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

EXPERT CONSULTATION
18–20 January 2005

Food and Agriculture Organization
Rome, Italy

REPORT

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Abbreviations and Acronyms

AG: Agriculture Department
AGP: Plant Production and Protection Division
Bt: *Bacillus thuringenesis*
CGIAR: Consultative Group on International Agricultural Research
CIMMYT: International Maize and Wheat Improvement Center
EU: European Union
FAO: Food and Agriculture Organization
FSE: Farm-scale evaluations
GM: Genetically modified
GMHT: Genetically modified herbicide-tolerant
GMO: Genetically modified organisms
HSNO: Hazardous Substances and New Organisms Act
HT: Herbicide-tolerant
IDWG: Inter-Departmental Working Group
UK: United Kingdom
UNEP: United Nations Environment Programme

TABLE OF CONTENTS

I. Executive Summary

The Food and Agriculture Organization (FAO) hosted an Expert Consultation on "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 for, and procedures to establish, effective post-release monitoring of genetically modified (GM) crops and develop guidelines to strengthen member countries' capacities to design and carry out monitoring programmes. The participants represented a wide range of expertise from research institutes, universities, international agencies, regulatory agencies, the private sector and civil society. The consultation was jointly organized by the Plant Production and Protection Division of FAO's Agriculture Department and the Inter-Departmental Working Groups on Biodiversity for Food and Agriculture and on Biotechnology in Food and Agriculture.

The experts emphasised that GM crop deployment must comprise the whole technology development process, from pre-release risk assessment to biosafety considerations and monitoring post release. The positive and negative effects of GM crops on the environment are shaped by location and context, and monitoring programmes should recognize that there are important sources of variation within and among farming systems. It should inform decision making and provide feed back to the regulatory process and policies that support the development of sustainable practices. Wherever possible, the objectives of monitoring programmes should, therefore, be nested within processes that address broader goals.

The experts did not list or evaluate individual indicators needed for monitoring, but emphasized the critical importance of planning the process. Major outputs of the meeting were:

i) A review of scientific criteria and procedures that address the technical aspects of monitoring environmental effects of GM crops;
ii) Two strategies that could be used as the basis of efficient monitoring programmes and,
iii) Recommendations for scientists managing the monitoring process, policy and decision makers, FAO and other relevant international agencies.

The capacity to undertake monitoring varies globally. Several developed countries have undertaken large-scale, long-term research and post-release monitoring programmes for GM crops that have provided an effective basis for decision making. Monitoring programme development is, however, a greater challenge in the developing world, where possible hazards are less clearly understood and the stakeholders are less well defined. In addition, opportunities for engagement in public debate are limited, environmental protection measures are less effectively enforced, and there are insufficient resources for research and development or for strengthening local expertise.

To address these challenges, experts have developed a robust design for monitoring that could work within limited resource levels, using the example of herbicide-tolerant rice in Asia with the potential risk of gene flow to weedy rice. The core values of the monitoring programme are the 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 and address stakeholder concerns, and can trigger appropriate management or regulatory responses.

The key steps or actions for developing a monitoring programme are as follows:

- **Set monitoring programme goals and immediate objectives**

- Consult stakeholders, including farmers and managers, regarding the natural resources to develop the goals and immediate objective.

- **Identify potential barriers**
  - Prioritize and develop plans to overcome or minimize potential field barriers or otherwise.

- **Identify potential risks and benefits**
  - Use stakeholder and expert knowledge of potential risks/concerns and benefits of GM crops, and ways and indicators to measure these factors.

- **Develop a testing hypothesis to guide actions and decisions**
  - Ensure that the hypothesis is simple, robust and can be easily tested in the field.

- **Identify a limited number of potential indicators**
  - Ensure that the indicators meet the basic requirements of scientific rigor;
  - Reflect key elements of the hypothesis tested;
  - Compare with control sites and/or baseline values prior to GM crop release; and
  - Estimate the status and trends in indicator values.

- **Determine appropriate trigger values for decision making and action**
  - Anticipate the range of decisions and actions if triggers are exceeded; and
  - Prepare a follow-up action plan.

- **Cultivate a transparent and effective process**
  - Ensure follow-through continued involvement of stakeholder;
  - Maintain clarity in analysis and reporting, and identify needs; and
  - Build linkages with policy development and capacity building.

The consultation viewed these actions as occupying a toolbox. They should not be adopted as an inflexible, linear process. Full stakeholder engagement should be fostered through formal and informal networks, alliances and initiatives to promote resource mobilization, communication and information dissemination. Building trust and transparency is the only way to sustain an effective link between monitoring and the resulting actions.

II. Introduction

The Food and Agriculture Organization (FAO) hosted an Expert Consultation on “Genetically Modified Organisms in Crop Production and Their Effects on the Environment: Methodologies for Monitoring and the Way Ahead” from 18 to 20 January in Rome. The main objective of the consultation was to review the scientific basis for, and procedures to establish, effective post-release monitoring of genetically modified (GM) crops and develop guidelines to strengthen member countries’ capacities to design and carry out monitoring programmes. The consultation was a follow-up to the earlier FAO Expert Consultation on “Environmental Effects of Genetically Modified Crops”[1] which had recommended that the environmental effects of GM crops be assessed on a case-by-case basis and emphasized the emerging need to monitor possible medium- to long-term environmental impacts through adequate practical methodologies.

The meeting was a three-day event organized by the Plant Production and Protection Division (AGP) of FAO’s Agriculture Department. It was co-sponsored by the FAO Inter-departmental Working Groups (IDWG) on Biodiversity for Food and Agriculture and on Biotechnology in Food and Agriculture. Seventeen experts from around the world were invited to participate in their personal capacity, including representation from the scientific community, international research centres, private sector and the civil society. A background paper on monitoring was prepared and distributed to all participants.[2]

The consultation was inaugurated by Louise O. Fresco, Assistant Director General of FAO’s Agriculture Department. She welcomed the participants and emphasized the Organization’s commitment to providing tools to assist countries in making their own informed choices on the matter, as well as protect the productivity and ecological integrity of farming systems. She urged the experts to consider the importance of networks and partnerships for practicability and cost-effectiveness, and to provide access to necessary information and enable its dissemination, should nations introduce post-release monitoring to address both foreseen and unforeseen impacts of GM crop production. She felt confident that FAO would be better positioned to assist member countries in making appropriate choices in this area from the recommendations received from the broad range of expertise assembled in this meeting.

The Director of AGP, Mahmoud Solh, stressed the need for evaluating current monitoring methodologies and procedures, identifying the common elements and constraints so that the Organization can provide guidance for strengthening member countries’ capacities to establish effective monitoring of GM crops, as appropriate. He emphasized the facilitator role of FAO in the development of a follow-up mechanism for monitoring medium- to long-term environmental effects of GM crop cultivation involving United Nations agencies, Consultative Group on International Agricultural Research (CGIAR) centres and other international and national centres.

Peter Kenmore, Chairperson of the IDWG on Biodiversity for Food and Agriculture, introduced the Provisional Agenda which was adopted unanimously. He briefly described the process proposed for the consultation. The first section would be devoted to presentations on current monitoring procedures, country experiences, large-scale experiments on monitoring GM crops and management of monitoring programmes. This would be followed by the two thematic group discussions where the experts would analyze proposals from the perspective of (a) countries with well-established risk assessment procedures and scientific infrastructure, and (b) countries that have more limited capacities. He emphasized that the scope of the

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[1] Report of the FAO Expert Consultation on “Environmental Effects of Genetically Modified Crops”, 2003. ftp://ftp.fao.org/docrep/fao/field/006/ad690e/ad690e00.pdf

[2] FAO Expert Consultation background paper: Challenges to the design and implementation of effective monitoring for GM crop impacts: lessons from conventional agriculture, P. Jepson, 2005 (unpublished).

consultation was post-release monitoring and hoped that effective guidelines and recommendations would be developed through the deliberations.

Thereafter, the chairperson of the sessions invited the speakers to present their papers, followed by general discussions. On the final day, the meeting was closed with the adoption of the preliminary meeting report and with the draft recommendations. The Final Agenda and List of Participants are included in Annex 1 and Annex 2, respectively. A special note from the experts is presented in Annex 3. The background paper and handouts of the presentations by invited speakers will be available separately.

III. Monitoring Defined

The experts considered that it was important to properly define monitoring and to outline the role of monitoring in relation to other environmental data collection and analysis procedures. Monitoring was defined as a procedure that involves the systematic measurement of selected variables and processes that may be affected by a given practice. Reasons for monitoring include the need to meet environmental protection goals, concerns about deviations in ecological integrity from a predetermined standard or verification of risk assessment findings.

Monitoring does not substitute for rigorous risk assessment in protecting against adverse environmental impacts, although unlike risk assessment, it may also be used to quantify the potential benefits of GM crops.

Successful monitoring procedures build upon existing ecological data sources that establish the status of the system under investigation. Monitoring should not be confused with general environmental surveillance or ecological inventory: monitoring is goal-oriented, and designed to detect change in comparison to reference sites, and/or pre-treatment condition. When effective, monitoring addresses the priorities of people with a stake in its outcome, and feeds back to inform management and policy development.

Deployment of GM crops must encompass the whole process of technology development from pre-release risk assessment to post-release monitoring. Monitoring programmes should recognize and take into account important sources of variation between farming systems and GM crop types in order to properly address potential interactions between the GM crop and the environment. The positive and negative effects of GM crops will vary with location and context, and monitoring will require a new model of working in order to inform actions at the farming system level.

The capacity to undertake monitoring varies globally and reflects the level of ecological knowledge associated with particular systems, the local capacity to plan, implement and analyze the data, and the integrity of the pathway that leads from the data to decision making, and back to effective management.

IV. Elements of Environmental Monitoring Strategies

Presentation 1: *Principles and procedures for medium- to long-term environmental monitoring*. P. Jepson
Presentation 2: *Strategies and tools for monitoring biodiversity and ecological function*. A. Hilbeck
Presentation 3: *Soil ecosystem monitoring methodologies.* J. Thies

Paul Jepson reviewed monitoring principles based upon the Expert Consultation background review paper. Analysis of long-term biodiversity monitoring in agro-ecosystems tends to be retrospective, with time lags between data collection, analysis and response. Monitoring of functional, often abiotic, indicators has a better record for early detection of adverse impacts.

Decision making and effective responses are only possible when plausible mechanisms underlying effects are known, and when monitoring analysis has high inferential power. Measurements must also translate to the values and concerns of stakeholders in the final outcome if management responses are to be implemented. Post-release monitoring must consider functional, taxon-based and structural indicators to detect the drivers of change associated with GM cropping. Some farming systems will be more sensitive than others. Sensitive systems may be at intensification limits or ecologically fragile, with high species turnover rates and poor connectivity with natural areas. They may also be critically dependent upon the grower knowledge base, R&D support may be poor, and the policy environment may be inflexible.

Angelika Hilbeck discussed monitoring biodiversity and ecological functions in the context of European Union Directive 2001/18[3] which requires monitoring for all GM commercial releases. Monitoring designs must be case-specific (to verify risks) and general (to detect unanticipated effects). A project of the German Federal Agency for Nature Conservation is identifying faunistic indicators using a species-ranking approach, which characterizes and ranks species by ecological function, occurrence, spatio-temporal abundance and relevance, and an impact pathway approach, which identifies hazard scenarios using 'event-tree analysis' and 'fault-tree analysis'. The two tools are used in succession; the first prioritizes species based on characteristics and conservation goals independent of genetically modified organisms (GMOs) and the second subjects them to fault- and event-tree analyses to identify species at risk.

Janice Thies discussed methodologies for monitoring the soil ecosystem and its function. The soil provides many ecosystem services including decomposition and nutrient cycling. The agricultural soil food web, with crop residues as its base, includes decomposers (bacteria and fungi), and predatory protozoa, nematodes and micro-arthropods. GM crop residues have the potential to disrupt energy and material flows, and monitoring should be designed to detect detrimental changes in trophic structure and/or key ecosystem services. Soil scientists are yet to agree upon the factors that determine soil ecosystem integrity, and the level of change that might trigger concern. Promising indicators include the level of retention and form of soil organic matters[4], soil respiration rate, abundance of shredder species (collembola and mites), microbial biomass, nitrogen mineralization and nitrification, soil glomalin concentration, and molecular indices of soil community structure.

Discussion Summary

- Before/after comparisons, or comparisons with control (without GM crop) areas, are essential if analysis of monitoring data is to have inferential power. Data must span the whole cropping system.

- Background data required for all systems includes soil parameters, climatic conditions and crop management (fertilisers, crop protection chemicals, crop rotations and previous crop history).

- Existing biodiversity measurements and abiotic measures of system conditions should be collated, and availability of monitoring expertise must also be established.

- Monitoring should focus on potential positive and adverse effects of concern to stakeholders.

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[3] Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC. http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_106/l_10620010417en00010038.pdf
[4] Sohi *et al.* (2001). *Soil Science Society of America Journal* 65: 1121–1128.

- Available data on the turnover of GM crop residues in the soil should be compiled into a global database.

- Scientific experiments, undertaken by researchers to develop understanding of mechanisms, do not constitute monitoring; they are, however, essential precursors to effective monitoring because they provide a direct link between measures of change and the mechanisms that underlie such change if it is occurring.

V. Monitoring GM Crops: Methodologies and Practices

Presentation 1: *Issues and challenges in monitoring GM crop-specific traits*. D. Bartsch
Presentation 2: *Farm-scale evaluation of GMHT plants in the United Kingdom*. L. Firbank
Presentation 3: *Regulatory aspects for monitoring GM crops in New Zealand*. F. François

Detlef Bartsch discussed the impact of monitoring GM crops on the environment. GM crop environmental risk assessment in the European Union (EU) identifies areas of uncertainty, including the potential for large-scale and long-term cumulative impacts that should be addressed by monitoring. The types of variables to be monitored must be identified with the procedures to measure them and an appropriate time period for measurement. Monitoring designs must be within logistic limits. Monitoring can also be linked with conservation goals, e.g., via the EU Directive on environmental liability. Damage in this context can include effects on aquatic and terrestrial protected areas and natural habitats, with reference to a baseline or conservation status, ecosystem services that are offered, and the capacity to recover. Damage is not considered to have taken place if impacts consist of fluctuations within normal variability, effects of natural events or normal management, short-term effects, or improvements in condition. Agro-ecosystems may already be included in national environmental monitoring programmes, and surveillance systems may already exist. Having a legal definition of damage may help to focus the monitoring effort and make it more cost-effective.

Leslie Firbank discussed the farm-scale evaluations (FSEs) of spring-grown GM crops in the United Kingdom (UK). They constituted a very large experimental regime, and were not designed as monitoring studies. Biodiversity impacts of genetically modified herbicide-tolerant (GMHT) sugar beet, maize, spring oilseed rape and winter oilseed rape were evaluated in separate experiments, each with 60–70 replicates that represented UK farming environments. Herbicide regimes in GMHT sugar beet and spring oilseed rape reduced weed numbers more than conventional crops, with effects on invertebrates. Currently, these two crops are not allowed to be grown in the EU. Weed numbers were higher in GMHT maize and commercial growing was allowed. The requirements for ongoing monitoring should be based on an understanding of what is an unacceptable impact on biodiversity. The same results in a different part of the world may give different policy responses if the conservation goals differ or if the balance between environmental, social and economic goals differs.

Fleur François provided a regulatory perspective on approaches and challenges in conducting risk assessment and monitoring in New Zealand, which has regulated GMOs since the late 1980s. Over 50 GMO field tests have been conducted but no GMOs have been released. The Hazardous Substances and New Organisms (HSNO) Act 1996 requires consideration of the sustainability of native and valued introduced flora and fauna, intrinsic value of ecosystems, public health, Māori (indigenous people) culture and traditions, economic costs and benefits and international obligations. Applications to release GM crops are declined if they fail to meet minimum standards relating to environmental impact. Monitoring may be required for conditional release approvals, if technically feasible and cost-effective. Post-release monitoring of GM crops is not considered a substitute for adequate pre-release risk assessment.

VI. Monitoring GM crops: Sharing Country Experiences

Presentation 1. *Monitoring GM crops in Canada*. R. Blackshaw
Presentation 2. *Monitoring GM crops in China*. Bao-Rong Lu
Presentation 3. *Monitoring GM Crops in Brazil*. E. Fontes
Presentation 4. *Field experience in monitoring GM crops in South Africa.* G. Bothma

Robert Blackshaw outlined approaches to studying the environmental effects of GM crops in Canada, where 5 million hectares of GM crops are grown annually. A 12-year field experiment is examining environmental and economic effects of herbicide-tolerant (HT) canola, maize and potato (until 2003), and *Bacillus thuringenesis* (*Bt*) maize. Data include soil quality and weed seed bank at initiation, weed density by species (species shifts), assessments of resistance development, target insects and plant diseases, arthropod community dynamics (diversity), soil microbial biomass and diversity, transgenic DNA persistence in soil, *Bt* toxicity persistence in soil, DNA transfer to soil microorganisms, crop yield and quality, and production economics. A second study addresses an HT canola seed in the soil seed bank. It was pointed out that although much scientific evaluation is conducted before GM crops are approved for commercial production, post-commercialization studies are prudent because some environmental impacts of GM crops are likely to be scale- and/or time-dependent.

Bao-Rong Lu outlined methodologies for monitoring environmental effects of GM crops in China, with special emphasis on rice. Biosafety research has been funded on GM cotton, rice, soybean, wheat, tomato and *Brassica* species, including gene flow and its ecological consequences, impact of transgenes on non-target organisms, changes in biodiversity, development of *Bt* resistance, fitness of inter-specific hybrids, and field performance of GM crops. Research on rice and its wild relatives provides a model for selfing, wind-pollinated crops. It addresses pollen flow, crop-to-crop and crop-to-wild gene flow, biodiversity influences of GM rice, fitness performance of hybrids between GM rice and wild rice species, and cost-benefit analysis. The objectives are to determine the most effective methodologies for monitoring environmental effects of GM crops and to develop guidelines for safe management.

Eliana Fontes presented details of monitoring for the environmental effects of GM crops in Brazil, where agricultural crops are grown in all five geographical regions, which differ in topography, climate, ecological and socio-economic characteristics and biodiversity. New agricultural technologies must fit within a culturally diverse society, a mega-biodiverse country and subsistence to industrial farming systems. Field trials of GM crops have been held since 1997, but only GMHT soybean is commercially cultivated. There are concerns about adverse effects on non-target organisms, and some crops have sexually compatible wild, feral and backyard relatives. Gene flow may pose a threat to the long-term preservation of crop species' genetic diversity. The diversity of agricultural systems in Brazil and the variety of expertise and baseline information needed for monitoring, poses a significant challenge. A Post-Commercial Monitoring Plan required by the National Technical Biosafety Commission for commercial release of GMHT soybean and an impact assessment of *Bt* cotton were presented.

Gurling Bothma discussed field experience and methodologies for monitoring the environmental effects of GM crops in South Africa, where GM yellow and white maize, soybean and cotton are grown. Monitoring by seed suppliers is required by the Office of the Registrar: Genetically Modified Organisms Act, 1997[5] to ensure refugia are maintained. Seed

[5] Office of the Registrar: Genetically Modified Organisms Act, 1997. http://www.info.gov.za/acts/1997/act15.htm

companies have established a GM Seed Standing Committee to coordinate an Insect Resistance Management system and a protocol is under development. Indirect monitoring of seed sales is also used to monitor the maintenance of refugia in cotton, to prevent resistance build up. A different strategy is used to manage and monitor compliance by less technologically advanced farmers. Companies selling the GMHT crops are required to monitor for herbicide resistance in weeds, but this has not been detected yet. Monitoring and management systems are being synchronized in South Africa to make them accessible across the diverse farming community.

Discussion Summary

- The types of variables to be monitored must be identified with the procedures to measure them and appropriate time-periods for measurement. Monitoring designs must be within logistic limits.

- All biodiversity effects in the UK FSEs arose from the effects of herbicides whose use was enabled by the GM technology rather than because of the mode of crop breeding.

- Although the FSEs were not monitoring studies, their design criteria (i.e., procedures built from a clear hazard scenario with an identified mechanism) were equivalent to those required in monitoring programme design.

- Several countries already have good procedures in place that provide a useful model for implementation in other countries, and some countries have made a commitment to conduct long-term research on monitoring environmental effects of GM crops.

- Several countries that have adopted GM crops do not have a monitoring process in place yet. In rice, to date, the major concern has been the presence of wild rice relatives and the impacts of the foreign gene in these species. The level of out-crossing between transgenic cultivated rice and weedy rice is still low; however, it may change as the infestation increases. Procedures are also needed to monitor the impact of GM soybean and cotton, but in several cases, countries did not have trained personnel or resources allocated to this purpose.

- In one example, the private sector has shown interest in investing in the monitoring process, but there is not enough human capacity to carry it out.

- Policy makers vary in their capacity to exploit details about GM crop ecological effects, and ecological impact data vary in the degree to which they can inform and assist the development of effective policy. Emphasis in some policy arenas tends to be on crop production goals, whereas in others (e.g., the EU), ecological effects are a priority.

- Monitoring must consider factors of concern to stakeholders, and to be effective, they must establish a relevant location, scale and duration. The specific GM traits may guide design, as may significant changes in crop management.

- Capacity building for GM crop monitoring is needed in developing countries. There should be a responsible institution/organization in the country to coordinate monitoring. CGIAR centres may help with regional implementation and play a role in information gathering.

VII. Management of Monitoring Programmes: Options, Stakeholders and Participation

Presentation 1: *Monitoring GM potato in Peru and in the Netherlands*. R. Visser and M. Scurrah
Presentation 2: *Field monitoring and research on GM crops in CIMMYT*. R. Ortiz
Presentation3: *Management of GMOs in ex situ collections in genebanks*. C. Hoogendorn
Presentation 4: *Monitoring strategies and management of GM crops: Perspective from the Industry*. R Layton
Presentation 5: *Monitoring strategies and management of GM crops: Perspective from the civil society*. S. Sahai

Richard Visser reviewed GM potato work in the Netherlands and Peru in collaboration with Maria Scurrah. Monitoring of GM potato for volunteer plants in the Netherlands has occurred since 1990. For GM crops in centres of origin, special additional procedures are required, including analysis of gene flow, investigations of pollinators and pollen flow. These procedures were developed in GM nematode-tolerant potato[6]. In the high Andes, improved varieties of *Solanum tuberosum* spp. *andigena* mix with the seven other cultivated and wild species. Gene flow was quantified, with overlapping flowering periods, sexual compatibility, presence of pollinators, and seed survival. Hybridization between cultivated and wild species occurred despite chromosome and endosperm balance differences, and more hybrids were obtained than predicted.

Rodomiro Ortiz presented experience with monitoring GM crops in the International Maize and Wheat Improvement Center (CIMMYT); one of the CGIAR centres. Its goal is to improve low diversity traits and generate public-sector-provided products, which include drought-tolerant wheat and insect-resistant maize. A public-awareness campaign 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 CGIAR-wide concern, with emphasis on the quality of genebanks. Decisions, policies and procedures about monitoring should be science-based, and this requires education, an area where CIMMYT/CGIAR can play a 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.

Coosje Hoogendoorn discussed the adventitious presence of transgenes in CGIAR *ex situ* collections. A 2004 workshop provided genebank managers with measures to adopt in response to requests for GM-free material[7]. High-risk crops currently include maize, which is wind cross-pollinated and has a sexually compatible wild species, Teosinte, in Mexico and Central America. Varieties may be protected by applying isolation distances and rotation. There is a need to develop screening tools and to ensure that best practices are adopted. Other high-risk crops, now or in the future, include canola, sorghum, pigeon pea, millet, Cruciferae, sunflower and forage grasses.

Raymond Layton provided an industry perspective of monitoring strategies and management of GM crops. Monitoring should be designed to test a hypothesis and it should be conducted only if recommended by scientifically based risk assessment. Monitoring studies should be located and designed to reduce uncertainties. The controls and end points should be clearly defined before monitoring is conducted. Important questions to be answered prior to

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[6] Celis *et al.* (2004). *Nature* 432.

[7] Workshop on: "Technical issues associated with the development of CGIAR policies to address the possibility of adventitious presence of transgenes in CGIAR *ex situ* collections" 30 August–1 September, 2004. http://www.ipgri.cgiar.org/Policy/GMOWorkshop/

monitoring include: “What are we seeking to protect?” and “How will the data be used?” Trained personnel and appropriate sample collection and analysis techniques are needed to ensure that the data will be useful. The audience for monitoring must be clearly defined and personnel who interpret and communicate results should be trained.

Suman Sahai discussed development of socio-economic indicators to assess the impact of GM crops. Socio-economic impacts of GM crops are relevant in a developing country context where livelihoods could be affected. Indicators for GMHT crops include changes in family income due to wage loss and shortage of weeding impact on health and veterinary care (loss of medicinal plants), impact on household nutrition and family income (loss of fodder for livestock and loss of supplementary crops grown on field bunds and field margins), soil erosion through loss of vegetation cover, and development of HT-tolerant weeds and the costs of eradicating them. The impact of using *Bt* crops should be assessed by monitoring the impact on lepidopteran resistance development that may be caused due to overuse of *Bt* transgenes. Measurements of the impact on organic agriculture, crop diversification, mixed farming and inter-cropping are needed, as well as agro-ecosystem and adjoining natural ecosystem effects, and the impacts on traditional farming practices and indigenous knowledge.

Discussion Summary:

- GM crop monitoring is an international issue. The CGIAR centres, relevant UN agencies, national and international centres and universities should assist in the development of effective procedures.

- The experts recommended that the biotechnology industry should work with the public sector. The majority of the information collected by the industry is not in the public domain, and a greater degree of sharing is needed. The capacity to do risk assessment and monitoring is often lacking in developing countries.

- Socio-economic indicators may also need to be developed to address monitoring of GM crops, especially in the context of developing countries.

- Raising public awareness and building confidence among all stakeholders is essential for establishing a successful monitoring programme.

VIII. Thematic Working Session 1: Examining the Scientific Basis for Monitoring

The experts were asked to focus on the scientific criteria and procedures for effective protocol design and to broadly address the technical aspects of monitoring. Some of the conclusions reached are itemized below. The experts were unanimous in concluding that monitoring programmes need to be developed in ways that recognize important sources of variation between farming systems and GM crop types. The effects (both positive and negative) of GM crops will vary with location and context, and monitoring will require a new model of working in order to inform actions at the farming system level. The main conclusions reached in the working sessions are summarized below.

The experts discussed data needs and development of minimum datasets. The challenge will be to address variation within and between countries in: (i) regulatory requirements; (ii) the organisms, process and systems to be monitored; and (iii) individual goals for monitoring programmes.

All possible sources of data should be taken into account and identified including biodiversity surveys and inventories, soil databases, genebanks, plant protection services, farmer organizations, private sector (including sales figures), plant variety rights agencies, pre-release monitoring databases, environmental groups and water authorities.

The experts recommended that coordinators of post-release monitoring be appointed (possibly from the lead GM regulatory agency) for coordinating the collection of data, compiling the information in an appropriate way and performing the analysis and reporting. The challenge will be to link data sources and systems that were not set up for this purpose.

The experts made a case for the broad surveillance of practices in farming system that are to include GM crops. The specifics of the monitoring programme depend on the GM trait, and the farming system and the broader (natural and managed) habitat context. Agricultural systems have unique social, economic and environmental properties.

The experts also presented several challenges for the scientific and technical development of monitoring including differences between farmers, environmental groups and agencies in perceptions of risks and benefits, lack of available expertise, absence of extension services and lack of available resources.

IX. Thematic Working Session 2: Designing the Monitoring Process

Two separate expert working groups undertook programme design exercises, using examples that reflect the range of capacities to develop and undertake monitoring. They proposed processes and mechanisms for developing a monitoring programme that meet the needs of country or region with a) substantial knowledge of potential hazards and programmes for monitoring environmental effects of GM crops and b) limited knowledge of potential hazards and little experience in monitoring environmental effects of GM crops**.** Two Monitoring Programme Design Templates are presented below in Table 1a and Table 1b.

Table 1a: This example illustrates the systematic development of a programme of goal-setting, monitoring, analysis and assessment that is possible where potential hazards and their consequences are known, and environmental protection standards and policies are effective such that they enable monitoring goals to be refined to address the specific concerns of stakeholders. Some key recommendations following this analysis are given at the foot of the table.

Programme design elements for regions with substantial prior knowledge	Points to be considered in programme formulation	Case example Monitoring programme for GM potato cultivation in the Netherlands
Identify responsible (lead) organization	The organization should have the trust of all stakeholders and should follow a transparent process for requiring, reviewing and using monitoring data	Monitoring was conducted on GM potatoes in the Netherlands. The responsible group was the "Commission on Genetic Modification (COGEM) who advise the Ministry of Housing, Spatial planning and the Environment.
Determine general societal concerns	A list of general societal concerns should be developed through broad consultation (e.g. direct and indirect ecological impacts, gene flow, impacts on traditional or protected farming systems)	The primary concerns were the potential for gene flow to non-GM potatoes and the presence and importance of antibiotic resistance as a marker
Determine trait specific	Specific concerns related to the	Two trait-specific concerns were

Programme design elements for regions with substantial prior knowledge	Points to be considered in programme formulation	Case example Monitoring programme for GM potato cultivation in the Netherlands
concerns	crop, the cropping system, and the trait or traits (e.g. persistence of transgene products in soil, cumulative effects)	investigated prior to field-scale monitoring: frost tolerance and alkaloid content. Smaller experiments allowed for higher levels of statistical control prior to full field studies. The trait-specific concern in field monitoring was whether volunteers would occur in follow-on crops and if they could be controlled. This could not be fully investigated in smaller experiments.
Prioritize concerns	Some data may be of scientific interest, but may not play a significant role in decision-making (e.g. differences between GM and non-GM crops that are less than differences between conventional crop varieties)	The presence of volunteers in following crops was the primary concern. Changes in frost tolerance or alkaloid content were viewed as items of lesser importance in the monitoring studies because it was believed that these parameters had been effectively investigated using small plot studies conducted earlier.
Identify information gaps	Closely examine the data that are available to see what "data gaps" exist. Gaps may be filled by using data from the literature, from previous studies, or using modeling. Conceptual models are extremely effective tools for identifying gaps in knowledge or understanding.	Two information gaps identified: 1) What was the rate of volunteers in typical potato culture, and 2) would the problem be significantly greater with GM potatoes? The first gap was filled using results from previous studies. Data were not available to fill the second gap
Clearly define question(s)	It is important to define the questions that need to be answered before a decision can be made. For example, can a hypothesis be tested for a specific crop-trait-geographic scenario, and will the results assist a management or regulatory decision?	The specific question could be defined as "Under commercial cultivation (flowering, harvesting, etc.), is the level of volunteer plants significantly different with GM potato than with typical potatoes?"
Determine actions to be taken to answer the question	The process of defining the question can also define the type of study that is most appropriate to answer the question. For example, if the question has to do with the potential variation in response, then multiple sites will be needed. However, if the question concerns variation over time, then multiple growing seasons may be needed. Some questions are better addressed	Smaller studies were used to determine potential changes in frost tolerance and alkaloid content. Then field monitoring using fields undergoing commercial cultivation was deemed appropriate to answer the question about the increased presence of volunteers at the commercial scale

Programme design elements for regions with substantial prior knowledge	Points to be considered in programme formulation	Case example Monitoring programme for GM potato cultivation in the Netherlands
	with small-scale or semi-field studies	
Design, conduct, interpret, and communicate appropriate study(ies)	Careful study design is a critical step in obtaining data that are useful in making a regulatory decision. Study design should take into account the appropriate endpoints, robustness of sampling and interpretation techniques and the statistical power of the study	Prior data were lacking. Sufficient resources were available to design and conduct a relatively large monitoring study using three potato varieties and 200 farmers. Potatoes were grown for one year and harvested. The fields were then rotated into grass (typical agricultural system) and the presence of volunteer potatoes was noted. Appropriate control fields were also included in the monitoring design.
Refine conceptual model and integrate data within the regulatory process	Once the study has been conducted and the data have been analyzed, the new information can be integrated within the conceptual model and/or used in crop management or a regulatory decision making process. This is the major test of the rigor and integrity of the previous steps.	The data compiled showed no significant differences between GM and non-GM varieties. When the results from the field monitoring studies were combined with the previous data on frost tolerance and alkaloid content, all of the original concerns were addressed. One variety had excessive flowering, two varieties had only slightly lower yield and one variety had a very low yield. All three had a kanamycin resistant marker (something that became a concern after the study was conducted).
Develop a basis for country/global/regional networking and communication	Communicate the results of monitoring so that others might make use of the information. It is important to note, however, that different countries may have different perceptions of risk. At present there are no mechanisms to help in regional communication of GM monitoring results	

Further discussion that related to the process described in Table 1a

- Developed countries have the infrastructure to undertake monitoring, but there is no consensus on the types of questions to be addressed or basic data requirements
- Stakeholders can be polarized, with broader society concerned about adverse effects, adopting farmers focused on positive effects and non-adopters (e.g. organic farmers) concerned about adverse impacts on livelihood
- There are many data and data flow challenges e.g.:

- “Obvious”/clear adverse effects that require direct action: easy to monitor and observers can issue alerts,
- “Less obvious”/multi-causal effects require analysis by the monitoring coordinator and sophisticated outreach efforts,
- Much of the information will be collected for other purposes and it may not be immediately reconcilable with new monitoring data (resolution in time and space, units of expression, differing levels of precision etc.)
- Data compilation from multiple sources may require formal meta-analysis,
- If the data do not deliver the requested answers, how are resources to be obtained to address questions more effectively?

Table 1b: Monitoring programme development is a greater challenge in cases where possible hazards are not clearly understood, the stakeholder community is not well defined, the level of protection afforded by environmental protection measures is low, and there is a lack of capacity and resources. The outline below examined the process from the perspective of a monitoring design template: the elements of the programme, points to be considered and the challenges of implementing the various elements in the context of herbicide tolerant lowland rice in Asia are addressed. Some key recommendations following this analysis are given at the foot of this table

Programme design where there is limited information and experience	Elements for programme formulation	Points to be considered	Hypothetical example: monitoring programme for herbicide tolerant (HT) rice in a developing country in Asia.
Develop and state programme goals in consultation with stakeholders in the final outcome (e.g. farmers, stewards of local protected areas etc.)	Identify and engage stakeholders, recognizing that different skills tend to be found in different sectors. Define the ultimate goals of the monitoring programme, expressed in terms that stakeholders value Develop consensus on *precisely stated* goals to enable effective monitoring design, and eventual follow up	Are the goals clear and simple enough to be addressable? If there are broader concerns, should the programme be nested within a larger process*?* Does the programme adhere to laws and relevant conventions? Has a fair and equitable selection programme been used to identify relevant stakeholders?	Goals: To avoid weedy rice becoming more weedy because of gene flow and selection To maintain the native gene pool of rice To maintain the livelihoods of Asian farmers
Identify barriers to achieving goals	Identify all the practices, and stressors that may compromise the system Identify the resource affected by each practice or stressor. This will aid the later identification of indicators. Summarize the characteristics of the above in terms of frequency, extent, magnitude, selectivity and variability.	Competing interests and marketing forces could prevent consensus Lack of success can result from failure to engage civil society: people with important expertise may be excluded from communication and access to resources Poor communication between stakeholders limits goals setting, and engagement	Weedy rice is already widespread in direct seeded areas, less so in transplanted areas. Good management practice is well understood, but not always practiced for various reasons Marketing forces will influence the adoption of GM rice, and may not acknowledge risks No obvious *technical* barrier to effective monitoring
Develop a simple, robust, conceptual model for the system based	Outline interconnections between system components, the strength and direction of links and the state of the system.	Engage all sources of knowledge from farmer, public, private and civil society sector.	GM technology, with low adoption of good practice leads to HT gene flow into wild relatives. Herbicide resistance in weedy rice is

Programme design where there is limited information and experience	Elements for programme formulation	Points to be considered	Hypothetical example: monitoring programme for herbicide tolerant (HT) rice in a developing country in Asia.
upon stakeholder and expert knowledge	Outline the scales at which processes operate and consider how the system 'works' with an emphasis on response to practices or stressors. What is acceptable variability and what constitutes a normal pattern?	Need to ensure their participation throughout the programme.	selected by increased use of herbicides (which can happen with or without gene flow). Weedy rice densities can increase and production consequently decreases
Identify possible indicators that are connected to key elements of the conceptual model, and to the concerns of stakeholders	Make measurements that reflect agricultural and ecological processes that are sensitive to change across the range of GM crop release and provide information on the status of unmeasured resources. Temporal and spatial scales must be stated.	Indicators may work, but must be able to be measured cost-effectively. Need provisions for entry and validation of data received from farmers and other stakeholders.	Counts of weedy rice m^{-2} Yield loss Seeding rate, kg/ha Frequency of herbicide use Need to establish sampling regime that may be undertaken by extension services, farmer groups, farm consultants etc.
Estimate the status and trends in the indicator, in comparison with control areas, baseline values before crop release or ideally both	Determine the required frequency and intensity of sampling effort to obtain the necessary level of statistical power. A successful outcome depends on a high level of inferential power in the comparisons that will be made	The choice of reference site or condition is complicated where adoption is rapid or widespread. Reference points and baselines may be hard to identify if GM cropping becomes the norm	Reference point – non-GM systems (may want to use sentinel plots/farms) Need to report variation in indicator responses, as well as mean values Important to clearly visualize results and express in terms that have clear meaning to stakeholders
Determine trigger values for the selected indicators that lead to management action	Determine appropriate magnitude of effect size for a response, based on an understanding of spatial and temporal variation in response relative to baseline or reference condition.	The trigger value must be connected to an adverse effect on resources of concern to stakeholders. Intensively managed systems tend to become depleted and trigger values must take into account broader goals for sustainability, as well as the status and trends	To be effective in early warning about serious hazards, triggers are needed that result in a change in farmer behavior in time to reverse adverse impacts Need to address balance between long- and short-term costs and benefits May ask farmers to make decisions that are not cost-effective or valued in the

Programme design where there is limited information and experience	Elements for programme formulation	Points to be considered	Hypothetical example: monitoring programme for herbicide tolerant (HT) rice in a developing country in Asia.
		in the indicator in the reference site(s) Placing long -term societal goals for sustainability ahead of short-term, possibly unsustainable goals is a challenge and requires confidence building measures among stakeholders	short term
Link monitoring results to decision making through clarity, transparency, effective policy development and capacity building	List and evaluate all possible interpretations of indicator values, the likelihood of each being true and the societal values associated with each interpretation. This engages stakeholders and provides guidance in effective decision making	The experts recognized that there were few effective models for this process in the recent history of adopting new technologies in agriculture. Full stakeholder engagement however, is essential for adaptive and effective technology adoption.	Establish chains of multi-way communication that extend from local government to farmer, to researcher, educator, regulator and policy developer

Further discussion that related to the process described in Table 1b

- The experts were optimistic that monitoring could work, within reasonable resource levels.
- The outline for programme design was considered to be a powerful basis for developing a monitoring system.
- The monitoring system will work best if nested within other processes that address wider goals, otherwise the process can easily become burdened with multiple tiers of questions and concerns.
- Stakeholder engagement is intrinsic to the system, from the beginning right through to the end. It is vital to build trust, legitimacy and transparency. It is the only way to deliver an effective link between goals on the one hand and triggers and decisions on the other.
- Expertise is available in both the formal and informal sectors, but it needs to be identified and engaged.
- Collaborate with UNEP to build capacity with the National Biosafety Framework, and the Biosafety Clearing House.
- Establish pilot workshop processes on a small scale in several areas to work the process through as a thought experiment and establish pilot systems that include collection, management and reporting of field data.

X. Recommendations of the Expert Group

In their discussions under Thematic Session 3 (**Sharing experiences, international context and Networking**) the experts developed a series of recommendations and follow-up actions to be carried out through sharing experiences and networking. It was agreed that a monitoring programme should incorporate existing environmental surveillance and ecological inventory data, and the available expertise in monitoring and taxonomy. They must also consider the organisms, functions, ecological and socio-economic processes that stakeholders value, and would seek to have protected. Post-release monitoring can work, even within the restricted resource levels, but only if there was a continuous engagement of all the stakeholders. This has to be fostered through formal and informal networks, alliances and initiatives which promote communication and information dissemination. The outcome of the monitoring programme must inform decision making. It should feed back the regulatory processes and policies that support the development of sustainable agricultural practices. The experts agreed to a monitoring system that would be implemented on a case by case basis and nested within broader environmental goals. It was more important to get imperfect monitoring systems up and running quickly, in circumstances where these are required, rather than wait until we have perfect systems.

In this context, the experts discussed the role and contribution of the international community in the process of establishing effective monitoring procedures, including UN agencies, CGIAR centres, and national and regional centres of excellence. The FAO and other international organizations have a major responsibility to start a process to develop a comprehensive understanding of country and local community needs with respect to post-release monitoring of GM crops. Their recommendations are as follows:

A. Scientists and International Community Managing Monitoring Programmes

- The scientific community is strongly encouraged to engage in research, development and education associated with the effective implementation of post-release monitoring programmes. Critical and innovative thinking was essential to develop new and appropriate methodologies.
- Identify and mobilize relevant expertise, especially field and traditional expertise, as well from biotechnologists, biologists, ecologists and environmental scientists. Include expertise from other fields, like social sciences. Engage scientific societies.
- Involve stakeholders early and continuously in the process.
- Collaborate and develop inventory(ies) and biodiversity assessment in agro-ecosystems and neighbouring natural habitats, to provide baseline data and current trends coupled with measurements of agricultural practices and the patterns and distribution of crops that can assist in determining potential indicators.
- Participate in data sharing mechanisms including access via the Internet, where appropriate.
- Avoid selection of inappropriate indicators by following a robust process:
    - Define the amount of change in any recommended indicator that should trigger concern and what aspects of the environment and cropping/soil management practice that might affect (increase or decrease) trigger values
    - Gain awareness of all potentially useful datasets, and identify the most robust (precise/accurate) sources of existing data (regionally, nationally, internationally) that might be used as the indicator or as a surrogate.
    - Define the most relevant scale, time-frame(s), at which the indicator operates to guide sampling and analysis.
    - Ensure that appropriate, accessible methods exist to measure recommended indicators with the precision required.

- Improve dialogue between stakeholders and scientists by focusing stakeholder input towards specific questions you wish to address. The process should be transparent, comprehensive and include an education and information dissemination programme for stakeholders.

B. Policy and Decision Makers at the Regional and National Level

- Identify clear goals and specific objectives for environmental monitoring programmes, and when/where these programmes are appropriate. To achieve this engage stakeholders to the greatest extent possible to understand what your society values and what their main interests and concerns are for deployment of GM crops. Competing policy goals exist and should be integrated
- Carefully identify the values (e.g. environmental, cultural, and economic) to be protected to analyse whether implementing a monitoring programme would protect those values or allay concerns?
- Responsibility for monitoring and reporting are national, but programmes can be undertaken using sub-national levels or jointly among countries.
- Ask definitive questions. Formulate a monitoring programme to measure effects that are connected with clearly stated protection values. State the amount of change over a defined time scale in any recommended indicator that should trigger concern. This requires setting thresholds and quantifying effects, including defining statistical detection limits.
- The process should be transparent, comprehensive and include an education and information dissemination programme for stakeholders.
- Develop policies to involve and strengthen public institutions, and to build capacity to develop, maintain and learn from well constructed monitoring programmes. Priority must be given to educational programmes and capacity building for relevant stakeholders (farmers, consumers, public, etc.)
- Identify what actions need to be taken in response to information from a monitoring programme. If it is unclear for what purpose monitoring data will be used, the monitoring programme will be ineffective and irrelevant. Additionally outcomes of the monitoring programme should inform public debate.
- Determine trigger criteria and action plans for intervention, remedial action.
- Ensure that any requirements set forth are feasible in terms of costs, personnel, expertise, protocols, and relevance of data generated. Adequate resources are required for monitoring programmes. Funding may sourced through partnerships between the public sector, biotechnology industry and other private sectors, and various stakeholder groups.

C. FAO, CGIAR Centres and International Organizations

- The FAO has a big responsibility to initiate the process and continue the dialogue started among stakeholders with respect to monitoring.
- Build upon the process to develop a comprehensive understanding of country needs and local communities. Be prepared to take on a stewardship role as the need arises.
- Support establishment of Pilot Monitoring Projects for collection, management and reporting field data as appropriate through joint initiatives.
- In countries/regions where CGIAR centres are located, they should provide national/regional support. For crops under their mandate, they should provide global support and serve as repository of regional information that has been deemed of sufficient quality that “mining” for monitoring change can occur. Provide the expertise to use those data for, regional meta-analyses. In some cases the centre will be the source of the GM technology and it will have special responsibilities to insure that independent, rigorous monitoring procedures are established.

- FAO, UNEP and other international and regional organizations collaborate to build national capacity for monitoring programmes, facilitate data management, leverage funding, partnerships and collaborations for monitoring programmes.

ANNEX 1

Final Agenda

	Genetically Modified Organisms in Crop Production and Their Effects on the Environment: Methodologies for Monitoring and the Way Ahead 18–20 January 2005 FAO, Rome, Italy

Day 1 (18 Jan 2005)	**Lebanon Room D209**
08.30-09.30	Registration
09.30-10.15	**Opening Ceremonies**
	• Welcome Remarks: L.O. Fresco, ADG, AG • Introduction: M. Solh, Director, AGP • Framing the Monitoring Challenge: P. Kenmore, AGP • Adoption of the Agenda
10.15-10.30	*Coffee/tea*
Session I	**Elements of Environmental Monitoring Strategies** Chair: D. Bartsch
10.30-11.00	Presentation 1: *Principles and procedures for medium- to long-term environmental monitoring* Speaker: P. Jepson
11.00-11.30	Presentation 2: *Strategies and tools for monitoring biodiversity and ecological function* Speaker: A. Hilbeck
11.30-12.00	Presentation 3: *Soil ecosystem monitoring methodologies* Speaker: J. Thies
1200- 13.00	General discussion led by the Chair
1300- 14.00	*Lunch break*
Session IIa	**Monitoring GM Crops: Methodologies and Practices** Chair: Bao Lu
14.00-14.25	Presentation 1: *Issues and challenges in monitoring GM crop-specific traits* Speaker: D. Bartsch
14.25-14.50	Presentation 2: *Farm-scale evaluation of GMHT plants in the United Kingdom*, Speaker: L. Firbank
14:.50-15:.15	Presentation 3: *Regulatory aspects for monitoring GM crops in New Zealand*. F. François
15.15 -15.30	*Coffee/tea break*
Session II b	**Monitoring GM crops : Sharing Country Experiences** Chair: A. Hilbeck
15.30 - 15.50	Presentation 1: *Monitoring GM crops in Canada* Speaker: R. Blackshaw

15:.50-16.10	Presentation 2: *Monitoring GM crops in China* Speaker: **Bao Lu**
16.10-16.30	Presentation 3: *Monitoring GM Crops in Brazil* Speaker: **E. Fontes**
16.30-16.50	Presentation 4: *Field experience in monitoring GM crops in South Africa* Speaker: **G. Bothma**
16.50 - 17.30	General Discussion discussion led by the Chair
19. 30 - 21.30	*Reception Dinner*
Day 2 (19. 01. Jan 2005) Lebanon Room D209	**Session III: Management of Monitoring Programmes: Options, Stakeholders and Participation** Chair: J. Dargie, AGE, FAO
08.30-08:.50	Presentation1: *Monitoring GM potato in the Peru and in the Netherlands.* Speaker: **R. Visser and M. Scurrah**
08.50-09.10	Presentation 2: *Field monitoring and research on GM crops in CIMMYT* Speaker: **R. Ortiz**
09.10-09.30	Presentation 3: *Management of GMOs in ex-situ collections in genebanks* Speaker**: C. Hoogendoorn**
09.30-09.50	Presentation 4: *Monitoring strategies and management of GM crops: Industry perspective* Speaker**: R. Layton**
09.50-10.10	Presentation 5: *Monitoring strategies and management of GM crops: Perspective from the civil society* Speaker: **S. Sahai**
10.10-10.30	General Discussion led by the chair Group formation for Thematic Working Sessions explained by P. Jepson
	Thematic Working Sessions in two groups Group A**:** Develop a long term monitoring strategy/initiative for GM crops to meet the needs of countries/regions with substantial knowledge of potential hazards and existing monitoring programsprogrammes. Group B**:** Develop a practical medium term monitoring strategy/ /initiative for GM crops to meet the needs of countries/regions with limited knowledge of potential hazards and little experience in monitoring programmes.
10.30 - 13.00 Group A Lebanon Room Group B ESD Meeting Room, B540	**Thematic Working Session 1:** Examining the Scientific Basis for Monitoring Group A and Group B separately focus on the scientific criteria, procedure and protocol design, measurements and technical aspects of monitoring design
13.00-14.00	*Lunch break*

14.00 - 14.45	Presentation by Groups and discussion on monitoring design and scientific criteria Chair: P. Jepson
15.00 - 17.00 Group A Lebanon Room Group B ESD Meeting Room, B540	**Thematic Working Session 2: Designing of the Monitoring Process** Group A and Group B to reconvene in their groups to discuss and develop the process and mechanism for a working program programme for monitoring, including documentation, decision support and information management and stakeholder participation. Groups may wish to focus on management (agro-inputs and new agri-practices), process (stakeholders, risk communication) and networking at national and regional level.
17.00-17.45	Presentation by Groups and discussion: focus on monitoring process, mechanism and stakeholder participation. Chair: P. Jepson
Day 3 (20.01. Jan 2005)	
08.40-10.15 Group A Lebanon Room Group B Canada Room	**Thematic Working Session 3: Sharing Experiences, International context and Networking** Discuss role and contribution of the international community in the process and mechanism for a working program programme for monitoring, including the UN agencies, CGIAR Centres and national and regional centres of excellence
10.15-10.30	*Coffee and tea break*
Lebanon Room D209	**Session IV : Presentation of Monitoring Strategies** Chair: P. Jepson
10.30-11.30	Basic guidance for scientists managing the monitoring process, including the CGIAR.
11.30 - 12.20	Recommendations to policy, decision makers in countries, regional groups
12.30 - 13.00	Recommendations to FAO
13.00 - 15.00	*Lunch break* and Draft Report of meeting prepared
Session V	**Meeting Report Adoption** Chair: M. Solh, AGP, FAO
15.00 - 16.00	Final review of meeting report summary
16.00 - 16.30	Adoption of Report and Recommendations
16.30	Closing Ceremony.

ANNEX 2

List of Participants

FAO Expert Consultation

Genetically Modified Organisms in Crop Production and their Effects on the Environment: Methodologies for Monitoring and the Way Ahead

18–20 January 2005

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ANNEX 3

Special Note From The Experts Who Participated In The Consultation

The responsible deployment of GM crops needs to encompass the whole process of technology development from pre-release risk assessment through biosafety considerations to post-release monitoring. Our working group agreed on the need for post-release monitoring, in appropriate circumstances, without endorsing the technology. Monitoring programmes need to be developed in ways that recognize important sources of variation between farming systems and GM crop types. Such monitoring needs to address the interactions of the organisms with the environment. The effects (both positive and negative) of GM crops will vary with location and context, and monitoring will require a new model of working in order to inform actions at the farming system scale.

We are confident that post-release monitoring can be made to work, even within the restricted resource levels available in the developing world. The expert group recommended that the monitoring design guidelines that were developed within the workshop, could act as an effective basis for determining the need for monitoring, and the form of monitoring programmes should they be required. This step-by-step protocol was based on the successful experiences of environmental monitoring worldwide. This protocol provided a powerful basis for guiding our thinking within our workshop, and we believe it can be readily developed as the basis for an effective monitoring process. It particularly revealed the critical role of stakeholder engagement *throughout* the process. Not only is stakeholder engagement vital to build trust and public confidence, it is the *only* way to deliver an effective link between the goals for monitoring and the potential actions that may be triggered. The workshop formed a powerful consensus that stakeholder engagement is intrinsic to the system.

Our report does not list or evaluate indicators, but emphasizes the critical value of developing a planning process from which appropriate indicators will emerge. The background paper summarizes international efforts that are underway to standardize certain functional indicators for the condition of agro-ecosystems and we support the development of standardized procedures wherever this is possible. There is also a need to establish new methods that further develop capacity to measure gene flow and its consequences in plant communities in the ecosystems of the developing world

We note that an environmental monitoring system for GM crops could easily become overburdened by broader social, economic and cultural issues unless it is nested within other processes that address wider goals, *e.g.* farming system evaluations and Millennium Development Goals. Even so, we stress that environmental goals encompass maintaining the environmental resource base required to deliver these goals; thus, protection of soil, water and biodiversity need to be considered together.

In order for the process to be coherent, the goals for protection, and the balances between them, need to be addressed by the stakeholders. We recognize that important stakeholders are not yet participating and should be engaged better; stakeholders, scientists and policy makers need to develop a common working language. We also recognize that there is expertise available in both formal and informal sectors, but it needs to be identified and engaged. The perceptions and local knowledge of people who live and work in the agro-ecosystems is critical for an effective monitoring programme.

We consider that the establishment of monitoring systems is a matter of urgency. This can be built up in stages, with a limited programme, taking advantage of local expertise and readily available tools as a first stage.