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Evaluating Environmental Risks of Bt Maize in the US and EU: Lessons and Challenges for Kenya

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Executive Summary

This paper reviews experiences in the United States, France and Austria surrounding the evaluation of environmental risks associated with the large-scale release of genetically engineered *Bt* maize. It then attempts to draw lessons that may serve to inform the regulatory debate in countries where similar crops may be introduced in the future, specifically taking Kenya, where *Bt* maize is currently under development, as a case-study. In this respect it outlines the agro-ecological and socio-economic contexts into which *Bt* maize would be introduced, describes the studies currently under way to evaluate the environmental risks of *Bt* maize in the African context, and identifies some of the challenges associated with the environmental release of this transgenic staple crop.

The regulation of environmental effects of *Bt* maize in the US and EU has primarily focussed on 3 risk issues currently of relevance to the Kenyan context: non-target effects, development of target insect resistance to *Bt* toxin and gene-flow to wild relatives and non-*Bt* maize. The different positions taken by various jurisdictions can be linked to the framing of these various issues, the normative reference point against which *Bt* maize was assessed, and differing interpretations of similar scientific evidence. Knowledge claims regarding the potential effects of *Bt* maize have been contested as different experts have critically examined the available scientific evidence, and areas of uncertainty and ignorance continue to be debated.

African scientists are currently evaluating the potential effects of *Bt* maize on Kenyan agro-ecosystems, where a significant proportion of maize farmers are smallholders using saved seed. The likely spread of *Bt* transgenes to local seed stocks can be viewed as a benefit (as it could lead to increased yields without requiring investment from poor farmers) but may also subject farmers to involuntary food safety and environmental risks. The framing of the gene-flow issue is therefore a key challenge to Kenyan regulators. The paper discusses the multi-dimensional nature of risk and suggests that several dimensions will diverge under African conditions in comparison to those in developed countries. The food security imperative for example, will affect the sensitivity of various stakeholders, while the extent of seed-recycling in Kenya in comparison to that in the US and EU is suggested to affect dimensions including reversibility and distribution. This paper argues that in such a context, public participation may supplement data emerging from regulatory science with information on the values and perceptions of end users, and thus has an important role to play in democratic decision-making over the release of *Bt* maize.

Introduction

Non-GM bacterial preparations of the soil bacteria *Bacillus thuringiensis* (*Bt*) have been used commercially as a biopesticide for several decades, primarily in horticultural and forestry applications. The narrow target range and rapid degradation of the δ-endotoxins contained within these preparations has led to their recognition and licensing in organic agriculture by international bodies such as the International Federation of Organic Agricultural Movements (IFOAM 2002). In an effort to improve the efficacy of insect control using *Bt*, toxin genes have been inserted into other bacterial groups and more recently into plant species.

Maize transformed with the genes coding for these insecticidal toxins (specifically Cry1Ab) from *Bacillus thuringiensis* was first developed to target stemborer pests, primarily the European cornborer, *Ostrinia nubilalis*, a Lepidopteran which causes significant (approximately 5-7%[1]) pre-harvest losses in both the USA and Europe. Transgenic maize engineered with *Bt* toxin genes produces the toxins within specific tissues, thus avoiding the problems of very low environmental persistence experienced with microbial sprays and providing effective control against pests that have penetrated the maize stalk. There now exist several commercial varieties of *Bt* maize, targeted at various pests or containing additional value-added traits such as herbicide tolerance. The technology has been adopted widely in the US, although less so, and to varying degrees, in European states (see next section).

Developing countries' adoption of *Bt* maize has lagged behind that of North America. In Sub-Saharan Africa, South Africa is the only country in which the crop has been cleared for commercial release. Stemborers have been identified as a significant constraint to maize production in Kenya, causing estimated pre-harvest losses of around 14% (IRMA 2001c). If *Bt* maize effective against local species of stemborers is developed, therefore, the potential exists for yield gains resulting from the adoption of the technology.

As with many technological advances, transgenic crops, including *Bt* maize, have the potential to bring about socio-economic changes as well as ecological and human health effects. Although all of these may feed into regulatory decisions (either implicitly or explicitly), this paper concentrates specifically on ecological effects. Regulatory mechanisms to assess these potential effects have developed alongside the technology, with significant progress in OECD countries since the early 1990s. The lack of effective biosafety regulatory mechanisms in most parts of Africa has been cited as a major constraint to progress in biotechnology in the region (Krattiger 1997). In this respect, significant capacity-building has taken place in Kenya with the support of international programmes such as the UNDP-GEF Pilot Project on Biosafety, Bio-EARN, and projects funded by USAID and the Syngenta Foundation for Sustainable Agriculture.

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[1] Pre-harvest losses vary greatly by season, geographical area and with insecticide treatment.

Bt maize in the US and Europe

Applications for the commercial release of *Bt* maize in the US and EU were made in the early-mid 1990s and resulted in divergent assessments across jurisdictions. In the US (the world's largest maize grain exporter) the Environmental Protection Agency approved the release according to existing *product-based* regulations such as the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)[2]. Following the issue of experimental use permits in the early 1990s, in 1995-6 three types (events) of Cry1Ab *Bt* maize were approved for commercial release based on the absence of predicted adverse effects on humans, non-target organisms or the environment, for a limited period of 5 years. At the time of this initial registration, insect resistance management plans were voluntary, to be implemented by the companies marketing the seed. These companies were also required to collect relevant data and formulate resistance management plans by April 1999 (EPA 2000d). Following recommendations of an expert panel (see ILSI 1998) and the mobilisation of environmental groups and scientists arguing for stricter regulations to protect the effectiveness of *Bt* toxin as a public good (see, for example, Mellon and Rissler, Eds, 1998), the EPA issued insect resistance management guidelines in January 2000 which specified structured refuge sizes of 20%, or 50% in certain areas with high levels of *Bt* cotton cultivation. In the Autumn of 2001, the time-limited registrations were reviewed by the EPA, incorporating new scientific data and information that had become available in the five years since initial registration. Although one Cry1Ab event (*Bt*176) was withdrawn by its manufacturers prior to reregistration, the agency approved the two others (Mon810 and *Bt*11) for continued commercial use. Currently approximately one third of the US field corn harvest is made up of transgenic varieties expressing *Bt* toxins.

In the European Union, the application was administered under 'Directive 90/220 on the Deliberate Release into the Environment of Genetically Modified Organisms' via a procedure based on the *process* by which *Bt* maize had been developed. The directive provided for a step-by-step procedure, with Part B consent required for experimental (R&D) release and additional Part C consent required for commercial release (placing on the market). As the member state where the product was to be placed on the market for the first time, France (the primary maize producer and exporter in the EU) first assessed the 1994 (*Bt*176) and 1995 (MON810) *Bt* maize dossiers and was the "rapporteur" to the other member states. The French competent authority delivered its approval of the first *Bt* maize dossier (Ciba *Bt* 176) to the European Commission in March 1996, and was the only European state to vote in favour of the approval at the Council of Ministers in mid-1996. While the European Commission, despite rejections from most European environment ministers, acted on this advice to approve commercial release throughout the union, the French national policy on the cultivation of *Bt* maize proceeded to shift no less than three times over the following three years. These policy shifts occurred outside the process of Directive 90/220, and were based on national legislative mechanisms (notably the Official Catalogue of Varieties and a State Council decision judging that the original assessments were invalid due to their failure to evaluate the potential impact of the antibiotic resistance marker gene present in the variety). The first of these policy

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[2] For a discussion of product/process-based risk assessment, see Jasanoff, S. (1995). Product, process, or programme: three cultures and the regulation of biotechnology. Resistance to New Technology. M. W. Bauer (Ed) Cambridge, New York, Melbourne, Cambridge University Press.

reversals, when *Bt*176 maize was not admitted to the Official Catalogue of Varieties (12 February 1997), catalysed the ensuing controversy over *Bt* maize, and marked the beginning of a series of changes in the French GM regulatory system These changes included the adoption of a more precautionary approach with greater emphasis on public participation and the inclusion of "non-scientific" issues and expertise within regulatory committees (Marris 2000).

In relation to Directive 90/220, Austria holds that a product must be better for the environment rather than no worse, as other competent authorities argue, and uses organic farming as a normative reference point (Torgersen and Seifert 1999). The country adopted a more stringent approach to other EU member states, even before public protest arose, and called on Article 16 of the Directive to ban the import of *Bt* maize from shortly after the initial notifications of *Bt*176 and Mon810. Article 16 allows states to restrict or prohibit the use and/or sale of an authorised GMO in its territory if it considers that it constitutes a risk to human health or the environment. The government of Austria provided reasons for its decision to the European Commission and to other EU member states, however the scientific committees advising the Commission judged that the data presented did not represent new relevant evidence of harm to humans or the environment. Although the legality of Austria's continuing ban is questionable, no formal action has been taken against the country by the European Commission, and the positions of other member states have in fact moved closer to that displayed by Austria in the mid 1990s. A *de facto* moratorium on new authorisations for commercialisation of GM crops was supported by no less than 12 of the 15 member states in June 1999 (Marris 2000). At the time of writing, Spain is the only EU member state where *Bt* maize is grown in significant quantities (approximately 4-5% of the maize area), primarily for fodder.

Bt Maize in the Kenyan Context

Maize is the primary staple crop throughout East and Southern Africa. According to the Food and Agriculture Organisation of the United Nations, Kenya produced on average approximately 2.4 million tonnes of maize grain, a figure that has remained fairly constant over the past 10 years. Population during the past decade has been increasing at a rate of approximately 2.5% per year, reaching 31 million in 2001. Thus in a country where per capita consumption is estimated at 103kg per year (Pingali 2001), average per capita production from 1992 to 2001 has been nearer 86kg and is decreasing (figures calculated using data from FAOStat, 2002). Small-holders are widespread and account for 70-80% of total production. Large-scale production is primarily concentrated in the Rift Valley and Western Province, in moist transitional areas around Kitale and Njoro, and accounts for 20-30% (Mwangi and Ely 2001; Ely *et al.* 2002).

Six primary agro-ecological zones of maize production have been identified in Kenya (Hassan 1998). Low potential areas, including the lowland tropics, dry midaltitudes and dry transitional zones, are characterised by low yields, producing 11% of the country's maize. The high potential areas include the highland tropics and moist transitional zones which produce around 34 and 46% respectively. The moist midaltitude zone around Lake Victoria has intermediate yields, producing around 9% of the country's maize (IRMA 2001a).

Stemborers including *Busseola fusca*, *Chilo partellus*, *Eldana saccharina, Chilo orichalcociliiellus* and *Sesamia calamistis* represent a significant constraint to maize production in all six zones. Of these the two most important species are the African stemborer *B. fusca* and the spotted stemborer, *C. partellus*. Recent sampling suggests that *C. partellus* is the most abundant stemborer, found at all locations with elevations below 1500 m (especially in the semi-arid zone of Eastern Kenya), and at some locations between 1500 and 2300 m. *B. fusca* on the other hand is dominant in highland areas. *B. fusca* is also dominant in some areas of the Lake Victoria Basin, which has an elevation of about 1100 m, but overall in this region, *C. partellus* was seen to be more abundant (Zhou *et al.* 2001).

Several approaches to the control of these stemborers already exist in Kenya. *Bt* maize has been proposed as an additional tool to be used alongside and in conjunction with these.

Bt Maize and other Stemborer Control Strategies

Conventional methods of stemborer control employ chemical insecticides or biopesticide sprays (including those based on *Bt*). These methods present challenges, however, with respect to the timing of the applications to coincide with the most susceptible stages of stemborer larval development. Due to the protection afforded to the insect by penetration inside the stalk, these methods suffer significant difficulties in eradicating the pest once it has infested the crop. For these reasons, only a minority of farmers use these techniques in the US and Europe, where high-input maize production is practised, and even fewer in Kenya.

Neem extract or a small handful of pyrethrum marc (with about 0.3% pyrethrin content) placed in the heart of the plants at the critical time when the stemborers' eggs hatch, has been reported to almost completely control maize stemborer problems (Thijssen 1997). The application of ashes or chilli powder to the whorl of the maize plant is also effective. In all cases (as with the chemical/ biopesticide application strategies described above), the timing of the applications is crucial and the practise can be labour-intensive.

The removal of stover (crop residue) for fodder (or by burning) after the maize is harvested can be used to prevent repopulation of the fields by the progeny of any stemborers remaining in the stalks. This method may have negative effects on soil conservation as it can reduce soil fertility and increase the risk of soil erosion.

The approach of classical biological control has been employed by the International Center for Insect Physiology and Ecology (ICIPE), which has led a project to strategically release *Cotesia flavipes*, a parasitoid of the introduced stemborer *Chilo partellus*.

ICIPE is also pioneering habitat management practises compatible with traditional multi-cropping systems common in some areas of Kenya. These involve various intercropping regimes with wild grasses, which repel gravid stemborer females and attract their parasitoids, and the planting of other species at the periphery of maize fields which, as highly susceptible trap plants, attract the stemborers away from the crop. Fodder legumes such as silverleaf desmodium (*Desmodium uncinatum*), which act to suppress parasitism by witchweed, (*Striga hermonthica)* are planted among the crop. Such "push-pull" strategies have been shown to result in substantial yield increases over maize monocropping (Kahn *et al.* 1997).

Although there have been no commercial applications to import *Bt* maize into Kenya to date, the Insect Resistant Maize for Africa Project, an international public-private partnership involving the International Centre for Maize and Wheat Improvement (which also goes by its Spanish acronym CIMMYT), the Kenyan Agricultural Research Institute (KARI) and the Syngenta Foundation for Sustainable Agriculture is currently working to adapt the technology to Kenyan conditions.

Potential Food Security Impact of Bt Maize

The Insect Resistant Maize for Africa (IRMA) Project was initiated in 1999 to increase maize production and food security through the development and deployment of improved maize varieties that provide high resistance to insects, particularly stemborers. So far scientists from KARI and CIMMYT have used conventional breeding techniques to produce a maize variety with improved resistance to stemborers. They have also identified a range of *Bt* maize events with varying degrees efficacy against the pests, and conducted economic and environmental studies to guide the development and deployment of the *Bt* maize product and to assess potential impacts of its introduction. Bioassays of new events and combinations, baseline surveys and other project activities are continuing, and it may still be several years before the IRMA maize products are developed to commercialisation (Otieno 2002). As future demand for maize in sub-Saharan Africa is projected to almost double relative to its 1995 level by 2020 (Pingali 2001, page 1), it is possible that in the future the IRMA project, if successful, will expand to other areas.

In 2000-2001 the IRMA project investigated the extent of damage caused by stemborers in the various regions. Studies of farmer perceptions suggested that on average across the country stemborers caused losses of 15% annually each year. These were followed up by East Africa's first studies to systematically and directly measured losses to stemborers under natural infestation conditions. Total losses from stem borers, derived from direct measurements, were estimated at 14 %, ranging from 11% in the highlands to 21% in the dry areas. The full range of these new results was incorporated into a GIS-based ex ante impact assessment model and used to guide the technological development of the IRMA maize products (IRMA 2001c).

Among other factors, the potential impact of *Bt* maize on production in each region will depend on:

i) the severity of stemborer damage by each species - although species-specific data for i) is not available at this stage, data on combined yield loss from all species of stemborers and knowledge of the distribution of stemborer species can be used (IRMA 2001c 2.3).

ii) the effectiveness of the maize against regional stemborers - results from IRMA's first round of bioassays (IRMA 2001b, 2.1) provide information on the likely efficacy of currently available events.

iii) the rate of adoption of the maize - the IRMA project has information on the adoption rates of improved maize varieties in various (IRMA 2001c

2.3) We can use these data as an approximate guide to probable adoption patterns of *Bt* hybrid varieties[3].

i) Severity of stemborer damage by each species in the region - Only four stem borer species have been found to inflict crop losses above 10% in at least one region, and only two species are reported to be of major economic importance: *Busseola fusca* (81% of all stem borer losses in Kenya) and *Chilo partellus* (16%). In order for *Bt* maize to prevent these losses, *B. fusca* resistance would be required in the moist transitional zone and highland tropics, and resistance to *C. partellus* in the moist transitional and the dry and lowland areas; apart from in the highlands and lowlands, resistance to both species would be optimal.

ii) Effectiveness of the *Bt* maize events against regional stemborers - Bioassays carried out by IRMA in 2001 (using maize transformed with Cry1Ab, Cry 1B, Cry Ab-1B, Cry1E and Cry1Ac) found very efficient *Bt* maize events for control of *C. partellus* and 3 other stemborers, but not of *B. fusca* (IRMA 2001a). The IRMA project is continuing with the search for *Bt* maize events that are effective against *B. fusca* and has recently acquired new constructs, Cry1C and Cry2A, which are expected to have moderate activities against the species. Strategies for control of *B. fusca* will be based on the stacking of events to minimise the risk of resistance development (Stephen Mugo, personal communication, September 2002).

iii) Rate of adoption of the maize - The moist transitional zone has a high adoption rate of improved varieties (95% of farmers). Along with the high yields and high proportion of total losses sustained in this zone, this makes it a promising target area for insect resistant maize. Should a well adapted variety with high resistance to *B. fusca* be produced and widely adopted, maize production in Kenya could be expected to increase significantly. In lowland areas adoption levels for modern varieties are lower. Although the severe stemborer losses suffered in these areas could be combated using currently available varieties of *Bt* maize events with high resistance to *C. partellus* and other stemborers of minor importance, poorer small-holder farmers in these regions are less likely to be able afford the seeds. As open pollinated varieties (OPVs) and seed-recycling are more common in these areas, transgenes would gradually spread through the maize gene bank, leading these benefits to be distributed over the populations of these marginal areas (IRMA 2001c). The mixing of improved varieties with land-races or OPVs, sometimes referred to as "creolisation", represents a way in which the benefits of the transgene can effectively be incorporated into a wide diversity of locally-adapted germplasm.

IRMA has identified the problem of low adoption rates and has conducted studies of the seed sector in the semi-arid areas of Eastern Kenya, identifying access to credit, seed quality and availability as major constraints. Interventions such as credit provision provide one possible approach, and have been already been used in the deployment of agricultural biotechnology in Kenya. For example, tissue cultured banana plantlet sales have been aided by a revolving loan fund managed by a village bank (ISAAA 2002). The possibility of forging partnerships with NGOs involved in rural extension has also been examined.

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[3] The pricing of the IRMA product(s) can be expected to affect adoption rates.

Bt maize addresses one specific agronomic problem – pre-harvest losses by cereal stemborers. Studies by IRMA's economics team uncovered a wide range of other constraints, and corresponding criteria on which farmers base their maize variety preferences. These differed from region to region but included early maturity, yield (not as important in dry areas), drought tolerance and tolerance to field pests and storage pests. *Striga* tolerance, large grain size, tolerance to low soil fertility were especially cited in moist mid-altitude zone around L. Victoria, and in the moist transitional zone around Kitale farmers included compact grains and number of rows in their criteria. The project hopes to develop maize possessing the required characteristics for each zone (derived through conventional breeding), including resistance not only to stemborers but also to storage pests (maize weevils *Sitophilus zeamais* and larger grain borer *Prostephanus truncates*) (IRMA 2002a).

The introduction of *Bt* maize to Kenya could potentially lead to increases in national levels of grain production. In addition to yields, however, food security can also be seen as a product of unequal distribution and entitlement. Poor governance, weak infrastructure and lack of resources and capacity for storage and distribution may still prevent surplus maize from high potential areas from reaching those whose harvests have failed. "While at such times the national food security situation is usually favorable, in other parts of the country, household food security goals are never realised due to a complex web of factors" (Odame *et al.* 2002).

Kenya's international obligations to reduce subsidies and other forms of support for its agricultural sector have required Kenyan maize producers to compete with cheap imported grain whilst enduring rising input costs. This compounds difficulties in selling surplus grain, threatening livelihoods gained through semi-subsistence maize farming. "While one of the potential benefits of *Bt* maize is increased yields per unit area, this may be counterproductive if there is increased surplus produce leading to more serious marketing problems" (Odame *et al.* 2002).

Biosafety Regulation in Kenya

Kenya is moving towards a process-based biosafety system and practises a step-by-step approach, evaluating risks to the environment and human health under controlled conditions before moving progressively towards wider-scale use. The National Council for Science and Technology is the government agency responsible for overseeing the biosafety system through the National Biosafety Committee, a multidisciplinary group drawn primarily from government and research establishments. The NCST has been involved in the publication of four documents describing Kenya's biosafety system and experiences associated with its development (NCST 1998; Thitai *et al.* 1999; Wafula *et al.* 2001; NCST 2002), however the formal legal framework under which this system is to be implemented is currently under development.

Food safety issues represent a major concern. The insecticidal activity of *Bt* toxins is based on their ability to bind to specific proteins on the mid-gut wall of target insects, which the toxins then perforate. The food safety of *Bt* toxins is theoretically linked to the fact that such receptors have never been found in species outside the target range of the toxin. In addition, since the introduction of *Bt* products, adverse health effects resulting from consumption of biopesticide-treated or transgenic crops have not been documented. A review of the mammalian safety of *Bt*-based insecticides (which include both toxins and bacterial material) concluded that "based on laboratory studies and field experience, *Bt* insecticides have an excellent safety record" (Siegel 2001). There have been no long-term feeding trials of using *Bt* engineered crops, however, and in such situations it is important not to interpret an absence of evidence of harm as conclusive evidence of absence of harm. Food safety assessments based on the principle of "substantial equivalence" (OECD 1993) neglect the possibility that proteins produced in the novel cellular environment of a recipient organism may possess an altered structure (and therefore activity) to the protein coded by the same gene in its original host, also neglecting the possibility of pleiotropic effects. As with plants modified through other techniques (such as enhanced mutagenesis), our ability to predict these processes in a transgenic plant is currently limited, representing a persistent source of ignorance in the food safety assessment of genetically modified foods.

Kenya's national policies over food safety have largely focussed on wholesomeness of food and procedures against pest infection (Odame *et al.* 2002). The importance of nutritional quality (mainly in terms of a balanced diet) has been cited as a factor in food security debates (Scoones 2001), however the examination of links between food safety and food security remain relatively understudied.

In both areas of food safety and biosafety, as well as loss of biodiversity and IPRs, capacity building is required to promote the safe development and transfer of agricultural biotechnology applications. "These complex issues require institutional and national capacity building through regional and international collaboration. However, new R&D policy and legal frameworks alone may not be sufficient, unless there is change towards multi-disciplinary approaches, leadership/supervisory training and problem-solving skills, especially for research and extension personnel, linkages with private sector and meaningful participation of farmers and their organisations." (Odame *et al.* 2002).

Potential Environmental Effects of Bt maize

The evaluation of specific environmental effects resulting from the release of genetically modified crops remains the subject of ongoing international debate. Regulators have displayed divergent interpretations of what constitutes an adverse effect and have also varied in the relative emphasis placed on potential negative effects when these are assessed against potential benefits. In the case of *Bt* maize, the effects that are most consistently cited, have been identified and assessed in the USA and Europe, and are also relevant to the Kenyan situation can be broadly categorised into three groups: impacts on non-target organisms (including soil organisms), accelerated resistance to *Bt* among target insects, and gene transfer to non-GM maize (sometimes referred to as "genetic pollution"). Food safety issues (including allergenicity) and effects relating to horizontal gene transfer of antibiotic resistance marker genes have also been cited by countries blocking *Bt* maize imports in Europe (Government of Austria 1998), and more recently by Zambian scientists following their country's refusal to accept genetically modified maize donated as food aid (Banda *et al.* 2002). Although these effects will also play a role in the assessment of environmental release of GM maize, they fall outside the scope of this paper and will not be discussed in detail.

In Europe and the USA, the potential ecological impacts of *Bt* maize have been investigated both within the industry-financed (usually not peer-reviewed) studies required by regulatory agencies, and by subsequent research carried out by a wider range of scientists, more usually published in peer-reviewed journals. In addition, the accuracy and relevance of existing data has been challenged by scientists on both sides of the debate (see for example Hodgson 1999; Ecostrat GmbH 2000). Different experimental design protocols, scales and study species have been used, and these have contributed to an increasing appreciation of the complexities of the effects in question and the importance of interpreting findings within relevant and appropriate contexts. In particular, the application of data deriving from the laboratory/field plot/computer model to the prediction of impacts on the wider environment has proved a significant challenge. Environmental studies are continuing to deliver more data on *Bt* maize, and this paper can only hope to deliver a snap-shot summary of some of the areas of research that have been undertaken to date.

In Kenya, the same three primary areas of ecological impact mentioned above are being investigated by the IRMA project and the results will be provided to the Kenyan National Council for Science and Technology for regulatory appraisal of the novel variety. Another project, funded by USAID and implemented since 2001 by the International Centre for Insect Physiology and Ecology (ICIPE)(the lead institution), the South African Agricultural Research Council–Grain Crops Institute (ARC-CGI), the University of Nairobi, and North Carolina State University, aims to complement and expand on IRMA's work, thus providing important additional (and independent) data to regulators. Both projects are continuing their studies of ecological effects and may develop new research projects prior to the introduction of *Bt* maize into the country.

Non-target organisms

Traditionally, δ-endotoxins from *Bacillus thuringiensis* have been known for their specificity of action to a limited range of insect groups. For this reason, proponents argue that *Bt* maize represents a more environmentally sustainable option than the use of conventional insecticides. Nevertheless it has been suggested that *Bt* maize has the potential to affect insects other than those stemborers which it has been engineered to target. The primary categories of non-target organisms most commonly cited can be described as natural enemies, pollinators, soil organisms and other species of concern.

Natural Enemies

In cases where such non-target organisms play an important and beneficial role in maize agro-ecosystems, decreases in their populations could have a negative impact on maize production. Such agronomic impacts might be expected when the non-target organism is a natural enemy of a maize pest, for example a predator or parasitoid of stemborers. For such species a decrease in their number could lead to reduced natural control of stemborer populations. If this effect was larger than the reduction in stemborers resulting from the planting of *Bt* maize (a situation which might only occur once resistance to the *Bt* toxin had built up in the stemborer population), the overall effect would be an increase in local stemborer numbers, with resulting increases in herbivory pressure. A decrease in predator populations could also lead to the emergence of secondary pests, as has been known to occur in response to broad-spectrum synthetic insecticides.

The localisation of these effects would depend on the ecology and behaviour of the species in question and would also be linked to characteristics of regional farming systems such as the spatial arrangement of *Bt* and non-*Bt* maize cultivation and systems of seed recycling. The potential for non-target effects on natural enemies to cause significant agronomic impacts (and thus food security impacts) is thus dependant on a wide range of geographically specific variables linked to local ecologies, farming practises, and the development of resistance among target pests, the timing of which is difficult to predict.

Various experimental designs have been employed to evaluate the effect of *Bt* maize on specific maize/herbivore/natural enemy systems. Most of the studies have followed protocols and guidelines formulated for toxicity testing of chemical insecticides, measuring 1-2 season effects on population numbers in the field or acute toxicity in the laboratory. Field trials were carried out prior to the initial applications for commercial environmental release of *Bt* maize in the US and EU and did not report significant effects. Some of these field studies, however, have been criticised for insufficient detail in their reporting (taxonomic level and developmental stage) and insufficient duration/ same-site replication (Ecostrat GmbH 2000). Bitrophic laboratory studies (feeding insect predators on *Bt* maize pollen or other *Bt* preparations) were also carried out and found no toxicity, however the suitability of the dietary preparations for some species has been queried.

Box 1. Case Study: Laboratory Effects of Bt maize on the Green Lacewing *Chrysoperla carnea*

The initial Swiss laboratory studies suggested a direct effect from Bt Cry1Ab toxin on the larvae of green lacewing *Chrysoperla carnea* (an important natural enemy of stemborers, which also feed on alternative prey such as other Lepidopterans, spider mites and aphids) as well plant x herbivore x natural enemy interactions contributing to increased mortality or delayed development of the *C. carnea* larvae (Hilbeck *et al*, 1998a; Hilbeck *et al*, 1998b; Hilbeck *et al*, 1999). These results contrast with other (bitrophic) experiments on *C. carnea* (Pilcher *et al*, 1997) and tritrophic studies which used aphids as the prey species (Lozzia *et al*, 1998), however it has been argued that in these latter two studies *C. carnea* may never have ingested the Bt toxin (Ecostrat GmbH 2000). More recent research on tritrophic effects, comparing a range of three prey species fed either on Bt maize or non-Bt maize, showed mortality and development time effects in *C. carnea* fed on one (*Spodoptera littoralis* - cotton leaf worm) but not in those fed on the other two (*Rhopalosiphum padi* – bird cherry-oat aphid and *Tetranychus urticae* – two spotted spider mite)(Dutton *et al*, 2002), further illustrating the significance of study species selection in experimental design. The ongoing debate demonstrates the complexities involved in assessing such tri-trophic impacts and the uncertainty that remains even after significant investment in regulatory science.

Tritrophic effects were also studied using more complex experimental designs involving laboratory-rearing of prey species on *Bt* maize and subsequent feeding to predators. A series of bitrophic (using a specially designed dietary system) and tritrophic (using two alternative prey species) studies carried out in Switzerland after the initial US/EU applications for environmental release provide a good demonstration of the difficulties involved in studying such systems in the laboratory (see Box 1).

As well as the difficulties involved in clarifying effects within the laboratory, additional complexities must be confronted when applying these to the open agricultural field situation. Even if a tritrophic effect on a predator or parasite is identified in the laboratory, it is not necessarily the case that this will directly translate to an ecologically significant change in field populations. This will be dependant upon factors such as whether the target insect is accessible to the the natural enemy, whether the natural enemy has other available prey/hosts or displays any preference for them. For example, European corn borers feeding on *Bt* maize are largely inaccessible to lacewings as the first instars die as soon as they start eating the tissue, and those that survive will feed within the maize stalk for most of their life (EPA 2000a). In addition, choice tests between species which are accessible to lacewings have shown that the predators preferred to prey on an *R. padi* (aphids) to *S. littoralis* larvae, (Meier and Hilbeck 2001). These factors are highly specific to the ecosystem under consideration, however in general, compared to predators, parasitoids are relatively host specific, completing their development on a single host species. Predators often need several prey species to complete their life-cycle, but may be generalists, able to survive on alternative prey if one species is absent or sub-optimal.

In Kenya, KARI entomologists have conducted surveys in five different regions in order to build up a database of non-target organisms in maize-cropping systems, in particular parasitoids and predators of the primary Kenyan stemborers. The IRMA project scientists have already conducted trials to assess the comparative impacts of conventional insecticides with those of *Bt* biopesticide spray on maize/bean intercropping systems at the KARI Katumani station. In both long rain and short rain seasons, control plots showed the highest parasitoid diversity, followed by *Bt* biopesticide-treated plots, followed by insecticide-treated plots. Ladybird beetles (coccinelidae) and Rove beetles (staphylinidae), important predators of stemborer larvae, were also seen to be affected more by conventional insecticides than *Bt* biopesticides (IRMA 2002b).

Further studies will only be possible once the IRMA project *Bt* maize product(s) have been fully developed and appropriate test facilities have been constructed. First, direct and indirect non-target impacts will be measured within the biosafety greenhouse. Second, using the current data as a baseline, invertebrate populations will be monitored first in field trial sites and subsequently in farmers' fields (IRMA 2000). The initial studies are currently awaiting the completion of a biosafety greenhouse at KARI headquarters, Nairobi. IRMA has in the mean time initiated mock trials in order to train staff in the management of *Bt* maize in open-field sites(IRMA 2002b).

The ICIPE project has not yet imported *Bt* maize germplasm into Kenya, however has started non-target studies using local *Bacillus thuringiensis kurstaki* isolates expressing the Cry1Ab toxin. The project has begun to assess the impact that feeding *Chilo partellus* larvae on a diet incorporating *Bt* toxin has on the mortality, development time, mass, longevity and fecundity of larval and pupal parasitoids. Similar studies on non-target organisms will be carried out by ARC-GCI in South Africa, where *Bt* maize, as opposed to bacterial *Bt*, may be used.

Pollinators

Effects of *Bt* maize on pollinator species were also studied prior to the application to release *Bt* maize in Europe and the US. One such study took the form of acute toxicity tests using water/pollen preparations fed to larvae for 45 minutes. Although no adverse effects were noted, questions have been raised about the suitability of the dietary system (Ecostrat GmbH 2000).

In Kenya, insects play an important part in crop pollination, and the IRMA project has included pollinators in its initial base-line survey of non-target organisms (IRMA 2000). The project's *Bt* biopesticide trials demonstrated a negative effect on honeybees in comparison to untreated controls, however the effect was not as great as that for conventional insecticide treated plots (IRMA 2002b).

Soil organisms

Soil-dwelling invertebrates and micro-organisms play an important role in the maintenance of soil fertility. Early studies have drawn attention to the persistence of *Bt* toxins in certain soils (Tapp *et al.* 1994) and their sustained toxicity (Tapp and Stotzky 1995). Effects of *Bt* maize on soil dwelling organisms such as springtails and earthworms were carried out prior to applications to release the crop. Acute toxicity studies showed no significant effect on earthworms *Eisenia foetida*. Chronic studies on springtails *Folsomia candida* using *Bt* maize leaf protein in soil showed some effect at higher concentrations, however alternative studies which used different dietary preparations showed no toxicity (Novartis 1999). Toxicity of some bacterial *Bt* isolates towards certain soil-dwelling organisms has been demonstrated (Collembola - see Obrycki *et al.* 2001; Nematodes - see National Research Council 2002 p. 162) however the impacts of the crop on soil ecology still represent a significant area of ignorance. The recognised importance of soil health and fertility means that soil impacts are a growing area of interest in the regulation of GM crops.

The IRMA project has included decomposers such as earthworms and termites in its initial baseline studies (IRMA 2000). In addition, the ICIPE project has initiated studies on the persistence of *Bt* in various soil types and the effect of *Bacillus thuringiensis* isolates on various microbial soil communities. Specifically, studies have concentrated on mychorrizal fungi, *Rhizobium* and soil-borne nematode communities.

Other species of concern

Species which do not fall into either of the above categories, and do not have any obvious agronomic significance in maize cropping systems have also been studied in the US and Europe. Effects of *Bt* maize preparations on a range of other insect groups were evaluated prior to the initial applications for environmental release. The possibility exists for previously insignificant species (non-target/secondary pest species) to become more relevant to cropping systems in the *Bt* maize system, or for wider biodiversity to be affected by the introduction of the insect-resistant crop. It is not feasible to test for effects on every one of these potentially significant species, however evaluations of effects on certain organisms, for example those of cultural or conservation significance, can play an important role in guiding policy.

Probably the most high profile area of scientific controversy surrounding *Bt* maize has come in response to a letter to the journal Nature reporting the crop's ability to harm monarch butterflies *Danaus plexippus* in the USA (Losey *et al.* 1999). The original letter reported that monarch butterflies reared on milkweed *Asclepias curassavica* which had been dusted with *Bt* maize pollen ate less, grew more slowly and suffered higher mortality than larvae reared on leaves dusted with untransformed corn pollen or on leaves without pollen. The methodology and significance of these findings was questioned by other scientists (Hodgson 1999), and contrasted to other studies which showed no effect from *Bt* maize pollen on other non-target Lepidoptera (Wraight *et al.* 2000). Following the publication, the USA Environmental Protection Agency (EPA) announced a "data call-in", and a series of more detailed studies costing approximately $400,000 were carried out. The results of these studies, which used specified doses of pollen from different *Bt* maize varieties and took into account the degree of temporal and spatial overlap of monarch larvae and maize pollen, suggested that earlier concerns had been misplaced. Although arguably significant mortality was observed from the pollen of some varieties (*Bt*176), the risk posed to monarchs from the varieties that comprised over 90% of the US *Bt* maize area was reported to be negligible (Sears *et al.* 2001).

In Kenya, the ICIPE-led project intends to study the effects of *Bt* maize on indigenous lepidopteran species (obtained from local butterfly farms), if necessary using *Bt* isolates instead of the transgenic plant. IRMA's *Bt* biopesticide trials measured family and abundance of non-target arthropods using pit-fall, sticky and water traps. In the long rains arthropod diversity was found to be highest in control plots and lowest in conventional insecticide-treated plots. While in the short rains the insecticide-treated plots retained the lowest number of arthropod families, the highest number were interestingly represented in the *Bt* biopesticide-treated plots (IRMA 2002b).

Insect resistance to Bt crops

Resistance to *Bt* among target insects has already been observed in one species in the field and in several others in the laboratory. In addition, Tabashnik *et al* (1997) found field populations of diamondback moth *Plutella xylostella* (a pest which has often been targeted by *Bt* sprays) possessing one gene conferring cross-resistance to four different *Bt* toxins. If resistance were to develop to the *Bt* toxins in transgenic *Bt* maize, this would not only render the crops ineffective but could also jeopardise the future option of using the equivalent biopesticide preparation on that particular target species. It has become clear that insect resistance management (IRM) strategies must be put in place in order to avoid the development of resistance and such strategies have been developed for US and EU maize cropping systems.

In the US, where *Bt* maize has been grown since 1996, the EPA has adopted the "high-dose/refugia strategy" for insect resistance management. Under this system, transgenic maize is designed to express high levels of *Bt* toxin so that the minimum number of target insects survive. Stemborers that do emerge may possess a gene conferring resistance to the *Bt* toxin. They must be prevented from mating with other resistant individuals if the frequency of resistance is to remain low in the population.

In order to do this, "refugia" (areas of non-*Bt* maize) are grown nearby which act as a reservoir for susceptible individuals, greatly decreasing the likelihood of the mating of two resistant individuals. Resistance in the population is predicted to be delayed for longer if larger refugia areas are enforced, however, for economic reasons farmers often want to maximise the area cultivated under *Bt* crops. At the time of writing, field resistance among target stemborers to *Bt* toxins has not been recorded since *Bt* maize was first commercialised in the USA. There exist various options for IRM, and a range of systems of enforcement, the best options available for developing world scenarios varying according to local agro-ecological and administrative circumstances (Whalon and Norris 1996). A more promising strategy for insect resistance management under some circumstances is the use of several different *Bt* toxins and resistance mechanisms within the same transgenic plant (Roush 1997).

If resistance were to develop rapidly while cultivation of *Bt* maize was widespread, there might be a resultant drop in subsequent yields, increasing food insecurity. Both of the Kenyan projects are working to gather the data required to assess and manage this risk. IRMA has initiated the development of insect resistance management strategies for *Bt* maize which are suited to Kenyan circumstances, based on the identification of alternative hosts of stemborers which can be used as refugia and also incorporated into Kenyan maize farming systems (eg. through providing fodder in zero-grazing cattle husbandry)(IRMA 2001b). The project has conducted surveys in Kenya's primary maize-growing regions to assess the adequacy of available natural refugia. This information will enable trained extension officers to target those regions where structured refuges will be most essential, primarily the areas around Kitale where natural refuges are less abundant. Awareness-raising and training of extension workers in resistance management and other issues relating to *Bt* maize has already begun (IRMA 2002b). The refugia strategy has historically been employed alongside that of high toxin doses that minimise the emergence of homozygous susceptible and heterozygote stemborers. Definitions of "high dose" vary, however some conservative versions in the US have aimed to ensure that *Bt* maize hybrids produce enough toxin to kill a high percentage (99%) of heterozygote stemborers (ILSI 1998, p. 64). Under such definitions, currently identified *Bt* events do not constitute a "high dose" to all Kenyan stemborers, as bioassays to date have only shown partial effectiveness against *Busseola fusca* (IRMA 2001b). The project is continuing to investigate new *Bt* maize events and stacked gene combinations to address this concern.

ICIPE scientists have started to assess the abundance of existing refuges (including wild grass species) in the Trans Nzioa district by conducting transects through maize growing areas. The project has also conducted bioassays on the major stemborers using a local *Bt* isolate (Cry1Ac) and, using *Chilo partellus* as a model, is examining the potential for resistance development in the stemborer by endeavouring to select a resistant population over successive generations. Also under investigation are the dispersal behaviours of stemborers (the characteristics of which will affect the effectiveness of the high-dose/refugia strategy, which relies on dispersal prior to mating.)

Gene-flow and contamination

Wild relatives of maize are not known to exist outside Central America, therefore the primary concern outside this area is the transfer of transgenes to other maize varieties. This would be expected to occur in open fields where transgenic and non-transgenic maize is open to cross-pollination. In Mexico, such an instance was reported in 2001 (Quist and Chapela 2001), however some of the authors' conclusions were criticised as unsupported by their data (Hodgson 2002aa; Hodgson 2002bb). Maize pollen is known to travel over great distances, especially under certain weather conditions (Emberlin *et al.* 1999), so with current technologies and conventional cultivation methods some escape of transgenes into the maize gene-pool is practically unavoidable. There is widespread disagreement between scientists as to whether this sort of transgene spread in itself constitutes any risk to maize genetic diversity. We would expect a gene such as that coding for a *Bt* toxin to confer an advantage on maize plants. In such a case the gene's frequency would increase in the population, possibly resulting in a loss of genetic diversity through a process known as "swamping" (Ellstrand 2001). Regardless of its impact on maize genetic diversity, uncontrolled spread and increased frequency of the *Bt* toxin gene through the maize gene pool will amplify the risks of non-target harm and insect resistance described above.

Unless specific mechanisms have been put in place to prevent gene-flow, the spread of *Bt* transgenes to nearby non-*Bt* maize may be expected from current commercial transgenic varieties. Quantification of the likelihood and rate of this process can be useful to further understand its effect on IRM strategies, non-target impacts and the possibility of genetic erosion of the maize gene pool. As environmental release of *Bt* maize is not yet approved in Kenya, both IRMA and ICIPE have initiated experiments to assess the potential distances over which gene transfer can occur by using a yellow maize/ white maize model to simulate *Bt* maize pollen dispersal. When initial open trials of *Bt* maize do take place, IRMA intends to remove the plants' tassles in order to prevent gene-flow.

The ICIPE project will also work to clarify the likely effect that farmer selection will have on the process of transgene spread by investigating the cultural practises that farmers use in seed selection. Building on these, and pollen dispersal studies, the South African Agricultural Research Council – Grain Crops Institute, a partner in the ICIPE project, will investigate the relative agronomic characteristics of crosses between *Bt* hybrids and non-*Bt* maize varieties used by resource-poor South African farmers.

Evaluating Ecological Risks – Science and Regulation

Areas where scientific knowledge is incomplete, such as in the case of *Bt* maize, present several challenges to policy makers aiming to maximise benefits and control risks. As the summaries above show, many of the scientific issues involved are still being debated; consensus has been difficult to obtain in a situation where contradicting scientific studies have been selectively employed by different stakeholder groups each aiming to legitimise their respective viewpoints.

The general challenges facing developing countries in the regulation of agricultural biotechnology have been discussed by Newell (2001) and Scoones (2002). The regulation of *Bt* maize in Europe and America provides an example of the difficulties involved. Previous analyses of the use of regulatory science in appraisals of *Bt* maize in the US and Europe have pointed to differences in geopolitical contexts (including biotechnology, agricultural and trade policies) and cultural differences over what "environment" must be protected (Levidow 1999). The explanation that some policies stem from "sound science" whilst others are a product of politics has been offered by some advocates of GM crops. This distinction has been called into question as analysis has suggested that socio-cultural values have played a large part in framing assessments both in the USA and the EU, through influencing the criteria for evidence (Levidow 2001).

The form of agriculture against which *Bt* maize was judged reflected not only what was most commonly practised in each jurisdiction, but also the future vision of agriculture to which the country in question aspired. In Austria, the benefits and risks of *Bt* maize were assessed against the normative reference point of organic agriculture, while the government has actively promoted the development of an organic agricultural sector. In the US, advocates of GM crops have compared environmental impacts of *Bt* maize to those of conventional agriculture, which used insecticide sprays, linking with a future vision of high input agriculture that maximises production for export. This comparison was despite the fact that only approximately 8% of total US field corn is treated in this way (EPA 2000a).

Regulators have adopted different approaches to the risk of target insects developing resistance to *Bt* toxins. After consulting experts, environmentalists and industry representatives the EPA responded to widespread concerns by putting in place more stringent IRM requirements. The European Commission, which viewed the matter as an agronomic issue, only formulated resistance management policies at a later stage, possibly because the number of farmers adopting *Bt* maize remained low. The Austrian government, in comparison, framed insect resistance management as an adverse environmental effect, and one of sufficient magnitude to justify banning the cultivation of the maize on its territory.

Gene-flow is a critical issue for policies in EU states due to labelling requirements for GM products. In the US, where labelling has not been mandatory, the EPA assessments have framed the issue as an ecological one of environmental fate, concentrating on risks of gene-flow to wild relatives such as Tripsacum and Teosinte. Certain Kenyan documents do refer to a need for labelling (Thitai *et al.* 1999, page 96; NCST 2002, page 49), however the country's policy regarding the matter is yet to be finalised. Labelling standards for pre-packaged foods are still in the process of being implemented, primarily for produce destined for export. In terms of produce for domestic consumption, it is doubtful that the capacity and infrastructure required for stringent labelling of GM products will be in place in the near future. In contexts where seed is recycled, the gene-flow issue has added implications relating to the reversibility and distribution of risks (see next section).

With regards to the first *Bt* maize event notified in the EU, *Bt*176, the additional issue of increased antibiotic resistance (due to the presence of a marker gene conferring resistance to ampicillin) was highlighted by authorities in several EU member states.

The revised European directive 2001/18 calls for the phasing out of antibiotic resistance markers in transgenic plants for commercial release by the end of 2004. In contrast, the US regulatory authorities largely disregarded the issue. The IRMA project has already made it clear that it will concentrate on clean events without antibiotic resistance markers (IRMA 2000 1.3,4).

Within these different framings of each risk issue, regulators have displayed divergent interpretations of similar scientific evidence. These differences have included varying emphasis of scientific uncertainty and precaution. Box 2 (overleaf) describes the differing interpretations of some of the studies listed in Box 1. Even though the initial communication on monarchs (Losey *et al*, 1999), was widely recognised as a preliminary study with limited ecological significance, it was cited by Austria in one of its Article 16 communications to the European Commission. The extensive US studies and risk assessment that followed showed that field impacts will vary greatly with the event of maize used, the extent of adoption and the agro-ecological conditions under which non-target invertebrates come into contact with the crop. The extrapolation of findings across events or bacterial formulations may therefore present challenges to Kenyan regulators, and adoption through creolisation will confound efforts to conduct quantitative non-target risk assessment of the kind conducted by Sears *et al* (2001).

Regulation based on science like that described above is limited in its capacity to predict long-term, cumulative effects. The term "uncertainty" can refer specifically to outstanding scientific questions to which further investigation will eventually provide conclusive answers. In relation to the effects on natural enemies covered in Boxes 1 and 2, for example it has been argued:

> "In contrast to insecticide treatments, potential adverse effects of *Bt*-plants on most beneficial insects are expected to be more subtle and on a long-term scale. Even if effects like those observed in studies 8, 9 and 10 would translate identically to the field, population effects in the field would probably manifest themselves after many years." (Ecostrat GmbH 2000)[4]

In contrast to "uncertainty", the failure of regulatory science to consider the full range of causal pathways, processes and variables in any natural system (some of which may fall outside the current field of ecological understanding), represents a lack of full scientific certainty of a type sometimes referred to as "ignorance". The extent and significance of uncertainty and ignorance are often areas of fierce debate. It can be argued, however, that with any new technology where complex systems such as the environment are involved, there are economic constraints to completely eliminating uncertainty, and some degree of ignorance is inescapable.

Full scientific certainty would require predicting complex and often non-linear interactions within ecological science, the difficulties of which are acknowledged by many ecologists (Obrycki *et al.* 2001, Sutherland and Watkinson 2001). A more common outcome is the clarification of direct risks, and the indication of additional indirect or uncertain risks which can then lead to further research (eg. monarch studies in the US) or precautionary measures (eg. Austria). The studies being carried out by ICIPE and IRMA will illuminate direct risks, however the extent to which they will eliminate uncertainty and ignorance is to be debated.

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[4] Studies 8, 9 and 10 refer to the three Hilbeck *et al* studies 1998a, 1998b and 1999

Multiple Dimensions of Risk

Box 2. Case Study: Divergent Interpretations of Bt Maize Studies on Green Lacewing *Chrysoperla carnea*

The potential for divergent interpretations of similar scientific evidence is illustrated well by the examples cited in Box 1. Based on their interpretations of the same data, various regulatory agencies/ advisory panels came to different conclusions regarding the extent to which the laboratory results revealed significant risks to field populations of the predator.

In their reasons for the invocation of Article 16 against Mon810 Bt maize, the Austrian government cited two studies by Hilbeck *et al* (1998). They interpreted the studies as showing unintended effects on non-target organisms, noting that "because of the feeding of European corn borer-larvae, *Ostrinia nubilalis*, and caterpillars of *Spodoptora littoralis*, which were raised on transgenic maize, to larvae of *Chrysoperla carnea*, the mortality of the larvae of this beneficial insect doubled" (Government of Austria 1999).

In its reply to the Austrian communication, the European Commission's Scientific Committee on Plants did not directly mention the Hilbeck *et al* studies, however as a general comment on tritrophic studies, noted that "these results are difficult to interpret and extrapolate to field conditions." The committee noted the difficulties in "reproducing realistic field exposure levels and routes and achieving experimental rigor to allow for the effects of reduced growth in affected herbivorous prey", and concluded that the new evidence presented by Austria did not warrant any change in the advice previously given (SCP 1999). This interpretation was mirrored by that of the French CGB's comments on the Ecostrat Report, which included details of the same Hilbeck *et al* studies as well as one carried out in 1999 (CGB 2001).

The US EPA conducted formal reviews of two studies by Hilbeck *et al* (1998a, 1998b) as part of the reregistration process. The agency questioned the significance of the identified mortality effect to field conditions, and cited earlier field studies which showed no population effects. In relation to the 1998a study, EPA suggested that the poor quality study diet, as opposed to the Bt toxin, was responsible for the mortality differences (EPA 2000c, page IIC42), neglecting the fact that the effect was seen both when *O nubilalis* and *S littoralis* were used as the prey species. Some members of the FIFRA Scientific Advisory Panel later commented that the EPA had been wrong to dismiss the Hilbeck *et al* results based on standards that had not been applied to other non-target studies, and that a hazard to *C carnea* had in fact been identified (FIFRA SAP 2001, page 54).

Risk is often conceptualised as a function of two dimensions: the probability of an impact and the magnitude of its consequences. While this formulaic approach forms a useful basis for scientific risk analysis, it neglects other dimensions of these impacts which are important in characterising the risks of new technologies (Stirling, 2001). As with the probability and magnitude of possible impacts, these dimensions are also specific to the context into which the technology is introduced. Among the multiple dimensions of risk, those which can be expected to deviate in the Kenyan context (as compared to that in Europe and the USA) include sensitivity, reversibility and distribution.

The importance of maize as a staple crop in East and Southern African contrasts directly with its role in the US and Europe, where it is used primarily as a fodder crop and forms only a small part of the human diet. In this way the sensitivity of the end-users in Kenya to any risks to the maize supply can be anticipated to be higher than that amongst US and European consumers.

US and EU maize agriculture is based almost exclusively on the seasonal purchase of hybrid seeds. This characteristic is shared by South Africa, the only country in the region where *Bt* maize has been approved for environmental release. In sub-Saharan Africa excluding South Africa, farm-saved seed is estimated to constitute 63.9% of maize area, while 13% of Kenyan maize area is planted to farm-saved seed (Pingali 2001, pages 32 and 53). The majority of Kenyan farmers in marginal regions recycle at least a portion of their seed from season to season. Where seed recycling is commonplace, we can expect the *Bt* genes to spread in the maize population, making environmental release an essentially irreversible process. The frequency at which the *Bt* transgene remains in the maize population will reflect the advantage conferred by it both through natural and artificial selection.

The research into ecological effects currently being carried out will clarify many of the risks posed by *Bt* maize to Kenyan ecosystems. As has been shown by the experiences in the US and EU, however, uncertainty and ignorance are likely to remain, especially regarding risks that may only become apparent in the long-term. When questioned about new evidence suggesting possible ecological risks, a common response of advisory committees in France and the UK has been to critically analyse the evidence and to assure regulators that future developments in the scientific literature are being monitored. This suggests that, in the event that a genuine adverse effect is documented, policies (of authorisation for environmental release) may be reversed to remove any future hazard. In the US, EPA documents have predicted that following the withdrawal of *Bt*176 "the plant-pesticides will be gone from the environment long before resistance would have been predicted to develop" (EPA 2000b, page 14). The difficulties involved in this process of reversing the policy of environmental release were also demonstrated by the withdrawal of Starlink maize. Should new compelling evidence of adverse effects appear in jurisdictions where recycled seed is commonly used, the effectiveness of such policy reversals will be severely limited, raising the stakes of the initial policy decision. These arguments are also applicable to other seed technologies for which uncertainty and ignorance exists around food safety and environmental effects.

The distribution of risks resulting from ignorance and uncertainty is also affected by geographic patterns of seed recycling. Depending on the characteristics of local commercial seed sectors, farmers who buy seed each season may be able to recover from any unforeseen adverse effects by switching to alternative (eg. non-*Bt*) seed in subsequent seasons. Those who are forced to rely on saved seed for reasons of poverty will not have that opportunity. It is therefore in the marginal areas where seed saving is common that any risks resulting from uncertainty and ignorance will be most enduring. Focussed research would help to further clarify the "irreversibility" and "distribution" dimensions of risks in the Kenyan context.

Precaution and Public participation in the Regulation of Bt maize

Insofar as it cites circumstances under which there exist "threats of serious or irreversible damage" and "lack of full scientific certainty", the Rio version of the precautionary principle (UNCED 1992) can be applied to the environmental release of *Bt* maize. The debate surrounding the implementation of the principle not only covers the extent of scientific uncertainty or ignorance surrounding the threats of damage from *Bt* maize, but also the desirability of "cost-effective measures to prevent environmental degradation" (in this case the prohibition of environmental release). The sensitivity of Kenya's rural poor to food security concerns may diminish the desirability of forgoing any positive impacts from *Bt* maize.

In past decades the field of risk has seen a progression from quantitative risk assessment carried out by experts towards joint decision-making by partnerships of diverse stakeholders (Fischoff 1995). Non-state actors have played a prominent part in the US and European debate over agricultural biotechnology. In the USA, organisations such as the Union of Concerned Scientists have formed alliances with academic researchers and engaged with the policy process to promote more stringent insect resistance management practices. In addition, environmental NGOs have filed lawsuits against the authorities, claiming that risk assessments were flawed and demanding the withdrawal of registration of *Bt* crops.

In Europe, public consultation, legal contests and non-violent direct action have been witnessed at the national level in several EU member states. In France, for example, the government held a citizens' conference in 1998 to solicit public views on agricultural biotechnology and improve the democratic debate (Roy and Joly 2000). NGOs such as Greenpeace, Confédération Paysanne and Ecoropa, and later individual members of the public, appealed to the Conseil d'Etat on the grounds that the French competent authority's evaluations of the risks posed by *Bt* maize varieties had been incomplete. In Austria, campaigns by environmental groups were supported by the national media, possibly contributing to existing public hostility towards the new technology (Wagner *et al.* 1998). Within the "ladder of participation in policy" described by Glover *et al* (2003), these examples go beyond mere information-sharing and represent "consultation", "joint decision-making and prioritisation" and "citizen-led initiatives".

Kenya's biosafety system currently promotes participation at the "information-sharing" and "consultation" levels. Whereas French developments towards wider expertise and precaution resulted largely from the controversies surrounding the crop's commercialisation, Kenyan regulators have the opportunity to involve wider stakeholders and the public in the early stages of the decision-making process. Several established approaches to public participation in environmental and biosafety decision-making exist (for reviews see Holmes and Scoones 2000; Glover *et al.* 2003).

Without labelling, benefits and risks from *Bt* maize will be borne involuntarily by farmers and consumers. Accordingly, consumer groups such as the Consumer Information Network are beginning to play a more prominent role in the policy debate, stressing the importance of biosafety laws, labelling and rigorous food-safety tests for GM products. Other NGOs such as the African Biotechnology Stakeholders' Forum have been instrumental in raising the level of awareness on biosafety and biotechnology. These efforts are yet to reach the resource poor farmers who are the final beneficiaries of the technologies being developed (Odame *et al.* 2002). One constraint, the lack of vocabulary in Kiswahili and local languages for "GM crops", "*Bt* maize" and other technical terms is being addressed by groups such as the International Service for the Acquisition of Agri-biotech Applications (ISAAA) and the IRMA project. Together with the second phase of the UNEP-GEF Biosafety Enabling Project, these initiatives are likely to result in progress towards public participation and democratisation of biosafety in Kenya. The challenge is to involve those sections of the public for whom risks are irreversible and involuntary in a context of joint decision-making.

Conclusion

Bt maize has been offered as a method for the control of Kenyan stemborers, which represent just one of the many constraints to maize food security in Kenya. It is introduced as an alternative or additional strategy to several other techniques for the control of the pests.

The available evidence suggests that some *Bt* maize events screened so far offer the possibility for increases in grain production. In high potential areas, this would increase significantly if events with higher levels of resistance to *Busseola fusca* were obtained. In lower potential areas, especially in the East of the country where *Chilo partellus* is the primary stemborer, significant benefits for small-scale farmers are possible, but will be constrained by low adoption rates of improved varieties, themselves a result of social factors related to poverty. Unless these issues are addressed, small-scale farmers in marginalised areas are likely to acquire *Bt* maize mainly inadvertently through cross-pollination and through purchasing "contaminated" seed.

Extensive research and experience in the US and Europe suggests that risks will be specific to agro-ecological conditions, and may also vary with different *Bt* maize events. African scientists are currently evaluating a wide range of potential ecological effects of *Bt* maize under local agro-ecological conditions, using a variety of *Bt* crops and microbial preparations.

Whereas the policies in the US and European nations may be linked to trade and industrial strategies, the focus on food security in the Kenyan context means that the framing of the risk debate may be expected to diverge greatly from that in the US and Europe. Questions of labelling and of the framing of the gene-flow issue are among the key challenges in the evaluation of *Bt* maize in Kenya.

Distinctive differences exist between the agricultural systems and socio-economic circumstances in Kenya in comparison to those in most countries currently cultivating *Bt* maize. These may affect specific dimensions of the risks and benefits from the crop, including sensitivity, reversibility and distribution. Focussed research and deliberative processes involving a wide range of stakeholders may help to further reveal and clarify these dimensions in the Kenyan context, supplementing data emerging from the scientific studies. If risks (particularly long-term, involuntary risks linked to scientific uncertainty and ignorance) are to be borne primarily by one specific section of society, the input of that group into the regulatory process should be a priority for democratic decision-making.

List of Acronyms Used

CGB – Commission du Génie Biomoléculaire, (French scientific advisory body)
CIMMYT – International Centre for Maize and Wheat Improvement
EPA – Environmental Protection Agency
EU – European Union
FIFRA – Federal Insecticide, Fungicide and Rodenticide Act
IFOAM – International Federation of Organic Agricultural Movements
IRM – Insect Resistance Management
IRMA – Insect Resistant Maize for Africa Project
KARI – Kenya Agricultural Research Institute
NBC – National Biosafety Committee (Kenya)
NCST – National Council for Science and Technology
OECD – Organisation for Economic Co-operation and Development
SAP – Scientific Advisory Panel
SCP – Scientific Committee on Plants (EU scientific advisory body)

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