NATIONAL BIOSAFETY AUTHORITY

Manual for post release monitoring of genetically modified crops in Kenya

July 2021

FOREWORD

The National Biosafety Authority (NBA) is a State Corporation in Kenya mandated to ensure safety of human and animal health and provide adequate protection of the environment from harmful effects that may result from genetically modified organisms (GMOs).

The Authority was established pursuant to the provisions of the Biosafety Act, 2009 to regulate all activities involving GMOs in food, feed, research, industry, trade and environmental release and it fulfills its mandate by ensuring and assuring safe development, transfer, handling and use of GMOs in Kenya. NBA is the National Focal Point for the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (CBD) and is mandated to implement the provisions of the Cartagena Protocol on all biosafety matters pertaining to GMOs.

The Authority has made great strides in establishing strong Biosafety framework in Kenya by developing and publishing the implementing Biosafety Regulations namely; Contained use, Environmental Release, Import, Export and Transit, and, Labelling Regulations. These regulations lay down clear procedures on handling GMOs whether plants, animals or microorganisms.

Basic operational, mandatory and departmental procedures have been developed based on the International Organization for Standardization (ISO) standards. The key operational manuals and policies have also been developed and implemented. This manual developed by the National Biosafety Authority (NBA) is intended as a resource for Biosafety Officers and others designated by NBA to check compliance with regulatory requirements for post-release of GM crops. The regulatory requirements for each activity are provided in the terms and conditions detailed in the approval document issued by the Authority. It is important that Biosafety Officers be well trained or versed in monitoring procedures and response to non-compliance whenever identified. The manual is also an important reference material for relevant regulatory agencies as well as the technology developers. However, it is the responsibility of the applicant to ensure compliance with the terms and conditions detailed in the approval documents from the Authority.

Clear and established procedures, continuous education and oversight, and clear communication are the ingredients of a productive working relationship between Biosafety Officers and the applicants. This relationship should be developed to assist in achieving a high level of safety with GMOs for the benefit of Kenya and its citizens.

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ACRONYMS

CBD : Convention on Biological Diversity

CFT : Confined Field Trials

DNA : Deoxyribonucleic acid

EFSA : European Food Safety Authority

ERA : Environmental Risk Assessment

FAO : Food and Agriculture Organization

GMOs : Genetically Modified Organisms

NBA : National Biosafety Authority

PMEM: Post-Market Environmental Monitoring

RA : Regulatory Agency(s)

DEFINITION OF TERMS

Adverse effects: Abnormal, harmful, or undesirable effect on an organism that causes anatomical or functional damage, irreversible physical changes, or increases the susceptibility to other biological, chemical, or environmental stresses.

Applicant: means a person submitting an application pursuant to the provisions of the Biosafety Act, 2009 and the Biosafety (Environmental release), Regulations, 2011.

Authority: means the National Biosafety Authority established under section 5 of the Biosafety Act, 2009

Assessment endpoints: An explicit expression of the environmental value that is to be protected, operationally defined as an entity (such as salmon or honeybees, soil quality) and its attributes (such as their abundance, distribution or mortality).

Baseline data: A description or a measurement of existing conditions of an environment, or its attributes or components without the GMO under consideration and taking into account different practices in use (e.g. agricultural practices). The baseline description or measurement may provide quantitative (e.g., number of organisms, variability of abundance) and/or qualitative information about the receiving environment as a reference for estimating effects of the GMO or its use including, if applicable, information on the assessment endpoints

Biosafety: means the avoidance of risk to human health and safety, and the conservation of the environment, as a result of the use of genetically modified organisms

Biosafety Officer: In the context of this manual, a Biosafety officer is a technical officer of the NBA appointed as a Biosafety Inspector or a technical officer from the relevant Regulatory Agency.

Case specific monitoring: is a process done to confirm that any assumptions regarding the occurrence and impact of potential adverse effects of the GMO or its use in the environmental risk assessment are correct.

Confined field trial (CFT): A field trial of GM plants not approved for general release, in which measures for reproductive isolation and material confinement are enforced in order to confine the

experimental plant material and genes to the trial site and to remove them from the site at the end of the trial.

Confinement: Restriction of an organism and its genetic traits to a specific and defined area of the environment, called 'trial site'.

Contained use: means any activity undertaken within a facility, installation or other physical structure which involves genetically modified organisms that are controlled by specific measures

Environment: includes the physical factors of the surroundings of human beings, including land, water, atmosphere, soil, vegetation, climate, sound, odor, aesthetics, fish and wildlife

Environmental Release: introduction into the environment of a genetically modified organism for which an approval has been granted in accordance with the Environmental Release Regulations and-

(a) For which no specific containment measures are used to limit their contact with and to provide a high level of safety for the general population and the environment; and

(b) Includes making genetically modified organisms available to the public.

Environmental Risk Assessment (ERA): means the evaluation of risks to human and animal health and the environment, whether direct or indirect, immediate or delayed, which the environmental release or placing on the market of genetically modified organisms may pose and such evaluation is carried out in accordance with the Second Schedule to these Regulations and the Fifth Schedule to the Act:

General monitoring: the process of identifying the occurrence and impact of unanticipated adverse effects on human health and the environment associated with the release of a GMO that were not predicted in the environmental risk assessment

Genetically Modified Organism (GMO); means any organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology techniques

Intentional introduction into the environment; means any deliberate use of genetically modified organisms other than for contained use

Measurement endpoints; means environmental parameters or indicators which should be measured to determine whether protection is effective

Modern biotechnology; includes the application of-

(a) in-vitro nucleic acid techniques including the use of recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles; or

(b) fusion of cells beyond the taxonomic family that overcome natural physiological, reproductive and recombination barriers and which are not techniques used in traditional breeding and selection:

Monitoring: Regular, systematic and consistent assessment of the progress achieved in the implementation of an activity that is aimed at meeting set objectives, to ensure accountability, cost effectiveness, timeliness and quality and must include taking corrective measures.

Non-target organism; An organism which is affected by an interaction for which it was not the intended recipient.

Permit; means a permit or approval granted by the National Biosafety Authority under the Biosafety Act, 2009

Placing on the market; means making a genetically modified organism available for sale

Post release monitoring/post market monitoring/post commercialization monitoring; monitoring done after environmental release in order to assess the impact of the identified or unknown risks of a GMO on the environment.

Protection goals: Defined and valued environmental outcomes that guide the formulation of strategies for

the management of activities that may affect the environment.

Regulatory agency; means a regulatory agency as set out in the First Schedule to the Biosafety Act of 2009, or such other agency as the Minister may, by Order in the Gazette, determine.

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CHAPTER ONE

INTRODUCTION

1.1 Background Information of NBA

The National Biosafety Authority (NBA) is a state corporation in Kenya mandated to ensure safety of human and animal health and provide adequate protection of the environment from harmful effects that may result from genetically modified organisms (GMOs).

The Authority was established pursuant to the provisions of the Biosafety Act, 2009 to regulate all activities involving GMOs in food, feed, research, industry, trade and environmental release and it fulfills its mandate by ensuring and assuring safe development, transfer, handling and use of GMOs in Kenya.

NBA has made great strides in establishing strong Biosafety framework in Kenya by developing and publishing the implementing Biosafety Regulations. These regulations laid down a clear procedure on handling GMOs whether plants, animals or microorganisms.

NBA is the National Focal Point for the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (CBD) and is mandated to implement the provisions of the Cartagena Protocol on all Biosafety matters pertaining to GMOs.

1.2 Vision Statement

A World-class Biosafety Agency

1.3 Mission Statement

To ensure and assure safe development, transfer, handling and use of genetically modified organisms (GMOs) in Kenya.

1.4 Our Core Values

a) Integrity
b) Professionalism
c) Transparency
d) Accountability

1.5 Our Objectives

a) To facilitate responsible research and minimize risks that may be posed by genetically modified organisms.

b) To ensure adequate level of protection in the development, transfer, handling and use of genetically modified organisms that may have an adverse effect on the health of the people and the environment.

c) To establish a transparent, science-based and predictable process for reviewing and making decisions on the development, transfer, handling and use of genetically modified organisms and related activities.

1.6 Our Core Functions

The Biosafety Act no.2 of 2009 lists the functions of NBA as follows:

a) Consider and determine applications for approval for the development, transfer, handling and use of genetically modified organisms, and related activities in accordance with the provisions of the Biosafety Act.

b) Co-ordinate, monitor and assess activities relating to the safe development, transfer, handling and use of genetically modified organisms in order to ensure that such activities do not have adverse effect on human health and the environment.

c) Co-ordinate research and surveys in matters relating to the safe development, transfer, handling and use of genetically modified organisms, and to collect, collate and disseminate information about the findings of such research, investigation or survey.

d) Identify national requirements for manpower development and capacity building in biosafety.

e) Advise the Government on legislative and other measures relating to the safe development, transfer, handling and use of genetically modified organisms.

f) Promote awareness and education among the general public in matters relating to biosafety.

g) Establish and maintain a Biosafety clearing house (BCH) to serve as a means through which information is made available to facilitate exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms.

h) To exercise and perform all other functions and powers conferred on by the Act.

CHAPTER TWO

2.0 Introduction

Post market monitoring is done to identify any unanticipated effects of the organism and its use to human, animal health and the environment after placing on the market. It should serve as an early warning system and indicate the need for risk management measures and/or a re-assessment of the released GMO. Monitoring results will serve as the basis for subsequent regulatory decisions such as the adaptation of monitoring plans or withdrawal of GMO approvals.

Post market monitoring can be either general or case specific. General Monitoring involves the process of identifying the occurrence and impact of unanticipated adverse effects on human, animal health and the environment associated with the release of a GMO that were not predicted in the risk assessment (ERA). Case-specific monitoring is done to confirm that any assumptions regarding the occurrence and impact of any potential effects of the GMO or its use identified during risk assessment, are correct. It is an additional safety measure put in place to mitigate risks by detecting any potential effects at an early stage of commercial use so that action can be taken.

Monitoring, and the submission of monitoring reports, is the responsibility of the applicant who has been granted an approval by the Authority. However, the National Biosafety Authority (NBA) in conjunction with other relevant regulatory agencies shall conduct joint monitoring to verify the presence and characteristics of a GMO or derived products in the market after environmental release or placing on the market.

The relevant parameters to be monitored will be identified by NBA in consultation with other regulatory agencies on a case-by case basis and the methodology to monitor these parameters shall be clearly identified and outlined, including techniques for sampling and analysis.

A requirement to monitoring methodology is the collection and analysis of data in exact and unbiased manner. The data collected should be accurate, comparable and reproducible. Use of standardized methodology for post market monitoring shall be applied. Standardised methodology will effectively represent high quality criteria, create transparency and therefore acceptance of the monitoring results.

2.1 Scope

This guideline describes the requirements and methodology that will be applied by NBA for monitoring

of GMOs and their derived products for the purpose of compliance with Biosafety Act, Regulations and other relevant existing laws. It will also serve as guidance to applicants in identifying the requirements by NBA for post market monitoring after environmental release of a GMO.

2.2. Selection of protection goals, assessment end points and monitoring indicators

The selection of monitoring indicators shall be based on Kenya's protection goals. They should be able to clearly show the changes introduced into the receiving environment after planting of the GMO. The monitoring indicators shall be defined on a case-by-case basis depending on the type of the GMO and the environment where it will be introduced.

Among the indicators that may be monitored in relation to the environment, human and animal health are listed below. These shall be used to determine the occurrence of any unintended effects (positive or negative). It is however important to note that the specific indicators will have to be determined on a case by case basis. The manual creates guidance on the following general focus areas:

- Spread and escape of genetically modified plants into the environment
- Volunteers in subsequent crops
- Hybridization and introgression with wild relatives and feral crop plants, establishment of hybrids
- Effects on non-target flora and fauna in cultivated areas and non-target environments
- Secondary infestation of crops and hybrids with bacterial, fungal and viral phyto-pathogens
- Consequences of altered farming practice
- Effects of herbicide tolerance trait and subsequent development of crop and weed resistance
- Effects on interrelations of the food web
- Effects on grain and plant-feeding animals
- Effects on soil functions, effects on soil fauna and flora

- Horizontal gene transfers on microorganisms
- Effects on water bodies and water organisms
- Effects on species biodiversity and habitat diversity
- Unexpected gene expression
- Unexpected physiological and biochemical plant properties
- Any new information

2.3. Environment Baseline data

A range of event specific indicators shall be selected in order to determine impacts of the cultivation of the GMO on the country's protection goals. The scale of effects can only be assessed if comparable baselines are available for the selected indicators. The applicant will be expected to compare these indicators both before and after the introduction of the GMO (subsequent comparison) and/or simultaneous comparison of an area where the GMO is not being grown with an area that is exposed to the GMO (time-parallel comparison). For this reason, the applicant shall conduct a baseline survey in study sites representative of all ecological zones where the GMO will be released upon receiving an approval document from NBA and such a survey shall be done before the release of a GMO.

2.4. Monitoring Plan

Before the start of monitoring, a detailed monitoring plan shall be developed on a case-by-case basis, taking into account the intended use of the individual GMO as well as its characteristics, the environmental risk assessment and the local receiving environment. The plan will also include descriptions of the monitoring strategy, methodology, and procedures for reporting of the results and recommendations for decision making. In addition, the plan has to be approved by NBA and the range of indicators can be selected; and be crops-specific/event-specific.

Table 1: Sample monitoring plan highlighting some of the focus areas for monitoring:

Action	How	Who?	When?
1. Observation of any adverse	General monitoring	Applicant, farmers growing the GM	After approval for open field cultivation

effects originating from release of that crop		crops, persons living around areas growing the GM crop	and placing on the market or period specified by NBA after consultation with the applicant
2. Development of breakdown of claims such as development of insect resistance, herbicide tolerance etc.	Case specific monitoring	Applicant, farmers growing GM crops, persons living around areas growing the GM crop	After approval for open field cultivation and placing on the market
3. Compliance with approval conditions outlined in the NBA Board approval document	Periodic Inspection	NBA in conjunction with relevant regulatory agency	After approval for open field cultivation and placing on the market or period specified by NBA after consultation with the applicant
4. Reporting - including a notification of any unanticipated effects	General Monitoring	Applicant and farmers growing GM crops	After approval for open field cultivation and placing on the market

2.5. Selection of monitoring sites

In order for post release monitoring to be effective, monitoring sites to be studied should be considered carefully. The number of sites selected shall be determined after consultation between NBA and the applicant and appropriate for the statistical analysis that will be conducted. Some of the criteria that

shall be applied when choosing monitoring sites include:

- Representativeness of sites exposed to GMOs, with special focus on sites under repeated or long-term exposure
- Representativeness of ecological regions containing the chosen monitoring indicators;
- Availability of sites already under investigation by complementary monitoring programmes
- Sites facilitating spread or persistence of GMOs due to favorable environmental conditions.

At the time of identifying study sites the applicant shall also identify control sites that will be comparable with those where the GMOs will be released to allow for effective decision making and conclusions.

2.6. Frequency of Monitoring

For the determination of both immediate and long-term effects of a GMO in a receiving environment, appropriate time periods will need to be put into consideration. The individual characteristics of the GMO such as average lifetime, generation time and risk for persistence in the environment, should serve as guidance for assigning relevant monitoring periods.

Post release monitoring shall be conducted for ten years from the date of open field cultivation or placing on the market in accordance with the Biosafety Act 2009. For crop species with a longer maturity period such as trees, the post release monitoring period shall be indicated in the approval document. In all instances, the applicant and relevant regulatory agency shall be obligated to conduct post market monitoring once or several times a year depending on potential risks identified during risk assessment, and data provided to NBA who will disseminate information to the relevant agency depending on the product.

2.7. Methodology for general monitoring and case-specific monitoring

It is the responsibility of NBA to identify the appropriate general monitoring tool during post release monitoring aimed at identifying any adverse effect of the GMO following post release. The tool used for monitoring will be determined by the potential risks/effects identified during the risk assessment process as well as the preliminary baseline data collected. NBA shall consider the effectiveness of the tools

used and whether they are sufficient to detect any unanticipated effects of the GMO following post release.

2.7.1 General Monitoring

The objective of general surveillance is to identify the occurrence, if any of unanticipated effects of the GMO or its use on human and animal health or the environment which were not anticipated in the risk assessment. General monitoring is required to monitor for unanticipated adverse effects as well as indirect or prolonged effects that the GMOs may pose over a long period of time. Multiple locations shall be assessed in this kind of surveillance and focus will be mainly on the aspects of the environment which would have maximum exposure to the GM crop and where any adverse effects would be expected to become evident first.

2.7.1.1. Tools for General monitoring

General Monitoring shall use a combination of tools, to maximize the chances of detecting any adverse effects. It is recommended using at least three main tools for General Monitoring: the Farmer Questionnaire, the use of existing Monitoring data and scientific literature review: this is the international/global best practice approach.

a) Farmer Questionnaire

The objective of questionnaires is to obtain information from those directly involved production of GM crops such as farmers. The questionnaires will ask them to describe the management of the GM crops and to identify any differences in management, plant growth and development, productivity and their interactions with other biota in the receiving environment. The GM crop and its cultivation sites, the receiving environment around these cultivation sites and the management of the GM crop will be monitored for impacts on the environment in comparison with a non-GM crop.

b) Existing data

Existing monitoring networks or established routine surveillance networks used by other government agencies can be used where applicable. For example, agencies under the Ministries of agriculture,

environment, and health among others, are required to collect data at least once a year. They preserve relevant information and statistics relevant to their mandates. Other private bodies such as NGOs are also in existence and do collect a wide array of data based on their operations. Such records can serve as baseline or monitoring data that can be used by NBA or the applicant to design a monitoring plan or monitoring strategy for post release monitoring of GMOs. Applicant responsible for collecting data depending on their product after approval by NBA and the data will be subject to independent verification.

c) Scientific literature

Many countries have approved and allowed environmental release of GMOs in the past 20 years. Consequently, many studies have been conducted to investigate post release effects of GMOs as part of requirements by regulatory bodies in these respective countries. Results of these studies have been published in peer reviewed journals and can serve as a reference point for general surveillance. Review of scientific literature results in identification of gaps that can help predict unanticipated adverse effects that were not covered in the risk assessment.

d) Other methods

Other methods that can be deployed to gather data include;

- Focus group discussions
- Community Opinion leaders
- Interviews
- Use of a Checklist

2.7.2. Case-Specific Monitoring (CSM)

This is an additional safety measure put in place to mitigate risks by detecting any unanticipated effects at an early stage of commercial use so that action can be taken. This is done to confirm that any assumptions regarding the occurrence and impact of potential effects of the GMO or its use in risk assessment are correct. It is needed in situations where, following risk assessment, a specific hypothesis remains as to how GM crops or derived products could cause adverse effects. This must include a pathway as to how harm could occur and the design of case specific monitoring will depend on the hypothesis being tested.

It is important that not only direct and immediate, but also indirect and delayed effects of GM crop cultivation as identified in the RA, are included in the monitoring strategy.

2.7.2.1. Methodology for CSM

The design of the CSM will need to consider the practicality and feasibility of observing, and recording data of sufficient quality to provide a valid assessment. Where appropriate CSM should be directed at the individual GMO or the assessment endpoints of concern in the surrounding environments where effects are most likely to be detected.

Planning and carrying out of CSM is under the responsibility of the applicant and relevant regulatory agency. However, the applicant shall identify appropriate expertise to contribute to the planning, conduct and/or analysis of the CSM. Applicants shall clearly identify and describe the methodology to monitor the selected parameters, including techniques for sampling and analysis. Standard methodology, such as those provided for by internationally agreed European CEN Standards and OECD-methods for monitoring organisms in the environment should be followed where appropriate and reference to the source of the methodology provided.

2.7.2.2. Statistical design & analysis

For CSM studies, all the relevant scientific questions that the study is designed to address shall be listed explicitly at the design stage of the study. Additionally, each of these questions shall be re-stated in the form of the null hypothesis that is to be tested to answer the question. Clear and explicit statements concerning the minimum levels of data acceptable for each variable being assessed shall be made, below which results would lack credibility. Applicant will identify the relevant statistical software/method and involve a Biometrician during statistical design.

2.7.2.3. Choice of comparators

Comparators shall be selected to fulfill the requirements of replication, control of variability and the use of blocking factors, such as field/farm size, previous management. Sampling units for CSM will be larger than the plots typically used in agricultural or variety trials, otherwise the effects studied are not representative.

Applicants shall describe the chosen comparators and explain why they are preferred, as well as the range of variability expected from them, and the main factors influencing them (e.g. cultivation practices) shall also be included.

2.7.2.4. Types of Case-Specific Monitoring

a) Spatial scale of Case-Specific Monitoring

This is the analysis of the data collected by existing monitoring networks by comparing the effects of two different regimes i.e. comparing the data collected at sample sites in areas of GM cultivation with those in areas where GM crops are not cultivated. The comparison could be undertaken at a single snapshot in time or may compare trends over time under two different regimes.

Being hypothesis-driven, it is important that CSM is carried out at sites where there is the greatest likelihood of measurable impacts occurring. The methods selected, the choice of monitoring sites, the extent or number of monitoring sites and the parameters to be monitored will be determined on a case-by-case basis and shall be clearly explained by the applicant in their CSM plan.

b) Temporal scale of Case-Specific Monitoring

As there is no way of predicting when an unanticipated adverse effect might occur, any significant effect which occurred following the introduction of GM crops would need to be investigated further by using the temporal scale of case specific monitoring.

Sufficient time period is required for CSM to be carried out in order to test the hypothesis. The time period should also be of sufficient length to detect potential delayed adverse effects which have been identified in the RA.

The life cycle and production cycle of the GM crop should also be taken into consideration, particularly in relation to long lived and slowly generating perennial species. Additionally, the growth, reproduction cycles and lifespan of biota, identified as being at potential risk in the ERA conclusions, should also be considered when designing the CSM plan. Applicants will be required to describe the likely time scale for effects to be detected in their monitoring plan and explain why they consider their plan is of sufficient length to detect these effects.

2.8. Data analysis, validation and review

Once data has been collected it needs to be analyzed to determine its significance. Data validation shall be done and appropriate methods used for reporting and displaying the findings. The findings should give feedback to the relevant stakeholders, decision makers and the general public. Such results will be used by the relevant regulatory agencies in decision-making and in future policy decisions. All reports shall be sent to NBA which will disseminate the data to relevant stakeholders.

2.9. Review of the monitoring plan

After conducting monitoring for the first ten years, obtained data shall be used to review the monitoring plan. The effectiveness of the obtained data shall be evaluated including the statistical analysis. It should be determined whether the monitoring variables are effective in assessing the potential adverse effects of the GMOs to human and animal health and the environment and adjustments and improvements should be made where necessary.

2.10. Conclusion and recommendations

Applicants and relevant regulatory agency shall ensure that their monitoring plan describes in detail the monitoring objectives, the methodology to be used, analysis, reporting and the review process in line with the guidance stipulated in this document. Monitoring may inform on the need for appropriate response measures such as changes to risk management strategies, emergency response measures, a new risk assessment, or re-evaluation of prior decisions.

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Table 1: Protection goals identified for general surveillance (GS) of genetically modified products and assessment endpoints, their indicators and measurement endpoints, including measurement tools.

FQ= farmer questionnaire **ED=** existing monitoring data **SR =** Scientific Literature Review

PROTECTION GOALS	ASSESSMENT ENDPOINTS & INDICATORS	MEASUREMENT ENDPOINTS	TOOLS FOR GS
Conservation of biodiversity: **Flora**	Wild species, protected species, weeds, seed banks	Change in populations, establishment and persistence Hybrids with wild species Survival ability of seeds, germination Botanical diversity	**FQ**: E.g. Dominant weeds & volunteers in crops and weed infestation levels; herbicide usage/efficacy/control failures. **ED**: E.g. botanical surveys in different environments (including farmland); herbicide sales/usage & weed resistance data; pollen records; seed certification. **SR**: data on efficacy of different herbicide management systems and of target effects.
Conservation of biodiversity: **Fauna**	Vertebrates (e.g. mammals, birds) and invertebrate's populations (e.g. arthropods) populations) e.g.: non-target arthropods from functional groups (e.g. herbivores detritivores & saprophytes, pollinators, parasitoids, predators) with focus on beneficial organism and protected species	Abundance, population change Growth, development Change in host range Decrease of natural pest regulation mechanisms (i.e. monitor [novel] pest infestations)	**FQ**: Failures in natural pest regulating mechanisms (or increases of pesticide use): indirect indication of predator/parasite functions losses in crops. **ED:** E.g. Surveys on farmland biodiversity (e.g. bees, butterflies, pests (like aphids)); **SR**: Data on GMP interactions with NTOs.
Soil quality/ functionality	Soil biota (e.g. soil microorganisms, invertebrates),	Populations change (e.g. earthworms,	**FQ**: E.g. Crop growth, yield and health; soil pesticide, sterilant usage; soil analysis, fertilizer usage; tillage,

	fertility, texture, respiration, biomass decomposition, nutrients dynamics, erosion, organic matter	spring tails) Change in soil microorganism communities (e.g. rhizobia) Analysis of organic compounds Fertiliser usage Nutrient analysis	crop residue incorporation; erosion, cracking, panning, water logging, sub-soiling, drainage; dominant weed species. **ED**: E.g. Fertilizer and soil nutrient usage; national networks on soil quality; crop productivity and losses due to water capacity; botanical surveys (see flora above); surveys on soil pest and disease and on soil pesticide usage. **SR**: Interactions of GM crops with soil flora and fauna and consequences for soil functioning and crop production
Water	Physical (density, silt load) and chemical (pollutants, pH, nutrients levels, algal content) characteristics; oxygen content	Pollutants: pesticides, silt load Anoxia Turbidity	**FQ**: Crop performance in relation to water availability and usage **ED**: Fishing records, watercourse management info (e.g. weed clearance), farm waste and effluent management. **SR**: Interactions of GMOs and products with aquatic biota and/or water usage.
Sustainability of agro-ecosystems, including plant health	Fauna (e.g. pollinator populations) and flora indicators of functionality as above, at the field and landscape level Crop management factors such as rotation, varieties, pesticide and fertiliser usage, mechanical operations:	Pollinator Abundance (colony survival and/or development); foraging behaviour; levels of pollination; change in honey production. IPM indicators: e.g. predation levels, pests, diseases, weed incidence,	**FQ**: All parameters related to crop production (growth/yield/quality), performance (pests, diseases, and weeds), inputs (seeds, pesticides, fertilisers). **ED**: E.g. Surveys on e.g. varieties, pesticide and fertilizer usage, pests and diseases, weeds, bees, crop production and performance; Data collection by Pest Control Products Board services on e.g. pesticide usage, pest monitoring; **SR**: Interactions of GM crops (& associated agricultural practices) and

	sowing/ploughing/ harvesting and the timing; crop performance and productivity data Plant diseases and pests	pesticides and fertilisers usage	products with other biota, inputs, outputs.
Human & domestic animal health (excluding food & feed consumption)	Pathogenicity, toxicity, allergenicity	Animal performance Human & animal health	**FQ**: E.g. Experiences with performance of exposed livestock; health of exposed farmers/workers. **ED**: E.g. Directorate of Veterinary Services surveys. **SR**: E.g. Interactions of GM crops and products with farm animals and humans.