PART II. PAPERS PRESENTED BY INVITED SPEAKERS

GENETICALLY MODIFIED ORGANISMS IN CROP PRODUCTION AND THEIR EFFECTS ON THE ENVIRONMENT: METHODOLOGIES FOR MONITORING AND THE WAY AHEAD

1. Challenges to the Design and Implementation of Effective Monitoring for GM Crop Impacts: Lessons from Conventional Agriculture

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Abstract

Agricultural productivity and the environmental impacts of agriculture are most effectively managed using procedures that are based on sound ecological thinking. Monitoring procedures for genetically modified (GM) crops that are now a part of international protocols and post-market requirements should be developed to protect the productivity and ecological integrity of farming systems. Risk assessment procedures are in development, and monitoring must compensate for deficiencies that will only be rectified through field experience in GM commodities. The history of monitoring in agriculture tells us that even clearly adverse impacts of GM cropping will be difficult to detect because of the inherent complexity and heterogeneity of farming systems. Ecosystem-level indicators are relevant (e.g., those employed in PAGE and MEA), as well as crop-specific indicators, and their relative contribution is dependent upon the specific farming-system context. Long-term monitoring has made positive contributions to the retrospective analysis of trends associated with production and off-crop impacts in agriculture. Globally, farming systems differ significantly in the forms of monitoring that are required to protect them. This is because of differences between crops and cropping practices, differences in underlying ecological processes and climate, differences in the distribution of knowledge among growers and researchers, differences in policy and regulatory environments and the degree of feedback to agricultural change and differences in the quality and availability of relevant monitoring data. All monitoring programmes for GM crops should be designed in such a way that their potential value is clear, and in ways that will result ultimately in effective management. They should provide a clear and rigorous explanation for the selection of indicators, including a sampling design that meets the requirements for statistical power. Critically, there should be a clear connection between the results of monitoring and decision-making.

Introduction

The dominant paradigm for western agriculture is changing from an industrial, production-based model to an agro-ecosystem-based model. The agro-ecosystem concept (1)[12] has evolved over more than 30 years to a stage where agricultural land uses are widely considered to comprise a definable and distinct ecosystem type that is now incorporated explicitly within integrated ecosystem assessments and global analyses of biodiversity (Box 1). Agriculture is viewed increasingly as being intrinsic to, rather than separate from, functioning ecosystems, and dependent upon ecosystem services from within and beyond the farm for continued productivity. A new language

Box 1

Examples of integrated ecosystem and global biodiversity assessments that explicitly incorporate agricultural land uses:

Global:
- Global Biodiversity Assessment (Heywood, 1995)
- Millennium Ecosystem Assessment (Alcamo *et al.*, 2003; MEA, 2004a)
- Pilot Analysis of Global Ecosystems (WRI, 2000; Wood *et al.*, 2000)

Regional:
- MEA Southern Africa Sub-global Assessment (MEA, 2004b)

National:
- EPA Draft Report on the Environment (EPA, 2003)
- The State of the Nations Ecosystems (The Heinz Center, 2002)

Sub-national:
- Oregon State of the Environment Report (Oregon Progress Board, 2000)

[12] See Note 1 at end of paper.

and new measurement currencies are gradually evolving to define and quantify the underlying components of agricultural productivity and of agro-ecosystem degradation. The challenge of correcting the course of agriculture towards economic, ecological and social sustainability remains, however, one of our most daunting challenges. It is yet to be established whether or not this new ecologically informed, agricultural paradigm will provide the common language and tools that are required to reconcile the diverse stakeholders and interests in agriculture's future, provide a pathway to the widespread adoption of sustainable practices and establish principles for the adoption of new agricultural technologies, including biotechnology.

There is repeated evidence in the historical record of millennia for catastrophic losses of agricultural productivity resulting from over-intensification and the unintended consequences of government policies, subsidies and development schemes (McNeely *et al.*, 1995; Wood *et al.*, WRI, 2000; 2000). Technical solutions to overcome constraints on agricultural productivity are sought, but their implementation has frequently led to 'replays' of these historic events, where ecosystem services are degraded below the limits necessary to sustain productivity. The repeated tendency to ignore the warning signs of agro-ecosystem failure, reflect symptoms of what has been termed "the Tragedy of the Commons", where common goods (i.e., in this case, the ecosystem services that underlie agricultural productivity) are overexploited (Hardin, 1968) because of a failure to respond to the incremental degradation of the system over repeated cycles of agricultural production. Hardin argued that technical solutions are unlikely to be available to solve problems of overexploitation of common goods, and that solutions lie in the ability of society to make more fundamental changes to the way in which the goods themselves are exploited. This defines two polarized extremes in a global debate about the future of animal and plant agriculture, and the requirement for higher productivity as world population grows. Will the path towards sustainable productivity be guided by technological advances, or does success lie along a path of more fundamental changes to the structure and functioning of agriculture, based upon our growing knowledge of the factors that underlie agro-ecosystem integrity?

Biotechnology is acting as the lightning rod for this broader, global debate about agriculture. Its rapid expansion over a very short period raises alarm about excessive and inappropriate adoption, and concerns about the potential for further degradation of agro-ecosystems that are showing symptoms of incipient decline, or which do not have the capacity to incorporate cropping regimes of significantly different character. The lack of agreed upon measures of agro-ecosystem health and integrity (WRI, 2000; Wood *et al.*, 2000) serves to increase uncertainty about the possible outcomes of widespread adoption, and efforts are underway to develop monitoring frameworks that will provide much-needed data concerning possible impacts (Box 2).

Box 2

Protocols and guidelines for monitoring GM crop impacts

Legal instruments and conventions that address monitoring for GMOs

- Cartagena Protocol on Biosafety (United Nations, 2000)
- Directive 2001/18/EC on deliberate release of GMOs and the decision of the Council to the European Union establishing guidance notes on GMO monitoring (Council of the European Union, 2002)
- International Plant Protection Convention (IPPC) phytosanitary standard for pest risk analysis (FAO, 2004)

Monitoring guidelines

- European Food Safety Authority (EFSA) guidance document on GMO risk assessment (EFSA, 2004a) p. 41–43
- GMO monitoring in Germany (Wilhelm *et al.*, 2003)
- UK guidance on best practice for post-market monitoring (Defra, undated)

This paper summarizes recent experience with the application of monitoring in agriculture. It attempts to determine whether or not monitoring is capable of generating the knowledge that is necessary to protect agro-ecosystems, rural livelihoods and broader ecological integrity. The effort and resources that may be expended in developing monitoring protocols for GM crops may also serve a wider need in agriculture for high quality data concerning the status and trends in the production of goods and the ecosystem services that underpin this productivity. To operate effectively, monitoring programmes for GM crop impacts should contribute to informed decisions about the possible implementation of the technology in specific locations, assess the effects of implementing the technology, where this has taken place, and also enable continuous testing and validation of the assumptions that link implementation with effects. Monitoring may therefore operate in a number of phases, and to be effective, there must be direct feedback to decision-making, policy formation and effective communication of new knowledge at each stage (see Appendix I). Applied on a global basis, this will require flexible, adaptive and rapidly evolving mechanisms for programme design, implementation and analysis, which progress beyond anything that currently exists.

International Requirements for Monitoring GM Crops

Annex III of the Cartagena Protocol (United Nations, 2000) specifies the use of risk management or monitoring in cases where uncertainty about impacts of living modified organisms (LMOs) remains after risk assessment has been undertaken. Case specificity is built within the protocol by requiring data on location, geography and climatic and ecological characteristics to be included as components of the risk assessment procedure. The protocol is global in scope; it applies to all signatories and will therefore be implemented across the full spectrum of agricultural and economic development that exists internationally.

The European Union (EU) guidance notes on monitoring are far more explicit regarding monitoring procedures, plans for which are required from notifiers (e.g., seed companies) prior to regulatory approval (Council of the European Union, 2002; Wilhelm *et al.*, 2003). They are however geographically restricted to the agro-ecosystems of Europe, and hence to a context that is supported by a rich array of monitoring data and experience, and a long history of risk assessment in the regulation of agricultural inputs.

Monitoring and feedback to the risk assessment process is also recommended in the International Plant Protection Convention (IPPC) standard for determining the potential pest status of GM plants that are the subjects of trade (FAO, 2004). A requirement for monitoring data is also implicit within the standard in as far as the Convention applies to the protection of wild flora (in this case, from gene flow, or as a result of indirect effects).

Significant differences in the intended scope and purpose of monitoring exist between the Cartagena Protocol and the EU guidelines. Pre-release monitoring is required by the EU guidelines, to provide the baseline reference data against which effects may be measured. This is not, however, specified within the Cartagena Protocol, where monitoring is an option, not a requirement. Additionally, the EU guidelines are far more explicit with regard to the purposes of monitoring, which include confirmation or refutation of assumptions about risks that were identified during the risk assessment process and, also, detection of unanticipated effects (clarification of the differentiation between these two requirements is provided by the EFSA guidelines (EFSA, 2004a; Den Nijs and Bartsch, 2004).

The specification of a reference or baseline condition in the EU guidelines provides a very important standard for assessment of effects. Additionally, the requirement for feedback from monitoring to the risk assessment process in the EU guidelines provides the necessary condition for learning, and the evolution and development of the process (Defra, undated; OECD, 2000).

From an ecological perspective, all the protocols and guidelines listed in Box 2 assume implicitly that: (a) monitoring tools exist and are available for global implementation; (b) data of sufficient quality can be obtained from monitoring to provide a basis for decision-making that is protective of the goods that are derived from agriculture, ecological services and biodiversity in general; and (c) native biodiversity is sufficiently well understood for monitoring data to be interpreted, and for unacceptable hazards to be identified.

Isolating the Biodiversity Impact of Specific Practices from the Strong Signals and Loud Ecological Noise Associated with Agriculture

Agriculture in all of its forms and conditions generates strong ecological 'signals' (i.e., specific, quantitative measures of impact that can be isolated from normal sources of variability) on the hierarchy of scales (ecosystem, down to individual farms and fields) addressed by historic and current monitoring measurements and assessments. Identifying and isolating a distinct signal from monitoring of individual practices is a challenge, unless effects are large and distinctive (McNeeley *et al.*, 1995). Assigning a cause to a given signal is also challenging.

Agricultural conversion alters the structure and functioning of natural ecosystems with a loss of native flora, loss of wildlife habitat, further potential biodiversity impacts from pesticide and nutrient exposure and run-off, and effects on the soil biota, soil quality, nutrient cycling and soil water relations that result from cultivation (Conway and Pretty, 1991; NRC, 1993; McLaughlin and Mineau, 1995; Mooney *et al.*, 1995a; Matson *et al.*, 1997; Vitousek *et al.*, 1997; Tilman, 1999; Wood *et al.*, 2000; Tilman *et al.*, 2001). Although there are efforts to achieve a more sustainable set of land-use practices in human-dominated ecosystems (Tilman *et al.*, 2002), land conversion itself is one of the most important mechanisms that underlie the accelerated extinction rates of the global flora and fauna (e.g., Barbault and Sastrapradja, 1995; Purvis and Hector, 2000; Novacek and Cleland, 2001; Pitman and Jorgensen, 2002; Pitman *et al.*, 2002; Thomas *et al.*, 2004). It may compound with the effects of global climate change to further reduce biodiversity (e.g., Warren *et al.*, 2001).

Some of the measures that have been closely associated with the move towards greater sustainability may themselves carry inherent threats to biodiversity if they are not properly managed. For example, ten percent of classical biological control introductions, and 49 percent of inundative or augmentative releases are thought to have led to population level effects on non-target invertebrates (Lynch *et al.*, 2001). The potential hazards associated with GM cropping have to be placed within the broader context of impacts (positive and negative) associated with all agricultural practices.

The ecological consequences of biodiversity loss, whatever its origins, include impairment of basic ecological functions (Loreau *et al.*, 2001; Sekercioglu *et al.*, 2004). The degree to which functional redundancy (i.e., the capacity of an ecosystem to lose elements of biodiversity, but retain basic ecological function) exists within communities and functional groups is still not fully understood (Hunt and Hall, 2002) and is likely to be highly variable in space and in time, and dependent upon the sensitivities and responses of organisms and functional groups in the disrupted system (Symstad *et al.*, 2003). There is an urgent need for monitoring to explore variation within land-use mosaics and along environmental gradients to quantify effects on biodiversity and ecological function, both above and below the ground, particularly in systems that are sensitive to change (Wolters *et al.*, 2000).

The ecological 'noise' associated with the crop production process (i.e., variation in the timing and strength of the signals listed above, combined with natural sources of variability) also deserves careful consideration. The ecological signals from agriculture may be strong in aggregate, but many are distributed unevenly in space and in time. Growers themselves are diverse, and vary in the degree to which they use different practices, including pesticides, within and between farms, and between different crops and regions (Hollingsworth and Coli, 2001). Crops have widely differing biological assemblages associated with them, both within (e.g., Booij and Noorlander, 1992; Buchs, 2003) and between agro-ecosystems (Mooney *et al.*, 1995a). The regular cycle of cultivation practices has significant impacts on non-target invertebrates (Thorbeck and Bilde, 2004) and the below-ground fauna (Mooney *et al.*, 1995). These patterns of practices intersect with landscape complexity, which must be considered if the impacts of crop management regimes on ecosystem services, including pollination (Kremen *et al.*, 2002; 2004) and biological control (Thies and Tscharnatke, 1999), are to be understood.

The challenge for GM crop monitoring is that it must be able to detect the signals of impact within a system that already radiates strong, if noisy, signals from a number of practices, as well as from the act of land conversion itself. To achieve this, monitoring protocols will need the greatest possible inferential base, combined with the efficiency and rigor that is associated with good design.

Critical design elements include, at the outset, the need to define the nature of an unacceptable impact, and the spatial and temporal scales to be addressed in the assessment. This is followed by the requirement for rigorous selection of control or reference sites, collection of baseline data prior to release, enabling a ”before and after” analysis with reference to locations that are beyond the influence of the novel crop, careful selection of variables, including possible indicators (biotic and abiotic), effective sampling that considers sources of variation and rigorous selection of analytical models. *There is no way to rescue data from weak or poorly designed monitoring schemes* (Stork and Samways, 1995; Downes *et al*., 2002; Noon, 2003). Appendix I summarizes some of the key considerations in the effective design of monitoring programmes.

The lack of explicit guidance concerning the nature of unacceptable hazards, and of critical design elements in any of the protocols or guidelines listed in Box 2, virtually guarantees the widespread occurrence of both Type I and Type II errors in subsequent decision-making.

Indicators of Agricultural Impact at the Ecosystem Level

The Pilot Analysis of Global Ecosystems (Wood *et al*., 2000) evaluated data available globally for a set of indicators for the productivity and ecological integrity of agriculture, derived, to a large extent, from monitoring programmes. These measures capture the impact of individual practices in aggregate, and rarely isolate specific agronomic procedures or inputs. They are likely to be of particular importance in situations where the concern regarding GM crop introduction relates to potential impairment of a sensitive or poorly understood agro-ecosystem. The global indicators included food, feed and fibre production statistics and measures of soil condition, water quality and quantity, biodiversity and soil carbon storage.

Although trends were discernable in each of these indicators, poor data quality and lack of harmonized protocols had an impact on the resolution and accuracy of assessment for all of the key indicators. Wide-scale monitoring of soil degradation is urgently required, and there are no globally consistent indicators of water quality. Water quantity data are currently coarse-grained, often based on aggregated national statistics and extrapolation models; biodiversity data are based upon inference from habitat mapping, and high-quality land-use–land-cover data are required for the development of accurate carbon storage estimates (Wood *et al*., 2000). Very similar limitations to data quality for the indicators of ecological integrity, including those in agriculture, are outlined in the US-wide ”*State of the Nations Ecosystems*” (The Heinz Center, 2002; EPA, 2003) and the ”*Oregon State of the Environment Report*” (Oregon Progress Board, 2000).

These limitations represent real constraints to the effective development of monitoring systems for the impacts of any practice or technology on overall ecosystem health. We know about the ecological impacts of agriculture from a rich array of formal experimental studies (Gregory *et al*., 2002), but the challenge for effective monitoring is to translate these possible outcomes to sampling protocols that might detect them in heterogeneous systems. The acquisition of the high-quality monitoring data that would enable these indicators to operate effectively remains a global imperative. Without monitoring data for indicators that meet basic standards of uniformity and accuracy, errors will arise in our ability to establish the agro-ecosystem condition and to select between alternative pathways to intensification.

Indicators of the Impact of Specific Practices from Monitoring Data

There is a long and successful history of focused, ecosystem-level, taxon-based monitoring in agricultural systems, particularly in Europe. This offers some reassurance that more localized impact-focused monitoring programmes can be effective, if specific hazards can be identified or if a specific indicator species or assemblage is apparent.

The European programmes have often, however, engaged hundreds of amateur naturalists and professional scientists on a time-scale of decades and may be a poor model for the design of equivalent programmes in the developing world. Overall, they have detected significant declines in many groups of organisms (invertebrates, vertebrates, higher and lower plants: expressed as the proportion of programmes exhibiting decline, stability or increase in populations of indicator taxa), particularly habitat specialists associated with intensification of farming (Robinson and Sutherland, 2002).

Declines in farmland birds have been particularly significant (Ormerod and Watkinson, 2000), and data on birds, invertebrate prey and climate are of sufficient quality in some areas (e.g., Scotland) to be able to postulate that agricultural intensification has influenced birds through changes in food quality or quantity on the farm (e.g., Benton *et al*., 2002). It has also been possible to generate evidence for linked temporal change between farmland birds, invertebrate numbers and agricultural practices, through sophisticated analyses that used 25-year datasets incorporating records of land use and production regimes and the intensity of practices within them. Invertebrate prey data (a major diet source for farmland birds) were provided by a pest monitoring network with a long-term, synoptic dataset from a network of aerial suction traps (discussed in Woiwod, 1991).

Benton *et al*. (2002) were able to speculate that the reduction in non-crop plants associated with herbicide-tolerant GM crops (Watkinson *et al*., 2000) might result in reductions of seed resources and invertebrate prey, further exacerbating the pressures on farmland bird populations. Insightful analysis of this form may only arise where complementary arrays of long-term, ecological monitoring data are publicly available. They are also enabled by the establishment of farmland birds as an indicator of agricultural condition: there is no reason to believe that birds will be a universal indicator, although declines and extinctions in bird species globally may lead to impairment of ecosystem processes, including decomposition, seed dispersal and pollination (Sekercioglu *et al*., 2004).

The experience of the United Kingdom (UK) in agricultural monitoring illustrates the importance of long-term datasets for the detection and analysis of adverse trends associated with agricultural intensification, and for the identification of indicator taxa. It also reveals, however, the challenge of attributing the causes that underlie the adverse effects that have been detected, and analyses of monitoring data, although sophisticated, yield purely correlative outcomes that require exploration through further experimentation and more detailed observation. This conclusion is supported by research on disturbance dynamics and ecological responses in the Long-Term Ecological Research Network in the United States of America (Turner *et al*., 2003).

On shorter time-scales in Europe, a large number of long-term farming-system studies, with focused programmes of sampling for specific taxa or functional groups, have detected altered patterns of abundance and diversity associated with agricultural systems of varying intensity, exploiting monitoring regimes that are distributed over large-scale experiments (summarized in Holland *et al*., 1994). These investigations lie at the interface between formal experiments and monitoring programmes. They are often compromised by lack of statistical power with designs that have sacrificed replication for scale of treatment, and they also suffer from the disadvantage that they are extremely expensive and time-consuming to undertake.

The rigorous selection of ecological indicators is critical to the success of monitoring programmes, and it will certainly apply to the selection of appropriate indicators for GM crop impacts. Limited numbers of indicators fail to capture the complexity of the system, but multi-species suites, representing differing taxa can only be of value if their selection is based upon sound quantitatively based knowledge built from existing monitoring data (Dale and Beyeler, 2001; Carignan and Villard, 2002). All reviews and guidelines for effective monitoring emphasize the need for rigorous design of the programme before it is initiated, including the selection of indicators (e.g., Stork and Samways, 1995; Griffith, 1998; McGeoch, 1998). All assume the availability of taxonomic expertise to identify specimens and maintain voucher collections (Appendix I).

Adapting Monitoring to Different Farming Systems

Classification of farming-system types

No single protocol will be suitable for all cases where the need for monitoring arises under the terms of the Cartagena Protocol. Arguably, however, a limited set of detailed protocols could be developed to address a representative range of farming systems. This set of system types might simply be divided between the major terrestrial biomes, where fundamental differences in climate, geology and biota confer profound differences in the mechanisms that underlie key ecosystem functions, particularly nutrient cycling (Mooney *et al*., 1995a). They might also be divided between agricultural regimes that differ in scale or intensity (e.g., Gregory *et al*., 2002), or systems at different positions on the spectrum of sustainability to impairment.

Agro-ecosystems may be assigned to broad categories of intensification that differentiate their impacts within the ecosystems that contain them and ecosystems that are hydrologically and atmospherically connected with them (Mooney *et al*., 1995a; Dixon *et al*., 2001; Gregory *et al*., 2002). The transition from low-intensity, through medium- to high-intensity management is accompanied by increasing agricultural land use, by reductions in the diversity of crops and crop varieties that are planted, habitat heterogeneity, the stability of long-term yields and the ability to withstand disturbances.

Increasing area and specialization in agricultural land use can reduce the complexity of the connections between ecosystem units in the landscape and can lead to impairment of functional biodiversity (e.g., pollination, biological control) and effective synchronization of nutrient and sediment fluxes at the agro-ecosystem scale. This synchronization can overwhelm the capacity of sinks to intercept and absorb nutrients and sediments in the landscape, and can result in net transfer between systems that would otherwise have been retained within the system boundaries (Mooney *et al*., 1995a). It can also render the system more susceptible to pest and disease outbreaks. Land use and habitat structure indicators are being adopted increasingly to address the need for information about the form of landscape change that agriculture imposes (e.g., The Heinz Center, 2002; EPA, 2003), although landscape structure alone may not be an effective indicator of the intensity of agricultural practices (Roschewitz *et al*., 2005).

The ‘halo’ (i.e., the area, beyond the borders of the agro-ecosystem that experiences measurable effects of agricultural practices) of impact of agriculture (including nutrient and sediment fluxes, trace gases and pesticide losses that result from increased reliance on external inputs for pest management) beyond the agro-ecosystem itself is therefore coupled with agro-ecosystem type and level of intensification (Gregory *et al*., 2002). Monitoring regimes must be developed that account for the level of integrity or degradation of each system to be investigated, and record the parameters that most effectively reveal the capacity of the ecosystem to support increasing intensification.

The most comprehensive classification of farming-system types in the developing world identified 72 farming systems in six regions (Box 3), and eight broad categories into which each of these fell (Box 3) (Dixon *et al*., 2001). The strategy for poverty reduction and food security varies by category, based upon resource endowments (i.e., agro-climatic condition and soil), level of intensification and support infrastructure, all of which varied within the farming-system categories, and with geographic region.

Box 3. Classification of farming system types in the developing world†

Box 3a: Farming system categories in the developing world with broad development recommendations for food security and poverty reduction

	Irrigated farming	Wetland rice-based	Rainfed, humid	Rainfed, highland	Rainfed, low potential	Dualistic, mixed	Coastal artisanal fishing and mixed farming	Urban-based
Number of sub-systems	3	3	11	10	19	16	4	6
Production surplus	High	Medium	Medium	Low	Low	Medium	High	High
Diversification	*	*	*	*	*	*	*	*
Intensification	*	*	*			*		
Increase farm size						*		*
Exit farming				*	*		*	

Box 3b: key regional initiatives relevant to agro-ecosystem resources and infrastructure

	Sub-Saharan Africa	Middle East and North Africa	Eastern Europe and Central Asia	South Asia	East Asia and the Pacific	Latin America and the Caribbean
Sustainable resource management	*	* **(including irrigation management)**		* **(water resources)**		*
Improved resource access	*		*		*	*
Reoriented agricultural services		*	*	*		
Rationalized agricultural policies		*				
Strengthened resource user groups				*		

† For definitions and details see Dixon *et al.* (2001).

Three factors of significance to the design of an appropriate monitoring regime arise from this analysis:

1) The research and management priorities identified by Dixon *et al.* (2001) varied widely, but tended to cluster around farming-system classification, whereas the infrastructural needs, which were also diverse, tended to cluster around geographic location. The optimum monitoring design for any system will lie where these factors intersect, and guidelines for programme design will need to be highly structured in order to arrive rationally at the most informative and focused approach (Appendix I).
2) The classification system includes many of the factors that will impinge upon monitoring system design (e.g., farming-system constraints and priorities, status of the resource base, mode of potential productivity increase, access to support mechanisms and subsidy). Guidelines for monitoring development must consider the contribution that each of these makes to the design of the programme.
3) Public service support infrastructure and agricultural subsidies have been disproportionately reduced throughout these farming systems as a result of trade liberalization, limiting the overall potential for management and oversight of effective monitoring strategies. Civil society groups, non-governmental organizations (NGOs)

and the private sector may all therefore substitute or complement government agencies in the delivery and management of effective monitoring systems. Monitoring guidelines will need to be credible, clear and practical across a wide spectrum of capacity and opinion.

Determination of adverse effects

The exercise of determining potential adverse effects is an essential precursor to the design of effective monitoring programmes. It focuses the monitoring effort, and it determines the level of statistical power that is required to detect change (i.e., an *x* percent effect over *y* years). In the case of GM crops, that may be associated with intensification of agricultural practices (e.g., within cropping regimes receiving a novel crop with higher requirements for water, nutrients, pest management or cultivation), monitoring should be designed to evaluate the consequences of intensification as well as the potential for adverse effects of specific traits or products associated with the new commodity. Where the GM crop represents simply a modified genotype of a crop that is already widely grown in the ecosystem type in question, with few additional agronomic requirements, then the scope of the monitoring programme may be reduced somewhat. Three classes of adverse effect can be identified, in order of permanence or longevity:

1) *Transition (i.e., a significant and sudden negative change within a farming system) to a lower state of agricultural productivity:* Significant state shifts may occur in natural and managed ecosystems following perturbation, leading to undesirable states with low productivity, and which require considerable resources to restore (Mooney *et al.*, 1995b). There is no current basis for determining the limits to intensification in a given system and the likelihood that a given agro-ecosystem type might transition to an adverse, less productive state, although there are many examples of this taking place. Reduction in productivity may arise through direct damage to soil or water resources, or to biodiversity and the ecological processes that this engenders. Fragile ecosystems tend to be characterized by high rates of species turnover and high amplitude in population fluctuations (Nilsson and Grelsson, 1995); features that are associated with some developing country agro-ecosystems, particularly those in marginal climates for agriculture (Grant, 1989). Ecological forecasting is in its infancy (Clark *et al.*, 2001), and our ability to manage systems to avoid state shifts is highly dependent upon our ability to detect adverse trends in productivity, biodiversity or key taxa, and to respond to these. Yield records alone will be insufficient, because of the inherent time lags that occur when growers compensate for lower productivity by increasing inputs: the challenge is to find a limited number of effective indicators that feed back to the farming system before critical limits have been reached.
2) *Aggravated ecological impacts or impairment to ecological processes in neighbouring ecosystems, with feedback to reduced agricultural productivity via inhibited ecological services:* This category of effects includes increased erosion or pollution, transmitted through atmosphere or water, restrictions to water resources brought about by new cropping regimes, reduced survival of wildlife that visit or complete part of their life-cycles in the farming system, and the impacts of gene flow to wild relatives of the crop. Certain indicators of impact may already be presented in systems that reveal impairments of this form. There may also be legally enforced standards for water quality protection or wildlife protection that guide measurements and monitoring. It is far easier to test whether a sample exceeds a threshold than to determine if it is contributing to an increasing or decreasing trend.
3) *Increased impact within the agro-ecosystem, temporarily impairing a key service underpinning productivity:* This category of effects includes direct biodiversity impacts of crops with plant incorporated protectants (PIPs). It also includes indirect ecological effects on crop-dwelling species, or the effects of changes in the perturbation regime, including synchronization brought about by increased uniformity of the cropping system, that may respond to mitigation. Symptoms of impact include pest resurgence and secondary pest outbreaks for invertebrate pests, which may either result in depressed yields or in higher external inputs and greater costs.

The three classes of anticipated impact above would each require different monitoring strategies to detect them, with differing spatial and temporal scales, differing requirements for reference condition or control site and different sampling regime designs to accommodate the requirements of the most relevant statistical models. Will monitoring stray beyond farming-system boundaries for example, and include aquatic as well as terrestrial ecosystems (effect class 2 above)? Will it focus upon production data and broad indicators of agricultural integrity (effect class 1 above), or will it be more taxon-based, with designated indicators or functional groups under investigation (effect class 3 above)? These impacts nest within each other in a spatial and temporal hierarchy of possible adverse effects.

The cost, methodological and logistic implications of making the right choice are probably sufficient to seek evidence that monitoring programme selection is dependent upon specific features of the system in question, its ecological fragility and the characteristics of the GM commodity under scrutiny and the stresses that it may impose. The capacity of the country or agro-ecosystem in question to undertake monitoring may also limit the extent of the programme to the most basic measurements, and guidelines are required that isolate the regimes with the highest likelihood of detecting an adverse effect.

Simple Rules for Allocation of Monitoring Regime to Farming-System Type

1. *Transition to a lower state of agricultural productivity:* Systems that are unknown, sensitive to perturbation or particularly dependent upon close connectivity with unmanaged systems combine the need for highest quality data with, in all likelihood, the lowest capacity to provide these data. The rigorous approach to monitoring in these cases requires an inventory to be undertaken prior to release, that establishes a baseline for ecological condition and the availability of ecosystem services that contribute to production (Stork and Samways, 1995). Inventory and subsequent monitoring should then encompass the agro-ecosystem where the crop is to be grown, which requires knowledge of land use. Effective monitoring systems can only be designed from the detailed knowledge-base that inventory is capable of providing. Reference sites for fragile systems, or those that are dependent upon a close association with natural systems, may actually be the associated natural systems. This permits establishment of baselines for natural variation, species composition and other key elements of effective monitoring (e.g., Stork and Samways, 1995; Noon, 2003; Busch and Trexler, 2003; Appendix I).
2. *Aggravated ecological impacts or impairment to ecological processes in neighbouring ecosystems, with feedback to reduced agricultural productivity via inhibited ecological services:* Although the same principles to those above may still apply, the existence of known threats to productivity should focus and narrow the scope of monitoring to critical biotic and abiotic indicators, including those that can be aggregated at the national level and contribute to ecosystem assessments (Box 1). Indicators may include yield and productivity, abiotic indicators in off-crop habitats (erosion and water quality) or wildlife monitoring. The reference condition, where current systems are already revealing degradation, may consist of segments of the cropping system that are subject to conventional practices. Grower questionnaires or surveys may provide a mechanism for obtaining information that relates to readily assessed indicators (USDA, 2003; EFSA, 2004b). The exception to this is the need, in all cases, for inventory and biogeographic analysis of related flora as a prerequisite for the identification of floristic indicators for gene flow (as is implicit within the IPPC in FAO, 2004).
3. *Increased impact within the agro-ecosystem, temporarily impairing a key service underpinning productivity:* In the case where a specific property may confer a risk following risk assessment, monitoring will need to address indicators for that specific risk. This places the highest demand upon statistical power and replication for the detection of the adverse impact of concern. In some cases, formal experiments, rather than monitoring, will need to be substituted to provide the rigor necessary to be able to attribute cause. Adequate controls are an essential requirement for monitoring or experimentation to be effective and should correspond to the current regulatory requirements for crop genotypes that are similar to the GM crop, but lacking the genetic event of concern. This category of risk is addressed by the EU guidelines and the

various elaborations and expansions of these that are being undertaken (e.g., Sanvido *et al.*, in press). Impacts in this category may evolve to have impacts at the ecosystem scale, particularly in cases where the new commodity or practice extends to a large proportion of the cropping system (e.g., Jepson, 2002); this may not, however, require monitoring to extend to the whole system scale if a specific risk is known.

Example allocation exercise

Box 4 defines six hypothetical states of agriculture that are characterized by level of impairment or sustainability, level of impact on neighbouring ecosystem types, the quality of the intrinsic knowledge-base, the level of support from research and extension infrastructure and the risk of transition to a permanently degraded or un-harvestable state. These hypothetical states have been developed from classification approaches and analyses of Dixon *et al.* (2001) and InterAcademy Council (2004) (for developing country farming systems and Africa, respectively), complemented by NRC (1993) and Tiffen and Bunch (2002), who developed farming-system classifications in the humid tropics. It supplements the approach to defining levels of agricultural intensification and their environmental consequences of Gregory *et al.* (2002) by considering risks of transition to adverse states, and the condition and connectedness of the regulatory environment. The farming-system states include systems more reflective of the developed world and northern hemisphere (see Mooney *et al.*, 1995a for a broad outline).

Box 4a-f: Selection of monitoring strategies associated with a set of hypothetical states of agriculture

Box 4a

Agro-ecosystem state	Attributes	Form of monitoring
Ia Agricultural conversion	Indigenous systems (including globally important agricultural heritage systems), low dependency on external inputs for productivity, may evolve over time, characterized by high dependency on knowledge, diverse plant genetic resources. Productivity may be climate dependent, and may be nutrient limited. Low halo of impact on neighbouring systems. Not supported by R&D infrastructure or high technology input. Poor support from policy or legal protection and limited feedback from monitoring. Present in all terrestrial biomes, but persist when disconnected from intensive land-use practices, and more prevalent in the developing world.	Baseline data, based upon inventory methods, are essential, prior to release, to generate knowledge-base from which indicator assemblage may be selected for monitoring. Environmental state monitoring (not focused on an anticipated impact), with reference to a natural system, may be the most appropriate mode of monitoring, given the fragility of the system, and likelihood of transition to Ib or II. The hazard of concern is an extreme change in ecological state, driven by deviation from the range of variation in biodiversity and ecosystem services. Pre-release data may indicate system is unsuited to introduction of novel cropping systems, because of high uncertainty.
Examples	Includes many of the 27 low-intensity systems identified by Dixon *et al.* (2001), including agro-pastoral, pastoral, high-altitude and sparse agricultural systems (supporting 350 million people). Higher productivity is sought for some	Biodiversity inventory data are largely lacking for these systems. Environmental side-effects data, including some monitoring data, from locust, grasshopper and Tsetse control operations, is likely,

Agro-ecosystem state	Attributes	Form of monitoring
	of these systems (Dixon *et al.*, 2001), but the mode of achieving this requires exceptional care, given the dependency of these systems on practices that have evolved over generations, in response to environmental variability.	however, to be of great assistance in identifying vertebrate and invertebrate indicator taxa (Peveling and Nagel, 2001) for sub-Saharan Africa savannah, north of the equator (Everts *et al.*, 1997; Peveling *et al.*, 1999a; Langewald *et al.*, 2003), Madagascar (Tingle, 1996; Peveling *et al.*,1999b; 2003), riverine forest in West Africa (Everts *et al.* (1983; 1985) and in proximity to endangered ecosystems (Peveling, 2001). Statistical analysis of biomonitoring data is challenged by availability of adequate controls, high sampling error and insufficient taxonomic resolution (Grant, 1989).

Box 4b

Agro-ecosystem state	Attributes	Form of monitoring
Ib **Low- to medium-intensity systems**	Occupying less than 30 percent of terrestrial land use. Dependent upon external inputs, and may have high levels of pesticide use. Technology adopters, and may substitute technology for biologically based alternatives. Yields climate-dependent, and often nutrient-limited. Access to R&D support, but also grower-knowledge-dependent. Greater disconnect from surrounding ecosystems, but low intensity limits immediate impacts on ecosystem services, and halo of influence beyond the farm. Benefits from environmental regulations and habitat conservation policies where available, but minimal feedback from monitoring and assessment. Present in all terrestrial biomes, but more common in marginal environments and climates and in the developing world.	As above, but signals of impairment to aquatic resources, and other off-crop impacts may provide an indicator of stress, as may impacts on fauna. Baseline data again essential, and of sufficient duration to capture variability in possible indicators. Presence of indicators of concern (organisms, functions impaired by current practices) may enable impact-based monitoring to be undertaken (i.e., impacts measured with respect to pre-treatment condition, with reference to control sites). Grower survey or questionnaire may provide critical data and data can be analyzed statistically (EFSA, 2004b).
Examples	Includes some low intensity systems (see Ia) and some (the more extensive) of the 26 medium-intensity systems identified by Dixon *et al.* (2001), including 20 'food-oriented systems supporting 950 million people (e.g., more extensive implementations of the maize-mixed and cereal root-crop mixed systems in Africa; highland mixed system of the Middle East, North Africa and South Asia; large-scale cereal-vegetable system of Eastern Europe and Central Asia; maize-(beans and rice livestock systems of Latin America, and, 6six 'market oriented' systems, serving 100 million people (e.g., more extensive examples of tree crop systems of Africa and E.ast Asia; horticulture, mixed system of Eastern Europe and Central Asia; coastal plantation and mixed systems in Latin America and the Caribbean).	African savannah (in Ia above) and Asian tropical rice (in III below) also relevant to this category. In general, this category is under-served by inventory and monitoring in many parts of the world.

Box 4c

Agro-ecosystem state	Attributes	Form of monitoring
II **Over-exploitation**	<u>A transitional state (to III or IV)</u> Soil degradation and poor support from ecosystem services as a result of disconnection from other ecosystem elements. Compensated for by high nutrient and pesticide input in the short term. A biodiversity sink, with impacts in a wide halo beyond the farm or field, particularly through low water quality. Access to R&D, but production-oriented, and limited feedback from monitoring. Poor support from policy which is not synchronized with signals of incipient loss, and limited access to resources or support for restoration. Knowledge-base may be limited, with poor access to education and outreach. Historically within all terrestrial biomes, but now particularly focused in the developing world, and associated with export horticulture and increasing local consume demand for vegetables. Does, however, include western systems that have pursued a production imperative with inadequate feedback from monitoring and policy.	Sufficient indicators in a critical or impaired condition to permit narrower, more focused and economical, impact-based monitoring study. Study may be supplemented by bioassays or measurements of impact or impairment to systems beyond the agro-ecosystem. Lack of flexibility and ability to employ mitigation practices require careful consideration, and may result in a decision not to introduce a GM crop with inherent risks or to accelerate the introduction of GM crops that engender reduced risks.
Examples	May include some of the more intensive implementations of the list of farming systems from Ib. Classical examples include the repeated challenges to cotton production driven by the consequences of excessive pesticide use (e.g., Eveleens, 1983). Also, however, includes sophisticated research and regulatory infrastructure, but with critical capacity gaps; e.g., the increasing evidence for constraints in the capacity of the UK farming system to develop ecologically sustainability, resulting from decoupling of research from the grower, brought about by limited stakeholder engagement in research planning and reduced extension services (Birnie *et al.*, 2002; Buhler *et al.*, 2002; BCPC, 2004). May enter farming state III, now commodity support diverted to farm environment enhancement (BCPC, 2004).	a) Short to long-term decline brought about by production focus and escalating inputs; e.g., Sudanese cotton (Eveleens, 1983). b) Long-term decline, possibly resulting from poor feedback mechanisms to agriculture in the presence of adequate monitoring, e.g., in the UK (BCPC, 2004). Extensive use of indicators derived from monitoring (Birnie *et al.*, 2002), and long-term farming-systems research (e.g., Young *et al.*, 2001) and models revealing underlying mechanisms of wildlife decline (Topping *et al.*, in press) and local extinction of beneficial invertebrates (Sherratt and Jepson, 1993; Halley *et al.*, 1996; Bilde and Topping, 2004). UK government indicator of sustainable development for agriculture is the trend in farmland bird decline. No indicator of production is included (UK Government, 2004)

Box 4d

Agro-ecosystem state	Attributes	Form of monitoring
III **Mitigation or compensation**	Intensively managed systems, with significant feedback to practices from monitoring of ecosystem services, and indicators of agro-ecosystem integrity. Inefficiencies and impacts on soil erosion and water quality, masked by mitigated practices which are implemented in response to elaborate environmental standards. Tax-payer-derived support for mitigation measures limits halo of impact beyond the system to within legal limits, although ecological impacts still occur. Knowledge widely dispersed among grower and R&D community, but R&D may be detached from ecologically based approaches, with limited access to feedback from monitoring. Researchers may be isolated from agriculture, and extension programmes may be declining or under threat.	As above, but availability or level of possible success of conservation measures on soil or ecological services, including pollination or wildlife, may permit these to become additional indicators. Access to data from multiple existing sources a vital consideration in being able to narrow the focus of the analysis. Flexibility and financial support may enable adjustments to management to mitigate risks posed by the GM crop.
Examples	Tropical rice systems that have adapted to reduced pesticide and IPM-based cropping regimes, exploiting ecological knowledge, fall within this category. Also, very large-scale and heterogeneous systems such as those in the United States of America, where agriculture and its impacts are embedded in a regulatory environment that employs many triggers to effectively prevent degradation of the system beyond unacceptable levels (e.g., FIFRA, the FQPA, the Endangered Species Act and the Clean Water Act). The United States of America also has an intact research and outreach infrastructure that is responsive and well connected to sources of stakeholder input. Local state of environment reports feed into national assessments, and there is a constant process whereby indicators are refined. Finally, production subsidies have now been replaced by conservation-based subsidies that will further distance US agro-ecosystems from their ultimate capacity to degrade. Arguably, there are lower risks associated with GM crop introduction in the United States of America than for other systems.	Environmental impact data from tropical rice have revealed contribution that complex food web structure makes to pest suppression where pesticides are withheld (e.g., Cohen *et al.*, 1994; Settle *et al.*, 1996; Heong and Schoenly, 1998). Intact food webs and aquatic community structure underlies long-term pest suppression and identifies functional groups that act as indicators of ecological integrity. Grower capacity in monitoring and experimentation has been developed within the Community IPM Programme (Pontius *et al.*, 2002). In the United States of America, in contrast, production-based and abiotic indicators (e.g., water quality), rather than ecological indicators, are employed nationally to guide policy and decision-making about agriculture (e.g., The Heinz Center, 2002). This is supplemented by widespread use of local indicators, based upon threatened and endangered species that interact with agriculture, e.g., Salmonidae in Oregon (Oregon Progress Board, 2000).

Box 4e

Agro-ecosystem state	Attributes	Form of monitoring
IV **Degraded or unharvestable**	System failure following transition from states I-III (with differing transition probabilities).	Too late for monitoring.
Examples	Erosion, salinization, comprehensive pest resistance, loss of soil productivity through nutrient depletion, loss of available irrigation sources, pollution of soil and water, isolation from key ecosystem services and colonization by exotic invasive species can all individually or in combination lead to local or large-scale loss of production.	

Box 4f

Agro-ecosystem state	Attributes	Form of monitoring
V **Advanced 'eco-agricultural' strategies**	Advanced, adaptive system, incorporating indigenous knowledge, and even new grower knowledge in western agriculture, but with access to facilitation via on-farm R&D. Access to financial support for transition, and already using some on-farm monitoring as a management tool. System built to be diverse and with low input. Variable impact of environmental standards and policies, and sustainability relies upon the intrinsic properties of the system and evolving grower knowledge.	Baseline data are essential, prior to release, to generate a knowledge-base from which indicator assemblage may be selected. Environmental state monitoring, with reference to natural system or a reference system, may be the most appropriate mode of monitoring, as in I. The focus of monitoring may address the ability to adapt the system to accommodate the GM crop, or new practice, given its intrinsic flexibility, adaptiveness, and probable resilience. The optimum indicator 'set' is yet to be established.
Examples	Upland shifting cultivation in Southeast Asia, where indigenous strategies for intensification are being built into regional research and implementation (Cairns and Garrity, 1999). Wheat, maize and sorghum-millet production in countries with extensive sustainable agriculture programmes, and in countries and commodities adopting participatory learning techniques and adaptive management (Roling and Wagemakers, 2000). Numerous specific examples in McNeeley and Scherr (2003) and Uphoff (2002).	Many examples but often in pockets with intensive systems, or in restoration programmes following system failure of degradation. Few examples of established monitoring, but a grower community focused on innovation, and with enhanced capacity to learn and adapt. Potential for specialized monitoring programme development in consultation with growers.

Conclusions

1. This paper argues, from basic principles and increasing precedent, that agricultural productivity and the environmental impacts of agriculture are most effectively managed using procedures that are based on sound ecological thinking.
2. It also argues that monitoring procedures for GM crops that are now a part of international protocols and post-market requirements should be developed, ultimately, to protect the productivity and ecological integrity of farming systems. This puts monitoring to its most effective use. Risk assessment procedures are still in a stage of development, and monitoring must compensate for deficiencies that will only be rectified through longer term and larger scale field experience in GM commodities.
   a. For example, in the most elaborate and institutionally experienced risk assessment system at present, in the United States of America, scientific advisory panels to the Environmental Protection Agency (EPA) have repeatedly outlined deficiencies in the design, conduct, analysis and interpretation of current risk assessment procedures for GM crops (e.g., EPA, 2002; 2004).
   b. The literature on risk assessment for invasive species also demonstrates that our ability to forecast which plant species will become invasive is excellent in retrospective assessment, but weak in prediction. Feedback from effective monitoring is an essential component for improving our ability to protect agricultural ecosystems, and systems beyond agriculture, from invasive species and potential new weeds.
3. The history of monitoring in agriculture tells us that even clearly adverse impacts of cropping practices are difficult to detect because of the inherent complexity and heterogeneity of farming systems. Monitoring programmes must be designed to take into account existing sources of heterogeneity and to explicitly incorporate measures of heterogeneity in the selection of indicators and in the design of sampling procedures (Noon, 2003).
4. Ecosystem-level indicators are relevant (e.g., MEA, 2004), as well as crop-specific indicators, and their relative contribution is dependent upon the particular farming-system context.
5. Long-term monitoring has made positive contributions to the retrospective analysis of trends associated with production and off-crop impacts in agriculture. It has been less effective in the mode of early warning of adverse impacts, where ecosystem-level measurements such as water quality, erosion and trends in crop productivity are easier to interpret in the short term.
6. Globally, farming systems differ significantly in the forms of monitoring that are required to protect them. This is because of differences in crops and cropping practices, differences in underlying ecological processes and climate, differences in the distribution of knowledge among growers and researchers, differences in the policy and regulatory environments and the degree of feedback to agricultural change and differences in the quality and availability of relevant monitoring data. Acceptance of these differences is critical to the proper allocation of monitoring regime, and further work is required to validate the designation of faming system types.
7. All monitoring programmes for GM crops should be designed in such a way that their potential value is clear, and in ways that will result ultimately in effective management. They should provide a clear and rigorous explanation for the selection of indicators, including a sampling design that meets the requirements for statistical power. Critically, there should be a clear connection between the results of monitoring and decision-making. Review of those countries where agricultural indicators based upon monitoring are formally incorporated within policy and decision-making frameworks provides a standard that other systems can use as an aid to developing their own procedures. One such example is the state of Oregon in the United States of America, where an Executive Order relating to sustainable practices establishes a policy environment for development of laws and regulations, and stakeholder input (including input from citizens) refines the indicators that are used by the legislature to examine trends, and state agencies to adjust their procedures (Oregon Progress Board, 2000; State of Oregon, 2004).

Notes

1. The term agro-ecosystem exists more as a concept than a reality, with a variety of usages (e.g., Smith and Hill, 1975; Loucks, 1977; Odum, 1984; Conway, 1985) similar in range to those applied to Tansley's (1935) original exposition of the ecosystem concept (Golley, 1993). These definitions vary in the degree to which they consider external inputs and exports from the system, the degree to which they define specific properties (e.g., a system that responds as a whole to perturbations) or specific elements within it (e.g., biodiversity, management intensity, energy balance, etc.) and the degree to which they see agriculture as part of a broad ecological continuum. For a helpful discussion see "*The Ecosystem Concept and Its Application to Agricultural Systems*" on the Internet at: http://www.dal.ca/~dp/reports/ecosystem.html (permission of the author, David Patriquin, Dalhousie University, Canada, is gratefully acknowledged). Recent global assessments (e.g., WRI, 2000; Wood *et al*., 2000) employed a practically derived definition of agro-ecosystem (areas with more than 30 percent of land in cropland or managed pasture), which is equivalent to 28 percent of the total global land area. This was modified from a definition by the International Geosphere-Biosphere Program (more than 40 percent of land area managed as above), which comprised 21 percent of the terrestrial surface. Based on national production data, the FAO estimates that 37 percent of global land use is for agricultural purposes. All three measures admit to underestimating the total extent of agriculture, particularly low intensity cultivation and urban agriculture. Dixon *et al*. (2001) defined farming systems (based upon resources, farm household activities and level of intensification as: "*A population of individual farm systems that have broadly similar resource bases, enterprise patterns, household livelihoods and constraints, and for which similar development strategies and interventions would be appropriate*".
2. There are no widely adopted definitions or currencies of measurement for agricultural health or integrity. Those definitions that do exist have economic, ecological and social dimensions (Haworth *et al*., 1998; Alcamo *et al*., 2003; Pimentel *et al*., 2000).

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APPENDIX I

Rational Design of Monitoring Programmes

Paul Jepson

Based on Noon (2003), Stork and Samways (1995) and Global Biodiversity Assessment (1995)

- **State programme goals** (i.e., the ultimate objective of the monitoring programme, expressed in terms that represent the values expressed by stakeholders affected by the introduction of the GM technology).
- **Identify barriers to achieving goals** (i.e., identify all the practices and the stressors that might affect the agro-ecosystem, identify the resources affected by each practice or stressor to provide a basis for identification of indicators, and summarize their characteristics (i.e., frequency, extent, magnitude and variability).
- **Develop a conceptual model for the system** (i.e., outline the interconnections between system components and the strength and direction of these links. Define normal levels of variation in system characteristics and define deviations from these levels that would be unacceptable. Outline the scales at which processes operate, and consider how the agro-ecosystem responds to practices or stressors that operate at different scales).
- **Identify possible indicators** (i.e., measurements that reflect agricultural and ecological processes and are sensitive to change across the range of release of the GM crop, and which provide information about the status of unmeasured resources. These indicators must be cost-effective to measure, and the appropriate temporal and spatial scales of measurement must be stated).
  - ***Guide to identifying possible animal or plant indicators (these rules can be adapted for abiotic indicators)***
    - *The dynamics of the indicator parallel those of the farming system, and relevant reference or control sites are available.*
    - *The taxonomy, ecological role (e.g., keystone?), sampling methods, life history and distribution of biological indicators must be understood.*
    - *The scale of population processes must be relevant to the scales addressed by the monitoring programme.*
    - *They must exhibit short-term but persistent responses to adverse changes in the agro-ecosystem.*
    - *They should exhibit high 'signal to noise ratios' for accurate and precise estimation.*
    - *The likelihood of detecting change in the magnitude of an indicator must be high.*
    - *Indicators should exhibit low natural variability, and an ability to separate change from natural variability.*
    - *Indicators should clearly exhibit relevance to a societal value, an explicitly stated concern expressed by stakeholders or a property of the agro-ecosystem that stakeholders value.*
- **Estimation of the status and trends in the indicator** (i.e., statistical power analysis, and analysis of the likelihood of type I *vs* type II errors). The necessary frequency and intensity of the sampling effort should be calculated.
- **Determine trigger values for management action** (i.e., determine the appropriate magnitude of the adverse effect size, based on appropriate levels of spatial and temporal variation in reference conditions. Consider if it is more appropriate to use a frequency distribution of indicator values, rather than a single value to express the characteristics of the effect.
- **Link the monitoring results to decision-making** (i.e., list possible interpretations of different indicator values, consider the likelihood of each occurring and the societal or stakeholder values associated with each interpretation).

2. Strategies and Tools for Developing Biodiversity and Non-target Monitoring Programmes

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Introduction

In the EU, according to Directive 2001/18, releases of genetically modified organisms (GMOs) into the environment – including both commercial releases and releases for research purposes – have to be monitored for the safety of human health and of the environment. A monitoring plan under the Directive 2001/18 (Annex VII) foresees case-specific monitoring and general surveillance. Case-specific monitoring aims to refute or confirm identified risks as identified in the required pre-release environmental risk assessment. General surveillance aims to detect unanticipated adverse effects and long-term cumulative effects that could not be detected during pre-release testing.

In contrast to existing environmental monitoring programmes typically invoked by documented damage (e.g., loss of biodiversity), the monitoring of GMOs in Europe is largely a precautionary measure. Since there is no large-scale GMO production in Europe yet, no documented damage has been reported so far. Therefore, the development of monitoring concepts, including indicators and parameters to be measured, has to rely on risk analyses and hazard scenarios. Currently, the risk assessment strategy for commercially available transgenic plants draws heavily on the ecotoxicity testing approach for pesticide registration. This approach relies on the use of a standard set of testing species to be used all over the world with the aim that the generated results are valid globally. The receiving environment is not taken into account. Aside of the fact that these conditions are not in compliance with the requirements of case-specific risk assessment under consideration of the receiving environment put forward in the Cartagena Protocol and the EU Directive, the results from such testing do not inform the development of the legally required monitoring systems (general and case-specific). Therefore, improved risk assessment concepts that support the design of monitoring programmes and exceed the ecotoxicity approach are necessary.

Any risk assessment of transgenic plants on biodiversity and non-target effects rises and falls with the selection of suitable testing organisms or ecological processes. For these functions or species, hazard scenarios are then developed that should be refuted or confirmed during the data collection step which finally allows to determine the actual risk. In the worst case, if the identified risk is too large, it will lead to a negative decision for registration. If the identified risk is judged to be negligible, no further post-release surveillance may be necessary. However, for any result in between these two options, post-release measures will be necessary either to (a) continue surveillance of the manifestation of these potential risks in the field, or (b) ensure the functioning of any executed risk mitigation measure. Ideally, the monitoring instruments should allow detecting any potential adverse effect early in its process of manifestation when the effect is still reversible.

Selection Procedure for Ecologically Meaningful Testing Species/Ecological Processes

A detailed selection procedure of testing species for risk assessment of transgenic plants has been developed within an international project by a group of scientists of a global IOBC working group[13] (Hilbeck and Andow 2004; 2006). This group of scientists has developed a multi-step species testing procedure that starts broadly with considering all known species relevant to selected important ecological functions identified for a given cropping system in the given receiving environment (Birch *et al.*, 2004; Hilbeck *et al.*, 2006). Based on a defined set of

[13] IOBC: International Organisation for Biological Control. The global WG on ‘Transgenic Organisms in Biocontrol and IPM’.

ecological ranking criteria, that extensive list of species is then stepwise narrowed down to a manageable and testable number of species. The first step is about selecting those species that have the largest temporal and spatial co-occurrence with the transgenic crop production area, are regularly present in significant numbers in the target crop and, most importantly, serve an important ecological function for the production of this crop (e.g., pollination or biocontrol). The second step of this procedure takes these selected species through a systematic exposure assessment procedure. In this process, all possible exposure routes to the transgenic plant and its transgene products (e.g., *Bt* toxins) or the corresponding cultural management measures (e.g., herbicide sprays) are identified, and its degree assessed. This step can be supported by applying a risk assessment tool originally developed for engineering technology risk assessment called 'fault-tree analysis'. This tool works by identifying possible causal chains of events starting with a pre-identified 'Top Event' (top down, e.g., combined effect of feeding on *Bt*-toxin in pollen and plant tissue on a selected species). The analysis further allows identifying gaps of knowledge that should be addressed through research. From this detailed exposure analysis, hazard scenarios can be developed and formulated as testable risk hypotheses that must be investigated in regulatory biosafety testing. With this procedure, the limited resources and available time for research can be allocated to those species that are at greatest identified risk and – if adversely affected – can induce severe consequences.

Information Gaps and Development of Monitoring Programmes

The comprehensive data compiled for the species selection procedure and the fault-tree supported exposure analyses also leads to identifying critical gaps of information and understanding. These can be ranked and differentiated into those that can be investigated in the laboratory, those that must be investigated in the field and those that cannot be investigated in short-term experiments but must be observed and followed up in long-term monitoring programmes upon release of the transgenic plant. Thus, this procedure and its compiled data basis can be used to develop research programmes as well as monitoring programmes. It informs the selection of possible indicator species or functions and the parameter to be measured as well as the identification of the potential receiving environments that should be included in the monitoring.

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3. Issues and Challenges in Monitoring GM Crop-Specific Traits

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Dealing with Uncertainties: The Role of (Environmental) Monitoring

It is recognized that any risk assessment of genetically modified plants (GMP) is only as good as our state of scientific knowledge at the time it was conducted. Pre-market biosafety studies can only address issues such as the potential adverse effects on non-target organisms for a limited number of species under limited environmental conditions. Thus, an additional concept called "monitoring" has been added to the EU legislation to address any remaining uncertainty.

Monitoring can be defined as the systematic measurement of variables and processes over time. It assumes that there are specific reasons to collect such data, e.g., to ensure that certain standards or conditions are being met or to examine potential changes with respect to certain baselines. Against this background, it is essential to identify the type of effects or variables to be monitored, an appropriate time period for measurements and, importantly, the tools and systems to measure them. Monitoring results, however, may lead to adjustments of certain parts of the original monitoring plan or they may be important in the development of further research (e.g., for plant gene flow consequences [Bartsch *et al*., 2003]).

Monitoring is not a substitute for biosafety research (Figure 1). The main task of biosafety research is to provide sufficient data for a solid risk assessment at the pre-market stage. However, even after placing a GMP on the market, specific biosafety research may still address cumulative long-term effects.

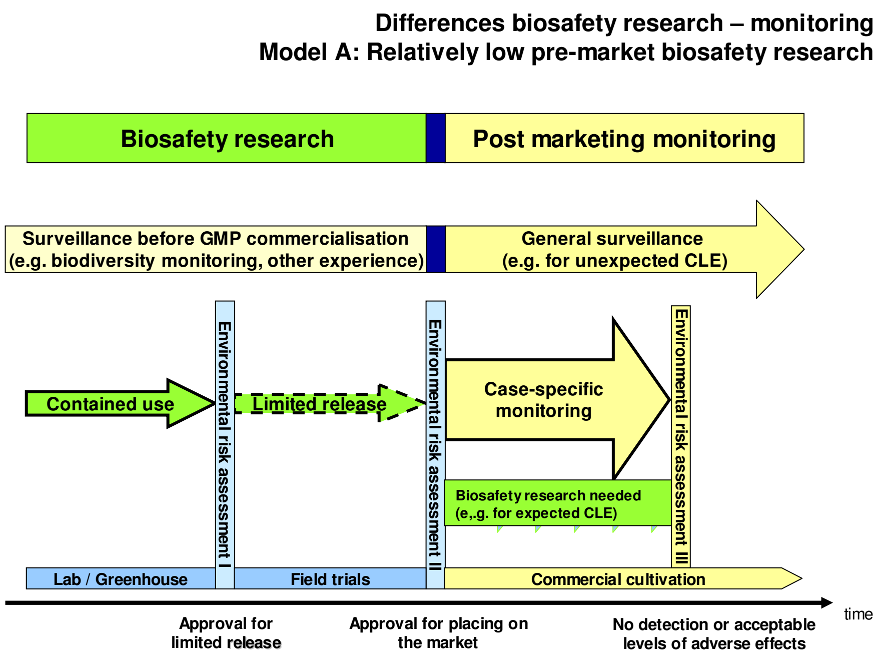

Figure 1: Relationship between biosafety research and post-market monitoring of GMP: CLE = Cumulative long-term effects. The size of the arrows reflects the amount of data available from biosafety research and the consequential monitoring requirement. In this model, few biosafety data at the Environmental Risk Assessment II would trigger a greater necessity for carrying out case-specific monitoring. However, even extensive case-specific monitoring should have a time limit, whereas General Surveillance should be conducted for a longer time period (Figure adapted from Sanvido *et al*., 2005).

Monitoring Framework – Foreseen and Unforeseen Effects

The concept of monitoring such as explained in the guidance document of the European Food Safety Authority (EFSA) should have two focuses: (1) the possible effects of the GMP, identified in the formal risk assessment procedure, and (2) identifying the occurrence of adverse unforeseen effects of the GMP or its use which had not been foreseen in the environmental risk assessment (EFSA, 2004; 2006). Where there is scientific evidence of a potential adverse effect linked to the genetic modification, then case-specific monitoring should be carried out after placing the GMP on the market in order to confirm the assumptions of the environmental risk assessment. Consequently, case-specific monitoring is not obligatory and is only required to verify the risk assessment, whereas a General Surveillance plan – as explained below – must be part of any application for placing GMP on the EU market. Companies that are proposing to have no case-specific monitoring are encouraged to provide arguments in support of this position. These arguments should relate to the assumptions that companies have made in the environmental risk assessment, as well as to the lack of any identified adverse effects in previous tests. An increasing amount of biosafety data provided by companies or public research institutions will decrease the monitoring intensity, but can not substitute the need for monitoring in general.

EU documents (e.g., EC, 2002) explicitly suggest that General Surveillance should include long-term monitoring, to allow for unforeseen effects that may occur after longer periods of environmental exposure. Changes in the management and cultivation techniques of new GM crops may affect the environment, e.g., through changes in agrochemical usage. The impacts of any such indirect effects, such as the changes in the cultivation methods, should be addressed by the monitoring plan based on the outcome of the environmental risk assessment. The environmental monitoring plan should describe in detail the monitoring strategy, methodology, analysis, reporting and review. In this respect:

(a) GM plant-based parameters will depend on the particular GM plant, trait and environment combination. Key parameters to be observed may refer to species/ecosystem biodiversity, soil functions, sustainable agriculture or plant health. Parameters should be measurable, appropriate, adequate in terms of statistical power and comparable with existing baseline data.
(b) Background and baseline environmental data, e.g., soil parameters, climatic conditions, general crop management data such as fertilizers, crop protection, crop rotations and previous crop history, should be collected to permit the assessment of the relevant parameters listed under (a).

Case-Specific Monitoring

The main objective of case-specific monitoring is to determine the significance of any adverse effect identified in the risk assessment. The scientific approach should be designed in order to test the specific hypothesis of expected adverse effects derived from the environmental risk assessment. The monitoring programme design should also reflect the levels of exposure in different geographical regions and GMP trait-specific influences (e.g., for *Bt* maize and Lepidoptera: Schmitz *et al.*, 2003). Such monitoring may be carried out at a limited number of sites (“local monitoring”), where exposure is greatest and intensive recording and data collection can take place. This would be particularly appropriate when it is envisaged that there would be a phased or gradual introduction of a GM crop into a limited number of regions. The scale of the monitoring should be increased as the area and range of the GM crop expands, and the crop is grown in more regions. The monitoring should consist of the systematic recording of relevant parameters at representative locations where there is significant and repeated growing of the GM crop. This might also be defined according to the extent of the cultivation of the GM crop, the occurrence of targeted pest species or particular climatic/eco-regions. The methods selected, the duration of the monitoring, the extent or number of areas and the parameters to be monitored should be determined on a case-by-case basis. Whilst the planning and execution of case-specific monitoring is strongly connected to the companies' responsibility, it may be appropriate to involve public institutions in contributing to the monitoring.

Focus of General Surveillance on Conservation Goals

General Surveillance should be adequate for monitoring any GM crop grown in any environment since it is not based on the risk assessment, but from a desire to observe unforeseen effects in the environments in which it is grown. Thus, there should be no principal differences between General Surveillance of similar crops grown in rotations. General Surveillance should not be experimental, should be largely based on routine observations and should be conducted over a wider range of sites and environments with a range of parameters observed at a low intensity. General Surveillance will record whether shifts in the distributions or variability of monitored characters occur and whether these shifts are related to exposure to, or presence of, GM plants. General Surveillance will tend to focus on areas of highest exposure to the GM plant without having any specific hypotheses on which components of an ecosystem may be adversely affected. By contrast, to prove a hypothesis would require detailed studies of a selected range of environmental indicators in order to fulfil basic requirements (Legg and Nagy, 2006). This would be a disproportionate approach for General Surveillance and might still miss an unanticipated adverse effect on a non-selected organism in the environment. A primary focus of monitoring should be sustainable agriculture as a substantial conservation goal. If unusual observations are reported, more focussed in-depth studies can be carried out in improved case-specific monitoring plans. Existing surveillance systems should be used where practical, e.g., routine farm recording systems, and any ”abnormal” effects not usually occurring in similar situations with conventional cropping should be recorded. However, direct comparison with non-GM crop reference areas is not always necessary. Reference can be made to the historical knowledge and experiences of the ”observer” (e.g., farmers, inspectors, botanical surveyors) in relation to the situation prior to the introduction of the GM plant.

Monitoring for unforeseen effects is potentially limitless in selecting all kinds of environmental parameters. It is inherently difficult, in fact principally impossible, to give *a priori* answers to questions like: “What, where and when will the unforeseen be?” Some of these aspects are discussed in more detail for gene flow and introgression of transgenic DNA from crops to wild relatives by Den Nijs and Bartsch (2004). A way forward is to link monitoring with environmental conservation goals and thus to environmental damage as defined in legislation, e.g., the new EU Directive on environmental liability (EU, 2004). In this Directive, (environmental) ‘damage’ is defined as “a measurable adverse change in a natural resource or measurable impairment of a natural resource service which may occur directly or indirectly” and which is caused by any of the activities covered by this Directive, including GMP. Environmental damage means effects on:

- **Protected species and natural habitats**, which is any damage that has significant adverse effects on reaching or maintaining the favourable conservation status of such habitats or species. The significance of such effects is to be assessed with reference to the baseline condition, taking account specific criteria listed in Annex I of the Directive.
- **Water**, which is any damage that significantly adversely affects the ecological, chemical and/or quantitative status and/or ecological potential.
- **Land**, which is any land contamination that creates a significant risk of adversely affecting human health as a result of the direct or indirect introduction, in, on or under land, of substances, preparations, organisms or micro-organisms.

The significance of any damage has to be assessed by reference to the conservation status at the time of the damage, the services provided by the amenities they produce and their capacity for natural regeneration. Significant adverse changes to the baseline condition should be determined by means of measurable data for which the Directive provides some more details. However, significant damage does not mean:

- negative variations that are smaller than natural fluctuations regarded as normal for the species or habitat in question;
- negative variations due to natural causes or resulting from intervention relating to the normal management of sites, as defined in habitat records or target documents or as carried on previously by owners or operators; or
- damage to species or habitats for which it is established that they will recover, within a short time and without intervention, either to the baseline condition or to a condition which leads, solely by virtue of the dynamics of the species or habitat, to a condition deemed equivalent or superior to the baseline condition.

Environmental protection goals would be a pragmatic starting point for focusing the General Surveillance. A number of intensively managed agro-ecosystems are neither 'natural habitats' nor do they harbour 'protected' species as defined in environmental legislation. Thus, General Surveillance might be better focussed on more valuable ecosystems.

Existing Surveillance Systems

Any monitoring plan should define the infrastructures that will be established or exploited in order to conduct General Surveillance of regions where the GM plant is grown. The monitoring plan should describe how to evaluate and select existing surveillance systems which are already monitoring one or more of the relevant parameters/elements. Further, the plan should describe how arrangements for collecting, collating and analysing data will be made. Where possible and cost-effective, additional environmental surveys should be conducted to contribute to the General Surveillance (for example, surveys of public institutions and farmer associations) in selected regions.

New Surveillance Systems

Useful information can directly be obtained from growers and seed suppliers of GM crops, e.g., by collecting data on seed sales, areas sown, crop management, etc. Companies should also be pro-active in developing reporting systems so that farmers (or their agents and advisors) intending to purchase genetically modified seeds will be involved in reporting adverse occurrences during and after the cultivation of the GM crop (Wilhelm *et al*., 2003). Reports on adverse effects can be collated via specific forms or by online reporting systems (e.g., farmer questionnaires). If unusual observations are reported, more focused in-depth studies can be carried out to determine cause and effect. Final decisions whether any identified effect is significant can only be made if causality is clear and endpoints are determined. These reporting systems will also allow the companies to check if farmers comply with the recommendations made (e.g., obligations related to an insect resistance management plan or recommendations related to stewardship plans).

Reporting and Interpretation the Results of Monitoring

Following the placing on the market of a GMP, there should be an obligation that monitoring and reporting are carried out according to specified conditions, and also companies should have a certain responsibility to submit monitoring reports to information points, e.g., a specific 'data office'. These information points are crucial for the success of any monitoring effort.

Reports, allowing for case-specific adaptations, should preferably be submitted as follows:

- annually, confirming that monitoring has been carried out according to the given consent together with a summary of major preliminary results that are important for a short-term feedback on the environmental risk assessment ('annual reports'); and
- periodically (e.g., every third year), covering longer periods in which observations and data collected are reported and analysed in detail and which therefore provide more comprehensive reports that are important for a longer term feedback on the environmental risk assessment ('comprehensive report').

A comprehensive monitoring report should include in more detail the results of any relevant monitoring by third parties, including the farmers/growers, seed companies and independent local, regional and national environmental surveyors. In addition, a responsible data office or applicant should evaluate these results and incorporate full analysis and conclusions in the submitted monitoring report. If appropriate, any responsible institution performing the monitoring should provide access to raw data for stimulating scientific exchange and cooperation.

Feedback of Monitoring Results to the Risk Assessment

The scientific knowledge and experiences gained from monitoring GM crops on a larger scale will also inform the risk assessment process. Thus, the results of monitoring are opportunities to continually update risk assessment in the light of any new knowledge. The ultimate goal of the environmental monitoring should be to determine whether the data collected during case specific monitoring and General Surveillance identify specific effects due to commercialization of the GM plant which alter the balance between the advantages of the introduction and any negative consequences, in both managed and natural environments, compared with current farming practices or other alternatives.

Outlook – Particularly on Cost Effectiveness

As to the nature of GMP, none should be marketed if there is an unacceptable risk of causing irrevocable harm. If potential risks have been identified during the risk assessment, there is a need for hypothesis-based, case-specific monitoring. Contrary, per definition in EU legislation, General Surveillance is to be applied when no specific risks have been identified in the risk assessment. Monitoring for unforeseen effects is potentially limitless in selecting all kinds of environmental parameters. Effort-benefit considerations are substantial for applicants and insofar cost-effectiveness is a substantial condition for General Surveillance. Costs have to be considered in regard of the information quality and richness that may be gained by monitoring data.

The precautionary principle promoted by the EU on a much broader level is, *inter alia*, based on the principle of non-discrimination (EC, 2000). Therefore, the decision on placing a GMP on the market has to be seen in relation to what is accepted for non-GM crops. This will consequently limit the efforts that have to be taken on behalf of GMP. Especially in case of General Surveillance – as being substantially a risk management tool – this means that an unlimited monitoring regime can not be the scope of any legislation.

Monitoring is both a novel and a contentious requirement of current regulations and is open to interpretation in many different ways (Bartsch and Schmitz, 2002). Scientifically robust data can be generated if resources are not limited. However, the companies as applicants have to bear much of the costs of monitoring so that costs should be proportional to the potential value of the new crop variety and the consequences of any adverse environmental impact (Figure 2). Striking the correct balance between sound science and practical reality will not be an easy task but is needed so that an unreasonable burden of evidence is not placed on companies or public sector applicants. It will be important to strike the correct balance between what is scientifically desirable and practically acceptable in terms of cost and other resources. There is the danger that overloaded monitoring plans can not be managed by public institutions, small and medium companies, and also big companies may hesitate to accept expensive monitoring plans.

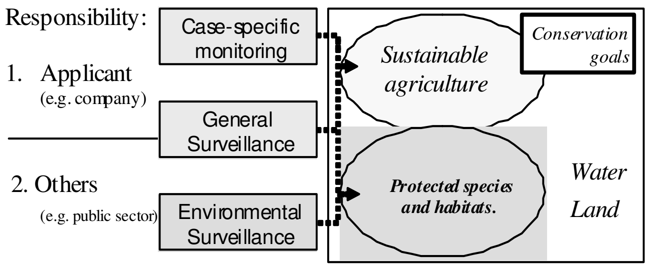

Figure 2: Responsibility, monitoring approaches and conservation goals. According to EU legislation, applicants are responsible for the establishment of monitoring plans covering case-specific and general surveillance aspects. Other parties may be integrated into the General Surveillance. Existing environmental surveillance networks are managed by third parties, and should be exploited for their usefulness to supplement monitoring.

Monitoring seeks to address both foreseen and unforeseen impacts of GMP. In this respect, legal definitions of damage in respect to hazard, especially environmental damage, will help to focus any regulation, research, and monitoring attempts to practicability and transparency.

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4. Farm-Scale Evaluations of Genetically Modified Crops: Lessons for Monitoring

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Introduction

The Farm-Scale Evaluations (FSEs) of genetically modified herbicide-tolerant (GMHT) crops were one of the largest ecological experiments ever undertaken. They sought to quantify the effects of GMHT crops on biodiversity by contrasting a range of biodiversity indicators on land managed with GMHT maize, beet and oilseed rape compared with land managed with conventional varieties of the same crops (Firbank *et al.*, 1999). They were intended to help assess one of the risks of GMHT cropping to the environment, and were never intended to act as a monitoring programme. Nevertheless, the experiment is large in scale, and emphasised the repeated recording of a range of indicators of biodiversity, production and land management, giving it elements of possible post-release monitoring programmes. In this paper, the FSEs in the context of possible lessons for the design for post-release monitoring are discussed.

The Design of the FSE

In 1998, several GMHT crops had passed the major regulatory hurdles and the commercial release looked likely; in fact, one of the crops, GMHT maize, had been approved for commercial use. However, concerns were expressed by England's statutory nature conservation agency, English Nature, (among others) that a major environmental risk had not been accounted for in these risk assessments. This risk was not a direct consequence of the method of breeding the varieties; rather, it arose from the effects of the herbicides that would be used with the varieties. In particular, the concern was that the herbicide would be so efficient that certain weeds would decline at a faster rate, reducing the food supply to certain farmland birds. This issue was taken seriously by the regulators, because the populations of these birds were being used as a headline indicator of the UK Quality of Life, and their conservation was a high-level target within the UK Biodiversity Action Plan, itself contributing to the Convention of Biological Diversity. These obligations and the very high public interest in environmental effects of agriculture at the time (Krebs *et al.*, 1999), legitimised the need for a detailed study of these issues. The FSEs were announced in the autumn of 1998, along with a voluntary moratorium for the companies involved not to undertake commercial growing until the FSEs had been completed (Firbank *et al.*, 2003a).

The conceptual model underlying the FSEs arose directly from these concerns, that differences in the herbicide regimes would give rise to differences in the weed populations in ways that may have implications higher up the ecological food chain, including populations of farmland birds. The formal purpose of the FSEs was to test the null hypothesis that the commercial management of GMHT beet, spring and winter oilseed rape and maize does not affect the abundance and diversity of farmland biodiversity compared with the management of the comparable non-GMHT crops, and to estimate the magnitude and consider the implications of any differences that are found.

As these effects could be positive or negative, the test was two-tailed. It was recognized that effects higher up the food chain might be too diffuse to detect without very large-scale studies, so a set of indicators were established that would indicate levels of food resources, including weeds, field margin plants and a wide range of invertebrates. The purpose was to compare the crop management, and so farmers were given the same flexibility that they would have had under commercial conditions, recognizing that a large number of replicates would be needed to represent the range of growing conditions and farmer behaviour likely to be encountered should the crops be commercialized. To make the comparison, two field approaches were piloted. The use of paired fields, one sown with a GMHT crop and the other with a conventional variety of the same crop, turned out to be impractical. Instead, the treatments were applied to two halves of split fields. The replication was aimed at detecting differences in major biological variables of the order of 50 percent, giving rise to values of around 60–70 replicates per crop (Perry *et al.*, 2003). There was a wide range of indicators, often measured several times each season (Firbank *et al.*, 2003a). This is because the conceptual model needed to be challenged against field data, and there was no clear vision about the most efficient variables to record, and when to record them. The result was that the experiment was very large and costly compared with many field experiments, but was expected to provide knowledge that would be used to greatly streamline any similar evaluations in the future.

Critics and commentators recognized that the outcome of the evaluations was very sensitive to the choice of comparator, and so this became the most controversial element in the study design. Some argued that two varieties differing only in the transgene should have been used, keeping other factors constant, thereby excluding the crop management components of the system. Others argued that the comparison should be with a highly biodiverse agro-ecosystem, such as organic farming. The comparison with current conventional practice was enshrined in the null hypothesis, and so it was transparent, even if contested.

It was critical to develop systems that maintained the quality of the data collected within the FSE. A key element of this was to use independent journal editors and referees; the quality of the science was to be assured through the peer-review process.

The Findings of the FSEs

The findings of the FSEs have been published in two groups. The spring-sown crops – beet, maize and spring oilseed rape – were reported in 2003 (Champion *et al.*, 2003; Heard *et al.*, 2003a; 2003b; Brooks *et al.*, 2003; Haughton *et al.*, 2003; Roy *et al.*, 2003; Hawes *et al.*, 2003) (Figure 1), while the results of winter oilseed rape were published in 2005 (Bohan *et al.*, 2005). The results were reported as tests of the null hypothesis for major taxa and selected species, and then interpreted in the light of probable interactions between crop management and species. All of the findings could be interpreted in this way, without reference to the way in which the crop was bred: the best evidence of lack of direct GM effect was the absence of effect on herbivores of the crop itself. Prior to the FSE, it was suggested that the GM cropping would reduce biodiversity by killing a higher proportion of the weeds on which other species depend (Watkinson *et al.*, 2000). This turned out to be the case for beet, winter and spring oilseed rape. It was also suggested that GM cropping might benefit biodiversity in that the spraying may be delayed for long enough to increase in-field invertebrates (Strandberg *et al.*, 2005), or to encourage less prophylactic weed control (Firbank *et al.*, 1999); but there was no evidence of either effect. However, an increase in dicot weeds in GM maize crops was observed, because the herbicide regimes were less effective than current conventional cropping. One important point is that differences between crop types were, by and large, greater than differences between GM and conventional varieties of the same crop (Firbank *et al.*, 2003b).

These results demonstrated several important points about the indirect impacts of GM crops, namely, that they are:

- *Case specific*
  The FSEs tested a set of crops with the same trait, in the same agro-ecosystem, on the same set of biodiversity indicators. Yet the results varied among the crops. This was not simply due to more subtle differences in the trait, because maize and spring oilseed rape were both tolerant to the herbicide glyphosate, yet had very different outcomes.

- *The crop management drives the impacts*
  The main reason why maize and spring oilseed rape differed so much was because of important differences in the *conventional* crops; the comparators were different. Conventional spring oilseed rape is subject to a light herbicide load, while maize is often treated with powerful, persistent herbicides such as atrazine (Champion *et al.*, 2003).

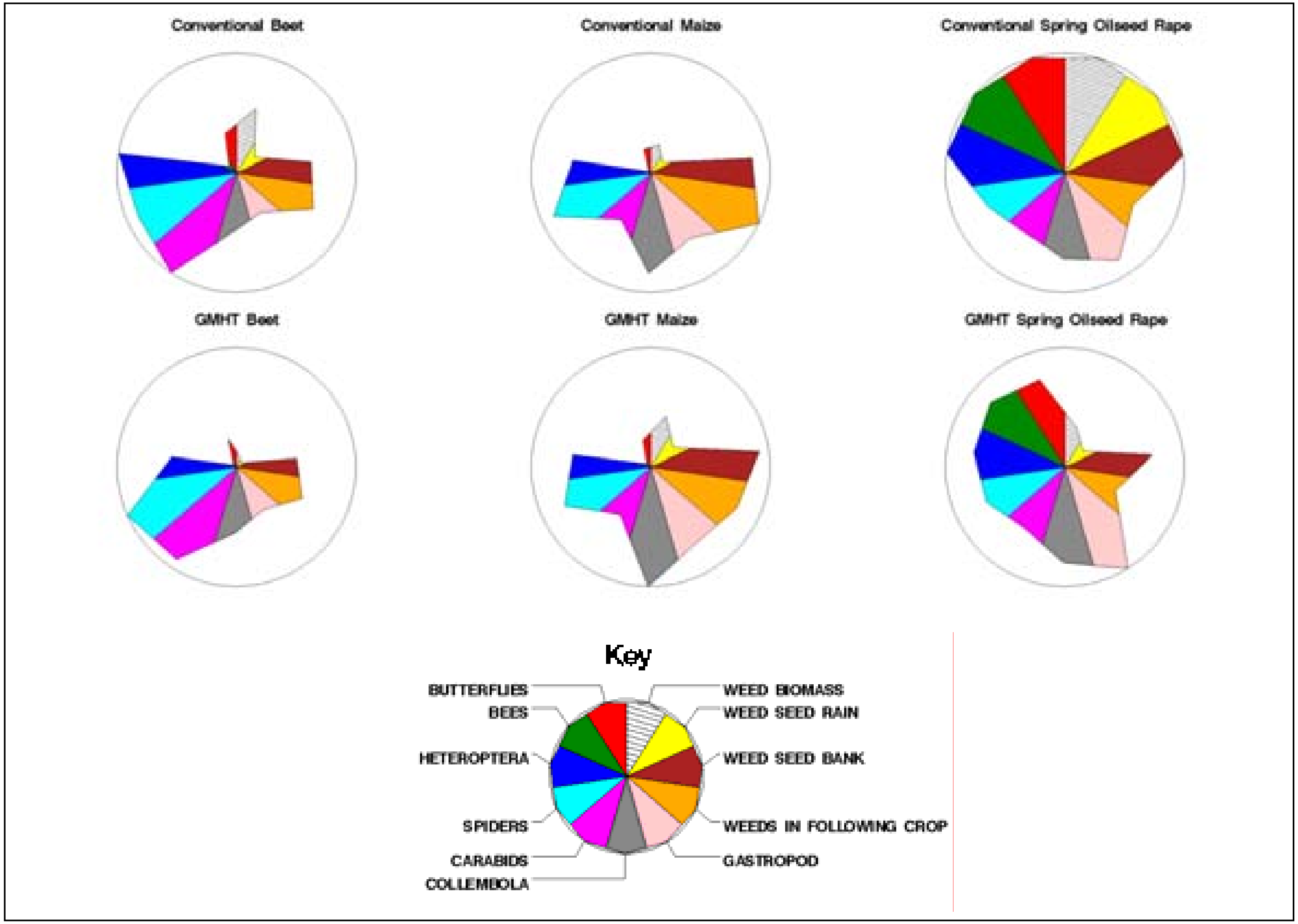

Figure 1: Star plots comparing mean values of major biodiversity indicators across conventional and GMHT treatments of beet, maize and spring oilseed rape crops. For each indicator, the length of the star corresponds to the value relative to the maximum value found in any of the six combinations of crop and treatment; for example, the most gastropods were found in GMHT spring oilseed rape. The key diagram shows which section of the star plots relates to which indicator. Reproduced from Firbank *et al*. (2003) by permission.

- *The outcomes are sensitive to variation in crop management*
  The analyses investigated a wide range of factors that affected the treatment effects. These included year of cultivation and geographic location. Surprisingly, none of these showed any interaction with the treatment effect. However, this was not true for differences in crop management (Perry *et al.*, 2004). This is not surprising, given that the mode of action of the GM crop was the result of differences in herbicide regime. Yet, even here, the differences in herbicide regimes tended to be rather small between farms.

- *Differences in biodiversity between GM and conventional varieties of the same crop may be less than the differences between different conventional crops*
  This result is important because it places the findings of the FSE in context. The differences observed between GMHT and conventional varieties were not simply statistically significant, they were also biologically significant, in that they seemed likely to be perpetuated from year to year. However, these differences were less than those observed between the conventional crops. The implication is that many changes in agriculture may give rise to differences of similar, or greater, magnitude. Data are still lacking on overall levels of variation within and between farming systems. Moreover, it is quite possible that historical introductions of other technologies (e.g., fertilizer, pesticide and winter cropping) might have been prevented had they been subjected to a similar test to the FSE.

The results of the FSE were subject to a range of external reviews; on the science base, on the management and on the wider implications of the study. In general, the FSEs were considered to have been an exemplary study of agro-ecosystems, and as a result of this and much additional work (especially on gene flow), the EU decided not to authorize the commercial cultivation of GMHT beet or oilseed rape. By contrast, this variety of GMHT maize was allowed, although it was withdrawn from the market by the company.

From Evaluations to Monitoring

The FSEs provided clear answers to the null hypothesis they were intended to address. The null hypothesis was, of course, limited, because important larger scale issues could not be fully dealt with, yet these issues must be considered when designing appropriate monitoring regimes.

Field scale and landscape scale impacts

The FSEs showed some effects on the observed numbers of butterflies that could be associated with differences in the number of flowering weeds at the margins of the crops. However, it was noted that larger scale importance of this result could not be readily determined, because butterflies depend upon the availability of alternative food sources in the landscape. If the farmed landscape as a whole is rich in sources of nectar and pollen, then butterfly populations would not be very sensitive to changes in the food supply at the margins of arable fields (Roy *et al.*, 2003).

The argument can be taken further. Perhaps any reductions in weeds that are important in the food chain can be mitigated by ensuring that increased numbers of the plants are allowed to grow, either within the field itself (May *et al.*, 2005) or on separate areas. After all, if the target for conservation has a home range large enough to cover areas of land larger than single fields, then as long as the food resources are available somewhere, the distribution of food among individual fields is less important. While models have been proposed to scale biodiversity impacts up to the landscape scale from the individual field levels (Watkinson *et al.*, 2000; Topping *et al.*, 2003), the uncertainties involved are very large (Firbank and Forcella, 2000).

The meaning of "harm"

The FSEs tested an ecological null hypothesis, which could be argued was value-neutral. However, the hypothesis was developed in the context that certain changes in biodiversity would be considered, in some sense, as being sufficiently harmful that the commercialization of the crops should be prevented – a context and an interpretation that are highly value-laden. Thus, the same species of weeds that are considered important food items for farmland birds in

Britain may be considered as undesirable alien plants in Australia. The implication is that the same *ecological* effects of GM cropping may have different policy outcomes if the goals for biodiversity conservation differ.

A most important issue is the balance between costs and benefits to biodiversity with costs and benefits for other goals from agriculture, including the protection of other natural resources, productivity, food quality, pesticide use and health of farmers. These balances are very sensitive to time and place; thus, in the mid-20th Century, policy makers gave greater value to increased food production than biodiversity conservation (Firbank, 2005), and so there would have been no relevance of an FSE-type study for decision-making.

The FSE null hypothesis was chosen in order to provide a tractable research question, it did not pre-judge the criteria to determine whether any ecological impacts were acceptable or otherwise. However, a monitoring exercise can only be designed effectively only if these criteria are decided in advance, in the context of overall costs and benefits of the new technology on a case-by-case basis.

Elements of a possible monitoring scheme

What might a monitoring system look like for the crops and treatment effects studied in the FSEs? The most relevant findings of the FSEs were that the effects on biodiversity were consistent with a conceptual model, based on impacts at the bottom of the ecological food chain, that the treatment effects were consistent from year to year and place to place and that they appeared to be sensitive to details of herbicide timing and regime.

The sensitivity of the effects to the herbicide regime means that the effects of commercial cultivation using different herbicide regimes cannot be predicted from the FSE results. Indeed, the advice to Government was that:

"Based on the evidence provided by the FSE results published in October 2003, if GMHT maize were to be grown and managed as in the FSEs, this would not result in adverse effects, as defined and assessed by criteria specified in Directive 2001/18/EC, compared with conventionally managed maize (ACRE, 2004)".

The implication is that checks on the herbicide regime should be a vital part of a monitoring programme. In principle, this should be easy in Great Britain, given that farmers are expected to retain detailed records of herbicide use and crop management. However, our experience from the FSEs suggests that such data can be very hard to acquire in a consistent and timely way.

Another vital element is the areas and locations used for cropping; a large treatment effect restricted to very small areas will obviously have a much smaller impact on national populations of farmland birds than a smaller effect distributed very widely. One could also imagine a monitoring programme that has specified biodiversity outputs that can be delivered either by within-crop decisions or by managing part of the land explicitly for biodiversity. This may be possible within agri-environment schemes in the UK (Carey *et al.*, 2003), but would be difficult to achieve within a crop monitoring programme.

The monitoring should establish whether the ecological change is that expected from the risk assessment. In the case of crops used within the FSEs, these changes were driven by changes in the weed community. Therefore, monitoring weed populations would be appropriate within a monitoring scheme, especially given that it could be undertaken by agronomists with little extra training.

It is more difficult to conceive surveillance programmes that would detect unforeseen effects. The difficulty is less the detection of ecological trends than ascribing those trends to specific causes of change, especially given that changes in land use and land management tend to be highly inter-correlated (e.g., Chamberlain *et al.*, 2000). Analyses of causes of change of populations of both birds and plants have used lengthy time spans of data (Siriwardena *et al.*, 1998; Smart *et al.*, 2003), and so are reactive, rather than pro-active.

Perhaps, therefore, the monitoring of these crops would involve four distinct components, each of which would require agreed trigger points for agreed action. Monitoring herbicide practice would be to ensure that the agreed practice was being maintained. Monitoring adoption is only needed if some form of national or regional quota had been established, perhaps through some form of scenario modelling (Topping *et al*., 2003). Data from weed monitoring would need to be collated and tested against forecasts developed from FSE data, with particular reference to checking the rates of decline of valuable species. Surveillance of unforeseen effects will need to consider isolated, anecdotal information if it is to be pro-active. Of course, other elements of environmental risk assessment, e.g., gene flow to wild relatives, will need additional monitoring protocols.

Lessons for Monitoring GM Crops

There are several practical lessons from the FSEs that are helpful in developing monitoring programmes; they include the importance of clearly defined institutional roles, data collection and training protocols, data management and dissemination procedures (Firbank *et al*., 2003a) and the establishment of appropriate sample strategies based on assessments of statistical power (Perry *et al*., 2003). However, the FSEs were never intended to act as a monitoring programme; instead, they were intended to provide detailed information about a particular kind of environmental impact prior to release of the crops. Any monitoring of crops following an FSE-type process simply needs to check that the effects continue to agree with the FSE findings, following the principle that “the deliberate release of GMOs is carried out in accordance with the conditions specified in the authorization for the placing on the market of a GMO” (EC, 2002). The risk assessment should guide the design of the monitoring programme.

Monitoring should be used to confirm an existing risk assessment, and not to generate a new risk assessment. However, there will rarely be data available of the quality of the FSEs, so there may be a case for more detailed assessments of sample crops immediately following commercialization to formalize some environmental risks. This could be considered to being equivalent to an FSE-type process, but where the GM produce could be sold commercially, prior to a less restrictive release.

But the most important lesson of the FSEs for monitoring GM crops is that the most contentious issues are those that focus on the framing of the question being asked. What is the basis for comparison? Why focus on one kind of risk, as opposed to a different one? How can costs and benefits among different interest groups be reconciled? Such questions are not the unique domain of scientists, statisticians and other experts, rather, a successful monitoring regime is one that grows out of a much more deliberative and participatory process, which grounds the monitoring in a wider context of social, economic and environmental costs, benefits and aspirations.

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5. Approaches and Challenges in Conducting Environmental Risk Assessment and Monitoring of GM Crops in New Zealand: A Regulatory Perspective

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Abstract

New Zealand has an active development and field test programme in genetically modified (GM) crops but no large-scale GM crops have ever been tested or commercially released in New Zealand. Currently, the release of GM crops in New Zealand is regulated by the Hazardous Substances and New Organisms (HSNO) Act. The HSNO Act has a wide scope of matters that must be taken into account during decision-making, including environmental, public health, cultural and economic effects. The HSNO legislation is “risk averse” with respect to environmental risk because an application to release a GM crop must be declined if it fails to meet the “minimum standards” that relate to the GM crop’s potential environmental effects. There are three types of application routes by which GM crops can be introduced to the environment: field test (contained), conditional release and full release. Controls requiring monitoring for environmental effects can only be imposed for field test or conditional release approvals. Experience in New Zealand has shown that appropriate scientific methods have not always been available for effective monitoring of environmental effects. Additionally, as a consequence of being a small nation, environmental research cannot always be carried out independently of the approval holder, and funding sources are limited for comprehensive long-term monitoring studies.

Introduction

New Zealand has had an active research programme in genetically modified crops and a voluntary regulatory system for genetically modified organisms (GMOs) since the late 1970s (for historical background, see Moeed, 1997). Over 50 small-scale field tests of GMOs have been conducted, but no large-scale GM crops have ever been tested or commercially released in New Zealand.

This paper discusses the legislative basis in New Zealand for environmental risk assessment and monitoring of GM crops as well as New Zealand’s experience in monitoring of GM crops in a field-test setting. The Environmental Risk Management Authority (ERMA New Zealand) has developed a set of principles to guide the implementation of monitoring programmes for GM field tests and conditional releases in New Zealand. However, post-release monitoring of GM crops is not considered to be a substitute for adequate pre-release risk assessment in New Zealand.

New Zealand Legislative Requirements for Monitoring GM Crops

A regime for regulating the field testing and release of GMOs in New Zealand has been in place since 1988. The Interim Assessment Group (IAG) for the Field Testing or Release of Genetically Modified Organisms was established by the Minister for the Environment under section 33 of the Environment Act 1986 as an interim measure (Ministry for the Environment, 1997). The IAG assessed GM field test and release applications and the Minister for the Environment (on the IAG recommendation) approved applications under a voluntary regime from August 1988 until 30 June 1997.

The Hazardous Substances and New Organisms (HSNO) Act 1996 established the legislative basis for the current New Zealand regulatory system for GMOs. The purpose of the Act is to protect the environment and the health and safety of New Zealand people and their communities by preventing or managing the adverse effects of hazardous substances and new organisms (including GMOs). To this end the Act has established ERMA New Zealand whose primary function is to decide whether hazardous substances and new organisms should be introduced to New Zealand and, if so, under what conditions.

The decision-making Authority of ERMA New Zealand is an independent statutory quasi-judicial body consisting of eight members with a range of expertise relevant to the HSNO Act and is appointed by the Minister for the Environment. The Authority of ERMA New Zealand is supported in carrying out its functions under the HSNO Act by an agency of approximately 100 staff.

In making its decisions, ERMA New Zealand is required to act in accordance with the Hazardous Substances and New Organisms (Methodology) Order 1998. The Methodology describes the assessment and evaluation of risks, costs and benefits, particularly in the face of uncertainty (ERMA New Zealand, 1998).

The HSNO Act prescribes a wide scope of matters, not restricted to environmental considerations, that must be taken into account in decision-making; these include:

(a) the sustainability of all native and valued introduced flora and fauna;
(b) the intrinsic value of ecosystems;
(c) public health;
(d) the relationship of Māori[14] and their culture and traditions with their ancestral lands, water sites, waahi tapu[15] valued flora and fauna, and other taonga[16];
(e) the economic and related benefits and costs of using a particular hazardous substance or new organism; and
(f) New Zealand's international obligations.

The wide scope of matters statutorily required to be addressed in risk assessments and decision-making may affect the types of monitoring requirements imposed on field test or release approvals for GM crops. For example, monitoring regimes may be required to mitigate cultural or economic concerns.

However, the Act specifies an environmental bottom-line for releases of GMOs which are described in section 36 as the "minimum standards". These state that:

"The Authority [ERMA New Zealand] shall decline the application if the organism is likely to
(a) cause any significant displacement of any native species within its natural habitat; or
(b) cause any significant deterioration of natural habitats; or
(c) cause any significant adverse effects on human health and safety; or
(d) cause any significant adverse effect to New Zealand's inherent genetic diversity; or
(e) cause disease, be parasitic or become a vector for human, animal or plant disease unless the purpose of that importation or release is to import or release an organism to cause disease, be a parasite or a vector for disease."

These minimum standards imply that if it is likely that significant adverse effects on the environment (for example, through hybridization and introgression of a GM crop with its wild relative or via non-target effects on invertebrate fauna) will occur, the GM crop cannot be approved for release. The HSNO Act also requires a "precautionary approach" where "the need for caution in managing adverse effects" shall be taken into account "where there is scientific or technical uncertainty about those effects".

The HSNO Act provides three separate routes by which GM crops may be approved for planting in the New Zealand environment: field test (contained), conditional release and release without controls.

[14] New Zealand's indigenous people.
[15] Sacred sites or sites of spiritual significance to Māori.
[16] Things deemed to be of value to Māori.

Field tests of GMOs are considered to occur within containment because the organism and all of its heritable material (for crops, this includes pollen, seed and any regenerative plant tissues) must be contained at the site and removed or destroyed at the end of the field test. In addition, controls can be imposed to ensure that some or all of the genetic elements remaining from the organism are removed or destroyed[17]. The issue of genetic elements is relevant to another section of the Act that requires ERMA New Zealand to take into account in its decision-making "any effects resulting from the transfer of any genetic elements to other organisms in or around the site of the field test". The strict requirements for containment mean that no flowering or normal crop management can occur during the field testing of GM crops; however, limited environmental monitoring studies could be conducted.

Conditional release allows the release of a GM crop with controls or conditions imposed by ERMA New Zealand. There is a large degree of discretion in the types of controls that may be imposed and there is no inherent requirement to contain the GMO if there are no significant risks to manage. Consequently, a large range of activities could be conducted under the category of conditional release, such as farm-scale trials of GM crops over multiple growing seasons with pollen/seed dispersal through to commercial release of a GM crop with crop management controls. Environmental monitoring studies potentially could be required as part of the controls on a conditional release approval. These studies could include detection of the spread of the organism or the incidence or adverse effects or measuring the effectiveness of the controls. It is intended that the timely monitoring of the effects of released GM crops could increase the ability to make changes, withdraw approval or take any other mitigatory actions deemed necessary.

The release of a GM crop can also be approved without controls as a "full release"; however, this provides no statutory option for requiring monitoring of environmental effects. All releases of GM crops must be declined if they fail the minimum standards in the HSNO Act. In the case of conditional release, controls can be imposed in order to allow the application to meet the minimum standards. All controls or conditions imposed on approvals given by ERMA New Zealand are enforced by Biosecurity New Zealand[18].

The assessment of all GM field test, conditional release and full release applications is a public and transparent process. These types of applications must be publicly notified and any member of the public can request a copy of the application "ERMA New Zealand's Evaluation and Review (E & R) Report" and can make a submission on the application. A public hearing is usually held and submitters who wish to be heard can present evidence at the hearing. ERMA New Zealand's decision is also publicly notified within 30 working days following the hearing.

New Zealand Experience

New Zealand is a small, island nation with a population of approximately 4 million people. The economy has a strong reliance on agriculture, specifically meat, dairy, horticulture and forestry produce. There has never been a full release or conditional release of a GMO in New Zealand although New Zealand has been used in the past by overseas companies for counter-season production of seed for GM varieties of canola and maize, which took place under field test approval from the IAG.

There are a number of reasons why GM crops have not been released to date. A statutory moratorium on GMO releases was in place from 29 October 2001 until 29 October 2003 while the *Report of the Royal Commission on Genetic Modification* (Royal Commission on Genetic Modification, 2002) was considered. This was preceded by a voluntary moratorium[19] on GM field tests and releases between 2000 and 2001. These two moratoriums have prevented the release and/or field testing of GM crops in New Zealand between 2000 and 2003.

[17] "Destroyed" includes leaving genetic elements to break down or become inactive at the site of the field test.
[18] Formerly known as MAF (Ministry of Agriculture and Forestry) Biosecurity Authority.
[19] The voluntary moratorium was an industry response in New Zealand to allow the Royal Commission Inquiry on Genetic Modification to be completed (Royal Commission on Genetic Modification, 2002).

Another reason for the lack of applications for GM crop releases is that the main GM crops released in other countries – soybean, cotton and canola – are not important crops grown in New Zealand. In addition, there are not the same pest pressures in maize production in New Zealand as experienced by North American and European growers.

Even though no GM crops have been released, New Zealand has an active research programme in the development of transgenic cattle, potatoes, onions and pine trees. The majority of field tests of GM crops are being performed by Crown Research Institutes (CRIs)[20] which are predominantly funded by the government, and there is very little activity from multinational corporations or large commercial operations. However, New Zealand has some experience in implementing monitoring programmes for GM field tests.

In the past, controls requiring monitoring of GM field test sites have been imposed to ensure that the GM crop and its heritable material are contained within the site and removed or destroyed at the end of the field test. An example is post-harvest monitoring of the site for volunteer tubers of a GM potato field test (ERMA New Zealand approval GMF98007[21]).

GM potatoes

A number of field test approvals have also required studies of potential adverse environmental effects. For example, approval GMF98007 required monitoring for non-target effects on soil organisms from anti-microbial peptides, cecropin and magainin, produced by the transgenic potatoes:

> "The applicant shall monitor in the buffer zone for the potential for the peptides magainin [II] and cecropin B to move from the containment location and their effect on soil organisms. To achieve this, the applicant shall prepare and implement a sampling and analysis programme that shall specify what samples will be obtained (e.g., soil, biota and/or moisture samples); where the samples will be collected (location and depth), the sensitivity of the analytical methods (e.g., at least half the inhibitory concentration, IC50, for the most sensitive soil organisms). The applicant shall also prepare and implement a programme to determine the effects these peptides have on soil organisms. This programme will include the identification of appropriate sentinel species, and the methods to determine the effects of the peptides on these organisms. These programmes should be submitted to ERMA New Zealand prior to implementation." (Control 24.)

In order to comply with this control, a method for detecting the magainin II or cecropin B peptides was required and which had not been established at the time of the application. At that time, there were no commercially available reagents (such as antibodies) able to detect cecropin B or magainin II peptides produced by the GM potatoes. Antibodies were eventually developed that were able to detect transgenic magainin II within foliage from the GM potatoes (Barrell, 2001), but the assay did not have significant sensitivity to meet the aims of this monitoring control.

The implementation of this control highlights a number of issues associated with mandating particular monitoring studies when no experimental methods to do this exist and no data from laboratory studies indicate that such studies would be feasible. In hindsight, it was unlikely that this control could be effectively implemented in the limited timeframe of a five-year field test as there were a number of knowledge gaps that needed to be addressed before implementing such a monitoring programme; for example, information on the stability or degradation of these peptides in the soil, information on soil flora and fauna in New Zealand agro-ecosystems, identification of relevant ecological indicators and sentinel species and the development of experimental methods with sufficient statistical power to yield meaningful results.

Our experience demonstrates that any control requiring monitoring for adverse effects should be based on validated experimental techniques which already exist. If experimental techniques are

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[20] CRIs are fully government-owned research companies.

[21] *ERMA New Zealand Approval for Application GMF98007*- To field test, in the Canterbury region over 5 years, potato cultivars genetically modified for increased resistance to bacterial soft rots, to evaluate resistance and yield performance of individual lines (http://www.ermanz.govt.nz/appfiles/execsumm/pdf/GMF98007-003.pdf)

yet to be developed, then the ability of the applicant to comply with requirements should be considered carefully in setting expectations and timeframes.

Horizontal gene transfer

As discussed previously, the HSNO Act requires ERMA New Zealand to take into account in its decision-making “any effects resulting from the transfer of any genetic elements to other organisms in or around the site of the field test”. ERMA New Zealand has taken the opportunity to seek information on the potential for horizontal gene transfer to occur in the context of a GM field test. However, this environmental monitoring information has often been encouraged by informal means rather than explicitly in the controls for an approval. For example, in ERMA New Zealand’s decision for GMF99005[22] (GM pine and spruce field test), they state:

> “The Committee considers that this field test provides an opportunity to conduct further research on the long-term effects of genetically modified trees on soil micro-organisms. The applicant provided evidence at the hearing that [the applicant] intends to conduct research on horizontal gene transfer, either themselves or in collaboration with other research institutes.”

Given the limitations of current methodologies for detecting horizontal gene transfer (HGT) events (Nielsen and Townsend, 2004), we have found informal encouragement of environmental studies to be a more feasible option then imposing prescriptive controls on approvals.

Principles of Monitoring Programmes for GM Crops

ERMA New Zealand has set out its principles for monitoring of field tests and conditional releases in the ERMA New Zealand (2004) Policy Series: “Policy documents relating to New Organisms”. Key components of this policy are that assessments of applications are on a case-by-case basis and that monitoring proposals should be assessed for their technical feasibility and cost-effectiveness. Ultimately, a monitoring programme should be implemented in order to detect a defined effect.

Aspects of technical feasibility include whether meaningful results could be generated as well as the availability of an appropriate scientific method. It is useful if monitoring programmes state the amount of change over a defined time scale in an indicator that would trigger concern and/or action. Often this may require the development of new experimental methods with sufficient statistical power to yield the required result. Our experience with GM potatoes illustrates the importance of designing monitoring programmes with appropriate experimental techniques that already exist to the ability to implement such a programme.

Aspects of cost effectiveness that are considered include whether other experiments (not associated with the particular application) would be more cost effective in providing the same information and the extent to which information generated will be useful in allaying concerns over related issues. The extent to which implementing a monitoring programme will help allay concerns will depend on the extent to which stakeholders are actively engaged in the process.

The actual cost of the work is an issue because in New Zealand there are limited funding sources available to scientists for long-term environmental monitoring research. This is particularly significant considering that the majority of GM crop research and field testing is being performed by CRIs or public universities whose predominant source of funding is the government.

A constraint on environmental monitoring programmes for GM crops is that the research can not always be carried out independently of the institution performing the research because of the lack of available expertise and research funds in a small local scientific community. However,

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[22] *ERMA New Zealand Approval for Application GMF99005* - To field test, in the Bay of Plenty (Rotorua), over a period of 10 years, *Pinus radiata* and *Picea abies* plants genetically engineered in herbicide resistance. The total duration of this project is 11 years. (http://www.ermanz.govt.nz/appfiles/execsumm/pdf/GMF99005-002.pdf)

any monitoring work is expected to be subject to independent peer review. Another constraint is the need for long-term control of land management of a site where GM crops have been cultivated in order to obtain long-term environmental data. In many cases, control of land, particularly surrounding a field test site, cannot always be guaranteed for the duration of the field test and beyond the end of the test.

Despite these constraints, a number of studies are currently being conducted into the potential environmental impacts of GM crops in New Zealand. These studies include horizontal gene transfer in the New Zealand environment, assessment of invasiveness of GM crops, non-target impacts of insect-resistant GM crops on non-target insects and soil biota and selection of non-target invertebrate species for testing the biosafety of GM crops. Many of these studies are aimed at collecting baseline environmental data (including data on native biodiversity) in the absence of a GM release and designing methodologies and selecting ecological indicators that are applicable to New Zealand environmental conditions.

Conclusion

As discussed in this paper, the implementation of environmental monitoring for impacts of GM crops may be by formal means (mandated controls) or by informal means. This distinction is guided by legal considerations because the Authority will not mandate controls which are not enforceable under the HSNO Act. A key issue for regulators is that they should ensure any monitoring requirements set forth are feasible in terms of cost, manpower, expertise, scientific methods and relevance of data generated to addressing concerns expressed by stakeholders in relation to the state of existing knowledge and research capability.

In New Zealand, our regulatory system recognises that post-release monitoring of GM crops is not a substitute for the adequate pre-release risk assessment of novel organisms.

Statement

The views expressed in this paper are the author's own, and not those of ERMA New Zealand or the Food and Agriculture Organization of the United Nations (FAO).

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6. Monitoring Genetically Modified Crops in Canada

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Abstract

Genetically modified (GM) crops are grown on 6 million hectares annually in Canada; with 80 percent of this area being GM canola (*Brassica napus* L.). Despite their rapid adoption over the last decade, and the significant potential benefits that may be realized in the future, much controversy surrounds GM crops. One of the biggest and most difficult issues to evaluate is the potential effects of GM crops on the environment. This paper outlines several studies that deal with the potential environmental impacts of GM crop production in Canada.

Introduction

Genetically modified (GM) crops continue to be adopted by farmers around the world and are now grown on over 90 million hectares annually. Farmers choose to grow GM crops to reduce input costs, improve pest and weed control, increase crop yield and, most importantly, to increase farm profitability.

GM crops are grown on approximately 6 million hectares annually in Canada. Herbicide-resistant canola (*Brassica napus* L.) accounts for 80 percent of this area with the remaining crops being Roundup Ready (RR) soybean (*Glycine max* [L.] Merr.), RR maize (*Zea mays* L.), Liberty Link (LL) maize, and *Bt* maize. *Bt* potato (*Solanum tuberosum* L.) was produced for a few years before marketing concerns led to its discontinuation.

Herbicide-resistant canola was introduced into Canada in 1996 and farmers rapidly adopted the technology. RR canola and LL canola now occupy 55 and 28 percent of the total canola area, respectively. Canadian farmers chose GM canola because it offered markedly better weed control at similar or lower costs and the post-emergence herbicides (glyphosate and glufosinate) utilized in these systems are a good fit in zero-tillage production systems. Of course, the biggest reason for adoption is that farmers are realizing greater profits from GM canola (Canola Council of Canada, 2001).

Improved pest management is the primary attribute of currently available GM crops, but GM crops potentially offer much more in the future. They may be more tolerant to salinity, drought, frost and acid soils, and consumers may directly benefit from crops that are more nutritious (Borlaug, 2000). Despite their rapid adoption over the last decade and the significant potential benefits that may be realized in the future, much controversy surrounds GM crops. The scientific community has an obligation to seriously consider these issues and address them in an unbiased manner. One of the biggest, and most difficult to evaluate, is the issue of the impact of GM crops on the environment (Dale, 2002).

Prior to commercial production, GM crops are subjected to considerable scientific evaluation. However, post-commercialization monitoring is considered to be prudent because some environmental impacts of GM crops are likely to be dependent on spatio-temporal scales (Pool and Esnaya, 2000). Some of the most pertinent environmental questions involve: (1) gene flow to wild relatives among cultivars of a crop or to soil micro-organisms; (2) effects on non-target organisms and overall biodiversity of cropping systems; (3) resistance development; and (4) shifts in pest populations over time.

Environmental Monitoring Studies in Canada

Since herbicide-resistant canola is the main GM crop in Canada, the majority of studies assessing potential environmental effects of GM crops revolve around canola. Gene flow from GM canola is one question that has been extensively examined. Canola is predominantly self-pollinated but can outcross. Under experimental conditions, interplant outcrossing rates ranged from 12 to 55 percent and averaged 30 percent (summarized in Beckie *et al*., 2003). Outcrossing varies greatly with separation distance between plants and is generally less than 1 percent at 100 m. However, outcrossing between canola has been detected at a very low frequency at distances as much as 800 m (Beckie *et al*., 2003).

Volunteer canola is routinely controlled in subsequent crops to prevent yield and quality losses. One surprise faced by Canadian farmers was that volunteer conventional canola (or LL canola) was not totally controlled with glyphosate used as a pre-seed herbicide in zero-tillage systems. This was determined to be due to gene flow from RR canola fields to neighbouring canola fields. Field surveys were implemented to determine the extent of this phenomenon. Results indicated that volunteer canola populations can include plants with various herbicide-resistant traits (single and multiple) in addition to conventional types. Volunteer canola plants with double and triple resistance traits (glyphosate, glufosinate and imidazolinone resistance) have been identified in farm fields (Hall *et al*., 2000).

Outcrossing among canola types also has implications in the canola seed industry. Friesen *et al*. (2003) collected seed from numerous pedigreed canola seed lots and examined them for purity. Of a total of 27 seed lots, 14 had contamination levels above 0.25 percent, thus failing the 99.75 percent cultivar purity guidelines for certified canola seed in Canada.

Another question that was addressed was the fitness of canola containing multiple herbicide-resistant traits as a measure of invasiveness. Simard *et al*. (2005) documented that there was no fitness difference between canola plants containing multiple herbicide-resistance traits compared with conventional canola. Herbicide-resistance transgenes do not enhance fitness unless plants are sprayed with the herbicide for which they have resistance genes. The fitness advantage conferred by herbicide resistance, whether to one or more herbicides, is thus limited to agroecosystems where herbicides are commonly used.

Potential gene flow from herbicide-resistant canola to weedy relatives is another important environmental question. Weed relatives of canola in Canada include birdsrape mustard (*Brassica rapa* L.), wild mustard (*Sinapis arvensis* L.), dog mustard (*Erucastrum gallicum* [Willd.] O.E. Schultz) and wild radish (*Raphanus raphanistrum* L.). Studies have shown that gene flow from canola to these weed species is a very rare event (Warwick *et al*., 2003). A field survey of wild radish populations found no hybrids in 17 202 and 4 912 seedlings from wild populations collected next to commercial canola fields in Quebec and Alberta, respectively (Warwick *et al*., 2003). In Ontario, one wild radish x canola hybrid in 32 821 seedlings was detected. The hybrid was almost male sterile, with 0.12 percent pollen viability, and did not produce seed when selfed. Overall, gene flow from canola to weedy relatives has been minimal in Canada.

As mentioned previously, farmers must control volunteer canola to protect succeeding crop yield. Control of volunteer RR canola in subsequent years is usually successfully accomplished using herbicides such as 2,4-D or bromoxynil. However, concerns exist over the number of years that control of volunteer RR canola may be required. Thus, a field study was conducted over four years at eight locations in Canada to determine the effect of various crop rotation and tillage systems on the emergence and seed bank persistence of RR canola. Rotations consisted of continuous cropping versus alternating crop and fallow years. Tillage consisted of low disturbance seeding (LDS) (zero tillage), high disturbance seeding (HDS) (no tillage before planting but utilizing sweeps on the seeding equipment) and conventional tillage (CT) (tillage the previous fall and immediately before planting spring crops).

Conventional tillage compared with LDS often encouraged earlier and greater emergence of RR canola plants the following spring. However, persistence over time increased slightly with tillage and may be related to secondary dormancy. Inclusion of fallow in the rotation did not decrease persistence compared with continuous cropping. The majority of volunteer RR canola emerged in the first year after canola production with only low densities present in the second year. No RR canola plants occurred in the third year after production. Soil seed bank data at the conclusion of the study indicated that only 0.1 percent viable RR canola seed was present three years after canola production. It was concluded that RR canola seed persistence does not pose any increased environmental risk compared with conventional canola seed.

A multi-faceted long-term (12 years or longer) field study was initiated in 2000 with the goal of determining the environmental impact of GM crop production in western Canada. The study objectives include assessing (1) population dynamics of weeds, diseases and insects (target and non-target species); (2) soil microbial diversity; (3) resistance development; (4) gene flow; and (5) crop yield and quality. This study includes only GM crops that have been approved for production in Canada; RR canola, LL canola, RR maize, LL maize, *Bt* maize and *Bt* potato. RR soybean was not included as it is not widely grown in western Canada due to the short growing season and *Bt* potato was dropped from the study in 2003 because it is no longer available. Scientists from Agriculture and Agri-Food Canada, Environment Canada, University of Guelph and University of Alberta are collaborating on this long-term study. Much data is being collected but only preliminary results are available at this time.

This paper is not meant to be an all-inclusive report of Canadian studies involved in monitoring GM crops for potential environmental impact. Rather, it outlines several environmental concerns surrounding GM canola (the main GM crop in Canada) and gives examples of field surveys and multi-year field studies conducted to assess those concerns. Additional studies are ongoing.

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7. Monitoring Environmental Effects of Genetically Modified Rice in China

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Abstract

The challenges of food security and rapid progress in transgenic biotechnology have significantly stimulated the development of genetically modified (GM) rice in China. Consequently, many GM rice varieties have been produced and some already entered production trials, which is the last step to commercialization. As GM rice will enter commercial production in the near future, it is urgently needed to develop methodologies for monitoring environmental effects of GM rice in China. Monitoring such effects from the commercialization of GM rice is challenging because of the complexity of such issue. This paper discusses the identification of potential environmental effects caused by insect- and herbicide-tolerant GM rice, particularly under the Chinese circumstances of rice farming at the small household scale. Environmental effects can be the impacts on non-target organisms and biodiversity, transgene flow and its related effects, development of resistance to insect-resistant transgenes and other indirect effects and influences on rice ecosystems by extensive cultivation of GM rice.

Introduction

Rice is one of the most important cereal crops in China, which covers a cultivation area of about 28.38 million hectares and contributes a total annual production of about 179 million tonnes, based on the statistics from the Chinese National Bureau of Statistics in 2004 (NBSC, 2005). Rice is also of very important cultural value for the Chinese and people from other Asian countries (Bellon *et al.*, 1998). It is one of the earliest crops that have been used in biotechnological studies and the first crop species for which the complete genome has been sequenced (IRGSP, 2005). All these have opened tremendous dimensions for rice genetic improvement to increase its yields and develop its agronomic characteristics. The severe challenges of food security and rapid progress in transgenic biotechnology have significantly stimulated the development of genetically modified (GM) rice in China (Lu and Snow, 2005). More than 60 Chinese institutions at the national and provincial levels have been involved in GM rice development or research (Lu, B.-R. unpublished data). Consequently, many GM rice varieties or lines have been produced, including those with increased yield (e.g., GM hybrid rice), quality (waxy) traits, disease resistance (*Xa21*), insect resistance (*Bt* and *CpTI*) and herbicide tolerance (*bar* and *EPSPs*). Some of these GM rice lines are under environmental biosafety testing, or have even entered production trials, such that they are very close to their commercial release. A few pest-resistant GM rice varieties are already in the pipeline waiting for commercialization (Jia, 2004; Xiong, 2004). Presumably, GM rice with agronomically beneficial traits will enter commercial production in the near future. For that reason, it is urgently needed to develop methodologies for effectively monitoring environment affects caused by potential commercialization of GM rice in China.

The Government of China has taken an active and cautious measure for biosafety assessment of GM rice, strictly following the National Biosafety Regulations endorsed by the Chinese authorities[23]. This is primarily because the commercialization of GM rice in China will have a great impact all over the world, and the commercial release and extensive cultivation of GM rice varieties in agro-ecological systems may pose potential environmental risks. The Government of China has invested enormously in biosafety research, hoping that more fundamental knowledge can be generated and more effective methodologies developed for assessing and monitoring biosafety risks (including environmental risks) from GM rice in China. This can be reflected by the tremendous research funding support provided by the Government of China through the Hi-tech Research and Development Programme (863 Programme) and the Development Plan of

[23] For example, the "Regulations for Agricultural Transgenic Organisms" endorsed by the Chinese Prime-Minister H.E. Zhu, Rong-Ji, and three other biosafety-related documents endorsed by the Minister of Agriculture of China.

the State Key Fundamental Research (973 Programme) of the Ministry of Science and Technology (MOST) and various research programmes of the National Natural Science Foundation of China (NSFC). Undoubtedly, the Government of China has emphasized and will continue to emphasize a science-based and case-by-case environmental biosafety assessment prior to the commercial production of any GM rice, and monitoring afterwards.

Biosafety assessment and monitoring of environmental risks or effects caused by the commercialization of GM rice is challenging because of the complexity of such assessment and monitoring that involve the nature of transgenes, frequency and scale of GM rice cultivation, intended environments for release and socio-economic situation of the intended regions for GM rice introduction. Therefore, the understanding and determination of the potential risks or effects from GM rice are essential. We need to clearly understand the following issues: Why should we have assessment and monitoring? Are these activities necessary for satisfying the regulatory requirement, or just for the interests in knowledge generating, or for the assurance of long-term and safe use of the GM rice varieties in a given agro-ecosystem?

We should always bear in mind that biosafety assessment or monitoring is a necessity rather than luxury. Enormous resources are needed to carry out the monitoring. How should we monitor the environmental risks or effects form GM rice in a cost-effective way? To identify the anticipated risks and effects from GM rice on the hypothesis and existing knowledge base will narrow down our focus on the most critical problems and, hence, facilitate the risk assessment and monitoring. Thus, we need first to answer the question of: "What are the anticipated environmental biosafety effects caused by GM rice?"

In principle, the biosafety assessment usually follows the formula: Risk = Hazard × Exposure. Here, Risk indicates the probability that any adverse effect occurs from an environmental hazard. Hazard is the intrinsic properties of a substance or object (in this case, a transgenic plant or transgene product) with potential adverse or harmful effects. Exposure is a quantitative measurement of the extent to which a given hazard is present in a particular dimension (in this case, environment or ecosystems). We can understand from the above explanation that hazards or negative effects represent the most important component for the potential risks. No matter how large the exposure, as long as the effect is small, the risk will also be small. As a risk assessment usually follows four steps: (1) hazard (effect) identification; (2) exposure assessment; (3) effects assessment; and (4) risk characterization (Andow and Zwahlen, 2006), it is essential for the environmental biosafety assessment and monitoring to first identify the negative effects that can cause adverse or harmful effects by GM rice released into the environment. However, the challenge is that our knowledge of monitoring GM rice for environmental impacts is still very limited. Before we can effectively monitor the environmental effects of GM rice, some questions still need to be answered: What are the anticipated risks/effects caused by GM rice? Which transgenes are more hazardous to cause environmental effects? What procedures are needed for the actual monitoring of environmental effects? We can not answer all the questions because of our limited knowledge, but can focus at the moment on identifying anticipated adverse effects caused by the environment release of GM rice in China.

As summarized by Snow and Mora'n-Palma (1997), the potential environmental risks caused by GM plants include three categories: (1) non-target and biodiversity risks, including non-target species, ecosystem functions and effects on soils; (2) risks associated with gene flow; and (3) risks associated with the development of resistance in the target organisms. However, the emphasis of these categories may vary considerably in different agro-ecosystems with different transgenes introduced. The categories are sometimes closely associated to each other, i.e., the non-target and biodiversity to gene flow effects. The case-by-case principle emphasizes that only the transgenes or transgene products with evolutionary selection advantage are likely to cause environmental risks and have environmental effects. In China, the most potential GM rice varieties that will be commercialized soon are those with insect (e.g., *Bt*, *CpTI* and *Bt*/*CpTI*) and disease (e.g., *Xa21*) resistance transgenes. In addition, some GM rice lines with herbicide resistance (glyphosate) are under rapid development. Therefore, this paper will focus mainly on the determination of possible environmental effects caused by these types of GM rice, particularly under the Chinese circumstances of rice farming at the small household scale.

Potential Environmental Effects Caused by GM Rice

1. Impact on non-target organisms and biodiversity

In China, rice is cultivated mainly in the irrigated, rainfed-lowland and upland rice ecosystems. When commercialized, GM rices will likely be planted in the irrigated and rainfed-lowland ecosystems. Currently, farmers frequently spray chemical pesticides to control pests (Huang *et al.*, 2005), due to the severe pest problems in irrigated and rainfed-lowland rice fields. As a consequence, many non-target organisms, including non-target herbivores, parasitoids and predators have already been negatively affected in these rice fields. The cultivation of insect-resistant (*Bt*) rice, accompanied by less application of pesticides, may promote a more balanced agro-ecosystem and biodiversity in rice fields. Studies of other *Bt* crops (e.g., cotton) showed no considerable effects on non-target organisms and biodiversity, which may serve as a reference to indicate minimal effects in *Bt* rice fields. The disease-resistant gene *Xa21* was isolated from a wild species of rice (*Oryza longistaminata*) and, so far, no adverse environmental effect has been reported from this wild-rice gene.

The long-term application of various herbicides may considerably affect the composition of herbal species and animals fed on the herbals within and outside the rice fields. This in general will influence biodiversity of agro-ecosystems through a food web. The prediction that cultivation of herbicide-tolerant GM crops might adversely affect skylark populations in the United Kingdom (Watkinson *et al.*, 2000) highlights the importance of effective monitoring of herbicide-tolerant GM rice for extensive and long-term cultivation. In addition, herbicide-tolerant GM rice may enhance the herbicide resistance of sympatric weedy rice populations through gene flow. This point will be discussed in more details in the following section.

There is still a great knowledge gap in our overall understanding of the impacts of GM crops on soil fauna. Very few studies have focused on the influence of *Bt* rice on the soil communities/organisms in paddy fields, despite the significant differences between the anaerobic and aerobic soils. Studies of other *Bt* crops (e.g., corn) have already shown the long-term persistence of the *Bt* product (Cry1Ab) in the soil (Saxena *et al.*, 1999) and negative influence on adult earthworms fed with *Bt*-corn-residuals (Zwahlen *et al.*, 2003). These results show a good rationale to appeal for more profound studies to assist in the identification of the effects from GM rice on the soil communities and organisms.

2. Risks associated with gene flow and its related effects

Gene flow refers to any movement of genes from one population to another. There are two types of gene flow: horizontal and vertical. Horizontal gene flow is the movement of genes between unrelated species, e.g., between plants and microbes. Vertical gene flow is the gene exchange between closely related species, usually through sexual hybridization. This paper focuses only on vertical gene flow because horizontal gene flow has not been shown to happen with transgenes, even though evidence has proven that genes have moved between unrelated species in evolutionary time. In rice, gene flow can happen via seed dispersal and pollination and, in the case of perennial wild rice (i.e., *O. rufipogon* and *O. longistaminata*), gene flow can also be mediated through vegetative organs, e.g., tillers or ratoons of the plants. Although gene flow through dispersion of seeds and vegetative organs can have a significant effect (Lu and Snow, 2005), this presentation will only focus on potential effects caused by pollen-mediated gene flow of GM rice.

There are two types of vertical gene flow: crop-to-crop (transgene moving from GM rice to non-GM rice) and crop-to-wild (transgene moving from GM rice to its wild relatives, including weedy rice) gene flow. Considerable studies have demonstrated variable frequencies of crop-to-crop and crop-to-wild gene flow in rice (Song *et al.*, 2002, 2003; Chen *et al.*, 2004; Messeguer *et al.*, 2004; Rong *et al.*, 2004, 2005); therefore, potential environmental effects caused by GM rice needs to be identified for risk assessment and monitoring. The effects from crop-to-crop transgene flow will be more related to the trading problems because of the unintentional "contamination" of non-GM rice by transgene(s), rather than environmental ones (Lu *et al.*, 2003; Lu and Snow, 2005). Given the extremely low frequencies of crop-to-crop gene flow at the zero distance (>1 percent gene flow, Rong *et al*., 2004, 2005), and after the spatial isolation at a short distance of about 6 m (>0.01 percent, Rong, J. *et al*. unpublished) from GM to non-GM rice, the effects even for the trading problems will be insignificant. In contrast, the frequency of crop-to-wild gene flow is generally high (up to 18 percent per generation for *O. rufipogon*), and the recurrent gene flow from GM rice to its wild relatives will accumulate the frequencies of transgenes in the wild populations rapidly, arousing considerable environmental effects and risks. Studies have already shown that genes from cultivated rice can persist in crop-wild interspecific hybrids, although there was no considerable change in fitness when no transgenes were involved (Song *et al*., 2004). For insect-resistant GM rice, the outflow of the transgenes to, and persistence in, wild and weedy rice populations may change the fitness of the wild rice plants that pick up the transgenes. Our studies have demonstrated the significant changes of cost-benefit fitness between three insect-resistant GM rice lines and their non-GM counterparts under different insect pressures (Chen *et al*., 2006, and the *Bt* gene will normally express in interspecific hybrids and progeny of GM rice with wild *O. rufipogon* (Xia, H., unpublished). The change of fitness may consequently enhance or reduce the competitive ability of wild rice individuals with the transgenes, which will either result in weedy problems or threaten the survival of wild rice populations. Weedy rice is already a serious weed in rice fields worldwide, and herbicide-tolerant transgene incorporated to weedy rice (Chen *et al*., 2004) will make the weed tolerant to herbicides and complicate the weedy rice control management. Weedy rice is now re-emerging in many parts of China with significant genetic diversity (Cao, Q.J. *et al*., unpublished), and the flow of herbicide-tolerant transgenes into weedy rice occurring in the same field will certainly make the control of weedy rice by herbicides more difficult. Wild *O. rufipogon* has its sparse distribution in southern China; the negative effects of turning this wild rice into a more invasive weed or bringing some endangered populations into extinction by demographic swamping are obviously prevailing.

3. Development of resistance to the *Bt* transgene

The evolution or development of resistance by insects to insect-resistant transgenes is a potential risk. The fast development of resistance to, for example, *Bt* genes by insects will result in a quick loss of this resistance resource. *Bt* crops are the earliest transgenic crops that have been released to the environment, but, at present, none of the *Bt* crops used has suffered a considerable resistance failure (Andow and Zwahlen, 2006). This may largely be attributed to the effective resistance management by applying the high-dose/refuge strategy that can significantly delay the evolution of resistance by selecting against individuals heterozygous for resistance (Andow and Zwahlen, 2006). Therefore, without an effective resistance management, there is a high potential for insects to develop resistance against various insect-resistant GM crops.

For *Bt* rice grown extensively in China, the risk for insects to develop resistance is relatively high. There are two major reasons for this prediction. First, the within-species genetic variation of different lepidopteran species in rice is significantly large according to the preliminary studies by Dr. K.M. Wu of the Chinese Academy of Agricultural Science (personal comm.). This is most likely attributed to the tremendous genetic divergence in rice, in which indica versus japonica, glutinous versus non-glutinous and lowland versus upland types were differentiated. Consequently, the opportunity for the development of resistance by insects from some of the genetic variants will likely be high. Second, the rice cultivation mode in China at present is essentially on the basis of individual farmer households at small scales. This provides a challenging situation for the designing and implementation of insect-resistance management, particularly with the high dose/refuge management strategy.

4. Other indirect influences on rice ecosystems

As mentioned earlier, the commercialization of GM rice may bring considerable changes in farming practices in China. For example, the cultivation of herbicide-tolerant GM rice at an extensive scale may significantly affect the ways of weed control in rice ecosystems, which may lead to the changes of the composition of biodiversity in rice fields. In addition, the use of insect resistance GM rice will significantly reduce pesticide use for controlling the major insect pests, which may increase the risk of secondary pest problems in rice ecosystems. Such indirect influences caused by the cultivation of insect-resistant (e.g., *Bt*) GM rice need to be taken into consideration, even though these may not be immediate effects. In addition, the dominant and unitary cultivation of a few GM rice varieties at a great scale will certainly lead to a significant reduction of rice varietal diversity that has already largely shrunk by the application of modern rice varieties. Therefore, identification of possible indirect environmental effects caused by the cultivation of GM rice is also very important. In conclusion, it is essential to strictly follow the case-by-case and science-based principles in identifying environmental effects from GM rice. During the practices, it is particularly important to take specific environments and actual situations into consideration, like the case in China with such great diversity in landscape, human culture and agricultural systems.

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8. Monitoring the Environmental Effects of Genetically Modified Crops in Brazil

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Introduction

Biotechnologies have been successfully used for more than 10 years in some countries. Because of some very successful examples, there is a general belief that all technologies can be introduced and adapted to the environmental requirements prevalent in different countries. There is also a general trend to ignore the unique relationships between agriculture, the local environment and farmers' traditions prevailing in each country. The introduction of new technologies must consider people's unique traditions and needs. As biotechnology moves to developing countries, there are serious needs for attention to how genetically modified crops (GMCs) will change farming systems, particularly how they will impact the dynamics of the predominant smallholder farming systems.

The release of genetically modified organisms (GMOs) in Brazil is controlled by a revised and updated Biosafety Law (No. 11.105/95) (CTNBio, 2006). The new Law provides a regime in which no live GMO may be released or marketed in the country without the consent of the regulatory authorities. Applicants for consent to release must supply a dossier of prescribed information about the GMO, and this should include a detailed risk assessment of its possible impact on human health and the environment. The Biosafety Law also regulates foods containing, or derived from, GM material, that are not live GMOs, and GM vaccines that constitute live GMOs. It also addresses the human health implications associated with their commercial release. A requirement for post-commercial monitoring of GMOs is not explicit in the Law, but can become mandatory based on decisions of the National Technical Biosafety Commission (CTNBio).

Many GM crop varieties of maize, cotton, sugarcane, rice and soybeans are in the development pipeline in Brazil, but only two crops have been approved for commercial cultivation in the country: Roundup Ready (RR) soybean and Bollgard cotton. In its decision to release the RR soybean for commercial use in 1998, CTNBio required an unprecedented post-commercial monitoring programme to be implemented by the proponent company.

Post-Commercial Monitoring Plan for RR Soybean

In 1998, CTNBio released a decision report (Communication of Decision No. 54) in which it approved the commercial planting of RR soybean varieties and required a pos-commercial monitoring plan (CTNBio, 2006). The main requirements of this decision are specified in Box 1.

Box 1: CTNBio's determination for the post-commercial monitoring plan for the herbicide-tolerant RR soybean

- The applicant should submit and implement a five-year monitoring plan.
- Motoring programmes should be established in every biome relevant to the soybean crop.
- The programmes should be developed in collaboration with public institutions.
- The monitoring fields should be open to inspection by the organized civil society if found appropriated and accompanied by CTNBio.
- The company should submit yearly reports to CTNBio.

The details of this monitoring plan[24] consist of a comprehensive research programme to evaluate the diversity of the weed community; development of herbicide resistance in the weed community; gene flow from RR soybean to conventional soybean and to the soil microbe community; glyphosate residue on the soybean plant, in the soil and in the water; agronomic evaluation in different crop systems; nutritional studies and chemical and physical characteristics of the soil under cultivation with RR soybean. Further analysis included the effect of RR soybean on ecosystem processes, such as the dynamics of residue decomposition; the dynamic of N, P and S mineralization; nitrification and ammonization soil organisms; enzymatic activities; microbial biomass; edaphical respiration; microbial biodiversity; protozoa populations; nematodes and micorhizic fungi; nitrogen-fixing micro-organisms; soil macrofauna; and visiting fauna during intercropping. The indicators of agricultural impacts are shown in Box 2[25].

Box 2: The applicant's plan

Objective: Compare RR soybean with other production systems

- weed species diversity;
- development of resistance in the weed community (gene flow);
- structure, diversity and dynamics of soil micro-organisms and soil functions;
- richness and abundance of insects and pathogens;
- monitoring areas less than 3 ha;
- monitoring areas inside the applicants' experimental stations;
- participation of six public institutions; and
- costs: US$1–3 million per year.

The methodology specifies that the sampling for the different evaluations would be made mainly during the crop growth; however, some samples would be made also during the winter crop or in the intercropping. About 15 000 samples a year would be made, and about 5 000 field evaluations, spread in 29 distinct parameters. The monitoring will be conducted for five years, under non-sowing cultivation. The following systems are being compared: RR soybean treated with Roundup for weed control, RR soybean treated with conventional herbicides for weed control and conventional soybean treated with conventional herbicides.

Due to a court injunction against CTNBio – decision that prohibited the commercial planting of RR soybean in the country for many years – the submission and implementation of the monitoring plan was delayed. In July 2002, CTNBio discussed and technically approved this post-commercial monitoring plan proposed by Monsanto do Brasil, but the formal approval would only be given after the jurisdictional impediment had been stopped.

The legal planting of the RR soybean in Brazil started only in 2003, and Monsanto started some of the studies in one of their experimental stations, even though this subject has not received any further attention from CTNBio. According to the company, there has been some difficulties in choosing the locations for the experimental monitoring due to the large size of the parcels required for the environmental monitoring, the diversity of the edaphic and topographic characteristics of the regions on which soybean is cultivated, the precedent history of the farm and the willingness of the farmer to collaborate within the monitoring plan for the period of five years, among other things.

To conduct these hypothesis-based studies, besides the Monsanto personnel responsible for the overall management of the work, the company hired a few consultants and four graduated agronomists. For the analytical evaluations, the company entered in agreement with 25 researchers from eight universities and six governmental and private institutes and companies that have the infrastructure and scientific personnel duly prepared to develop the work.

[24] Provided to the authors by Monsanto do Brasil, through Dr Geraldo Berger.
[25] Information also provided by Monsanto do Brasil.

Depending on the need, this infrastructure would be implemented or altered, aiming at improving the quality of the results.

An important aspect of the monitoring plan is its management, particularly in relation to the different results expected. Specific procedures for each of the evaluation parameters are being discussed with the researchers to improve the adequacy and executability of the proposed methodology.

Exclusion Zones for *Bt* Cotton

Some crop species have wild, feral and dooryard relatives and landraces in Brazil. Some of these are sexually compatible with the cultivated type, and gene flow from new conventional or transgenic varieties may pose a threat to the long-term preservation of the crop species' genetic diversity present in the country. This is the case of cotton. Three species of the genus *Gossypium* exist in Brazil, all of them allotetraploids and sexually compatible amongst themselves: *G. hirsutum*, *G. barbadense* and *G. mustelinum*. The two crop species, *G. barbadense and G. hirsutum*, may exist in cultivated, feral, landrace or dooryard populations. *Gossypium mustelinum* is an endemic rare species threatened with extinction. Parts of the natural area of distribution of these species are being replaced by upland cotton, and gene flow from new conventional or transgenic varieties of upland cotton may pose a threat to the long-term preservation of the species' genetic diversity.

In its decision to approve Bollgard cotton, containing a truncate form of the protein Cry1ac, for commercial release in Brazil, CTNBio required the establishment of zones of exclusion of Bollgard cotton to protect areas of distribution of wild and feral populations of the crops' related species and races (CTNBio, 2006). The commission's decision states that, for containing the gene flow, isolation zones should be established as proposed by Barroso *et al*. (2005), where large areas of distribution of natural *Gossypium* populations are isolated and the planting of Bollgard cotton is not allowed.

The crop time for the Bollgard cotton event 531 in the different cotton producing regions, mainly in locations with more than one cotton cropping in a year (*safrinha*), should also be determined and limited in order that the period of pest exposure to Cry1Ac is the shortest possible. Refuge areas with non-transgenic cultivars of cotton corresponding to 20 percent of the area to be cultivated with the Bollgard cotton event 531, and located at distances shorter than 800 m, are recommended. However, it may be required to review the refuge area when the total area of cultures *Bt* (cotton and maize, or only cotton in the event that the maize *Bt* is not released for commercial use) reach 50 percent of the cultivated area in a certain region. That is due to the fact that despite of the *Spodoptera frugiperda* (Lepidoptera: Noctuidae) not to be deemed a target pest of control as regards the Bollgard cotton event 531, there are reports in the literature of the low toxic activity of CrylAc against such species, and the answer to the selection pressure for a greater tolerance to CrylAc. In addition, there are reports in the literature on the genetic similarity between populations of *S. frugiperda,* arising out of cotton and maize cultures. If the genetically modified maize expressing the protein CrylAb were released for trading, the selection pressure for resistance shall be even greater in a certain region, as there are reports on the crossed resistance between CylAc and CrylAb (similarity of action). That could be avoided with the increase of the refuge area.

The relevant surveillance bodies shall be responsible for ensuring the compliance with the requirements contained in this CTNBio decision, mainly those relevant to refuge areas and exclusion zones.

Monitoring GM Crops in Highly Biodiverse Crop Systems

The species diversity associated with crop fields is influenced by the neighbouring vegetation. In general, only arthropod species of economic relevance for each crop is taxonomically known, with little reference to their ecology. For example, in Brazil, the biodiversity associated with cotton crop in each region is only partially known. There are several references about herbivores species reported as pests of the crop for each region and the importance of some predator and parasitoid species as natural enemies of main pests. The complex architecture of the cotton plant allows a rich and diverse fauna associated with each structure of the plant. There are at least 30 species reported as pests, and estimates of more than 500 species of natural enemies of these species. Flowers may be visited for pollinators and pollen or nectar eaters, but these species are poorly studied in different regions and should be better investigated. The large number of arthropods, weeds and microbes found associated with agricultural fields raises the question of potential adverse effects on a number of non-target organisms. These species and the structure of the communities that they assemble should be surveyed in different cropping systems located in each ecologically different regions providing information about local biodiversity for risk assessment. Several important crops, as cotton previously cited above, have the pest species and part of their natural enemies described in different degrees of precision in the literature. A systematic survey of the biota associated with each crop and the dispersion of this community for the surrounding natural vegetation areas is not available. The evaluation of GM plants potential to impact non-target species can not be based on a constant set of indicator species for all kinds of traits expressed by the plants. This eco-toxicological approach used for chemical products is not efficient in detecting direct and indirect effects on the community associated to the crop. Relevant species that should be tested would be selected from those that are more representative of important ecological functions considering regions and cropping systems.

The knowledge about the biodiversity associated with each crop for different cropping systems and regions is the basic information needed to understand the interaction of these species with those in the natural vegetation present in neighbourhood areas. The importance of these interactions emerge from a range of ecological information, including geographical range, alternative hosts or preys, prevalence in the crop, phenology and seasonality of key functions that play an important role in the functioning of ecological processes, that are essential to evaluate the impact of GM plants in the environment. The selection and testing of these key functions could assure that cropping of GM plants would provide sustainability to agro-ecosystems and play a role in the conservation of ecosystem biodiversity (e.g., the impact of indigenous bees on the production of the commercial crop and their importance in conservation of plant community). The understanding that agricultural practices have both positive and negative impacts on local diversity and that they affect the stability and sustainability of cropping systems an the surrounding systems is the starting point to propose a monitoring programme to evaluate the impacts of the technology.

The role played by biodiversity in the development of ecological services and the importance of its conservation for the stability and sustainability of the agro-ecosystem should be spread among farmers and stakeholders throughout a systematic programme of education and information developed by local extension services supported by federal research and development services.

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9. Field Experience and Methodologies for Monitoring Environmental Effects of GM Crops in South Africa

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Introduction

South Africa is the only African country that has approved the commercial production of genetically modified (GM) crops, namely, maize (both white and yellow), soybean and cotton. The planting of the first GM crop (*Bt*-maize) was approved in 1998. The traits that have since been approved are insect resistance (*Bt* genes) and herbicide tolerance (glyphosate). Both commercial and emerging farmers have adopted these technologies. The monitoring requirements by the Government of South Africa for these different crops and traits vary. Companies selling these technologies have placed a high priority on monitoring aspects they deem important to protect their commercial interests in the crops they have developed.

Monitoring by the Government of South Africa now falls under the jurisdiction of the South African National Biodiversity Institute (SANBI). Its mandate is contained in the National Environmental Management: Biodiversity Act No. 10 of 2004.

About 15 percent of the maize produced in South Africa is genetically modified for resistance to *Busseola fusca* (corn stalk borer) and is largely cultivated by commercial farmers. The only monitoring that is required is that the seed supplier has to ensure that the appropriate refugia are maintained. This is monitored indirectly by monitoring seed sales as well as feedback from farmers. This information is sent annually to the Office of the Registrar: Genetically Modified Organisms Act, 1997. The seed companies and other role-players have recently (2004) established a GM Seed Standing Committee under the auspices of South African National Seed Organisation (SANSOR) to coordinate an Insect Resistance Management System. A protocol, using corn stalk borers maintained in culture as controls, is being developed to measure any resistance development.

Eighty percent of the cotton grown in South Africa is genetically modified and is grown by both commercial and emerging farmers. Indirect monitoring using seed sales is also used to monitor the maintenance of refugia to prevent resistance build up. A different strategy is used to manage and monitor compliance by emerging farmers. A recent study has shown that no resistance has been detected in five populations studied. A seed company has also recently developed a new diagnostic system using a feed medium spiked with the *Bt*-protein.

Companies selling the herbicide-tolerant crops are required to monitor the build-up of resistance in weeds. To date only four cases have been reported internationally for glyphosate. Companies monitor this very closely, regardless of whether or not GM crops are cultivated. It is in their economic interest not to have weeds develop resistance to their herbicides and approach this from the point of view that the use of GM technology adds no additional risk to the development of resistance. All reported problems have been due to the incorrect use of the herbicide by farmers and not a build-up of resistance.

Most of the studies to determine the environmental impacts of GM crops were done during the pre-general release phase while the regulatory packages were being developed. Governmental monitoring requirements after this are kept to a minimum and thus far no problems have been reported. Monitoring and management systems are being synchronized in South Africa to make them “user friendly” for the various levels of education in the diverse farming community and the farming systems used.

Background to the Cultivation of GM Crops in South Africa

South Africa is the only African country that permits the cultivation of genetically modified crops. A number of other countries, e.g., Zimbabwe and Egypt, have allowed contained use trials to be conducted. Major obstacles are the lack of relevant legislation in most countries as well as insufficient scientific capacity to develop, administer and monitor GM crop research and commercial production. Recently, initiatives such as the Southern African Regional Biosafety Programme were launched to assist in training scientists, decision-makers and the media.

In South Africa, permits have been issued for the commercial production of both white and yellow maize, soybean and cotton. White maize is usually produced for human consumption and yellow maize for animal feed and industrial use.

The traits that have been approved are insect resistance using the *Bt* protein and herbicide tolerance (HT) to glyphosate. To date no stacked gene events have been approved. Following is a brief timeline of some of the milestones in the deployment of GM crops. The first GM cotton trials were planted in 1990 and a permit for the commercial production of Bt cotton was issued in 1997. This was followed by yellow maize (*Bt*), soybeans (HT) and herbicide-tolerant cotton in 1998, 2000 and 2001, respectively (Bennett, 2004). The acreage of these GM crops is shown in Table 1.

Table 1: The area of GM crops under cultivation in South Africa in 2003

Crop	Area under cultivation (ha)	Percentage of total area under cultivation
Cotton	28 000	80
Maize (w)	140 000	8
Maize (y)	190 000	20
Soybean	42 000	35

Source: AfricaBio (2004).

Regulation of GM crops

With the advent of modern biotechnology and recombinant technology, scientists realized that there was a need to regulate the science. Between 1990 and 1999,the South African Genetic Experimentation Committee (SAGENE) was set up to control genetic engineering and use was made of existing legislation. This was not an ideal situation and specific legislation had to be developed to regulate this technology. In 1999, the Genetically Modified Organisms Act No. 15 of 1997 came into effect. This act is currently being amended to accommodate International protocols such as the Cartagena Protocol. The decision to permit or prohibit the deployment of a genetically modified organism (GMO) is made by the Executive Council which consists of senior officials from the following Government Departments: National Department of Agriculture, Department of Science and Technology, Department of Environmental Affairs and Tourism, Department of Health, Department of Trade and Industry and Department of Labour. An Advisory Committee that assesses each application to use this technology advises them.

Food labelling legislation was also amended in 2004 to accommodate food derived from GM crops. In May 2004, the National Environmental Management: Biodiversity Act No. 10 of 2004 was officially signed into effect, which has important implications for the monitoring of GM crops after commercialization. The year 2004 saw the formation of the South African National Biodiversity Institute (SANBI) under this Act which is responsible for the implementation of the Act.

Monitoring of GM Crops in South Africa

Responsibility

Figure 1 summarizes the responsibility for the monitoring of GM crops in South Africa by the two relevant Government Departments. During the development or research phase, the National Department of Agriculture (NDA), Directorate: Genetic Recourses issues permits to institutions or companies to conduct the research. Monitoring requirements are stipulated on the permit. The department also has inspectors who verify that the permit conditions are being adhered to and annual reports must be submitted to the Department. After a commercial release permit has been issued by the NDA, no specific field monitoring is done. Permit conditions usually require monitoring by the permit holder and stipulate that regular reports be submitted to the Department.

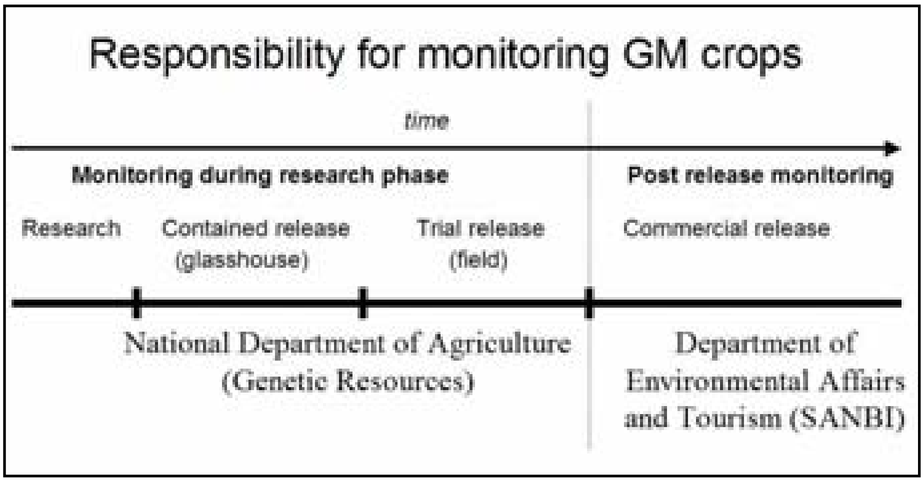

Figure 1: Summary of the responsibility for the monitoring of GM crops in South Africa by the two Government Departments

Responsibility for monitoring now falls under SANBI according the National Environmental Management: Biodiversity Act No. 10 of 2004. The two relevant sections of the Act are:

Chapter 2, South African National Biodiversity Institute, Part 1, *Establishment, powers and duties of Institute,* Functions, Section 11. (1) b:

"The Institute must monitor and report regularly to the Minister on the impacts of any GMO that has been released into the environment, including the impact on non-target organisms and ecological processes, indigenous biological resources and the biological diversity of species used for agriculture."

And

Chapter 5, Species and Organisms Posing Potential Threats to Biodiversity, Part 3, *Other threats,* Genetically modified organisms, Section 78. (1):

"If the Minister has reason to believe that the release of a genetically modified organism into the environment under a permit applied for in terms of the Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997) may pose a threat to any indigenous species or the environment, no permit for such release may be issued in terms of that Act unless an environmental assessment has been conducted in accordance with Chapter 5 of the National Environmental Management Act as if such release were a listed activity contemplated in that Chapter.
(2) The Minister must convey his or her belief referred to in subsection (1) to the authority issuing permits in terms of the Genetically Modified Organisms Act, 1997, before the application for the relevant permit is decided.
(3) For the purposes of subsection (1) "release" means trial release or general release as defined in section 1 of the Genetically Modified Organisms Act, 1997."

SANBI came into existence in September 2004 and was formed by amalgamating a number of botanical and ecological organizations. None of these organizations had any historical link to any activities pertaining to GMOs or GMO research and, as a result, do not currently have staff that is familiar with the technology. It is not essential to be familiar with genetic engineering techniques but it may help in developing monitoring strategies. Biotechnological techniques are usually used in detecting transformation events in plants or genes that may have moved to unintended recipients. During communications between the author of this paper and two SANBI directors, they indicated that currently SANBI has been in existence for too short a time to even consider a strategy for their mandate to monitor the impacts of GMOs that have been released into the environment. They also indicated that they may have to subcontract organizations and individuals that have the expertise to do this monitoring for them in the near future to fulfil this mandate.

What monitoring is currently taking place?

No direct monitoring by Government Departments is taking place but permit holders are required to submit reports to the NDA to comply with the monitoring requirements of their permits. In this manner, the NDA can indirectly monitor what is happening and can keep a central national record of all the monitoring actions by the various role players.

Non-governmental organization (NGO) groups that traditionally oppose the deployment of GM crops apparently do not have the resources to do any field monitoring either. Biowatch South Africa, a national NGO which monitors and researches issues on biodiversity, genetic engineering and sustainable farming, has the following standpoint on monitoring: "Biowatch S.A.'s monitoring function is one of oversight with respect to the implementation of legislation regarding genetic modification, particularly the Genetically Modified Organisms Act and our activities centres around reviewing the process of permit approvals, risk assessments etc. Monitoring the specific environmental impacts of GM crops falls outside our focus area. We believe that this is the work of Government. Government has provided very little information on the specific impacts of GM crops."

The multinationals that are in the GM crop market are required to monitor their products. It is also in their commercial interest to ensure that the technology that they have developed remains effective and does not impact negatively on the environment. Each permit issued will have its own monitoring requirements according to the crop and the trait. The broad requirements will be discussed later according to the crop trait. The companies selling the products are sponsoring most of the research or methodology development for various forms of monitoring. Research institutes, universities and consultancies are being contracted to do this research and monitoring, however, there appears to be a shortage of researchers competent in these fields.

Monitoring of insect resistant (Bt) crops

The main monitoring requirement for *Bt* crops is that companies must ensure that the required refuge is maintained. In general, the companies use their seed sales records to monitor this. They are required to keep accurate records of seed sold to all farmers that plant *Bt* crops as well as personal particulars of the farmers (name, address, contact information, etc.). By looking at the ratio of *Bt* and non-*Bt* seed sold, they can determine if the correct refuge area is planted. *Bt* maize still forms a relatively small proportion of the total maize planted and therefore if individual farmers do not comply with the requirements there will still be enough non-*Bt* maize in the region to negate this non-compliance. The seed company representatives also play an important role in monitoring as they have direct contact with the farming community and will become aware of non-compliance of the refuge requirements. Companies also pay special attention to educating farmers so that they are aware of the importance of the refuges. Literature is distributed to the farmers and farmer days are held where relevant information is communicated to them. Figure 2 shows a typical pamphlet distributed by one of the seed companies. There are, however, many small-scale farmers that grow *Bt* cotton that are only semi-literate. To accommodate them, seed suppliers have special bags that contain a small bag of non-GM seed and pictures on the bag showing the farmer how to plant the seed (Figure 3).

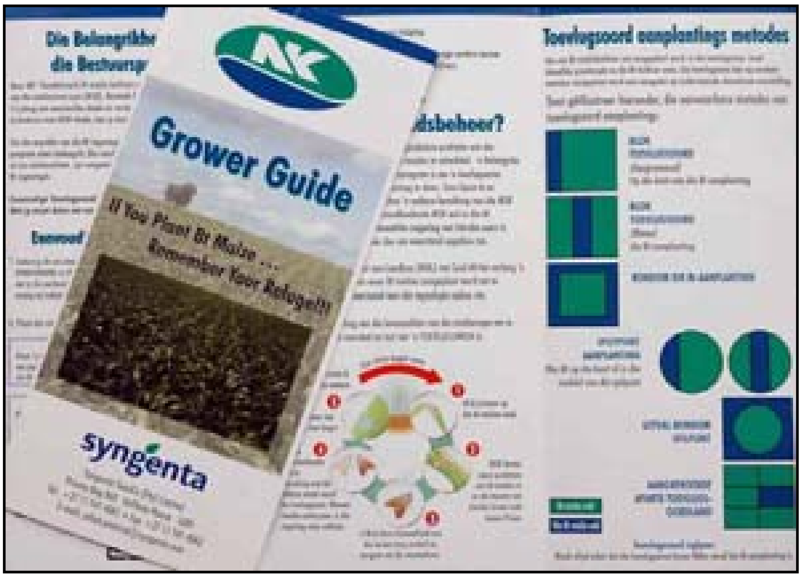

Figure 2: An example of pamphlets distributed to farmers by a seed company in two of the official South African languages

Figure 3: Example of *Bt* cotton seed bags for small-scale farmers who are often semi-literate. Bags contain both GM and non-GM seed to facilitate compliance with refuge requirements

Formation of an independent monitoring body

Under the umbrella of SANSOR, a genetically modified seed standing committee was formed to coordinate insect resistance management. The primary mission of SANSOR is to represent the seed trade, protect and promote industry interests, serve as a secretariat and render specific services to its members. The seed companies, to coordinate research in this field and to provide some transparency, initiated the committee. They felt it was important that all the resources are pooled and that the role players work together toward a common goal. It is also important that there is a common strategy by the companies so that they speak with a common voice to the farmers to reduce confusion.

The main components of the South African Insect Resistance Management (IRM) plan are:

- refuge areas (revisiting design, location, size)
- baseline studies
- alternate host studies
- insect behaviour/flight studies
- resistance monitoring
- grower education
- harmonization

Monitoring of herbicide tolerance

Permit holders are required to monitor herbicide tolerance. However, the seed companies make no distinction between GM and non-GM crops when considering herbicide tolerance in weeds. Their standpoint is that the use of herbicide-tolerant GM crops does not change the risk of herbicide tolerance developing in weeds. They take herbicide tolerance very seriously as any tolerance will shorten the lifespan of their product. Since 1974 only four reported cases of resistance to glyphosate have been reported internationally. This apparently is remarkable as herbicides often only have a useful life of between 5 and 10 years. Monitoring is done by investigating complaints by farmers. Until now in South Africa all apparent cases of resistance have been attributed to incorrect use of the herbicide, e.g., incorrect dilution or incorrect application.

Case Studies

Three case studies will be briefly discussed. They are all studies that investigated aspects of insect resistance in GM crops. No examples of monitoring studies on herbicide tolerance could be found. The studies are meant to give an indication of the type of research being done which can be seen as a form of monitoring of the impact that commercial GM crops have on the environment. The studies represent one paper presented at a congress, one poster presented at a congress and one publication. There are also a number of other similar studies that have been conducted by the same authors.

First* case study *(Mellet et al., 2003)

A paper presented at the 14th Entomological Congress (2003) of the Entomological Society of South Africa. The abstract from the proceeding is reproduced below. Due to the concise nature of the abstract it has been reproduced as published.

Helicoverpa armigera (Hubner) (Lepidoptera: Noctuidae) is one of the major pests of cotton crops. *Bt*-cotton (transgenic cotton that contains *Cry* genes from *Bacillus thuringiensis* var. *kurstaki*) was introduced as a control measure against *H. armigera*. *Cry* genes encode for toxins that are toxic to *H. armigera* and other Lepidopteran pests. The effect of *Bt*-cotton (NuOpal) on *H. armigera* population numbers and egg parasitism was investigated. Scouting was conducted once a week over two cotton-growing seasons at a cotton farm near Marble Hall, Mpumalanga, South Africa. The numbers of damaged bolls, bollworm eggs and bollworm larvae were determined in non-*Bt*- (Delta Opal) and *Bt*-cotton fields. No pesticides were used during the first season. A sprayed non-*Bt*-cotton field was included in the second season's study. Pheromone traps baited with the sex pheromone of *H. armigera* were checked on a weekly basis to determine the number of adults in the fields under investigation. Bollworm eggs were collected during the second season to determine egg parasitism. The number of bollworm larvae and damaged cotton bolls were kept under threshold levels by the presence of the *Bt*-gene in the *Bt*-cotton fields and by insecticide applications in the non-*Bt*-cotton fields. Moth numbers, egg laying by *H. armigera* and egg laying by the hymenopteran egg parasitoids *Trichogrammatoidea lutea* and *Telenomus* spp. were not influenced by the presence of the *Bt* gene. *Bt*-cotton can thus be useful in an integrated pest management programme by reducing the number of insecticide applications per season and not affecting biological control agents.

Studies such is this one give an indication of the continued efficacy of the Bt protein and any possible shift in the target organisms.

Second case study (Van Jaarsveld and Joffe, 2003)

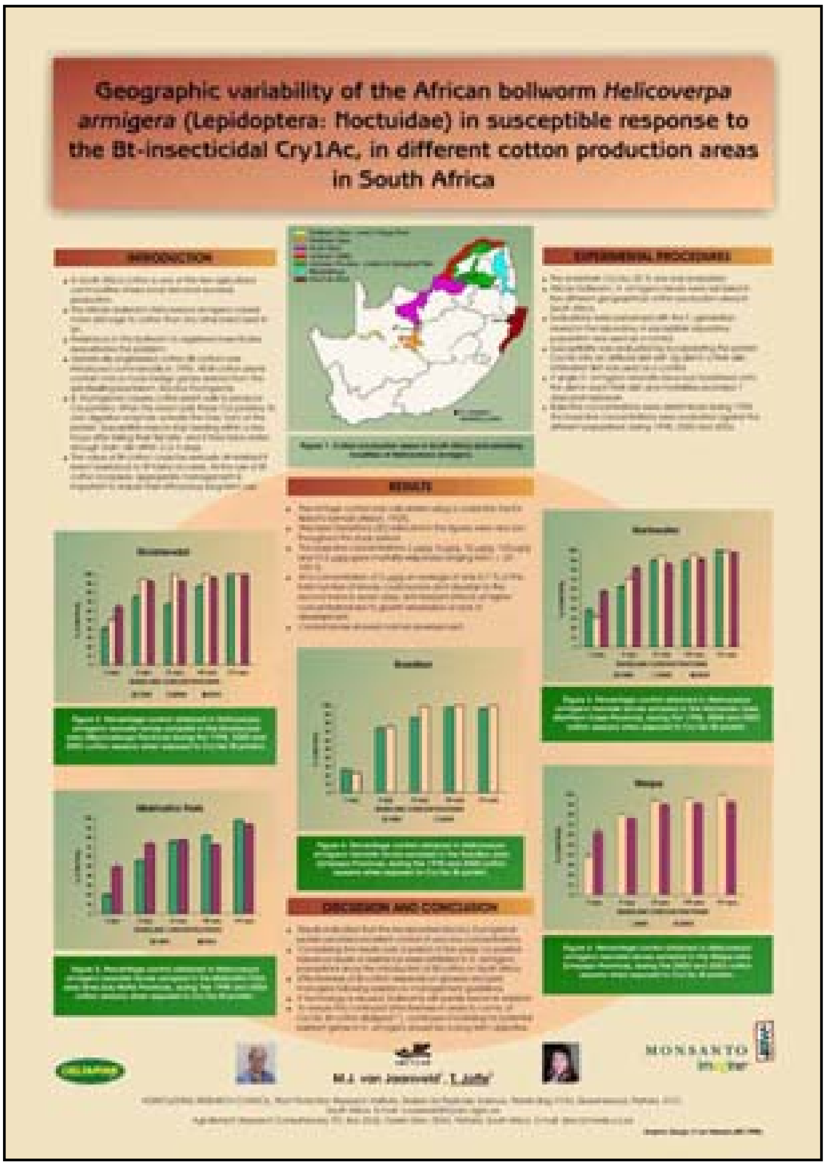

Figure 4: Poster on the geographical variability of the African bollworm in susceptible response to *Bt*-insecticidal *Cry*1Ac in different cotton production areas in South Africa

Outlined below are the experimental procedures, results and discussion and conclusion presented in the poster in Figure 4.

Experimental procedures

- The endotoxin *Cry*1Ac 20 percent w/w was evaluated.
- African bollworm *H. armigera* larvae were sampled in different geographical cotton production areas in South Africa.
- Evaluations were performed with the F_1-generation reared in the laboratory. A susceptible laboratory population was used as a control.
- Susceptibility was evaluated by incorporating the protein *Cry*1Ac into an artificial diet. An untreated diet was used as a control.
- A single *H. armigera* neonate larvae was transferred to a dish and mortalities recorded 7 days post-exposure.

- Baseline concentrations were determined during 1998. The baseline concentrations were evaluated against the different populations during 1998, 2000 and 2003.

Results
- The baseline concentrations 2, 8, 32, 128 and 512 µg/g gave mortality responses ranging from about 20 to 100 percent.
- At a concentration of 2 µg/g, an average of only 0.7 percent of the total number of larvae could survive and develop to the second instar in seven days. Anti-feedant effects at higher concentrations led to growth retardation or lack of development.
- Control larvae showed normal development.

Discussion and conclusion
- The incorporated *Bacillus thuringiensis* protein provided excellent control at very low concentrations.
- Over a period of five years, no positive tolerance levels or resistance were exhibited in *H. armigera* populations since the introduction of *Bt*-cotton in South Africa.
- Effectiveness of *Bt*-cotton depends on growers and pest managers following resistance management guidelines. If the technology is abused, bollworms may quickly become resistant.
- To ensure the continued effectiveness of *Cry*1Ac *Bt*-cotton, continued monitoring for potential resistant genes in *H. armigera* should be a long-term objective.

Third case study (Green et al., 2003)

Summary of methods used
- Five localities on the Makhathini flats were used in the study.
- Four bollworm species were investigated.
- Plants were sent to the herbarium of the National Botanical Institute for identification.
- Scouting was done at each location every 2 weeks. The following was noted: number and position of eggs, damage to fruiting bodies, number and stage of larvae and number of pupae or moths.
- Forty cotton plants and 10 weeds were scouted per locality which was later changed to 20 of each.

Summary of results
- Thirty four plant and weed species were scouted.
- Bollworms were found on nine of the species.
- Eggs were found on all plants including the *Bt* cotton.
- African bollworm larvae were also found on *Bt* cotton.
- Few weeds were found with the African bollworm.

Summary of conclusions
- Alternative hosts are available for all bollworms, which can act as a refuge.
- Stand-over cotton can also act as a refuge as well as a source of new infestation.
- However, stand-over cotton can also act as an incubation area for other pests.
- The natural vegetation to bollgard cotton ratio will affect the efficacy of the ability of the natural vegetation to act as a refuge.
- Growing conditions and agricultural practices will affect bollworm numbers.
- Cotton seems to be the preferred host for bollworms.

Concluding Remarks

Structures and organizations (e.g., SANSOR GM seed standing committee and SANBI) are being created to monitor the effects of GM crops on the environment but very little or no field monitoring is being done by other organizations at present. Seed companies are required to do monitoring to comply with their permit conditions. These companies are committed to monitoring as it is in their interest as it protects and prolongs the life of their own products. No insect resistance or herbicide tolerance problems have been detected or reported to date.

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10. Hybridization between Wild and Cultivated Potato Species in the Peruvian Andes and Biosafety Implications for Deployment of GM Potatoes

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Summary

The possibility of gene flow between *Solanum* species was tested through crossing 54 accessions from 13 *Solanum* species (seven wild and six cultivated), both in open pollinated fields in several areas of the Peruvian Andes and in greenhouse crosses. In this paper, the results of the greenhouse crosses are reported and only the Puno open pollinated field results, both with AFLP fingerprinting, as proof of hybridity and identification of the pollen parent. The cultivated species were selected on the basis of commonly grown native or hybrid varieties and wild species found near or around cultivated potato fields in five different agroe-eco-geographies of Peru, above 3200 m asl. Results from greenhouse and field crosses can be divided in two main groups:

1. Same ploidy and EBN number

Within the diploid group, hardly any crossing barriers were evident. Cultivated diploid species, such as *S. phureja*, *S. goniocalyx* and S*. stenotomum,* produced high quantities of seed in both directions with wild *S. bukasovii*, S*. sparisipilum*, *S. raphanifolium* and *S. megistracolobum.* The progeny proved to be 100 percent hybrid. The Puno field confirmed this finding as pollen from wild *S. sparsipilum* produced 43 percent of the hybrids and *S. bukasovii* 31 percent of the hybrids in the cultivated *S. phureja*. Similarly, 19 percent of the hybrids in *S. stenotomum* were traced to *S. bukasovii* pollen. Reciprocals also were abundant in the field, thus in seed collected from plants of *S. sparsipilum,* 21 percent the hybrids were traced to pollen from cultivated *S. stenotomum* and 19 percent form *S. phureja*. In *S. bukasovii,* 27 percent of the hybrids were from *S. phureja* but only 7 percent from cultivated *S. stenotomum* pollen on *S. bukasovii* female. In the greenhouse, hundreds of seeds were shown to be hybrids of this combination. Crossing barriers were encountered in the greenhouse with *S. stenotomum* crossed with *S. chomataophilum,* which may be genetically more distant.

2. Different ploidy and/or EBN

In the greenhouse, variable and surprising results were obtained. Much seed was obtained from *S. acaule* and *S. albicans* when crossed with tetraploid cultivated varieties of *S. andigena* or hybrids; however, AFLP data demonstrated that these seeds were products of self-pollination. Both wild species are self fertile and have small delicate flowers growing under the leaves to protect them from frost. In the greenhouse emasculation may either be too late or may damage flowers. In the field in Puno, *S. acaule* participated as pollen donor in 1.3 percent in *S. stenotomum* hybrids, 0 percent in *S. phureja*, 0.6 percent in *S. andigena* and 0.8 percent in hybrids and improved varieties. Reciprocally, the numbers are similarly low, where tetraploid cultivated species (*S. andigena*) provided 1.5 percent of the hybrids and cultivated improved varieties and 2.9 percent of the seed collected from *S. acaule* plants. The only high number of hybrids obtained in tetraploids with diploids in the field came from *S. andigena,* where 14 percent of the hybrids originated from pollen from wild *S. sparisipilum*. This was confirmed in the greenhouse crosses where 75 plants tested from this combination were all hybrid.

S. sparsipilum, S. raphanifolium and *S. andigena* proved compatible in greenhouse crosses in both directions, whereas crossing barriers seemed to operate to some extent with *S. bukasovii*, where the accessions tested gave a low number of seed both in the field and in greenhouse crosses. Different accessions tend to differ in their crossing abilities. The high rate of success in obtaining hybrids between these large numbers of species/accessions is strong evidence of the

relative ease with which hybridization can take place between cultivated species and these wild *Solanum* species commonly found in Peruvian potato fields. The 2n pollen in certain accessions may be the reason that ploidy and EBN numbers do not provide strong crossing barriers. Possibly these species have been exchanging genes since domestication.

Pollination insects were studied the following season and six species were identified sonicating stamens to obtain pollen. Since potato flowers do not produce nectar, insects visits are based on the harvest of pollen which have to be liberated by sonication. Three different species of *Bombus* were identified, of which only *B. funebris* was present in all sites, and *B. opifex* only in Puno, with a very high number of daily visits. The black bee *Lonchopria* spp. was the most active pollinator of potatoes, both in Puno and Junín.

Two types of tests were done to asses under what conditions new hybrids would survive. In one case berries were buried after harvest at the onset of the dry season in an abandoned field. The next rainy season, 529 plants emerged from a seed bank of 27 200 (or 1.9 percent). None lived to flower, but produced minitubers from which 34 plants re-emerged the following rainy season. These were similarly struck down by drought and frost. The second trial was to test survival under cultivated conditions and a set of tubers obtained from seed grown in pots was planted in a farmer's field. The farmer and his family were asked if they could select clones good enough to keep as varieties. Twenty were selected, most of which came from *S. andigena* self pollinations; however six genotypes were selected from proven hybrids between wild x cultivated with good agronomic characteristics, showing that survival is more likely under farmers' care than under wild conditions, and may be the reason for close genetic proximity.

11. Experience with Monitoring and GM crops in CIMMYT

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Abstract

The International Maize and Wheat Improvement Center (CIMMYT) aims to genetically enhance crops and generate public-sector-provided products for the resource poor, e.g., drought-tolerant wheat and insect-resistant maize and, through international–national partnerships, facilitate the acquisition of improved germplasm for non-mandate crops in the cropping systems where maize and wheat thrive; e.g., genetically modified (GM)-papaya through a national food security undertaking in Bangladesh. The Center also engages in public awareness campaigns in projects such as Insect Resistance Maize for Africa (IRMA), which includes food, feed and environmental safety, monitoring of resistance and establishment of refugia, non-target effects and gene flow. Monitoring of genetic resources is a wide concern among the centers of the Consultative Group on International Agricultural Research (CGIAR), with an emphasis on the quality of gene banks. Decisions, policies and procedures about monitoring should be science-based, and this requires education, an area where CIMMYT and other CGIAR centers can play an important role. There will be a need to continue to evaluate the need for, and type of monitoring, as new (and unique) products are developed and released in the emergent economies of the world.

Introduction

Many of the world's poorest people are small-scale farmers, whose livelihood is at risk because of low productivity and insecure harvests. At the same time, poor urban and rural consumers suffer from malnutrition, the so-called hidden hunger, which impairs productivity. The International Maize and Wheat Improvement Center (CIMMYT), together with its partners, works to solve these problems of poverty and food insecurity with a range of multidisciplinary research and capacity-building activities focused on food, agriculture and natural resources in maize- and wheat-cropping systems.

In the last two decades, biotechnology has produced a number of valuable tools and techniques that can be used to help improve and conserve all crop species. Thus, CIMMYT believes that biotechnology has an important role to play in improving the productivity, stability, quality and use of maize and wheat cultivars in developing countries while preserving the environment. CIMMYT, along with its sister centers of the Consultative Group on International Agricultural Research (CGIAR), is committed to making these new opportunities offered by biological sciences available as international public goods and thereby complementing private-sector research so that technologies can reach resource-poor farmers and malnourished poor consumers.

While plant breeding that utilizes non-transgenic approaches will remain the backbone of CIMMYT's crop improvement strategies, genetically engineered maize and wheat cultivars (popularly called genetically modified crops or GM-crops) will not be excluded as products capable of contributing to CIMMYT's principal goals. Indeed, in tackling certain intractable problems, using genetically engineered crops may be the best available approach for meeting the challenges of food security and environmental protection. CIMMYT believes that it is important that any variety, genetically engineered or not, that is released to farmers is safe and effective. Thus, efforts will be focused on evaluating the environmental and food/feed safety aspects on all new cultivars. Equally important is to ensure the sustainability of the technology for farmers. Thus, efforts will also focus on issues such as resistance management strategies, intellectual property rights and seed saving technologies that allow farmers long-

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term benefits, inexpensive access to the varieties and the ability to save seed from generation to generation.

Recognizing that both the scientific community and the general public express a range of conflicting opinions on the use of genetic engineering, CIMMYT favors public dialogue based on transparency and science. CIMMYT will take a holistic approach in this debate by examining, to the best of our ability, biosafety, food safety, trade, intellectual property rights and ethical and cultural aspects, all of which shape the science and policy actions related to the development and use of GM-crops (http://www.cimmyt.org/english/wps/transg/gmo_stmt.htm). In this regard, CIMMYT keeps in its Internet home page (http://www.cimmyt.org) a link under the icon "Transgenic Research and Statements", which provides updates both on policy guidelines and research (http://www.cimmyt.org/english/wps/transg/index_res.htm). Below we share examples of ongoing GM-crop research-for-development by CIMMYT and partners.

Assessment of Transcriptional Factor Genes to Enhance Drought Tolerance in Wheat

A number of strategies are being followed to enhance the tolerance of maize and wheat to water-stress conditions, including the development of genetically engineered cultivars containing various gene constructs to enhance the performance of these cultivars under water stress. While there are a number of issues that must be addressed if such transgenic cultivars are to be effectively deployed to farmers (e.g., intellectual property, biosafety, food, feed and environmental safety), if genetic systems based on transgenes can be found effective, they will provide an attractive and complementary option for improving a plant's performance under stress conditions. Particularly attractive is the single, dominant nature of the transgene that makes the transfer and maintenance of this system in any cultivar much easier than those based on polygenes.

Molecular mechanisms of water stress response have been investigated primarily in the model plant species *Arabidopsis thaliana* (Bennet, 2003 and references therein). Analyses of the expression of dehydration-inducible genes have shown that at least four independent signalling pathways function in the induction of stress-inducible genes in response to dehydration (Gilmour *et al*., 1998): two are ABA-dependent and two are ABA-independent. Several stress-induced genes, such as *rd29A* in *A. thaliana*, are induced through the ABA-independent pathway (Liu *et al*., 1998). The Dehydration-Responsive Element Binding gene 1 (*DREB1*) and *DREB2* are transcription factors that bind to the promoter of genes such as *rd29A*, thereby inducing expression in response to drought, salt and cold (Dubouzet *et al*., 2003; Kasuga *et al*., 1999).

The Japan International Research Center for Agricultural Sciences (JIRCAS) shared with certain CGIAR centers gene constructs containing the *AtDREB1A* gene under the control of various promoters. These were introduced into several crops with the expectation that *AtDREB1A* would recognize the DREs of endogenous genes and enhance stress responsiveness. For example, different transgenic groundnut lines were produced by the International Crops Research Institute for the Semi-Arid Tropics (ICRISAT), and the transgenic lines show delayed wilting under simulated drought by 20–25 days compared with non-transgenic controls (Mathur *et al*., 2004).

Likewise, transgenic wheat produced at CIMMYT and tested in small field plots in CIMMYT's biosafety greenhouse had a 10-day delay in drought-induced wilting (Pellegrineschi *et al*., 2004). Ongoing trials in CIMMYT's biosafety greenhouse will enable researchers to see whether the DREB-wheat responds well under more "natural" conditions. These trials represent the first time that transgenic wheat has been planted under field-like conditions in Mexico, and rigorous biosafety procedures are being followed. CIMMYT also plans to test the *DREB* gene in a variety of drought-tolerant wheat developed through conventional breeding to see if the resulting plants can use water even more efficiently (Iwanaga, 2004). If the results from these trials are positive, DREB-wheat will provide a powerful option for improving the yield of wheat under water-stress conditions, and will demonstrate the genes' potential usefulness in other crops, such as rice, maize and barley.

Insect-Resistant Maize for Africa

Maize is a major food crop in Africa, especially in the eastern and southern regions of the continent. Threats to this food source endanger food security, and stem borers pose just such a threat in much of Africa (De Groote, 2002). To tackle this problem, the Insect Resistant Maize for Africa (IRMA) project was launched in 1999 by the Kenya Agricultural Research Institute (KARI) and CIMMYT, with funding from the Syngenta Foundation for Sustainable Agriculture. The project is aimed at producing maize that is adapted to various Kenyan agro-ecological zones and is also resistant to key insect pests, primarily stem borers. Both conventional and biotechnology-based sources of resistance are being examined for their effectiveness against the borers. The project emphasizes public involvement and awareness through events such as its annual Stakeholders Meeting. Furthermore, major project objectives include environmental and socioeconomic impact studies, resistance management strategies and project documentation. Based on the experiences and results generated in Kenya, appropriate technologies and varieties will be extended to other African nations.

At this stage, the project produced stable, low-copy events of *cry1Ab* and *cry1Ba*, which were backcrossed into CML216. A biosafety greenhouse (BGH) was established in KARI and seeds of the *cry1Ab* and *cry1Ba* events were imported and growing in the BGH following approval by the Kenyan Government. A quarantine field site was established and is being used for mock trials and training of local staff and farmers. Testing of *Bt*-maize at the site is anticipated pending regulatory approvals. Events of *cry1Ca* and *cry2Aa* are now being produced.

Numerous experiments were conducted or are in-progress to determine effective insect resistance management strategies for Kenyan farmers. Environmental, food and feed safety aspects are also being investigated. Collecting baseline data is essential for effective monitoring and guiding of the project. Monitoring research includes efficacy of both products (determined in biosafety greenhouse, open quarantine site and national performance trials), build-up of resistance to both products (for *Bt* maize, now being studied in the biosafety greenhouse), adoption of refugia strategy; efficacy of refugia strategy; potential environmental impacts, impacts on non-target and beneficial insects and other organisms, adoption of products, consumer and grower acceptance as well as media coverage. Baseline studies and activities, which serve as the basis for current and future monitoring, include:

- Baseline participatory research assessments (PRAs) with 1 800 farmers of five maize growing agro-ecologies to determine the extent of losses due to stem borers and current insect management practices. Also, the PRAs are undertaken to determine salience of the problem among the farmers and regions as well as the demand for solutions.
- Assays conducted with maize farmers in the five maize agro-ecologies to identify the insects typically found and their relative abundance. Dry and digital collections were established for future reference. This undertaking can be regarded among the most extensive assays of its kind to date in Kenya.
- A large and diverse group of 880 farmers from the five maize growing agro-ecologies had their farms surveyed to determine the availability and quantity of plants that could serve as natural refugia in an insect resistance management scheme. Farmers were also queried about their potential acceptance of additional refugia plants based on their economic and practical implications.
- A survey was conducted in Nairobi at large and small supermarkets as well as posho mills, of urban consumers to determine their knowledge, attitudes and acceptance of GM-crops at large and *Bt*-maize in particular.
- Since the project’s inception, the print media has been monitored through a clipping service (news items, editorials and letters to the editor) to discern trends in media coverage that could affect attitudes of policymakers, parliamentarians and the general public.

Perhaps CIMMYT and IRMA’s most important contribution to future monitoring has been in the area of capacity building, particularly in the areas of biosafety greenhouse management, insect field assays and refugia plant surveys. Future monitoring efforts will clearly have to be conducted by national staff, although CIMMYT and other CGIAR centers might play a role in occasionally “monitoring the monitors” and providing training to update personnel in the latest procedures.

Recently, De Groote *et al*. (2005) assessed the risks and benefits of the IRMA project in Kenya. The authors indicated that most objections to *Bt*-maize cannot be substantiated. They recognized that it is indispensable to work with *Bt*-maize and introduce it in an experimental setting so that farmers, consumers and policy makers can make informed decisions. Their survey results indicate that *Bt*-maize responds to an important constraint, so farmers are very interested, and consumers are likely to benefit too. Furthermore, farmers do not express strong objections. In their *ex-ante* assessment, the poorer farmers in the low-potential areas seem to benefit relatively more, since they have relatively higher losses, and poor consumers will benefit relatively more since they spend proportionately more of their income on maize. According to the authors of this report, it seems that *Bt*-maize will be commercialized by local companies, since there are no restrictive intellectual property rights involved, and thus extra costs will be low. In this regard, because the *Bt* genes are dominant, farmers will not become dependent on the seed industry since they can recycle their seed. Their recycling methods, moreover, are likely to select for the *Bt* gene and, over time, incorporate the gene into local cultivars. As pointed out by De Groote *et al*. (2005), it will be difficult to inhibit this flow of transgenes into local landraces and cultivars, and will be difficult to remove the transgenes once introduced. Hence, the IRMA project staff took samples of all local landraces and cultivars in the different agro-ecologies to deposit in the National Genebank. Their report also suggests that natural refugia might be insufficient in certain areas, but this could be countered by pyramiding several *Bt* genes in appropriate cultivars or mixing seed with sufficient amounts of non-*Bt*-maize. Research of the effects of *Bt*-maize on non-target organisms has not yet been initiated, but identification of these organisms was started and comparative studies will start immediately with field trials.

Gene Flow, Genetic Diversity and Conservation of Landraces in Centers of Domestication

A different aspect of baseline data and monitoring accompanies issues related to genetic diversity and conservation of landraces in centers of domestication, e.g., maize in Mexico (Serratos *et al*., 1995). This issue has come into sharp relief in public debates over the presence of GM-maize in Mexico, and transgenes being discovered in landraces therein.

Transgenic crops were originally created to meet the demands of intensive farming systems, not traditional farming systems. A key difference is that under intensive farming systems, new seed is usually purchased (or one could say replenished) on an annual basis, while under traditional farming systems, seed is recycled, exchanged and selected by farmers. For this reason, monitoring under intensive systems is more controlled and easier than under farmer systems. Key to monitoring and modelling impacts and gene flow under the latter system is understanding it.

In the United States of America and Western Europe, research on gene flow in maize has focused mainly on measuring the distance over which wind-borne pollen can travel and still remain viable. In the case of maize in Mexico, however, gene flow is not just a biological phenomenon; it is a human one as well (Bellon and Berthaud, 2004). Gene flow may result from inadvertent mixing of pollen, which frequently happens when many small adjacent fields are planted to diverse maize cultivars. But it may also occur when farmers deliberately mix seed from different sources with the express purpose of hybridizing them. Mexico is within the center of domestication and diversity of maize, and many landraces are still grown by small-scale farmers. Through their preferences and management practices, these farmers foster gene flow between distinct, sometimes genetically distant, maize populations. Maize diversity in farmers' fields therefore is not static; rather, it is dynamic and changes constantly as a result of biological and social processes. By fostering gene flow, these processes give rise to and sustain genetic diversity.

CIMMYT has been working for some time on characterizing the ways in which small-scale farmers in Mexico manage their maize germplasm and on describing how farmers' management practices affect gene flow, the genetic structure of maize landraces, their diversity and evolution (Aguirre Gómez *et al*., 2000; Bellon and Risopoulos, 2001).

Genetic Factors and Farmer Management Practices Affecting Gene Flow

Mutations. An initial experiment conducted to measure the lethal and deleterious mutations present in these landraces detected high rates of deleterious mutations. On average, in the 17 elite landraces studied by the project, 53 percent of the plants showed a defect. The remaining landraces are being studied in an ongoing experiment, but preliminary results show a similar rate of accumulated mutations.

"Acriollamiento" or management of modern cultivars in traditional agriculture. In another project, management of modern cultivars within traditional systems has been studied on the coast of the state of Oaxaca (Bellon *et al.*, 2003) and in Chiapas (Bellon and Brush 1994). In these areas, traditional farmers have access to improved modern cultivars derived from the tropical maize race Tuxpeño. This research shows that farmers apply the same management to the modern cultivars as that given to the local landraces, and that in many instances, they favor mixing the two types. This process is called "acriollamiento" or local adaptation.

Case study in Cuzalapa, Jalisco (Mexico). Louette *et al.* (1997) conducted research in Cuzalapa, and their report indicated that seed exchanges between farmers and partial replacement were quite high. Of 484 fields in this research, planted with 25 local landraces, it was observed that farmers used their own seeds in only 53 percent of the fields. In the other fields, seeds were obtained either from the same village (36 percent) or neighboring villages (11 percent).

Learning from other continents: case study in Burkina Faso. In Burkina Faso, West Africa, maize cultivation may be classified into two very compartmentalized types. Early, yellow material is planted by women in their backyards; late, white maize is planted by men in larger plots, away from the village. Sanou *et al.* (1997) have shown that gene flow (genes from an improved modern cultivar distributed recently in this region) takes places between the two distinct types; genes from a modern cultivar, consistent with the second type of cultivation, were found in the landraces of the first type. We can conclude that this physical and cultural isolation is not effective in avoiding the exchange of genes between maize cultivars.

Sharing knowledge from partners: pollination between maize and teosinte. Gene flow occurs between maize and teosinte (*Zea* spp.) but at a low frequency. Recently Baltazar *et al.* (2005) investigated hybridization, flowering synchrony, pollen size and longevity, silk elongation rates, silk and trichome lengths and tassel diameter and morphology in gene flow research between a hybrid maize, landraces of maize and teosinte (*Z. mays* spp. *mexicana*, races Chalco and Central Plateau). Their research shows that crossing occurs mostly in the direction of teosinte to maize, and it supports the hypothesis that gene flow and subsequent introgression of maize genes into teosinte populations results likely from crosses where teosinte first pollinates maize. The resultant hybrids then backcross with teosinte to introgress the maize genes into the teosinte genome. Such an approach slows introgression and accounts for the co-existence of teosinte as a separate entity in the vicinity of large maize fields.

Issues for a Biosafety Policy and Monitoring in Traditional Agriculture

Due to permanent gene flow between different landraces, the probability is high that in these traditional agricultural systems, genes from introduced cultivars will find their way into the local landraces. We foresee at least two implications in terms of biosafety:

1. One could be tempted to establish strict rules and genetic barriers to restrict gene flow from the introduced cultivars in order to keep the landraces free of their genes. However, before establishing such rules and policy, one should carefully study the impact of such measures on the flow of other genes, and on the viability of the current landraces. In effect, if we consider our hypothesis that gene flow is one element of the farmers' genetic system, modifying it will have consequences on the adaptability and acceptability of the currently cultivated landraces. In this traditional system, limiting the existing gene flow for biosafety or

other reasons without changing other components of the farmers' management would lead to a loss of viability of the local landraces and their abandonment by farmers.

2. What if a gene diffusing from a variety that complies with all the biosafety requirements is later found to be harmful long after the initiation of the diffusion process? Or that a gene from a transgenic plant created to produce pharmaceutical compounds inadvertently escapes? How can we return to the pre-diffusion situation? Or, how can this system be made reversible? Could this be accomplished by avoiding any new gene flow, or through more gene flow from landraces and cultivars that are free of the offending gene? Are other options available? Overall biosafety will increase when rules and strategies are defined to establish when reversibility is needed and how it should be implemented in traditional agricultural systems.

Although much has been learned, many important questions remain unanswered. What are the relative contributions of biological processes (e.g., pollen drift) versus social processes (e.g., seed mixing) in causing gene flow? Are the practices that foster gene flow similar across types of farmers and farming systems? What factors influence these practices and determine their impact? To what extent do farmers deliberately manipulate gene flow? Does gene flow enhance or reduce genetic diversity? Which characteristics enhance diversity, and which characteristics reduce diversity? Has gene flow from improved varieties affected the diversity of landraces? What is the impact of gene flow on the livelihoods of farmers that plant landraces? How can answers to these questions be used to answer related questions about the impact of transgenic maize in these systems?

Monitoring of gene flow in and of itself will not be sufficient to project diffusion of transgenes and potential impacts. Traditional farmers' management of diversity and traditional agriculture are not static, therefore, the traditional systems themselves need to be monitored as they evolve or outside forces bring changes to them (i.e., increased arrival of transgenic seed from migratory workers). If we want to have a framework of effective biosafety rules in these traditional systems, we must consider and monitor all of the relevant variables and components of these systems.

Adventitious Presence of Transgenes in *ex situ* Collections

CIMMYT adds new maize and wheat genetic resources each year to those that are already conserved under long-term *ex situ* conditions, and the Center will continue to abide by the spirit of its 1994 agreements with FAO concerning the management of collections of maize and wheat germplasm held "in trust". CIMMYT also reiterates the intent to associate itself formally with the International Treaty on Plant Genetic Resources for Food and Agriculture and, as in Article 15.1(c) of that Treaty, which recognizes "*the authority of the Governing Body to provide policy guidance relating to ex situ collections held by them and subject to the provision of this Treaty*", including guidance on the subjects covered by CIMMYT Guiding Principles for developing and deploying genetically engineered maize and wheat cultivars. Hence, the Center will continue to develop and implement measures that are feasible, given current technology and funding to protect the genetic integrity of incoming (and already held) accessions and to maintain them according to international standards (e.g., see the recently published Plant Genetic Resources Operational Manual, Taba *et al.*, 2004). The data arising from screening undertaken during the implementation of these measures will be made available as produced and without restriction. Recently, the Genetic Resources Policy Committee of the CGIAR issued a draft guiding principles for the development of Future Harvest Centers' policies to address the possibility of unintentional presence of transgene in *ex situ* collections, to which the CGIAR centers will adhere when formally issued by the CGIAR system.

In summary, CIMMYT's ability for monitoring the potential impacts of new cultivars builds on over 40 years of ensuring seed health of international nursery sets that reach partners around the world every year. The Center considers that monitoring is a national issue that needs critical attention in the short-term, and that it should be for all products not just those developed by a specific process. In this regard, decisions, policies and procedures should be led by facts of science, which requires education – an area where CIMMYT and its sister centers of the CGIAR can play a critical role. We hope that as more GM-crops, especially those ensuing from public efforts, are released, regulations and monitoring will be more rational and based more on the traits released. Nevertheless, there will be a need to continue assessing monitoring issues as countries in the developing world deploy new (and likely unique) GM-crops able to tolerate better local stresses and that possess enhanced nutritional quality.

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12. Monitoring Strategies and Management of GM Crops: An Industry Perspective

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Abstract

Monitoring is one of many tools that can be used to gather information that can then be used as part of a science-based risk assessment process to make decisions. Industry supports the use of monitoring, when appropriate, to ensure that products meet farmer needs (product stewardship), when used by academic and government researchers to increase basic scientific knowledge and as part of, and when prompted by, scientifically based risk assessment in the regulatory process. Prior to designing and carrying out a monitoring programme, it is essential to ask and obtain answers to several important questions. These fall into the broad categories of: Why (study purpose), When (study timing), Where (study and sampling location), What (the information to be gathered), How (the methods to be used) and Who (personnel issues related to studies).

Introduction

Monitoring is generally conducted to respond to one or more of three different needs: (1) Product stewardship monitoring studies are conducted to ensure that products continue to meet the needs of farmers. An example of this would be the monitoring of insect or weed resistance. (2) Some monitoring studies are conducted with the goal of increasing general scientific knowledge. Examples of these studies are those conducted by academic researchers seeking to answer questions that are of scientific interest, but perhaps not of interest to the general public or of use in making regulatory decisions. (3) Monitoring studies may be conducted within the framework of regulations governing the production and use of genetically modified (GM) crops. Various regulatory requirements exist that may influence the need for monitoring studies. Some of these requirements are science based; others may be driven by a real or perceived public need for additional information.

While the general principles outlined in this paper are useful for designing studies to meet each of the three needs listed above, the discussion will focus primarily on monitoring studies that may be used within a regulatory framework to evaluate the potential GM crop effects on non-target organisms.

Monitoring studies are not risk assessments, but are part of a scientifically based risk assessment process (NRC, 1983; EPA, 1992, 1998; EC, 2001; EFSA, 2004). This process consists of a defined path: problem formulation, characterization of exposure and hazard and risk characterization. In practice, after the problem has been formulated, the hazard and exposure characterization process begins generally with simple studies, often conducted under laboratory conditions. In the case of GM crops, the laboratory studies can be done under controlled conditions at a relatively early stage of crop development. The laboratory tests utilize either microbially produced proteins or actual plant materials that are fed to organisms that represent general classes of organisms in the field. The results of the laboratory studies are then used to make decisions regarding risk. In certain cases, extended laboratory, semi-field or field monitoring studies may be used to obtain additional effects or exposure data to refine the risk assessment.

The risk assessment process used in a regulatory framework is generally described as tiered, iterative or step-by-step because: (1) as more information becomes available, it can be incorporated into the risk assessment; and (2) the process can be stopped as sufficient information is available to answer the regulatory need. Another significant advantage of the step-by-step risk assessment process is the ability to focus resource use on areas of greatest potential importance. Early tiers or iterations generally contain numerous conservative assumptions (high exposure scenarios, relatively worst-case hazard testing conditions, etc.). If no effects are seen, then it may be concluded that risk is acceptable. If effects are seen, then additional hazard and exposure data may be gathered to refine the risk assessment. For example, laboratory tests using insecticidal GM crops indicate that toxicity is usually limited to only a few target species of insects and no toxicity is seen in most insects, invertebrates, mammals or birds. These "early tier" or smaller scale studies provide sufficient information to assess risk and move forward with a product. If the early studies indicate unacceptable risk to certain organisms, they would serve to prompt and guide any later studies by indicating where effects are likely (or not likely) to occur. Later studies such as extended laboratory, semi-field, or field monitoring studies would then be focused on the specific areas of uncertainty not resolved by the earlier studies.

In general, industry has been supportive of post-commercial monitoring when it has been part of a scientific approach to risk assessment. Monitoring is a tool to obtain information. Like all scientific tools, it is not inherently good or bad. However, inappropriate use of monitoring can use valuable resources without providing useful information. In addition, significant monitoring requirements may limit the adoption of a technology to large companies with major products or to countries with the ability to conduct and/or interpret monitoring studies.

Once the decision has been made to conduct some type of monitoring study, it is essential to ask and obtain answers to a series of questions to define the study and make sure that the results will be as useful as possible (Table 1, below). These questions can be organized into six basic areas: Why (study purpose), When (appropriate time to conduct monitoring studies), Where (location of studies and sampling within studies), What (the information to be gathered during the study), How (the methods used to gather data) and Who (personnel issues related to studies).

Why – Study Purpose

The most critical step in conducting a monitoring study is a clear definition of need and purpose. Before a monitoring study is conducted, the need for the study should be clearly understood by all parties, the problem formulated, the question(s) to be answered defined and the overall framework of the assessment designed. The problem formulation phase includes taking into account any information available from previous studies. In general, these previous studies will help define the need for and the design of any later studies such as field monitoring. One potential result of the problem formulation/purpose definition step is a realization that monitoring studies may not be the best method to achieve the overall purpose.

The purpose of the study should be "specific and clearly stated" as a scientific hypothesis or answerable question (DEFRA undated). A vague purpose such as "investigate potential effects on the ecosystem" or "reduce uncertainties associated with the risk assessment" is not a testable hypothesis and will not effectively guide the study design. A testable hypothesis such as "a change from conventional to GM crops will have less of an effect on populations of _____________ (insert a taxon name of interest here) within no-till maize fields than the population level effects of commonly practiced crop rotation techniques" would be much more effective at guiding the study design.

Table 1: Categories and examples of general and specific questions to be asked when designing a field monitoring programme

Question Category	General Questions	Specific Questions
Why – Study Purpose	Is the purpose clearly defined?	• Have the needs and expectations for the study been clearly explained? • What is the source of the needs? (Product support, regulatory, basic research, etc.) • Is there a written, testable hypothesis?
When – Study Timing	Has a scientifically based risk assessment been conducted to prompt and guide monitoring design?	• Have hazard and exposure data both been used to determine potential risk using science-based risk assessment methods? • Did the risk assessment indicate a need for monitoring? • Have risk assessment techniques been used to focus monitoring efforts on areas of greatest importance?
	Are commercial products and cultivation methods available?	• What are appropriate, representative, commercial products to use in testing? • What are appropriate, representative, cultivation methods to be used in testing?
Where – Study Location	Will monitoring studies be conducted in relevant geographical areas?	• Have study locations been determined using a data-driven approach rather than being determined by political boundaries? • Under what circumstances can results from one area be applied to other areas (for example, areas with similar climate, soil, agriculture, etc.)?
	Are sampling locations and intensities guided by risk assessment and earlier studies?	• Does the sampling strategy emphasize the most important within field-sampling locations (soil, foliage, etc.) based on defined study needs? • Is sampling intensity appropriate? • Is sampling focused on time of probable effect? • What is the appropriate test size (plot size, number of sites, etc.)?
What – Data to be Gathered	Is the "control" clearly defined?	• What are any potential "effects" going to be compared to? • Are appropriate baseline data available? • Will positive controls (such as conventional pesticide treatments) going to be used to determine the potential sensitivity of sampling methods? • Will negative controls (such as use of a near isolines) be used to determine effects of a genetic modification?
	Are statistical endpoints clearly defined and attainable?	• Is there a defined list of data needed to make a conclusion? • Have criteria been determined for evaluating data quality and utility? • Have the appropriate statistical design and significance level been defined and agreed upon? • What species are to be monitored based on their abundance and ability to represent functional groups?
	Are the "ending points" or future decision pathways clearly defined?	• How will the results be used and will they be sufficient to accomplish the purposes of the study? • Under what conditions will monitoring be terminated, continued or redirected?

Question Category	General Questions	Specific Questions
How – Methods to Gather Data	Are appropriate and tested sample collection and analysis techniques available for use?	• Are tested methods already available or is method development needed to gather the data needed to accomplish the purposes of the study? • Are sample collection and analysis resources available where the test is to be conducted?
	Are trained personnel available to design and conduct the study?	• What level and type of training is needed to be able to design and conduct a study that will accomplish the defined purpose? • Are trained personnel available at a local level to conduct a high-quality study within the time requirements?
	Is there a clear understanding of how the data will be used?	• How will the data be received and reviewed? • What decisions are expected to be made using the data?
	Are appropriate and tested techniques available to avoid false negatives or positives?	• What level of "statistical power" is needed to accomplish the purposes of the study? • When using "surveillance" techniques without trained observers, how will false negatives and positives be analyzed and interpreted?
Who – Personnel-Related Issues	Is the audience clearly defined?	• Who is the primary audience for the results of this study; regulators, the academic community or the general public? • Is the study and subsequent interpretation and communication methods designed to provide the type of information needed by the defined audience?
	Are trained personnel available to interpret and communicate study results?	• What level and type of training is needed to be able to interpret and effectively communicate study results? • Are trained personnel available at a local level to interpret and communicate results, respond to future questions and make decisions based on the results?
	Are funding sources defined and available?	• Who will pay for the design, conduct, interpretation and publication of the study?

When – Study Timing

To be most effective, monitoring studies will be required and designed only after laboratory and other small-scale studies have been conducted and their results incorporated into a science-based risk assessment. If critical needs and uncertainties are identified during this risk assessment, various options are available to reduce the uncertainties and better understand the potential risks associated with cultivation. One of these options is field monitoring. If monitoring is selected as an option, then the results of the risk assessment should be used to focus the monitoring efforts on the areas of greatest importance. For example, if certain taxa are shown to be susceptible to the proteins in a GM crop while other taxa are not, then this will direct the monitoring study design to emphasize sampling on those taxa that have been shown to be susceptible. Or, if the risk assessment indicates that the protein is preferentially expressed in certain tissues or at certain times during crop development, then this should be taken into account when designing the monitoring study. Conducting a monitoring study prior to conducting a risk assessment or taking into account what is known about a GM crop will lead to a waste of resources.

Monitoring studies should be conducted using a representative commercial product in typical cultivation scenarios. In general, the purpose of monitoring studies will be to answer defined questions about the potential effects of a GM crop using common agricultural practices. This can only be done after the product has been commercialized, sufficient seed is available and large plots can be utilized. There may be some occasions, however, when an alternative study design might be more appropriate to answer a particular question of interest. In these cases, care must be taken to avoid extrapolation of these results to represent potential results under typical agricultural practices.

The appropriate timing of sampling can be determined based on the hazard and exposure data gathered during the risk assessment conducted prior to the start of the monitoring study. For insecticidal traits, a study strategy that links sampling to periods of likely effects and highest exposure will increase the ability to achieve the purpose of the study while at the same time conserving resources. For herbicide-resistant crops, it would be more appropriate to sample during the period when the herbicide is having its greatest effect (making sure that similar sampling and effects are being studied at the same time in the control plots).

Where – Study Location

Monitoring studies should be located and designed to best answer the study purpose. Usually, in order to obtain the greatest use of study data, monitoring studies should be conducted at locations that are representative of where the GM crop will be grown commercially. Study locations determined using a data-driven approach (e.g., use of cropping and soil databases, etc.) are preferable to those determined by political boundaries. In most cases, results from well-designed studies conducted in one area are applicable to other areas with similar agriculture and climate. Studies should contain the appropriate replicates and controls at each location; it would be inappropriate to compare results from GM crops at one location with a control field at a very different location. In addition to the general sampling location, the number of sites and number and size of test plots are important parameters to be determined based on the purposes of the study.

Sampling during a monitoring study should be focused on both the time and location of greatest likely effect as determined by the risk assessment carried out before the monitoring study is conducted. For example, if protein expression is present in the roots, but not in the foliage or pollen, then this will prompt a greater sampling effort in the soil area than that associated with leaves and pollen. Or, if effects were in laboratory studies on the larvae of certain organisms but not on the adults, then sampling of larvae should receive a greater amount of attention. Prioritization of sampling in time and space will allow the study to most effectively use the resources available to those conducting the study as well as those using the results of the study in conducting a risk assessment.

What – Data to be Gathered

A key factor in any monitoring study is the decision of what “controls” will be used as part of the study. Crop cultivation produces highly manipulated ecosystems. As such, monitoring studies involving GM crops differ from many basic ecological studies because comparisons are being made between two artificial systems. Effects due to the GM crop may be trivial or non-detectable against the background of ecosystem variability due to variety differences, crop rotation, cultivation and various environmental issues. Results from GM crops can be compared to baseline data or positive or negative controls.

Baseline data may be useful to understand the normal variability of the agricultural system that is being studied. However, due to differences in weather patterns from year to year, baseline data is not as useful for comparing one year of GM crop cultivation with an earlier year when GM crops were not used. Positive controls, using conventional insecticides or tillage practices, may be useful in determining the potential sensitivity of sampling methods as well as providing a comparison of the GM crop with the conventional crop. Negative controls, such as near isolines or similar varieties, can be used to investigate the potential effects of the GM crop trait. Care should be taken to make sure that all of the study areas are treated in an equivalent manner (cultivation, irrigation, fertilization, different pesticidal sprays, etc.).

The endpoints for the monitoring study should be determined as part of the problem formulation or study design phase. Endpoints and the study design will depend on the purposes of the study. For example, a study designed to evaluate the potential for an increase in resistance among pest populations will focus on the pest species, while a monitoring study designed to evaluate potential effects on non-target organisms will likely require vastly different sampling locations, timing, methods and endpoints. A study designed for a research publication may focus on a subtle ecological endpoint that may have little importance in a study designed to compare the population changes of non-target organisms in conventional and GM crops with changes caused by crop rotation.

Once a defined list of required endpoints has been assembled, then criteria should be established for evaluating data quality and utility. Taxonomic groupings as well as the statistical design and significance level should be defined and agreed upon as part of the study design. While some taxa will be collected in sufficient numbers to provide meaningful data, rare taxa may not be. Some taxa can be grouped into large taxonomic categories (e.g., “ground beetles” or “springtails”) and still achieve the purposes of the study. In other cases, targeted taxa may serve as indicators of effects on taxa that are more difficult to sample effectively. The use of taxonomic groupings or targeted taxa allow for a more efficient use of resources.

If possible, the “ending points” or future decision pathways should be clearly defined as part of the study design. A clearly defined purpose will generally lead to a logical ending point for the study. In addition to an ending point, the overall risk assessment framework should include criteria for stopping, continuing or redirecting efforts based on the results seen in the monitoring study.

How – Methods to Gather Data

Once the decision has been made to monitor, a clear purpose defined along with a location and a list of needed data assembled, then appropriate methods must be found to gather the needed information. In most cases, monitoring methods can easily be adapted from ecological studies; pitfall and sticky traps, visual observations and various soil or plant debris sampling methods are available. In some areas, university researchers or consultants are available and taxonomic references are generally up to date. In other areas, however, trained personnel may not be available and baseline data on typical target and non-target species may be nonexistent. In any case, careful consideration should be made on what data are really needed, how the data will be used and then what methods are best suited to obtaining the needed data in the time frame needed to come to a conclusion.

In addition to trained personnel to conduct monitoring studies, trained personnel are also needed to provide meaningful interpretation of study results. Three important considerations in the interpretation of monitoring data are: (1) Appropriate statistical methods and interpretation should be utilized in data analysis. The advantage of field monitoring is a greater level of realism as compared to laboratory tests. However, the disadvantage of field monitoring studies is the higher level of variability in the test systems, large amounts of data and potential covariance and other confounding factors in the dataset that may need to be considered during the analyses; (2) In monitoring studies where large amounts of data are collected, there will be occasional “statistically significant” differences found simply due to the high natural variability of the natural systems being studied. These should be expected and are not necessarily indicators of biological significance; and (3) GM crops have been designed to have effects. For example, plants that have insecticidal proteins will have effects on some types of insects. Herbicide-resistant crops will alter cultivation and herbicide application patterns, which then will alter population structures of organisms living near the field. These are not unexpected effects and one must guard against the conclusion that any change from the status quo is a negative or adverse result.

In addition to sampling in a standard field monitoring study, data may be gathered by way of the so-called “surveillance” monitoring. This may be in the form of scientifically designed survey techniques or through ad hoc reporting of events. Survey techniques are well established and understood. However, special data analysis methods will need to be designed to take into account the potential false positives and negatives and poor quality data within the dataset, especially if the reports come from untrained personnel.

Who – Personnel-Related Issues

Perhaps one of the most neglected parts of monitoring studies is a serious consideration of the audience of the monitoring results. Study needs for a graduate thesis committee may be significantly different from the needs of a regulatory committee investigating a GM crop. Even if the actual design of the study is not significantly different, the method and style of communication in a scientific journal article is quite different from that used to communicate the same results to the general public.

Universities and regulatory agencies in well-developed countries generally have experience in communicating complex scientific data to the general public. This may not be the case for developing countries, and some capacity building may be necessary to assure proper interpretation and communication of the monitoring study, risk assessments and risk management documents.

A final personnel-related issue involves the funding sources to be used to design, conduct, interpret and communicate the results of monitoring studies. Study costs related to product development and support are generally paid by the owners of the product. However, financial support for monitoring studies, such as those designed to expand basic scientific knowledge, generally would come from those persons who are conducting the research.

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13. Assessing the Socio-economic Impact of GE Crops

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Introduction

The Cartagena Protocol on Biosafety requires that risk assessment and monitoring of genetically engineered (GE) crops must be done where there is uncertainty about their environmental impact. There is a broad acknowledgment of the fact that GE crops and foods need to be monitored for their impact on the environment and human health. What is less recognized is the need to monitor the socioeconomic impact of such crops, especially in the context of developing countries. Despite the ambiguity of the Cartagena Protocol with respect to the socio-economic considerations associated with GE crops, developing countries must pay special attention to this aspect so as to prevent a situation wherein the introduction of agricultural biotechnology causes loss and distress among rural communities.

The Case of Herbicide-Tolerant Crops

The development of herbicide-tolerant (HT) crops provides a case study to examine the likely socio-economic impact of GE crops. This technology that is based on proprietary herbicides claims its goal as "to reduce drudgery" on the farm, especially for rural women. This claim has little to do with rural reality in most parts of the developing world where farm operations like weeding and winnowing are major sources of rural employment, especially for women.

Creating rural employment and income sources is one of the great challenges facing governments in agriculture-dominated developing countries. Agricultural labour constitutes the largest section of the labour force in developing countries; in India and in other South Asian countries, the agricultural labour force is growing at the rate of six to seven percent per annum. The herbicide-tolerance trait is a trait developed specifically to cope with agriculture in labour-starved industrial countries with large land holdings. Being a labour saving and therefore a labour displacing strategy, herbicide tolerance will have negative social and economic implications were it to be introduced in labour surplus developing countries.

To understand the likely impact of HT crops, weeding has to be seen in the context of the social and economic value of plants that are considered weeds. Weeds are considered a nuisance in the monoculture agricultural systems of industrial nations where many thousand hectares of wheat or corn would be planted. In the case of developing countries, the fields yield a myriad of other plants in addition to the main crop. The so-called weeds in farmers' fields have several useful functions critical to the well-being of rural communities.

Weeds in an agricultural field fulfil two important nutritional roles. They are largely nutritious leafy greens, which are a valued source of nutrition in the family's diet. A typical wheat field in India or Bangladesh would yield at least 20 types of leafy greens over the cropping season. These greens provide nutrition in a fresh and easily available form, at no cost. This access to free nutrition is one of the reasons why the nutritional status is better among the rural poor than among the urban poor who have to buy all their food.

The plants collected during weeding also serve as fodder for the livestock that rural families maintain as additional income sources. Increasing fodder availability is one of the key concerns of the agricultural research system. For rural families the livestock they keep are critical for increasing incomes either through milk or the sale of the animals for meat. If rural families had to buy all the fodder that was needed to maintain their cows, goats or pigs, many would not be able to afford keeping animals and would have to forego the extra income.

Apart from this, using HT crops would make it impossible to plant crops on the field bunds, as is done in many parts of Asia, both for additional food and for increasing farm incomes. Typically, farmers grow crops like yams, ginger or vegetables on the bunds surrounding rice fields. Thus, two or three kinds of produce are available from the field in the same season. This advantage would be lost if HT crop varieties were used. In addition, the practice of intercropping and mixed farming would suffer a setback. Mixed cropping is widely practiced, with differing combinations of crops depending on the region.

The so-called weeds are also the medicinal plants that rural families depend on for the health and veterinary care needs of themselves and their animals. The introduction of HT crops with the accompanying herbicide use would kill the surrounding vegetation and deprive rural communities of the medicinal plants which form the basis for indigenous healing traditions.

Based on this, we can discuss the kind of indicators that would need to be developed in order to assess the socio-economic impact of the introduction of GE crops on rural families. Impact assessment after the introduction of HT crops should include factors like changes in the family income due to the loss of wage labour from weeding, loss of income from products derived from additional livestock, the man days lost in collecting fodder from elsewhere or expenditure on buying fodder. This loss of income or additional financial burden will have an impact on other aspects of a family's life; less money may mean pulling out a girl child from the school, less money for school books or fewer clothes.

The impact on household nutrition should be measured in terms of reduced intake of nutrients like vitamins and minerals, resulting from the loss of green vegetables from the diet, especially in the case of women who, in any case, receive less nutrition than the men and children when food is scarce in poor families. Along with this, we need to assess the impact of reduced family income arising from the loss of supplementary crops like yams and vegetables that are grown on field bunds surrounding the principal crop.

Indicators will need to be developed to assess the impact of the loss of locally available medicinal plants on the health of the community and their livestock, the increased expenditure that the rural family will have to incur on procuring treatment from the commercial sector and the loss of man days in travelling to the nearest formal health facility to seek medical and veterinary help. Given that government medical facilities are scarce in rural areas, the destruction of medicinal plants will compel the rural population to access expensive, even unreliable medicines from private sources that are often dominated by unqualified people if not outright quacks. The loss of medicinal plants will deny the community its ability to be self-reliant in procuring health and veterinary care and will place financial burdens to acquire these services elsewhere.

One of the serious outcomes of introducing the HT trait is the development of new weeds because the herbicide is known to shift easily into other crops. In the case of canola, all the kinds of HT genes that have been used are found to have migrated into other non-GE canola (Biotechnology Australia, 2003). The crop of concern in developing countries though is rice. Several studies (Gressel, 2002; Lu *et al.*, 2003) have shown that the HT trait shifts quickly to rice relatives, specifically, from *Oryza sativa*, the cultivated rice, to *O. rufipogon*, a wild relative also called red rice, which is a commonly found weed in the areas where rice is cultivated. The shift of the HT trait into a rice weed like *O. rufipogon* will have economic implications because the red rice is a strong competitor of the cultivated rice and tends to take over rice fields. Socio-economic indicators should be developed to assess the economic impact on the farmer of poor rice yields and the impact on food reserves of shortfall in rice production in countries that continue to have food security concerns. In these countries, including India, a shortfall in rice production will impact directly and seriously on the country's ability to provide adequate food to the poor, as well as its ability to hold buffer stocks of food grains to meet emergencies. A related cost will have to be factored in as well, that of having to buy food grains from the international market, in order to maintain the grain buffer stocks which are central to planning for food security.

In the case of the *Bt* crops, the costs of introducing this technology under developing countries needs to be worked out. Unlike the large cotton plantations of the US for which this technology was developed in the first place, cotton in developing countries is cultivated by resource poor farmers with small land holdings, usually under rainfed conditions. These farmers by and large do not implement the insect refuge of 20 percent that is required to maintain the *Bt*-pest-resistant strategy (Sahai and Rehman, 2003). The refuge is not maintained because it is uneconomical for the farmer to divert 20 percent of the total land area, especially when the holding is less than one hectare. The *Bt* technology is therefore being implemented in a situation where, from the point of view of local agriculture practices, it should not. The socio-economic impact of quick resistance development on the farmers who have changed their farming practice to accommodate *Bt* cotton, will need to be assessed. What will also have to be assessed is the result of the indiscriminate manner in which the *Bt* gene is being deployed in a large number of crops (Sharma *et al.*, 2003), which will be planted in all the major crop seasons. With a *Bt* crop in the field all the time, the pests will not only develop resistance to the toxin but also start moving to other crops as fresh hosts. Appropriate indicators are needed to assess the cost of these developments.

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FAO hosted an expert consultation entitled *Genetically Modified Organisms in Crop Production and their Effects on the Environment: Methodologies for Monitoring and the Way Ahead* from 18 to 20 January 2005 in Rome. The main objective of the consultation was to review the scientific basis and procedures to establish effective post-release monitoring of genetically modified (GM) crops and develop guidelines to strengthen the capacities of member countries to design and carry out monitoring programmes. The major outputs of the meeting were:

- a review of scientific criteria and procedures that address the technical aspects of monitoring environmental effects of GM crops;
- two strategies that could be used as the basis for efficient monitoring programmes; and
- recommendations for scientists managing the monitoring process, policy and decision -makers, FAO and other relevant international agencies

The capacity to undertake a monitoring programme can vary globally, but the core values of such a programme should be a serious commitment to engage and consult with people with a stake in the final outcome and a judicious selection of indicators that meet the basic requirements for scientific rigour. This is essential to address stakeholder concerns and trigger appropriate management or regulatory responses.

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