudes, the dry mid-altitudes and the dry transitional. Improved varieties, on the other hand, dominate in the high-

[9] De Groote, (2001a.)

potential areas of the highlands and the moist transitional zones. Varieties are region specific, and in the highlands the most popular is the Kenya Seed Company’s (KSC) hybrid H614, grown by 73% of the farmers. In the moist transitional zone, the improved OPV Makueni (71%), the Pioneer hybrid PHB3253 (57%) and Kenya Seed Company’s H511 (50%) and H512 (30%) are the most popular. In the dry areas the KSC OPV Katumani is most popular improved variety, but is only grown by 20% of the farmers. Similarly at the coast, KSC hybrids PH4 (26%) and PH1 (24%), and improved OPV Coast Composite (23%) reach few farmers.

Farmers presented a list of the criteria they use to select varieties, and then proceeded to score those criteria on a scale from 1 (somewhat important) to 3 (very important). Two criteria receive an average score of importance between 2 and 3: early maturity and yield. While the score of early maturity is fairly even distributed, high yield is not that important in the dry area's. Three criteria have an average score between 1 (somewhat important) and 2: drought tolerant, tolerance to field pests, and tolerance to storage pests, but there are again important differences between regions. No other criteria have an average score higher than 1, although some regions have particular criteria, such as striga resistance around Lake Victoria.

The three major constraints to maize production ranked by farmers throughout the zones were cash constraints, lack of technical know-how and extension, and problems with maize seed: high cost, poor quality and low availability. Pest problems usually ranked in the top six. The two major pest problems farmers encounter all over the zones are stem borers and weevils. Both pests rank in the top three in all the agroecological zones. Other major pests are chaffer grubs (dry zones), termites (dry zones and moist mid-altitude) and striga (moist mid-altitudes).

The PRA showed great potential for insect resistant varieties. Stemborers are indeed a major problem perceived by farmers, and insect resistance is an important criterion for variety selection. Farmers in the high potential areas have largely adopted improved maize varieties, but this is not the case in low potential areas, where local varieties dominate. The project should also pay attention to the other selection criteria mentioned by farmers, in particular yield, early maturity, and resistance to other pest mentioned, in particular storage pests. Probability of adoption of the new varieties would be increased substantially by improving the institutional environment of the dissemination. Attention should be paid to the distribution of high quality seed, extension, and credit. The highest impact is expected in the high potential areas, highlands and moist transitional zones. In this area stemborers are identified as the first pest problem, they have the highest adoption rates and together account for more than 80% of maize production in Kenya.

Evaluation of new varieties by farmers under farmers' conditions

The new resistant varieties are not expected to be ready for testing by farmers for a few years. Still, the IRMA socioeconomics team has initiated work in this area by helping the CIMMYT and KARI breeders with evaluation of recently developed varieties with farmers, especially drought and low nitrogen tolerant varieties. A first round of evaluations was performed in the dry areas[10]. From this experience, a methodology for eliciting variety preferences was developed[11], to be used in modified mother and baby trials[12]. First results are encouraging, but they also show that the methods need some fine-tuning, especially through limiting data collection to what is relevant and what can conveniently be analyzed.

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[10] Bett *et al,* (2000)
[11] De Groote, Siambi *et al,* (2001c)
[12] Siambi, De Groote *et al,* (2001)

Maize sector study

The maize sector study was undertaken to assure that the economic environment is favourable to the introduction of the new varieties. Maize is the most important food crop in Kenya, constituting 21% of the total value of primary agricultural commodities. It is a subsistence and cash crop that is politically sensitive. In 1998, an estimated 3 million Mt of maize was produced on 1.5 million hectares. Smallholders accounted for 70-80% of total production and large-scale 20-30%.

To study the sector, separate topics were considered. First of all marketing was addressed, followed by the topics raised by farmers during the PRAs were addressed: seed systems, credit, technical knowledge and extension. To avoid the logistical and analytical problems experienced with the PRAs, it was decided to only use small-scale, local surveys at first, to be enlarged if the results are promising and the methodology is fine-tuned.

Marketing

About 40% of the total maize produced is marketed while the balance is consumed on-farm. The marketing of maize is either by the Government through the National Cereal and Produce Board or by the private sector that is dominated by many independent large and small traders. Kenya has seen a progressive liberalisation of the market since the late 1980’s, even though NCPB still fixes prices for the limited maize it purchases (0.56 million tons). Future cessation of remaining (although inconsistently imposed) government tariffs are expected to lead to further decreases in maize prices.

Seed systems

Based on secondary data from three previous surveys, a study of the seed systems in the semi-arid areas was completed[13]. Adoption of high yielding varieties and the distribution of the seed has not met with the same success in the semi-arid areas as in the rest of Kenya. After liberalization, the private sector and NGOs are expected to play an increasing role. To address the need to gauge the extent to which these developments might have affected farmer access to improved varieties of dryland crops, a study of the seed industry in the semi-arid region of Kenya was undertaken:

An inventory of players showed that public sector agencies such as KARI and the Ministry of Agriculture were found to play the key roles of varietal development, inspection and certification and the provision of extension advice. Several NGO's operating in the semi-arid area also acquired seed from the public sector agencies for distribution to farmers. The farmers' survey revealed that own farm was the most important source of seed followed by government agencies such as KARI, NGO's and small businesses known as *Agro-vets.* High prices (1.2-6 times the prices of local seed), unavailability of appropriate varieties, and low quality were some of the problems farmers gave as constraints to the use of improved seed. The most effective mode of providing seed to smallholders was the `seed loan' approach wherein farmers repay seed in kind, a method popular with voluntary sector agencies. A smallholder `seed farmers' survey indicated that they produced high quality seed, and realized higher prices and gross margins from seed than regular crops. However, low yields and high costs were the main problems. The results of a seed traders survey showed that the numbers of traders and the range of varieties increased considerably over the last 10 years. High supply prices, low demand by farmers and high competition were cited as major constraints to expansion of trade.

[13] Muhammad *et al* (2002)

Market Structure Analysis - Transnzoia District

To understand the organization of the market and assessing the degree of competition in maize hybrid seed production and retailing, the structure and conduct of the market were analyzed in Transnzoia District, a major maize producing area in Western Kenya[14]. The only identified impact of liberalization in the district is that the monopoly of distribution of the seed initially done by KFA has reduced and now there are many traders in the seed retailing. The analysis of market structure revealed the presence of factors that favor imperfect competition in Transnzoia hybrid maize seed marketing at the retail level, including unequally distributed shares of transactions among traders, the existence of product differentiation and barriers to entry. Kenya Seed Company provides 96.7% of the hybrid maize seed sold in Transnzoia District, with Pioneer Company providing the remaining 3.3% of the market share, a clear monopolistic seed production. Distribution, with a Gini Coefficient of 0.6 in this district, is categorized as oligopolistic, with 61.67% of the market share going to the largest 4 firms. Farmers showed their preference for the variety H614 but indicated their disappointment with KSC because of inefficiency and lack of seed purity.

Credit

To address the credit problem facing small scale farmers a study was launched in Siaya district in Western Kenya, to study the impact of self-help groups' credit on factor use in maize production. Results show that borrower farmers significantly use more fertiliser and hybrid seeds (19.39 and 6.58 Kilograms respectively) than non-borrowers (6.0 and 3.03 Kilograms respectively). Over 90% of the farmers stated that credit is their major constraint in improved input use. A link between formal and informal credit markets to increase the credit available to the farmers needs to be established. To facilitate the absorption of external

[14] Nambiro *et al* (2002)

funds in the informal credit sector, training in financial management is recommended for the groups.

Intellectual Property Rights

After a preliminary review of the literature and some discussions with key informants, a study is currently under way to chart the IPR environment in Kenya and analyze its implications for the release of new varieties. Preliminary results indicate that regulations are strict, although the regulatory agencies are poorly equipped to guarantee the quality of marketed products. Plant breeders rights are still being discussed and a lot of issues concerning transition from centrally-planned to liberalized systems and division of rights between old and new institutions and between individual breeders and their institutions, need to be settled. Unclear regulations, and uncertainty about rewards, probably play a role in the current level of new releases of the last years.

Extension and know-how

Two adoption studies, started on a previous project, were completed by the IRMA team. They concern a low potential area: the coast[15] and a high potential area: the moist transitional zone[16]. The studies confirm the importance of appropriate varieties for the low-potential areas, and the need for proper institutional environment, especially extension and credit. A study of NGOs as potential players in rural extension at the coast[17] revealed that NGOs are not as well established as often is thought, and have limited resources to play a major role in the distribution of new technologies and varieties. This was also confirmed by the PRAs[18].

[15] Wekesa *et al*, (2002)
[16] Okuro *et al*, (2002)
[17] Ndungu *et al*, 2002)
[18] De Groote *et al*, (2001)

Ex ante Impact assessment

Crop loss assessment

Previous estimates of crop losses caused by stem borers using artificial infestation established clear links between damage factors and yield losses. These results, however, cannot be extrapolated to estimate crop losses in farmers' fields under natural infestation. The value of these crop losses needs to be estimated in order to set research and extension priorities. Due to lack of field data, farmers' (subjective) estimates of losses under natural infestation and the incidence of infestation were used to estimate maize yield losses estimated for each of Kenya's major agroecological zones[19]. The yield loss was estimated to be 15%, amounting to 0.33 million tons of maize, at $230/ton estimated at US$ 90 million. The high-potential areas have relatively low crop loss levels (11–14%), while the low-potential areas have high losses (17–26%). Taking into account the higher yield of the former (more than 2.5 t/ha), the loss per hectare is remarkably constant, between 315 and 374 kg/ha, except for the dry midaltitude zones, where losses total approximately 175 kg/ha. The value of these losses is estimated at US$ 82–100/ha and US$ 46/ha, respectively.

To obtain field estimates of these losses, a representative sample of maize fields was selected during 1999 and 2000 for each of Kenya's 5 major agroecological zones[20]. Half of each field was protected against stemborers using a systemic insecticide, and the other half was left for natural infestation, and the comparison of yields gives an estimate of crop loss. Total loss in Kenya due to stem borers is thus estimated at 14 %, ranging from 11% in the highlands to 21% in the dry areas. In 2000, the price of maize decreased to $160/ton, leading to an estimated value of the losses of $ 59.8 million. Almost half of the losses (US$ 27.6 million) occur in the moist transitional zone. This area also has a high adoption rate of improved

[19] De Groote, (2001)
[20] De Groote *et al*, (2002b)

varieties (95%) making this area a promising target for insect resistant varieties. In the dry areas, losses are relatively high (21%), but its low yields reduce potential benefits but those benefits would go to more resource-poor farmers.

Economic Impact

These results were then combined with the distribution of stemborer species in Kenya[21], indicating that only four stemborer species cause crop losses higher then 10% in at least one region, and only two species are of major economic importance: *Busseola fusca* (82% of all stem borer losses in Kenya) and *Chilo partellus* (16%). The highest can thus be expected from breeding varieties resistant to *B. fusca* for the moist transitional and highland tropics ($ 27 and $21 million in yearly losses respectively), followed by breeding against Chilo for the moist transitional ($10 m), the dry areas ($8 m) and the moist mid-altitude ($5 m). Except for the highlands and the lowlands, developing combined resistance to both species is indicated. Since bioassays of Bt genes have found very efficient genes against *C. partellus* but not against *B. fusca*, the search for Bt genes against Busseola is likely to result in high benefits. The project clearly needs urgently to find genes that express resistance to *B. fusca.*

Impact on health

The PRA study was combined with interviews of stockists, which revealed that the most important pesticides used by maize farmers are Actellic for storage and several formulations against stemborers (especially Buldog).

[21] De Groote *et al*, (2002a)

Adoption

A base line data survey is currently being prepared and the questionnaires tested, to allow for a monitoring of the adoption of the new varieties. The data will also allow the statistical testing of several hypotheses as indicated by the PRA and case study results.

Evaluation of Socio-Economic Impact Assessments

The IRMA socioeconomics team had the advantage of adequate funding and experienced personnel. The impact studies so far show how PRAs combined with case studies, later to be combined with base-line data and national surveys, clearly lead to a good overview of the sector, and sound recommendations for the breeding.

Still, some problems demand attention. Availability of KARI economists is limited and turnover is high. KARI scientists have high incentives and financial rewards to participate in field research, but very little to analyze, write and publish. As a result, most dynamic scientists are overstretched in field activities, face a backlog of analysis, and only arrive at a sketchy reporting of the results. In the present incentive structure, scientific publication is very difficult.

Most scientific collaborators show a mild interest in the impact assessment, although it cannot be considered to play a major role, as is clear in the choice of regions and varieties to be transformed. For political reasons, breeding efforts are more or less equally distributed over the different regions, with disregard to the potential impact. Similarly, transformation of well established varieties (such as H614, currently good for half of maize seed sales in Kenya) with Bt genes hold no interest to breeders or their instutions, because of unclarity of their IPR. Breeders and seed companies have a very high interest in ignoring the old varieties and only transforming their own, disregarding the impact results which show that some old varieties are very well adapted and popular, and that very few new varieties have been successfully released over the last 10 years.

The project also suffers from dual objectives: developing resistant varieties on the one hand, and promoting biotechnology on the other. This last function makes it more difficult to focus on the potential impact as it muddies the water.

Ecological Impacts

Regulatory appraisals of Bt maize to the developed world have differed in the extent to which they have assessed ecological impacts, in the selection of impacts on which to focus and in the manner in which the findings of such investigations have been interpreted. Three primary areas of ecological impact (non-target effects, gene-flow, and insect resistance management) will be investigated by the project, and the results made available to the Kenyan National Council for Science and Technology in regulatory appraisal of the crop. Another project, implemented by the International Centre for Insect Physiology and Ecology (ICIPE), the South African Agricultural Research Council–Grain Crops Institute, the University of Nairobi and North Carolina State University, aims to complement and extend on IRMA's work, thus providing important additional (and independent) data to regulators[22].

Non-target effects

Effects of the introduction of transgenic crops on non-target organisms, especially agriculturally beneficial species (predators, pollinators and decomposers), have been an ongoing concern since the first ecological assessments of the technology in the USA in the early 1990's. Especially significant in the USA, has been the contraversy surrounding effects

[22] Overholt, W., Gould, F., Osir, E. O., Okech, M., van den Berg, J., Anyango, B. (2000) Project proposal submitted to USAID - Assessment of Potential Ecological Impacts of Introducing Genetically-engineered (GE) crops into Africa.

of Bt corn pollen on the monarch butterfly *Danaus plexippus*[23]. Adverse effects on agriculturally important species have also been reported (and usually contested), for example those towards the green lacewing *Chrysoperla carnea*[24]. IRMA aims to identify target and non-target organisms in maize cropping systems, assessing their relative abundance across various Kenyan agro-ecological zones. So far arthropod characterization studies have been conducted in three agro ecological zones: i) lowland tropics (Kilifi district), ii) dry mid-altitude (Machakos district), and iii) moist transitional (Kakamega). Formicidae (ants) and Forficulidae (earwigs), both known stemborer predators, were identified, as well as Blattidae and Araneida. Ladybird beetles such as *Cheilomenes sulphurea* (Olivier), which feed on stemborer eggs, were also present[25]. Using this information as a baseline the project hopes to assess the impact of transgenic maize on biological controls and other non-target organisms in the biosafety greenhouses that IRMA is building at KARI headquarters and in the open field.

The ICIPE-led project aims to build on the above by conducting its own toxicity studies on selected non-target Lepidoptera and examining survival and various fitness-associated characteristics of parasitoids reared on hosts fed on a Bt-incorporated diet. In addition to above-ground species, the ICIPE-led project aims to examine impacts of Bt maize on soil biota. These investigations will focus on persistence of Bt toxins in different soil types containing maize seedlings, activity of these residues on maize-associated fungi (Mycorrhiza

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[23] The original papers reporting effects were Hansen-Jesse, L. C. and J. J. Obrycki. (2000). Field deposition of Bt transgenic pollen: lethal effects on the monarch butterfly ***Oecologia*** on-line at http://link.springer.de/link/service/journals/00442/contents/ , 13/1/2002. and Losey, J. E., Raynor, L. R., Carter, M. E. (1999) Transgenic Pollen harms Monarch Butterfly, ***Nature*** 399, 214. These findings caused a wave of contraversy - Shelton, A. M. and R. T. Rousch. 1999. False reports and the ears of men. Nature Biotechnology 17:832., and have been followed up by more recent studies by various authors (2001) ***Proc. Natl. Acad. Sci.*** *USA*, Vol. 98, Issue 21, 11908-11912, 11913-11918, 11919-11924, 11925-11930, 11931-11936, 11937-11942

[24] Hilbeck, A., Moar, W. J., Pusztai-Carey, M., Filipini, A., Bigler, F. (1998) Toxicity of Bacillus thuringiensis Cry 1Ab Toxin to the Predator Chrysoperla carnea using diet-incorporated bioassays ***Environmental Entomology*** 27, 1255-1263 and (1999) Prey-mediated effects of Cry1Ab toxin and protoxin and Cry2A protoxin on the predator *Chrysoperla carnea.* ***Entomologia Experimentalis et Applicata*** 91, 305-316

[25] S. Mugo, H. DeGroote, B. Odhiambo, J. Songa, M. Mulaa, D. Bergvinson, M. Gethi and D. Hoisington. .2002. Advances in Developing Insect Resistant Maize Varieties for Kenya within the Insect Resistant Maize for Africa (IRMA) Project. Paper presented to the 7th Eastern and Southern Africa Regional Maize Conference and Symposium on Low N and Drought Tolerance in Maize, Nairobi, Kenya, February 11-15, 2002

and Azospirillium) and legume-associated bacteria (eg. Rhizobium), and will evaluate the effect of Bt maize plants on common parasitic nematodes (eg. *Meloidogyne spp* and *Pratylennchus spp*).

Gene-flow

No wild relatives of maize are known to grow in East Africa, however maize pollen can wind-disperse over many kilometers[26] under the appropriate conditions, and therefore transgene-spread to land-races can be expected if Bt maize is released to the field. In Kenya, where most farmers use saved seed, gene-flow of this sort has important implications for insect resistance management, labelling and consumer choice, and for quantitative estimation of any non-target effects. Starting in March 2002, IRMA aims to estimate the rate and character of gene-flow caused by artificial selection by examining the stage (cob/individiual grain) at which seeds are selected by farmers, and from which parts of the field (centre or periphery) they are taken. Pollen dispersal distances and models to quantitatively investigate the rate of transgene-flow through the maize gene pool are also planned for the future. The current variety distribution (derived from the PRAs) will be used as base-line data against which the project can conduct *ex post* monitoring of potential gene erosion.

The ICIPE-led project will further investigate the relative competitiveness of Bt and non-transgenic maize pollen. Fitness of hybrid Bt/non-Bt maize, which has important implications for expected selection rates by farmers, will also be a focus of this project.

Insect resistance management

It is likely that increased exposure to Bt toxins in transgenic maize will accelerate the development of resistance to Bt among African maize stemborers. In order to deter or

[26] Emberlin, J., B. Adams-Groom and J. Tidmarsh (1999). A report for the Soil Association on the dispersal of maize pollen. National Pollen Research Unit, University College, Worcester, UK

postpone the emergence of this resistance, IRMA intends to investigate various aspects of the maize-stemborer system in order to enable the formulation of a high dose/refugia strategy suited to Kenyan conditions. This involves the identification of non-maize "refuge" species of economic significance to Kenyan farmers and determination of pyramiding strategies of conventional and transgenic insect resistance genes. IRMA will also identify appropriate screening technologies and develop sampling protocols by which to monitor the development of resistance amongst stemborer populations throughout Kenya's primary maize growing regions. So far the project has gathered useful data regarding non-maize food crop and livestock fodder species that may act in refugia. After evaluating 30 different alternate hosts for stem borers, preliminary results showed Columbus and Sudan grasses as the most effective refugia for *C. partellus* and *B. fusca* and sorghum as the best host for *Chilo* and *Busseola*. Napier grasses attracted oviposition, but showed lower emergence of stemborers after larval development.

ICIPE, NCSU and ARC-GCI will investigate the toxicity of commercial Bt maize to African stemborer species (in order to assess suitability of the strain to the "high-dose" strategy) and the dispersal behaviour of maize pests (necessary before the adoption of a "refugia" strategy.)

Evaluation of Ecological Impact Assessment

IRMA's selection of research foci reflects the impacts widely-recognised as adverse effects in jurisdictions where the crop has so far been released. The relative lack of appropriate resources and capacity within local organisations, unavoidable with this new technology, has been countered by significant project investment in training and infrastructural development in the area of biosafety assessment (see Capacity Building section). In addition, the substantial resources required to comprehensively carry out ecological impact assessment studies have led to agreements being made with other specialist institutions, notably the

International Centre for Insect Physiology and Ecology, to ensure that regionally available resources are used efficiently in the assessment of environmental risks. This will allow a more thorough and independent review of the questions at hand.

General delays have been witnessed in the development of IRMA's Bt stemborer-resistant maize germplasm, partly due to delays in the import of Bt-maize leaf tissue for insect bioassays. Current applications for field trials of imported Bt maize seed are awaiting approval from the KARI Institutional Biosafety Committee. Early informal signals suggest that these may have to be carried out concurrently in a closed biosafety greenhouse and in the open field environment, thus requiring the construction of a biosafety greenhouse. This suggests a possible conflict of interest within KARI: the more institutional regulations to test genetically modified organisms stipulate experimentation inside specific structures, the more likely it is that the IRMA project will finance the construction of those structures for KARI. KARI, through its Institutional Biosafety Committee, influences the requirements under which the organisms can be tested.

Because the choice of *Cry* toxin employed, as well as the spatial and temporal patterns of toxin gene expression (compare for example different impacts of Bt176 against other events in US monarch studies[27]), may all affect the nature of environmental impacts, tests on non-target organisms would be premature if they did not reflect the exact nature of the insect resistant maize to be developed by the IRMA project. Full ecological impact assessment must, therefore, wait until the maize to be developed by the IRMA project is available.

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[27] Stanley-Horn, D. (2001) ***Proc. Natl. Acad. Sci.*** *USA*, Vol. 98, Issue 21, 11931-11936,

The regulatory decisions surrounding the introduction of Bt maize in Kenya, as anywhere else, cannot rely on "sound science" alone to produce definitive judgements about safety[28]. A complete ecological assessment would need to address the full extent of ecological complexity rather than focussing on toxicity to individual species[29], an impossible task for today's level of ecological understanding[30]. Kenyan regulators must be aware that the work carried out by IRMA and ICIPE in this field will be characterised by inherent scientific uncertainty, and that their assessment will necessarily stray into the realms of trans-science, where traditional scientific/political boundaries begin to break down.

Policy/ Institutional Impacts

Assessment of impacts on policy and institutional capacity is an important and growing field[31]. The IRMA project itself was not designed to influence institutional procedures or governmental strategies surrounding biotechnology policy, and therefore the formal assessment of these impacts has not been a major focus since the project's inception. However, inspection of primary sources and interviews with key informants from Kenya's biotechnology policy community has enabled qualitative observations to be made that point to the following perceived changes that may be attributed to IRMA's activities:

Capacity-building

Experience of assessing the IRMA applications has provided Kenyan regulators with opportunities for institutional learning and allowed the development of tacit knowledge associated with such assessments among individuals within the KARI IBC and the NBC.

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[28] "The politics of GM Food: Risk, science and public trust" UK Economic and Social Research Council Global Environmental Change Programme Special Briefing no. 5, October 1999.

[29] Obrycki, J., Losey, J., Taylor, O. and Jesse, L. (2001) Transgenic Insecticidal Corn: Beyond Insecticidal Toxicity to Ecological Complexity, ***BioScience*** 51, 5, 353-361

[30] Sutherland, W. and Watkinson, A. R. (2001) Policy-making with ecological uncertainty : lessons from badgers and GM crops, ***Trends in Ecology and Evolution*** 16, 5, 261-263

[31] IAEG Secretariat (1999) Impact Assessment of Agricultural Research: Context and State of the Art, paper prepared by the Impact Assessment and Evaluation Group of the Consultative Group on International Agricultural Research for the ASARECA/ ECART/ CTA Workshop on Impact Assessment of Agricultural Research in Eastern and Central Africa, Entebbe, Uganda, 16-19 November 1999

Kenya's emergent biosafety policy is currently determined by two NCST documents[32] and has not yet been enacted in national legislation. Experiences from the IRMA project and other early assessments of transgenic germplasm will determine the nature of the act of parliament that eventually governs Kenyan biosafety, and are therefore of the utmost importance.

IRMA has been directly responsible for the design and construction of a level II biosafety laboratory at the KARI head office as well as the design of a biosafety greenhouse (under construction) and an expanded laboratory for the KARI biotechnology center. Over the last two years senior representatives from the National Biosafety Committee, KARI and KEPHIS have visited bioassay facilities, biotechnology laboratories, and biosafety greenhouses at CIMMYT's headquarters in Mexico, and two KARI scientists have travelled there for instruction in biotechnology and ecological impact assessment methodologies. A further scientist attended a course on impact assessment at the International Institute of Tropical Agriculture in Nigeria. IRMA's training and familiarisation activities have contributed to the "...development and/or strengthening of human resources and institutional capacities in biosafety, including biotechnology to the extent that it is required for biosafety, for the purpose of the effective implementation of this Protocol, in developing country Parties..."[33] as outlined in article 22 of the Cartageña Protocol on Biosafety.

Awareness-raising among Kenyan population

Awareness raising of issues surrounding biotechnology is a major focus of the IRMA project. To date, the project has held two stakeholder workshops and one awareness raising workshop

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[32] *Regulations and Guidelines for Biosafety in Biotechnology for Kenya*, National Souncil for Science and Technology no. 41, Nairobi, Kenya, February 1998, *Kenya Biosafety Framework*, National Council for Science and Technology (UNEP/GEF Biosafety Enabling Activity Project, September 1999)

[33] Cartageña Protocol on Biosafety, text of the protocol. Article 22. Capacity Building

for media representatives. Working with the African Biotechnology Stakeholders Forum (ABSF), USDA and Rockefeller Foundation, CIMMYT also held a training workshop for scientists' communication with the mass media. A quarterly project-centered publication[34] has been initiated and regular co-ordination with various media has produced large numbers of articles on the project, however the impact of these activities on public awareness has not been measured.

As well as senior members of governmental departments and non-governmental institutions working on agricultural development in Kenya, representatives of food processors, journalists, farmers' co-operatives, seed companies, churches and other interested (environmental) NGOs were also present at stakeholder meetings. Although the importance of involving all sectors of society in the decision-making process is recognised, stimulation of debate among the mass media and public is limited by existing levels of awareness and interest. Due to the structure of Kenya's farming systems and food industry (and the resultant difficulties in labelling and segregation), the opportunities for individual consumer choice seen in Europe will not always be available. The importance of including a wide range of public viewpoints in impact assessment is thus enhanced, as adoption of the technology will necessarily subject all consumers to risks that in Europe may be avoidable at the individual's discretion. Although an organised movement against GM is almost absent in Kenya, consultation of organisations expressing concern about the technology is vital and democratisation of the debate in the early stages may prevent the polarised discussions and regulatory impasse that have arisen in many developed nations.

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[34] IRMA Impacts, online version available at http://www.cimmyt.org/ABC/InvestIn-InsectResist/htm/InvestIn-InsectResist.htm

Widening of policy network

Conflicts of interest are likely to arise when producers of a new technology are solely responsible for producing the evidence used in the regulatory assessment of that technology. In addition, the foci adopted for impact assessment by one organisation may exclude (deliberately or inadvertently) those that would be identified if a wider range of stakeholders had been consulted. The IRMA project's initial partnership between CIMMYT and KARI has developed to form mutually beneficial relationships with other non-government organisations based in Kenya such as ICIPE, ABSF, other parties. This widening of the policy network involved in biotechnology policy and public awareness has allowed previously excluded opinions to be considered in the debate, and diffused some tensions that existed between institutions before open channels of communication and partnership were initiated.

Incorporation of Socio-Economic Questions in Regulatory Assessment

As outlined above, the IRMA project has dedicated substantial funds and resources to the *ex ante* assessment of socio-economic impacts arising from insect-resistant maize. This involvement of the socio-economic dimension is a unique approach in the introduction of transgenic crops to Kenya, and shows a marked difference to the assessments carried out in preparation for the commercial releases of other transgenic crops such as Bt cotton. The inclusion of socio-economic factors at this stage may lead to a widening of the criteria on which regulatory assessments of transgenic crops are based in the future. Inclusion of some of the socio-economic issues targeted by IRMA (such as equity of benefits) in the Cartageña Protocol has been called for repeatedly by some African nations[35], but remain absent from the relevant article 26 (socio-economic considerations). Previous government documents

[35] Stabinsky (2000) Bringing social analysis into multilateral environmental agreements: Social impact assessment and the biosafety protocol." *Journal of Environment and Development* September 9, 3, 260-283

concerning the assessment of biotechnological products do not discuss the importance of such factors in regulatory assessment of transgenic crops. The IRMA project is thus addressing impacts outside those that are specified in current national and international policy.

Evaluation of Institutional Impacts Assessment

Incremental changes in policy and increases in tacit knowledge of regulators or public awareness do not lend themselves to simple measurement. Although policy impact assessment was never a primary focus of the project, some impacts of IRMA on Kenyan biotechnology policy have been brought to light through interviews with project staff, officials and policy commentators and from inspection of primary sources.

Modern understandings of risk communication emphasize the importance of working together with the general public rather than simply "educating them" about risks under assessment[36]. The IRMA project has attempted to raise awareness among a wide variety of stakeholders, however an "educational" approach has remained dominant. Use of deliberative inclusionary processes as an alternative or in addition to formal meetings would lead to more symmetric relationships between the project and stakeholders and facilitate more democratic decision-making on contentious issues[37].

It is likely that IRMA has had some influence on defining the focus of science-based risks assessed prior to the introduction of Bt maize, however the involvement of other Kenyan research institutions in the policy process has allowed independent evaluation of the selection of impacts addressed. IRMA's decision to address socio-economic impacts of the introduction of insect resistant maize sets a high precedent, widening the criteria against

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[36] Fischhoff (1995) "Risk perception and communication unplugged: Twenty years of progress" in ***Risk Analysis*** 15, 75-84

[37] Examples of such approaches include focus groups, citizens' juries, concensus conferences, multi-criteria mapping, in-depth groups and stakeholder decision analysis.

which future applications may have to compete in order to be judged favourably by regulators.

Conclusions

Under conditions in which the introduction of an agricultural technology is irreversible such as the environmental release of genetically modified crop, a comprehensive *ex ante* impact assessment approach is absolutely necessary to inform policy. The introduction of Bt maize to Kenya demonstrates the first thorough application of this approach with a transgenic staple crop on the continent.

Project Strengths

Socio-economic impact assessment activities have generated a good understanding of the farming systems into which the IRMA maize is to be introduced, facilitating effective design of the insect resistant maize product and allowing for the design of an efficient and appropriate distribution strategy, even though the direct use of these results has been hindered due to political and IPR-related factors. The dual objectives of the project have made it more difficult to focus clearly on potential impacts. Planned assessment of costs and benefits across all societal levels is an especially innovative development. Participatory evaluation of stakeholder impacts that consider the comparative distribution of costs, benefits *and risks* across these levels will be extremely valuable in appraising the role of the new technology in supporting food security for Africa's poorest.

Initial investigations into the possible ecological impacts of the introduction of Bt maize have begun to illuminate concerns that were previously plagued by an absence of data in Kenya. Collaboration with the International Centre for Insect Physiology and Ecology, the South

African Agricultural Research Council–Grain Crops Institute, the University of Nairobi and North Carolina State University involved in the concurrent ecological impact assessment project is expected to be mutually beneficial, both in terms of efficient utilization of nationally available research competences and in the provision of independent scientific data on which to base regulatory decisions.

The IRMA project has set high standards in its applications to the KARI Institutional Biosafety Committee and to the National Biosafety Committee. It has facilitated in critical capacity-building among regulators and scientists and has contributed to awareness-raising of biotechnology issues among the Kenyan public. IRMA has fostered transparency in its operations through engaging with a broad range of non-governmental organisations in the country, at the same time widening Kenya's existing policy network. Furthermore, the project's focus on socio-economic impacts has expanded on the currently considered risks in Kenyan regulatory appraisal.

Possible Areas of Improvement

Impacts to be assessed by IRMA were initially selected primarily by those managing the project and other scientists and experts involved in agricultural biotechnology. Current trends in impact assessment reflect the increasing involvement of multiple stakeholders and a emphasis on establishing "whose impact is to be assessed"[38]. Furthermore, experience of GM crops in Europe suggests that exclusion of some stakeholders in the early stages has encouraged subsequent polarisation of the debate, consumer opposition and later regulatory stagnation. Although IRMA's record on transparency is generally good, a dearth of

[38] Leeuw, F. (2000) "Program Evaluation and Social and Institutional Impact Assessment", paper prepared for the workshop organised by the Standing Panel on Impact Assessment (SPIA) of the Technical Advisory Committee (TAC) of the CGIAR The Future of Impact Assessment in the CGIAR: Needs, Constraints and Options, 3-5 May 2000, FAO, Rome

consultations and partnerships with environmental and consumer groups who might oppose the technology is a possible weakness of the project.

Awareness-raising and discourse with the general public has been embraced as an integral part of IRMA's work. Contemporary studies of risk-communication stress the importance of full acknowledgement of scientific uncertainty when it exists and partnership, rather than "education" as the favoured mode of public engagement. Public assemblies based around deliberative inclusionary processes might be a more effective means of achieving these goals than those practised to date.

If a policy of commercial release of the IRMA maize is followed by the Kenyan authorities, long-term monitoring will also be necessary for effective resistance management and to allow greater opportunities for mitigation of harm if adverse effects are discovered. As well as ensuring that adequate baseline data are collected at this stage in the project cycle, there is a pressing need to guarantee that partner organisations, resources and financial support will be available for continued follow-up in the event of widespread environmental release. Only through an enduring ecological, socio-economic and institutional impact assessment programme will the full value of this landmark project be realised.