PHASE 3 TOOLKIT MODULE PART (II) : THE ADMINISTRATIVE SYSTEMS FOR HANDLING APPLICATIONS

CONTENTS



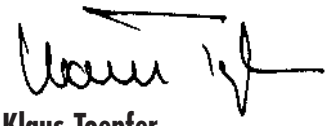
UNEP-GEF Toolkits for the Development of National Biosafety Frameworks

Foreword

On 11 September 2003, the Cartagena Protocol on Biosafety entered into force. Between September 2003 and April 2005, 119 countries have answered this call and have ratified or acceded to the Protocol, one of the fastest ever rates of ratification for any international environmental agreement. This high level of participation has brought with it a high demand for capacity building for effective implementation of the CPB from many countries where the introduction, and safe use, of Living Modified Organisms (LMO) biotechnology is new to both national governments and to the general public. UNEP believes that, for the success of the Cartagena Protocol, it is crucial that countries are assisted in building their capacity to implement the Protocol.

This unprecedented demand for capacity building assistance has presented a challenge to CPB Parties, and for this reason, UNEP welcomed the adoption by the Council of the Global Environment Facility in November 2000 of the GEF Initial Strategy on Biosafety, which aimed to assist countries to be prepared for the coming into force of the Cartagena Protocol. One of the components of the Initial Strategy is the UNEP-GEF global project on the Development of National Biosafety Frameworks. This project started in June 2001 and is assisting over 100 countries to develop a draft for a national biosafety framework.

UNEP, in its capacity as an Implementing Agency of the GEF, has been providing administrative and technical assistance to the countries participating in the Development Project through its team of Regional Coordinators, and through the organization of regional and sub-regional workshops. In addition the UNEP Biosafety Unit has coordinated the production of four toolkits that provide guidance on the main steps in the development of a national biosafety framework. Revised versions of the toolkits, incorporating lessons learned from the early participating countries are presented here in this publication as part of the overall efforts that UNEP is making to the successful implementation of the Cartagena Protocol on Biosafety.



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01 Introduction

1.1 Purpose of this toolkit module

This is the last module of a toolkit that aims to provide a practical "how-to" guide for countries to assist them in preparing their draft National Biosafety Frameworks (NBF), under the UNEP-GEF Project on Development of National Biosafety Frameworks. The toolkit is designed to be flexible and is tailored to meet the diverse needs of different countries, allowing them to select those tools and ideas that are most useful to their situation, needs and priorities. The toolkit is divided into four modules, each addressing one of the phases listed in the national project document:

Phase 0 Module — the vision (or rationale) of the project design, its guiding principles, and the establishment of institutional and management structures.

Phase 1 Module — the instigation of surveys and the preparation of inventories in the different sectors pertaining to biosafety and biotechnology within the country, including their entry into national databases.

Phase 2 Module — the involvement of stakeholders, and the consultation, analysis, and training activities needed to identify the priorities and parameters for the drafting of the National Biosafety Framework (NBF).

Phase 3 Module, Parts (i) and (ii) — this module of the toolkit, on the drafting of the NBF, consists of two parts: formulation of the regulatory regime, and design of the administrative systems for handling applications and notifications. The first part of this module focused on the regulatory regime, one of the main components of an NBF, and was published in August 2004. This is the second part of the module on the drafting of the NBF, and focuses on designing and running administrative systems for biosafety.

1.2 Using this toolkit module

The aim of this module of the toolkit is to provide practical advice for countries as they set up and implement an administrative system for national biosafety. Administrative systems for handling applications, decision-making on GMOs, and monitoring, inspections and enforcement of biosafety decisions form a central pillar of any NBF. Countries will set up an appropriate administrative system that builds on their existing systems, and is based on the regulatory regime formulated during the NBF development project.

This module covers the following aspects of an administrative system for biosafety:

- Handling applications *(Section 2)*;
- Decision making *(Section 3)*;
- Monitoring, inspections, enforcement *(Section 4)*. [1]

This module does not provide detailed guidance on risk assessment and management as these functions are part of implementing NBFs and will be dealt with when guidance materials are developed for implementation of NBFs.

The toolkit is designed to be of use to all countries participating in the NBF Development Project. It is therefore general in nature and recognises that, in the development of their administrative system for biosafety, different countries will use approaches, legal instruments, and terminology that are best suited to their own situation. For this reason, the issues and examples included in this module are intended to illustrate key messages: they do not take into account the individual circumstances of every country that may use the toolkit. Moreover, the toolkit is not exhaustive: countries are likely to identify other issues and to find other useful approaches that are not considered in this toolkit depending upon their particular needs, priorities and situation.

The toolkit addresses general considerations in terms of setting up the administrative systems for an NBF. However, countries should be aware that the precise administrative system requirements may vary according to type of GMO/activity concerned.

[1] This module draws on a training manual that was developed in the context of the 3 year capacity building project *"Implementation of National Biosafety Frameworks in pre-accession countries in Central and Eastern Europe"* which was funded and coordinated by the Dutch Government. That manual can be found on the CEE Biosafety website at: http://www.biosafety-cee.org/attachments/CEE%20-%20Training%20-%20%20manual.doc

Therefore, in providing assistance to countries as they design and implement administrative systems, this module of the toolkit is not intended to guide countries towards any particular outcome or approach. This module of the toolkit is intended as a resource for countries that want to ensure that their administrative system reflects their obligations under the Cartagena Protocol on Biosafety (CPB) as a minimum, but may wish to go beyond the CPB in developing their regulatory regimes.

1.2.1 A note on terminology used in this toolkit

Throughout this toolkit, an attempt has been made to use general terminology so as not to prejudge what approach a country may decide to take.

- The term "*application*" is used to cover all forms of notification or submission to the regulatory authority for permission to carry out activities with GMOs.

- The term "*applicant*" is used to describe the person or entity who will notify or apply to regulatory authorities in the country when a particular GMO, GM product or an activity involving a GMO or GM product requires notification or prior authorisation under the regulatory regime.

- The term "*GM activities*" is used to describe a range of activities that could be carried out with GMOs in the course of their development, testing and use. Not all countries will require permission for all activities.

- The term "*genetically modified organism*" or "*GMO*" has been used in most sections of the toolkit. Where there is a specific discussion of the Protocol, the term *"living modified organism"* or *"LMO"* that appears in the Protocol has been used.

- The term "*GM product*" is used to described products that are derived from GMOs but which do not themselves consist of, or contain GMOs.

- The term "*inspection*" describes the check for compliance with biosafety conditions for activities with GMOs. This may include the review and investigation of facilities, materials and documents related to GMOs.

- The term "*monitoring*" describes the scientific collection of biosafety data to support biosafety decisions. It also describes the systematic measurement of the effects of GMOs over time.[2] The aim of GMO monitoring is to identify direct, indirect, immediate, delayed, or unforeseeable harmful effects that GMOs and their application might cause on the environment, and on human health. The data obtained by such monitoring measures will, among others, be used to impose conditions, or to maintain, renew, or withdraw an approval for placing a GMO on the market.

1.3 Interrelationship of administration and the regulatory regime

The components of an NBF are linked to one another and are interdependent (Figure 1). A national policy on biosafety provides the rationale for the development of a regulatory regime and guides decision-making on GMOs. The regulatory regime in turn forms the basis for the other components: the administrative systems for handling applications and decision-making, systems for follow up and compliance, and mechanisms for public awareness, education, participation and access to information.

Therefore, in developing a regulatory regime to suit the requirements of a country, the relevant government bodies must also develop and implement an administrative system that will enable them to carry out the day-to-day activities required by the regime.

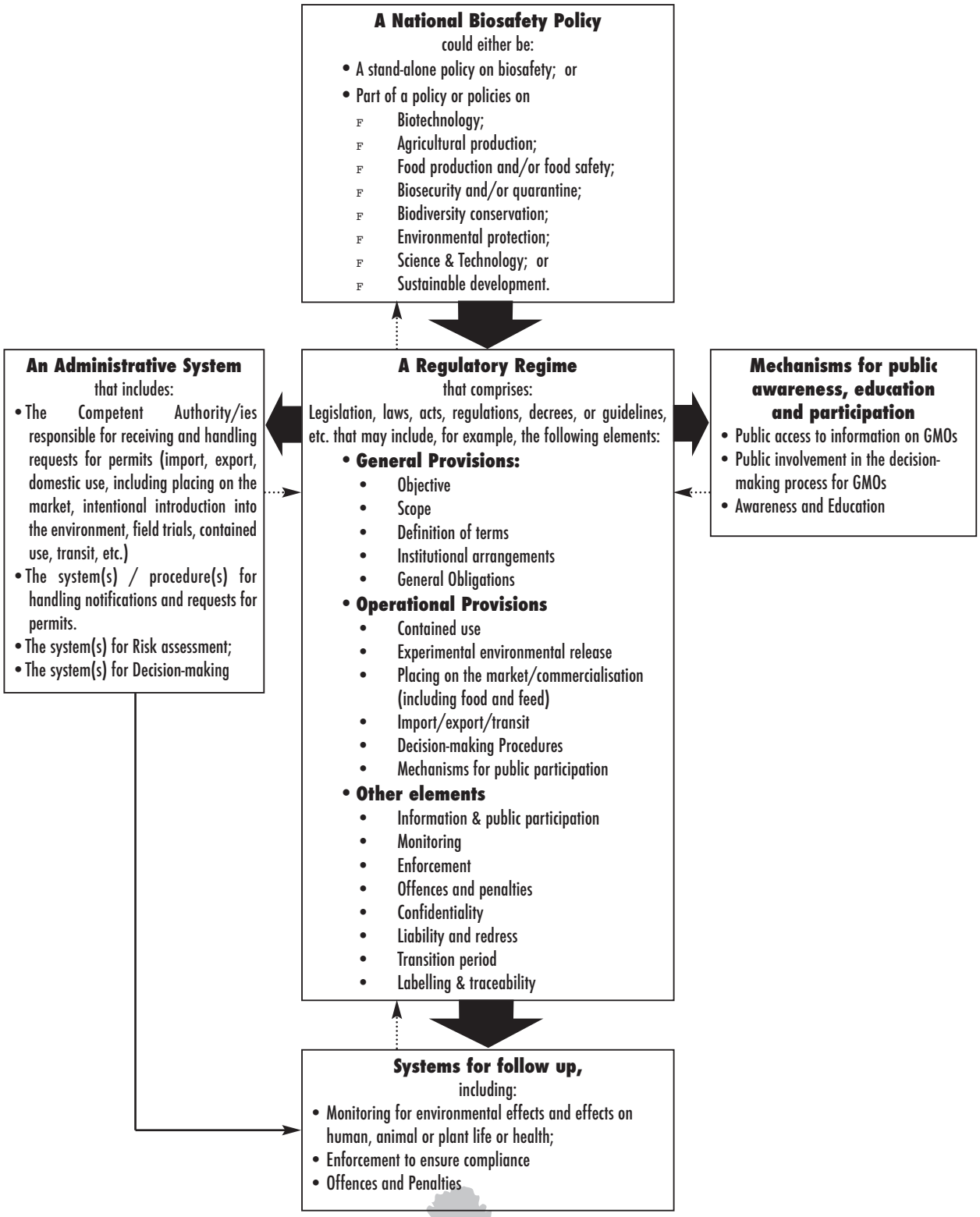
Countries developing their NBF will find that in order to meet their obligations, goals and objectives for the regulation of GMOs, GM derived products and activities involving GMOs, they may need to make changes to their existing systems. In many cases, these could build on the current systems rather than creating new, stand alone entities.

In the case of a regulatory regime, the options available to countries include: interpreting, guiding or amending the existing system; designing ways to fill gaps, or remedy overlaps in existing systems; or designing a comprehensive new system. Similarly, with an administrative system, countries need to first thoroughly analyse their existing systems to determine what actions they need to take. Countries may find it useful, and sometimes more effective, to build onto and/or modify an existing administrative system rather than to create something new. However, the choice of either building on existing systems or developing a new system will depend on each country's particular situation, needs and priorities Some countries may choose to build on existing systems whilst others may find it more effective to develop new administrative systems for handling applications for GMOs.

[2] EU Guidance notes on monitoring.



Figure 1: The components of a National Biosafety Framework (NBF)



2. Handling applications

2.1 Setting up an administration system

In order to obtain permission for activities with GMOs, applicants need to submit applications to government to obtain a decision. The administrative process needs to be designed to enable decision-making to take place efficiently, with adequate consideration and information. The administration process is distinct from the decision-making process.

Before receiving applications, a biosafety administration office needs to be established to:

- implement the institutional structures established by the NBF;
- appoint and train staff for identified positions;
- draft more detailed guidance, if this is still needed;
- set up internal procedures and publicise the system;
- provide for pre-application consultation, if required by applicants.

Not all countries have a single biosafety administration office. Some countries have biosafety administration responsibilities in several government departments. Others have centralised biosafety administration into one office responsible for co-ordinated governance of biosafety issues over a number of government departments. The choice of framework reflects existing regulatory structures and the resources available for sustaining biosafety regulation. National institutions responsible for a biosafety framework may include:

- A **national decision making body** that reviews data on proposed GM activities and approves or rejects them on the basis of the regulatory framework.

- A **biosafety administration office** that receives and processes applications for GM activities; carries out daily biosafety administration; and coordinates public input, risk assessment and decision making activities of the NBF. This office is usually responsible for issuing biosafety communications (information about biosafety) and consultation with stakeholders about the processes.

- A **scientific advisory body** that carries out or reviews risk assessments on GM activities and recommends what, if any, risk management measures may be needed to protect the environment and human health. This body may also advise on general biosafety issues.

- An **inspectorate** that is responsible for monitoring and ensuring compliance in cooperation with an enforcement regime.

- A **mechanism for public** participation in decision-making.

- A **biosafety focal point** and one or more competent authorities to fulfil the obligations of the Cartagena Protocol of Biosafety.

The placement, composition, responsibilities and inter-relationships between these bodies will vary from country to country, and will reflect the different legal systems used by countries.

While the regulatory regime will have specified the institutions responsible for the NBF,[3] establishing new institutions may require submissions to ministers or permanent secretaries, calls for nominations, and official appointment of people to committees or boards for the institutions. The appointment of staff may require advertisements for new posts; interviews for applicants, and the preparation of job offers and contracts when posts are fulfilled. These staff may need office space, office equipment and training. Much of this can be carried out within the responsible ministry, department or existing agency, but the process may need to be driven by a designated office or individual who is officially allocated this responsibility.

Once the administrative office is established, a review of the regulatory documentation would help to determine whether more detailed guidance is needed. For example, it may be useful to create standard formats (forms) for easy submission of applications for the different types of activities that are regulated. It may also be necessary to discuss and allocate internal administrative responsibilities, and establish internal, written standard operating procedures for the various activities that will form part of the daily tasks of the biosafety office. Establishing a website which allows access to all the documentation, and an explanation of the purpose and functioning of the biosafety office, is a valuable output of the setting up process.

Finally, it will be necessary to publicise the existence of the office to related ministries and decision makers, as well as applicants, stakeholders and the general public. It is likely that even before these activities have been completed, the office will have to deal with applications. This may mean that the development of the system runs parallel to its implementation.

2.2 Administrative steps in processing GMO applications

When applications for GMO activities are received at the biosafety administrative office, they need to be processed in a manner that is efficient and meets the needs and expectations of applicants and the general public, as well as obligations under international agreements. Governments need to provide clear guidance on the type of data and information they require for each type of activity. The administrative

[3] See section 5.2.5 on "Responsible Institutions" in the toolkit module on Regulatory regimes.



processes vary depending on the type of activity. Research, testing and general (commercial) use frequently have different administrative requirements because they can have different levels of safety and knowledge about the specific GMO. The following basic steps are used in many biosafety administrative systems, but are not all necessarily used in all systems:

- Acknowledge receipt of the application;
- Assess whether the application meets the requirements of the regulations, and whether approval for the proposed activity is required;
- Publicise the receipt of an application if required and call for public input. Not all activities may require public notification;
- Arrange for a review of risk assessment reports and/or arrange for a risk assessment to be carried out;
- Where information is missing or clarification needed, request the information from the applicant or schedule a meeting between the applicant and the scientific or other advisory body;
- Receive recommendations from scientific and other advisory bodies and forward these to the national decision-making body;
- Call a decision-making meeting when the necessary information is available;
- Receive the decision and prepare a decision document;
- Notify the applicant and issue an approval where granted;
- Make decisions (risk assessments and decision documents) publicly available, including on the BCH;
- Monitor the BCH for decisions on imports of GMOs for food, feed and processing and alert the national competent authority(ies) to relevant decisions;
- Schedule any necessary inspection(s) and monitoring of release sites during and after the activity;
- Review the inspection reports;
- Ensure that activity reports are received;
- Manage new information, appeals and accidental releases
- Review decisions as appropriate.

Each country's national biosafety framework determines how they deal with administrative activities. Some countries have chosen a system that centralises receipt of GMO applications at a single office. Other countries have chosen to use existing regulatory agencies for plants, animals, medicines, etc, as entry points for applications and to harmonise risk assessment through a centralised biosafety review process.

EXAMPLES OF DIFFERENT APPROACHS TO ADMINISTRATIVE SYSTEMS

The Netherlands receives applications at a central office appointed by the Ministry of Environment, which undertakes the biosafety administration. The final decision is taken by the Minister of Environment and this can be in consultation with other Ministers.
(see http://bch.biodiv.org/database/record.aspx?searchid=121966&recordid=5761)

South Africa - The biosafety administration office is in the Department of Agriculture. It receives applications for all types of GMOs and coordinates biosafety reviews and a central decision-making process, which involves the input of several ministries.
(see http://www.nda.agric.za)

In **New Zealand**, central government's independent agency, the Environmental Risk Management Authority, is responsible for dealing with all new organisms (including GMOs) applications to import, develop, field test, conditionally release, or release without controls.
(see http://www.ermanz.govt.nz)

France has an entry point for GMO applications in each of its existing regulatory agencies for plants, animals, medicines, etc. Each of these agencies has a compulsory consultation with a centralised scientific advisory body, the Commission of Bio-molecular Genetics, before decisions are taken.
(see http://www.ogm.gouv.fr/)

In **Georgia**, the Ministry of Environment (MOE) receives the applications for all GMO activities. The MOE forwards the application to other sectoral ministries for their approval and also to an advisory intersectoral body. The MOE makes the final decision based on the advice from ministries and this advisory body.

In the **Philippines**, the administrative functions are carried out by different government agencies depending on the type of GMO activity. The Department of Agriculture deals with GMO activities related to plants and plant products, fish and aquatic resources, domesticated animals and animal husbandry. The Department of Science and Technology deals with GMO activities concerning research and development. The Department of Environment and Natural Resources deals with GMO activities to do with bioremediation, forestry, and wildlife. The National Committee on Biosafety of the Philippines (NCBP) coordinates the decision-making on GMOs.

Even within these two major approaches there are numerous variations. In fact, almost every national biosafety framework is different in order to accommodate local regulatory structures and processes, and there is no 'perfect fit' model for administration of biosafety. All systems have the potential to function efficiently if they meet the objectives of the regulatory framework, are cost effective, and are harmonised into the local regulatory process.

Before an application for an approval is formally submitted to a national biosafety authority,[4] there can be informal consultations between the applicant and the competent authority, to ensure that the request contains the required information, and to enable the applicant to clarify the processes needed for biosafety review of applications.

Countries may use different terms for biosafety submissions, such as "request", "application", "dossier" or "notification". An application may consist of a letter signed by the legal person that submits the request, and an accompanying document containing the information requested by the regulatory authority for the proposed activity.

2.2.1 Acknowledge receipt of the application

When an application is formally submitted to a national biosafety authority, it is recorded and assigned an identifying or tracking number that will be used to distinguish this application from all others. Assigning a tracking number is the responsibility of the biosafety administration office and is useful for systematically keeping track of requests, and of the status of their administrative and technical progress through the national system. All records relating to the applications are stored under the tracking number, which is used to make information readily available to interested parties. Using a searchable electronic database enables easy location and sharing of specific information. The format for the database is determined by the country authority. The design of this database can facilitate easy information sharing of risk assessment reports and decision documents with the CPB's Biosafety Clearing House. The biosafety office needs to ensure that only authorised personnel can access the database.

EXAMPLES OF DIFFERENT APPROACHES FOR TRACKING APPLICATIONS

In the **United States**, the regulatory office, APHIS, in the Department of Agriculture, has a searchable website where applicants can monitor the progress of their applications through the administrative system.
(see http://www.aphis.usda.gov/brs/application_status.html)

In **Estonia**, the Ministry of Environment makes applications available to the public, so anybody who is interested can come and make comments up to a specified date. An open hearing could be organized if needed. Information on where and when the public can familiarize themselves with applications is on the web page of official announcements (see http://www.ametlikudteadaanded.ee/) the relevant information is also made available in the ministry's web-page (http://www.envir.ee).

Having recorded the application, an acknowledgement of receipt can be issued to the applicant, if this is a requirement of the regulatory regime. However, some regulatory regimes require the administrators to check for compliance with the information requirements of the regulations before sending the acknowledgement. In this case, the acknowledgement is sent out only after the next step, screening for completeness, i.e. meeting the requirements for an application (Section 2.2.2).

Under the CPB obligations for Advance Informed Agreement (AIA) notifications,[5] acknowledgement of receipt is required within 90 days. This acknowledgement of receipt must state whether the notification fulfils the information requirements, or whether more information or review time is being requested. In cases where these timeframes are being followed, the acknowledgement of receipt can state when the application review process officially begins and when it is likely to be completed.

2.2.2 Screening for completeness

If regulations stipulate the information that needs to be submitted with an application, it is usually necessary to assess whether the application meets these requirements. Two procedural aspects of the regulatory system should be checked before screening for completeness:

- The legal information requirements for applications;
- The timeframes allowed for procedures.

This is usually the responsibility of an officer in the biosafety administrative office, and can be facilitated by an information checklist. The checklist can be part of internal procedure documents. Information requirements for applications vary according to the proposed activity, the level of risk and the regulatory regime. The CPB lays out minimum information requirements for notifications in Annex I of the Protocol, and for GMOs intended for food, feed and processing in Annex II. Information required in acknowledgements of receipt of advanced informed agreement (AIA) notifications is given in Article 9(2).

Screening an application for completeness involves answering a number of questions:

1. Is it clear who the applicant is and what the request is for, *i.e.* who wants to do what, why, when and where?

2. Do the proposed activities **require** an approval under biosafety law?

3. Does the application comply with the **information requirements** laid down in the regulatory system for this type of activity?

Information requirements can include the following:

- **Administrative data**, such as name and contact information of the applicant;

- **Technical information**, which describes the GMO, the type of activity and the receiving environment. This information should be sufficient to **initiate** the risk assessment. Information requirements are frequently detailed in guidelines or regulations, but may differ from one GMO to

[4] A national biosafety authority can be the National Competent Authority on GMO issues related to the national obligations for Parties to the CPB.
[5] Article 9



the next. This requires that the detailed information requirements are provided in 'living documents', that can be changed to include new information needs as and when the need arises without having to wait for Ministerial or parliamentary approval. In addition, while conducting the risk assessment review, it may be necessary to request additional information or clarification of information provided with the original application.

Examples of lists of information requirements can be found in:
- CPB, Annexes I and II [6]
- EC Directive 2001/18/EC, Annex III [7]
- http://www.codexalimentarius.net/web/biotech.jsp

Examples of checklists for technical information can be found on the following web sites:
- Reviewers' Checklists: (http://www.inspection.gc.ca/english/plaveg/pbo/usda04e.shtml) ; and
- Checklist for Molecular Genetic Characterization Data: (http://www.cfia-acia.agr.ca/english/plaveg/pbo/usda03e.shtml and http://www.cfia-acia.agr.ca/english/plaveg/pbo/usda04e.shtml).

Guidelines may contain 'checklists' that can assist both the applicant and the biosafety officers in the evaluation for completeness of both administrative and technical information.

When an application does not fulfil the information requirements, additional information should be requested from the applicant. In such situations, the procedural 'time clock' may not start until the information is received, or may be stopped until the information is received.

The conclusion that a certain application complies with the information requirements does not mean that, during the risk assessment, additional information may not be requested by the reviewers through the national biosafety office. Requests for additional information can be made during the screening for completeness stage as well as during the risk assessment process. Reasons for 'stopping the review clock' need to be stated in the guidelines and provisions for applicants to ask for a 'pause' in order to collect new or verify existing information may also be useful.

There can be an overlap in information requested during "screening for completeness" and technical information requested during the risk assessment review. Technical information requirements depend on the nature of the GMO and the development stage of the activity. An application for a new GMO will have less [8] biosafety data than an application for a GMO already approved in other countries. Similarly, an application to place a GMO on the market usually contains more biosafety information than a request to move a newly developed GMO from a laboratory to a greenhouse for further testing. The availability of technical information has implications for the application of the precautionary approach in decision-making, and may result in requests for additional data on field trails before a decision is made.

As soon as it has been established that an application complies with the information requirements, the application can be processed for decision-making. If an acknowledgement has not already been sent (section 2.2.1.), this is a good time to do so.

2.2.3 Public participation

Many regulatory regimes allow for public consultation during their GMO decision-making process and this is a requirement for Parties to the CPB.[9] Having entered an application into the review process, it is necessary to ensure that the public have been informed and invited to comment, if this is allowed or required by the national regulations. How public input is obtained varies from country to country. Some of the new NBF drafts have left this responsibility to the administrators, and use a notice in the government gazette or on a regulatory website for public notification. In countries where the regulator publicises applications and calls for input, other consultation methods may be used.

In some countries the applicant is required to advertise the application and encourage input. Other countries require more direct interaction with the public in the form of public notices in municipal buildings in the release area, public meetings with interested and affected parties and the participation of the public in review meetings.

In general, the public input process reflects the culture of the country and is often similar to existing consultation on other social issues. One

[6] http://www.biodiv.org/biosafety/protocol.asp
[7] http://europa.eu.int/eur-lex/en/archive/2001/l_10620010417en.html
[8] Newly developed GMOs are first tested for efficacy before the complex task of biosafety data collection is undertaken. As such, early trials have less biosafety information on the GMO than trials approaching general approval.
[9] Article 23 (2).

common consideration is how effective the outreach programme is. A question to ask is: "how many people in the affected area are being reached by the process?" A review of the quantity and quality of the comments received helps determine the effectiveness and the importance of the process in a target community. Some applications will trigger a wide range of comments and input, while others may trigger a few general objections to the technology, with no specific comments about the proposed activity. As more and more regulatory systems turn to electronic handling of applications and for public consultation, there is a danger that communities may be missed out altogether. In some countries, regulators are setting up mailing lists of interested and affected parties to ensure wider outreach in the call for public input. In all cases, it is important to style public communication in an easily assessable format, including the use of local languages and non-technical wording.

The sustainability of the public participation in decision-making on GMOs is dependent on the cost-effectiveness of the consultation, and it is important to consider who will be required to fund the process of information output and feedback from the public. It may be difficult for many developing country governments to fund public consultation on applications. While some private sector applicants may be able to fund these activities, many government research institutes in developing countries may find it difficult to fund these activities. Some government institutes in developing countries already have programmes that consult the public on new technology, and these may be a cost-effective option for biosafety issues.

Having ensured that the interested and affected public are informed of the proposed activity, the biosafety administrator needs to collate public feedback for the decision makers. Where public concerns include safety issues, the administrator may wish to forward these to the scientific advisory body for risk assessment and recommendations before the final decision is made.

2.2.4 Arrange for a risk assessment

Under the CPB [10] all decisions for "*intentional introduction of LMOs into the environment*" or for "*domestic use, including placing on the market of LMOs that may be subject to transboundary movement for direct use as food or feed or for processing*" should be based on a risk assessment undertaken in accordance with Annex III of the CPB. In particular, according to the CPB, *the Party of import shall ensure that risk assessment are carried out* for decisions regarding the intentional introduction of LMOs into the environment (AIA), while for LMOs intended for direct use as food or feed or for processing (FFPs), a risk assessment has to be submitted to the BCH by the Party making its final decision on the LMO.

However at the national level, the regulatory regime determines what should be subject to risk assessment. Each country may decide if and when to conduct a full risk assessment, or to audit an existing risk assessment. The types of applications that require an independent risk assessment are determined by the regulatory regime. Generally this decision depends on the type of GMO, the nature of the activity, the sensitivity of the release environment, and the assessment of risk related to the activity.

There are no biosafety regulatory agencies that currently conduct their own risk assessment research, though a regulatory agency may contract research groups to carry out risk assessment research on specific issues. In many countries it is a common practice to require the applicant to carry out the risk assessment, and then have it audited by an independent group of scientists.

EXAMPLES OF PUBLIC PARTICIPATION IN GMO DECISION-MAKING

In **New Zealand**, the Environmental Risk Management Authority (ERMA) seeks submissions on publicly notified applications by (i) placing advertisements in the public notice section of the major newspapers and (ii) other methods, including a notice on its website http://www.ermanz.govt.nz, that provides effective public notification. ERMA also holds public hearings if requested by interested parties. In addition, ERMA, uses a mailing list to inform persons who have requested that they be informed of a particular type of application.

In **Australia** the regulator summarises the application and distributes it on request to interested and affected parties for their comments and input.

In the **EU** all applications are publicly available, and the public has 30 days to make comments (EU Dir 2001/18). Member countries use different ways to do this. The most usual way is publication of the notification in a newspaper, official gazette or on a special internet site (e.g. Estonia for latter), and the public can send their comments to the responsible authority.

In **South Africa** the applicant is required to publish their intentions in three newspapers that circulate in the release area and cover the majority of the population in that area. These adverts must contain specific information and must be published before the application is submitted. Original copies of the adverts must be attached to the application.
(see http://www.nda.agric.za/Legislation/Plant/GMO/regulations/section 6).

In **Turkey**, According to the draft law on biosafety, the person who is responsible for placing an LMO or its product on the market, is responsible for informing consumers.

Mexico, The Secretariat of Agriculture, as a competent authority, summarizes each request and puts it on a web site for the public to know about, and make their comments. After 30 days, suggestions are analyzed, and if the biosafety measures are modified, the applicant and the person making the suggestion are informed. The competent authority also sends the summary request to the local agriculture authority where the GM crop will be grown, so that the farmers in the region are informed and able to make submissions.

In the **Philippines** members of the public sit on institutional biosafety committees and on the scientific advisory body, the National Committee on Biosafety for the Philippines. Applicants are requested to place notices in public buildings and may be asked to hold public meetings to inform the community about the trials and to gather input from them. The regulators attend public meetings to provide input on regulation and the biosafety system.
(see http://www.dost.gov.ph/ncbp/pbg/pbg.pdf)

[10] CPB Articles 8 and 11.



The types of activities with GMOs that may have specific procedures for approval include:

- Import and export of GMOs including import for direct use
- Transit
- Contained use (e.g. for research and teaching, scale up and development or commercial production)
- Intentional, confined release for testing and development
- Intentional, unconfined release for commercial or non-commercial use

The type of activity regulated is determined by the NBF in each country. The CPB provides a Biosafety Clearing House [11] to assist stakeholders and regulatory agencies to find out about decisions made by Parties to the Protocol.

Some countries have a notification procedure for familiar, low risk activities. In this case the applicant is required to notify the regulator that an activity will be carried out and provide sufficient information to enable the regulator to trigger inspections or a risk assessment as required.

Initially, most applications may require a risk assessment, as they will be new to regulators and scientific reviewers. In some cases, the systems exclude contained use for research and teaching from this procedure,[12] but ensure that the facility is registered, and inspected and a written risk assessment may be required for all GMO activities within a registered facility.

Familiarity with specific GMOs, their conventional counterparts and with the level of risk they pose may lead to a situation where independent risk assessments are conducted through less stringent procedures, or considered no longer necessary. This leads to what is called a 'fast track' process where the decision-makers may decide to apply simplified procedures.[13]

The CPB makes allowance for LMOs identified as 'being not likely to have adverse effects on conservation and sustainable use of biological diversity' to be exempt from AIA procedures under a multilateral COP-MOP decision.[14] Article 13 also allows for simplified procedures to be applied by a Party of import where they have determined it is safe to do so.

[11] www.biodiv.org/bch/
[12] For example, the CPB excludes LMOs destined for contained use from AIA procedures, Article 6(2)
[13] Article 13
[14] Article 7(4)

EXAMPLES OF RISK ASSESSMENT PRACTICES

In **New Zealand**, responsibility for risk assessment lies with the applicant based on the criteria in the legislation. Forms and guides assist applicants understand the intent of the legislative criteria. ERMA New Zealand evaluates the information provided and if required can seek further expert information or reports as appropriate. Low risk activities that conform to the requirements of the regulatory regime are not publicly notified. Some activities are discretionary for public notification while there are others for which there is a mandatory requirement for public notification.
(see ERMA New Zealand website http://www.ermanz.govt.nz)

In the **United States**, USDA's APHIS identifies specific activities where notification only is needed before an activity commences. The regulators review all of these notifications and can request full risk assessment review if they believe the activity differs sufficiently from the familiar to warrant this additional regulation. Risk assessments are audited within APHIS, the EPA and the FDA depending on the nature of the GMO and its application.

In **Argentina**, once a plant GMO has been sufficiently field-tested, the applicant may request that the crop be 'flexibilized,' that is, be approved for unconfined (usually large-scale) planting for certain specified uses. These are: (1) for regulatory purposes – to provide material for analytical, toxicological and other required tests; (2) for export; (3) for off-season seed increase – not to be sold in the country; (4) for tests to be later presented (after approval for commercialization is granted) in support of new variety registration; or (5) for pre-commercial multiplication pending variety registration.

In **South Africa**, as a general guideline, if scientific reviewers consider a repeat activity of assessed risk to be one that does not differ from an earlier approved activity in terms of the nature of the GMO (host and modified DNA), the applicant, the release environment, the size of the release and the confinement conditions, they will consider a fast track procedure for approval.
In the United Kingdom, the UK Advisory Committee on Releases to the Environment (ACRE) reviews the safety of GMO activities at the request of Ministers and makes recommendations on whether activities should proceed and what minimum risk management conditions are needed to minimise harm to the environment and human health.
(http://www.defra.gov.uk/environment/acre/about/index.htm).

In **Mexico**, a group of scientists, together with authorities from the Secretariat of Agriculture, analyze the applicant's risk assessment on the basis of national legislation. This group may request help from other experts to decide on an application. When the Secretariat of Agriculture has become familiar with a GM crop, it may allow the applicant to increase the area panted for the crop, but the applicant will have to continue to present the risk assessment as was done for the first application. Any biosafety measures for a semi-commercial release would also have to be maintained.

In the **Philippines** The National Committee on Biosafety for the Philippines audits the risk assessment on GMO activities and calls on the expertise of the Scientific and Technical Review Panel to provide an independent safety audit and recommendations.

In **Canada** the risk assessment audits for plants with novel traits (includes GMOs) are undertaken in offices of the Plant Biosafety Office of the Canadian Food Inspection Agency (CFIA).
http://www.inspection.gc.ca/english/plaveg/bio/pbobbve.shtml

If an activity is deemed to require an independent risk assessment under the national regulations, the administrators need to ensure that this happens. In some countries applications move directly to a scientific advisory body that determines the risk assessment needed. In other countries, the administrators determine the procedures needed for specific applications during their review for completeness (see Box above).

Having assessed the nature of the GMO, the administrators or scientific advisory body assemble a scientific committee to carry out or audit the risk assessment of the proposed activity. The nature of the GMO and the proposed activity determines what expertise is needed to undertake the risk assessment, and recommend appropriate risk management conditions.

In some NBFs the scientific advisory body undertakes the risk assessment and calls in experts as needed. There may be requirements that scientific reviewers declare any conflict of interest if they are asked to review an application in which they have a personal, professional or economic interest. This is necessary to maintain the independence and credibility of the review process.

In some countries the necessary expertise resides in the regulatory agency and risk assessments are carried out internally. These agencies generally have the mandate to request additional expert input as they deem necessary.

Having identified the scientific experts for the risk assessment, the administrator is responsible for meeting the requirements of confidential business information, the dissemination of documents to all the reviewers and the organisation of meetings for review groups, if these are necessary.

2.2.5 Confidential business information

As a result of the innovative nature of modern biotechnology, some of the business and research applications have technical, business and efficacy data that applicants may wish to keep confidential, in order to maintain a competitive advantage in the market place, or to protect their right to patent the technology if the GMO or procedures prove effective.

Therefore, many NBFs make allowance for applicants to identify business information that they wish to keep confidential. The CPB requires parties to protect confidential information received under the Protocol [15] and to ensure that NBFs have mechanisms in place to protect such information.[16] The type of information that may be kept confidential is usually specified in the national regulatory regime. The accepted criteria for confidential business information should be stated clearly in NBF guidance documents. Regulators may require applicants to substantiate why certain information needs to be kept confidential.

In most cases the applicant is allowed to mark information that they wish to keep confidential and the regulator assesses whether this meets the requirements of the regulations. If the confidential information is acceptable, the administrators, reviewers and decision makers are bound not to release the information. Usually these officers of the biosafety system are required to sign confidentiality agreements when they accept positions in the biosafety regulatory office.

If the marked information is not deemed acceptable by the regulators, most NBFs allow a consultation with the applicant to review the request for confidentiality. If, after the consultation, the applicant wishes to withdraw the application rather than reveal confidential information, they are usually given the option to do so. This is a requirement of the CPB.[17]

The CPB requires that the following information is not kept confidential in any circumstances :[18]

- The name and address of the notifier;
- A general description of the LMO;
- A summary of the risk assessment; and any methods and plans for emergency response

Some NBFs may not allow other information related to the safety of a GMO to be kept confidential; in these cases, they will need to justify this decision.

When confidential business information is accepted in an application, it is marked as such in all documents distributed to reviewers and decision makers. In this way the information is not withheld from regulators and should not affect their ability to inspect and regulate the activity.

When a regulator makes applications available for public review, the applicant is usually asked to provide a copy of the application with the confidential business information removed, but marked. This copy can be made available for the public. It indicates where confidential information was deleted, but does not violate the rights of the applicant.

2.2.6 Dissemination of documents

The dissemination of copies of applications for review can be one of the most time consuming and costly activities of a biosafety administration office. Those regulatory offices with the requisite technology can deal with documents in an electronic form, greatly minimising the time and resources needed for this activity.

Regulatory offices in many countries frequently function under very tight resource constraints. To facilitate the dissemination of documents, these regulators sometimes ask applicants to provide the required copies for the reviewers and the decision makers.

[15] Article 21(1)
[16] Article 21(3)
[17] Article 21(5)
[18] Article 21(6).



2.2.7 Risk assessment completion

From an administrative point of view the responsibility for ensuring that the risk assessment takes place usually rests with the biosafety administration office. The procedures and minimum requirements for risk assessment and risk management are laid out in national regulatory regimes and in the CPB.[19]

When applications are for new GMOs or activities, it may be necessary to schedule a meeting for the scientific reviewers to discuss the application and audit the risk assessment, or advise on carrying out a risk assessment. Based on the risk assessment, the scientific reviewers would identify acceptable risk management procedures. Once reviewers are familiar with certain GM activities and GMOs, for example when the same GMO is being repeatedly assessed for the same use and released in the same location, then the risk assessment procedures may be simplified and attention would then focus on the risks posed by any new traits. The decision to simplify risk assessment reviews for specific GMOs is usually taken on a case-by-case basis with the approval of the competent authority and in accordance with the requirements of the regulatory regime.

During the risk assessment, scientists may identify gaps in the data or questions that they wish to address to the applicant. Mechanisms for this are usually outlined in national biosafety regulations. Some systems allow the reviewers to hold transparent meetings with applicants to address these issues.[20] Others require the reviewers to address these questions and data needs to the applicant through the biosafety administrative office.[21]

When additional information is requested the regulator usually stops the procedure clock and gives the applicant a set amount of time to submit the information before resuming the review and restarting the clock. This is important where timeframes are set to specific regulatory activities (see section 2.3). For reasons of efficiency and transparency, requests for additional information are best made in writing and should be both specific, and scientifically justified.

The outcome of the risk assessment consists of recommendations or advice for the decision-making body. The administration officer needs to receive these and send them to the decision-making body in time for a decision to be made.

The regulatory regime determines how decisions are taken. Parties to the CP are required to consider, as a minimum, a risk assessment that has been carried out in a scientifically sound and transparent manner as summarised in Annex III of the CPB. In addition, decision makers may take into consideration socio economic impact[22] and other issues allowed by the regulations, such as national imperatives and benefits. Some regulations require the consideration of alternative technologies that may address the same issue, or a comparison with existing practices.

2.2.8 Dissemination of decisions

Once the decision-makers have made a decision about a specific application it is usually the responsibility of the administration officer to

- compile a decision document;
- notify the applicant;
- issue a rejection letter, permit or other form of approval, with or without conditions;
- make the decision public;
- make the decision available to the Biosafety Clearing House;
- schedule inspections;
- review inspection reports; and
- review activity reports.

The requirements and formats for these activities are usually detailed in national regulations and vary from country to country to reflect national regulatory processes.

The CPB details the requirement for decisions logged on the Biosafety Clearing House[23] ; these requirements vary according to the type of GM activity.[24]

2.3 Timeframes

It is important to clarify when the procedure for handling requests starts and the time period within which a decision has to be made. The NBF may establish certain time limits within which decisions or other steps have to be taken. The timeframes for procedural steps generally are spelt out in the biosafety regulations or guidelines. The CPB stipulates specific timeframes for specific decisions and these are tabled below (Table 1). The timelines generally start at the receipt of an application. In addition to these, the Parties need to notify the Secretariat of the names and addresses of their focal point and competent national authority or authorities and of a contact point for emergency notifications.

[19] Article 15; Article 16; Annex III
[20] For example the AHPIS, EPA and FDA reviews under the USA system
[21] For example the South African biosafety system
[22] Article 26
[23] Article 20.
[24] http://bch.biodiv.org/decisions/

Table 1. Procedural timeframes obligated by the Cartagena Protocol on Biosafety.

Regulatory activity	Timeframe	Reference
Acknowledgement of receipt of notification and how to proceed with the first intentional transboundary movement of a LMO	90 days	Article 9(1)
Communicate a decision on an AIA import notification	270 days from date of acknowledgement	Article 10(3)
Take a decision on a GMO import for food, feed or processing (applicable to developing country Party or a Party with an economy in transition, in the absence of a domestic regulatory framework)	270 days	Article 11(6)
Inform the BCH of a decision to approve a LMO for domestic use as food, feed or processing, including placing on the market	15 days	Article 11(1)
Notify an applicant of a change in decision regarding a transboundary movement	30 days	Article 12(1)
Party response to changed decision on transboundary movement	90 days	Article 12(3)
Notification of unintentional transboundary movement likely to have significant adverse effect	Immediate	Article 17(1)

The time needed for an activity usually shortens as biosafety officers become familiar with the procedures and risks associated with specific GMOs, and gain confidence about the effectiveness of the process.

EXAMPLES OF TIMEFRAMES USED BY SOME COUNTRIES

In **South Africa**, after 14 years of biosafety regulatory experience the regulations to the South African GMO Act stipulate the following timeframes for issue of biosafety approvals:

1. Importation and exportation of GMOs (30 days)
2. Contained use of GMOs (30 days)
3. Trial release of GMOs (90 days)
4. General release and marketing of GMOs (180 days).

In **New Zealand**, unless there has been an agreed time waiver, statutory timeframe for processing non-notified applications is 60 working days and 100 days for notified applications.

2.4 Other administrative duties

In addition to handling request for activities with GMOs, biosafety administration offices carry out a range of other biosafety administrative duties that need to be factored into the time allocations and staffing of the office. These include:

- Frequently the administration office is required to provide **secretarial services** to the national biosafety bodies, such as decision-making committees and scientific review and other advisory committees.
- The office needs to have a **procedure for dealing with accidents, emergencies and unintentional releases,** which generally get priority over daily administration.
- Many regulations require applicants to submit **new information** to the biosafety office if it is likely to have relevance to the safety of a previously approved GM activity. Administration offices need to have procedures on how to process this information and ensure that remedial action is taken if needed.
- Where regulations make allowance for **appeals against decisions** of the national authority, these are frequently handled through the biosafety regulatory office. Procedures for appeals need to be developed to facilitate this process and assign responsibility for who should coordinate the process.
- Once the regulations have been in operation for a period of time it is advisable to **review** how they are working and whether changes are recommended. This review can be a time consuming process requiring consultation with stakeholders and submissions to Ministries for the required changes.
- As new GMOs and related activities become the topic of applications, it is common that new biosafety issues are raised. These may require **modifications or additions to guidance documents.** The responsibility for recommending these changes may lie with the scientific advisors, but the revision process is usually managed by the biosafety administration office.
- Frequently the biosafety administration officers are responsible for ongoing **liaison with stakeholders** such as parliament, ministries, applicants, the public and regional and international biosafety meetings and conventions.
- **Running websites and ensuring adequate communication** are tasks that may be left to the administration office.
- Finally, as detailed in section 2.5, the biosafety administration office is often responsible for the ongoing **training of the human resources** used in the biosafety review process. This may require coordinating biosafety training workshops, allocating training opportunities to personnel and participating in training on behalf of the NBF.

All of these activities can take up considerable administrative time and effort and need to be considered in the planning of national biosafety administration offices.



2.5 Resource requirements for national biosafety [25]

Scientifically sound safety assessments and measures for safe handling of GMOs and products require human, financial, and information resources as well as an adequate infrastructure. The following resource requirements are usually required:

2.5.1 Managers

In the course of implementing biosafety regulations, management responsibilities may be placed on individuals who have little or no prior experience in this area. New managers will therefore need skills in:

- Priority setting;
- Resource acquisition and allocation;
- Coordination with multiple agencies;
- Meeting management;
- Communications across many sectors;
- Information access and management;
- Handling of confidential or proprietary information.

2.5.2 Government officials and decision makers

The impact of biotechnology and GMOs on many sectors (health, agriculture, environment, development, trade) generally requires the involvement of a number of ministries in biosafety regulation. A coordinated approach, with strong political support, is essential in ensuring that a biosafety system functions effectively. In addition, it is important that officials from relevant ministries, and their science advisors, are kept well informed on the role of biosafety systems in ensuring safe development and testing, leading to informed decisions on applications.

Officials with formal responsibility for biosafety and who take decisions on proposed releases are, in essence, the gatekeepers who determine what biotechnology products, if any, will be allowed, and when. Those who have regulatory authority set the standard for testing and commercial release. The capacity and experience of these people may be the most important resource of all. Efforts to empower them and keep them well informed are worthwhile.

2.5.3 Scientists

The scope of scientific disciplines relevant to biosafety review is extensive. Expertise needs to be matched to each application taking into account the GMO, its use and the release environment. Scientists will need to adhere to the confidentially protection on some information in applications. The NBF will need a mechanism to deal with this.

An administrator can assess the required expertise for each application and pull together a team well skilled for the risk assessment. Whether these experts are voluntary or are paid will be determined by the policy in each country. Bearing in mind that a risk assessment review can take many hours or even days, especially for a new GMO, administrators need to spread the load across the available scientific community in order not to overload specific individuals and to expedite the process.

Some countries have a large pool of qualified life scientists with the knowledge and experience needed to review the safety of GMO activities, while others do not. Where countries lack sufficient scientific capacity they will find it difficult not to overtax the available experts. The Biosafety Clearing House [26] has established a roster of experts to help countries identify expertise to compliment their own scientists. Careful delegation of review responsibilities can also assist scientists to use their time effectively. For example, using the same set of reviewers for similar GMOs allows them to use their knowledge of earlier applications to speed up the review of repeat activities.

EXAMPLES OF HOW SCIENTISTS ARE INVOLVED IN DECISION MAKING ON GMOs

In **South Africa**, the regulatory office has a database of over 60 scientists and experts used in risk assessment. However, not all of these experts are needed for every review. The reviewers all sign a confidentiality agreement with the regulators.

In **New Zealand**, in addition to the in house expertise of ERMA New Zealand, an expert science panel of eminent researchers has been established and a roster of experts including overseas experts is maintained and is used as appropriate.

In **Belarus**, experts who will conduct risk assessment will be chosen from roster of experts that will be adopted by Government. In every case experts will be selected separately.

In **Mexico**, the Secretariat of Agriculture, which is the competent authority on Biosafety consults a group of Scientists to advise them on each request. The CIBIOGEM also has a database of 350 experts in different disciplines from whom they can seek advice.

[25] Adapted from Traynor, PL, Frederick, R and M Koch. 2002. A Workbook for technical training. Biosafety and risk assessment in agricultural biotechnology. ABSP. Institute of International Agriculture. Michigan State University. http://www.iia.msu.edu/absp/biosafety_workbook.html
[26] CPB, Article 20. www.biodiv.org/bch/

It is important that the relevant scientific expertise is represented. Often a multidisciplinary approach with the participation of ecologists, entomologists, soil biologists etc, is necessary in addition to molecular biology and biochemistry expertise. To be effective, the biosafety reviewers will need skills in risk assessment and risk management procedures in addition to their biological expertise. They will also need a broad understanding of the principles of inspections and monitoring. Ongoing training programmes can help provide biosafety skills for potential reviewers and provide case studies to build experience and confidence in the risk assessment process.

To help developing countries address capacity needs for biosafety, the CPB specifically addresses capacity building in Article 22. The first meeting of the Parties to the Protocol has adopted an action plan for building capacities for the effective implementation of the Protocol.

2.5.4 Information access

Scientific biosafety review teams require a significant amount of information and data on which to base their recommendations. Information increases the confidence with which decisions are taken and reduces the chances of errors. Much of the necessary information is supplied with the application. However, a predetermined set of questions may not elicit all the information that is necessary and sufficient to complete an informed risk assessment. Where gaps exist, or if supporting or confirming information is needed, review teams need access to other sources.

Information to support safety assessments and recommendations is available from a wide range of sources and in a variety of formats: peer reviewed scientific publications, experts in relevant professional fields (e.g., breeders, agronomists, seed suppliers), conference proceedings, review articles, and colleagues working in local institutions. Decision documents from other national biosafety committees are a particularly rich source of information on identified risks and management options for particular GMOs and products.

The Biosafety Clearing House of the CPB (Article 20) has started to establish links to these documents from Parties. Non-parties with considerable GMO experience are also making their risk assessment and decision documents available on databases, e.g. the US have pooled decisions from their three agencies (APHIS, EPA and FDA) on a site developed by USGS Center for Biological Informatics:
http://www.nbii.gov;
http://usbiotechreg.nbii.gov.
The OECD has a database called 'Biotrack'.

2.5.5 Feedback mechanisms

Feedback is a useful and often essential component for GMO trials and commercial releases. Trials are carried out to collect data of commercial and biosafety importance. Regulators can implement feedback mechanisms to ensure that findings are tabled for consideration by review teams. This keeps the reviewers informed of issues that arise during the trials and helps them to determine management procedures for future trials. It also provides regulators with information to address concerns that may arise during or after the trials. While significant impact data can be collected during trials, the large plantings of commercial GM crops provide unique conditions that may result in new data. Where a commercial release of a GMO is authorised, it is sometimes necessary to require that applicants continue to collect specific data after commercial release, based on the scientific findings of the review body. Feeding this back to regulators enables an ongoing monitoring of the impact of the crop on the environment. Many countries obtain this feedback by requiring a trial report to be submitted at the end of a trial period. Taking the time to specify the data required in each trial report ensures that the relevant data are received. Collecting data after commercial release can be requested as a condition of the approval to commercialise.

EXAMPLES OF FEEDBACK MECHANISMS

In **New Zealand**, a feedback mechanism is part of the approval process. This may require reports on a case-by-case basis at specified intervals as well as through inspection, monitoring, and enforcement regimes of the regulatory framework. These feedback reports are reviewed by ERMA New Zealand and if required appropriate actions taken.

In **Mexico**, the Secretariat of Agriculture requires applicants, on completion of field experiments or semi-commercial planting, to submit a report that provides details of biosafety measures applied in addition to agronomic measures. In the event of failure to supply this information, subsequent applications will not be authorized.

2.5.6 Financial support

Ultimately the sustainability of any national biosafety system will be determined by its recurrent funding. To this end, developers of regulatory frameworks and administrative systems need to balance efficiency and effectiveness to ensure an affordable system that maintains high safety standards.

Biosafety systems impose implementation and running costs for effective compliance. The costs of establishing and operating a biosafety system include:

- Education of policy makers and stakeholders;
- Development of regulations;
- Development and distribution of procedural information;
- Technical training for reviewers;
- Generating knowledge to support the regulatory system;
- Administrative expenses of the biosafety review committee;
- Salary and support for employees;
- Pre-release site visits (if required);
- Inspections during and upon termination of the release;
- Follow-up monitoring;
- Training for inspectors;
- Documentation and record keeping; and
- Training or familiarizing customs personnel on documentation that is required by the CPB to accompany GMOs that cross borders.



In some countries, applicants are charged fees to cover these costs. While this approach may be suitable for applicants from the private sector, where such costs are viewed as a normal part of product development, applicants from national research institutes, universities and other public sector organisations may find these regulatory costs prohibitive. Thus, in setting fees, regulators need to consider the constraints this will place on stakeholders.

Compliance costs refer to expenses incurred by the applicant in meeting regulatory requirements. Included are expenses for:

- Generating data needed for the application;
- Implementation of risk management measures;
- Post-release monitoring prescribed as a condition of approval; and
- Reporting and documentation.

Often food safety data can be used across many countries, but additional environmental data may need to be collected locally to supplement existing environmental knowledge. There are also instances where local regulators may require additional food safety data to evaluate impact on communities where foods are used differently or in greater quantities, or where there may be a genetic disposition in local populations that requires additional risk assessment. For GMOs that have undergone prior review in another country, requiring a complete replication of the data, particularly food safety data, can be a costly process and may need to be justified. The financial outlay for collecting a new set of data may preclude some applicants from testing GM derived products.

Part of achieving sustainability and effectiveness in biosafety is to ensure that risk management reflects the level of risk. Similarly, the risk assessment and public consultation efforts should also reflect the level of risk, while bearing in mind that public consultation also fulfils a transparency role. Initially public consultation costs may be high, but with time and a good regulatory track record, these costs are likely to decrease as confidence in the regulatory system and the technology grows.

3. Decision making

There are two clear aims in decision making on GM activities and GMOs:

- Accountability, determined by compliance with the regulatory regime; and
- Transparency, provided through decision documents.

Provisions for consultation and public input into decision-making could be added to these.

The decision-making criteria are defined in national regulations and policy. In countries where the biosafety system is based on the risk assessment processes used for pesticides, and biological control, safety is often the primary focus for decision-making. In countries that base their biosafety systems more closely on environmental impact assessments, issues such as benefits, socio-economic impact, public input and national imperatives are also taken into account before decisions are made.

Thus, many national biosafety frameworks make a clear distinction between decision-making and safety advisory bodies in their national biosafety frameworks. The types of decisions taken by regulators differ according to the activity that is regulated and the requirements of the national legislation. For research, some regulators have notification procedures that only require additional regulatory action when risk criteria trigger more extensive regulation. Some regulatory departments have introduced notification systems for specific activities with specific categories of GMOs to streamline their regulatory process, and respond to low risk categories of GMO research and development.

Development and testing of GMOs may require regulatory review until the risks are better understood and the risk management conditions are shown to work. After this, the level of regulatory input may diminish for familiar activities known to be of low risk. Whether regulation continues after general use approval depends on the type of GMO and its use. Some countries have included regulatory aspects in general use permits for some GMOs, such as the compulsory resistance management systems applicable to some pest resistance commercial GM crops. Other GMOs have been approved for commercial use without the need for any post-approval biosafety regulation.

3.1 Factors considered in national decisions

Countries make sovereign decisions about the development, import, or deployment of GMOs and their products. Activities carried out during the development and testing phase of a new GMO may initially focus on biosafety issues as long as these activities are well-managed transient releases, with a confined and finite impact. For this reason decisions on contained use, testing and clinical trials generally focus on safety issues and on the ability of the applicant to restrict the GMO to the test site and to remove it safely from the site at the end of the trial.

The testing and development phases of GMOs are used by the applicant to assess the safety and environmental impact of the new technology. Once applicants move toward general use and commercial release, they need to be confident that their products are safe for consumption and will not impact adversely on the environment, or on human health. These are the data they present to the decision makers, and the data required by the CPB [27] risk assessment process. Of necessity, the 'products of' GMOs are frequently assessed before commercial use permission is given. This is because it is sometimes necessary to review the safety of the food, feed, fibre and any other product derived from a GM microbe, crop or animal during the standard risk assessment.

For example, in reviewing the safety of insect tolerant cotton, the impact of the new protein on animal feed containing cotton seed cake was part of the risk assessment. Similarly, in reviewing the safety of insect resistant corn, the impact of the processing steps in production of glucose syrups and starches on the integrity and activity of the new proteins formed an integral part of the food safety assessments.

The recommendations on the safety of a GMO are just one of the sets of data that national decision makers take into account when reviewing an application for an activity with a GMO. Decisions regarding the general use and commercialisation of GM technology and its products may take into account non-safety issues as well. These may include national policies on technology, research and sustainable development. They may consider the potential benefits and role of biotechnology in meeting national goals and objectives in food production, food security, wealth creation, job creation, trade and related areas. They may compare the product of the new technology to existing products and consider what impact deployment may have on indigenous knowledge, heritage and culture. Table 2 illustrates some of the issues that have been factored into decision-making on commercial use of GMOs.

Table 2. Some decision-making considerations for commercial release of GMOs [28]

Case-by-case assessments are needed, but NOT ALL CONSIDERATIONS ARE NEEDED FOR EVERY GMO AND NOT ALL ARE TAKEN INTO ACCOUNT BY EVERY COUNTRY)

Molecular characterisation Insert effects, copy number, expression levels, stability, etc.		
Human & animal safety	**Environment**	**Other issues**
Food safety Toxicity Pathogenicity Allergenicity/Digestibility Nutrition Workers safety Unexpected products Gene stability	Impact on: **Living organisms** - Biodiversity - Outcrossing - Weediness - Invasiveness **Gene flow** **Gene stability** **Air, soil, water** Other	**National imperatives** - Food security - Wealth creation - Sustainable development **Economics** - Access and cost - Labour - Trade, etc **Social** - Ethics or religion, - Indigenous knowledge, - Traditional technology, - Gender impacts, - Equity issues, etc.

[27] "Annex I, Annex II, Annex III" of the Cartagena Protocol.
[28] Adapted from Kitch L, M Koch and I Sithole-Niang, 2002. Crop Biotechnology: A working paper for administrators and policy makers in sub-Saharan Africa. FAO, Harare.



Of necessity, decisions on GMOs need to be taken on a case-by-case basis, as each GMO may have a different impact on the release environment. GMOs may also differ in the benefits offered and the way in which they impact on different communities. Each GMO may also differ in comparison to conventional or traditional technology.

In considering the wider impact of new technology it may be necessary to consult with a wide range of stakeholders before making a final decision on local utilization. Public acceptance or concerns will indicate the degree of acceptance of the GMO in a particular locality. In addition, the decision-makers may wish to consider the potential impact on trade, labour, food security, gender, small business development, sustainable development and poverty alleviation. Under environmental impact assessment, it is often necessary to take into consideration the benefits of a new technology and also the impact of not using the new technology. These are just some of the socio-economic factors that may be important in the final decision. Some countries have economic and social impact advisory committee over and above scientific safety advisory committees.[29]

EXAMPLES OF ADVISORY MECHANISMS TO ASSIST DECISION-MAKING

Mexico does not have Committees on socio-economical issues. The SEA, which is the Advisory Committee for the Secretariat of Agriculture only discusses technical issues about GMO releases. Political, economic and social considerations are made by the Secretary of Agriculture.

In **Latvia**, GMO and Novel Foods Monitoring Council consists of scientist and people from relevant ministries (environment, health, agriculture, economy).

Argentina refers commercial release applications to both scientific and economic advisory committees. These committees submit recommendations to the decision makers that are used in decision-making.

Zimbabwe's Biosafety Board consists of life scientists, economists and social scientists and they consider both safety and non-safety issues in decision making. (http://www.unep.ch/biosafety/development/Countryreports/ZWprogressrep.pdf)

In **New Zealand**, ERMA is a one stop shop for any activity involving GMOs (refer to its website http://www.ermanz.govt.nz).

In the **Philippines**, the national committee on Biosafety of the Philippines (NCBP) includes representation from Departments of Science & technology, Agriculture, Health, Environment & Natural Resources, Foreign Affairs, Trade & Industry, Interior & Local Government, as well as representatives of civil society, community and industry. The NCBP sets up Technical Working Groups to provide advice on specific issues as needed.

All factors that are considered and those that lead to the final decision should be carefully laid out in a decision document that is freely available to the public. The CPB provides for taking into account socio-economic considerations in making a decision to import a GMO. In doing so, however, Parties are required to ensure consistency with their other international obligations.[30]

3.2 Decision documents

Communicating national decisions on GMOs is seen as an important contribution to transparency. The format and contents of a decision document will depend on who it is intended for, and what function it will play in the administration of GM activities. These criteria are set out in the national regulations.

The primary function of the decision document is to record the decision taken on an activity with a specific GMO in a specific release environment. As such the document could be just one sentence. However, when the decision is based on numerous inputs, it is useful to clarify what issues were raised in the discussion and how these were assessed. Much of this input could be a summary of the biosafety risk assessment submitted as recommendations by the scientific advisory body.

If the document is a rejection of an application, then the reasons for rejection need to be clearly stated so that the rejection letter can clarify these issues. If the decision document forms the basis of the approval it will be necessary to list any risk management conditions deemed essential for the safe implementation of the activity so that these can be recorded on the approval. Similarly, if the risk assessors consider specific inspections or monitoring to be necessary, these too should be stated in the decision document to alert the administrators, the inspectors and the applicant. The CPB requires a Party of import to set out the reasons underlying a decision except in the case of unconditional approval or consent.[31]

If the decision document plays a role in public information and awareness the administrators may wish to clarify the biosafety review process used to reach the decision. In the interests of transparency and disclosure, some decision documents list the people involved in the risk assessment and decision-making.

[29] See section 5.2.7 "The basis for decision-making" in the Phase 3 Toolkit Module Part (i) on "Developing the Regulatory Regime".
[30] Art 26.1
[31] Art 10.4

EXAMPLES OF TYPES OF DECISION DOCUMENTS

In **Mexico**, the Secretariat of Agriculture's decision document specifies the parts of the law that the decision is based on, the ruling and details of Biosafety measures, or the reasons of the rejection.

In **Estonia** the permit for field releases is a table, stating the name of GMO, its use, name of permit holder with contact data and some more information, without any preambles.

In the **EU**, permits for marketed GMOs (Decisions of Council) consist of preambles, description of the decision making process, and the decision itself explaining what kind of GMO or products were approved, how they could be used, how they should be monitored etc.

EU countries - for examples of "assessment reports" from all countries, see: http://gmoinfo.jrc.it

In **Canada**, regulatory decision documents all begin with a standard paragraph explaining the decision-making process (see CFIA decision document on Polish canola: http://www.agbios.com/docroot/decdocs/03-106-002.pdf) .

In **New Zealand**, the Environmental Risk Management Authority (ERMA) is the decision making body and its membership is publicly known. The application (except agreed confidential information) is a public document, as is ERMA's evaluation and review (E&R) report on the application. The E&R report includes names of ERMA staff as well as any experts involved in the preparation of the report. decision documents of ERMA are 'stand alone' documents that include information on the organism and reasons based on the legislative requirements for the decisions on a case-by-case basis.

The **Netherlands** - for examples of decision documents see: http://www.vrom.nl/biotechnologie_online.

Argentina – for examples see http://www.sagpya.mecon.gov.ar/0-0/index/programas/conabia/bioseguridad_agropecuaria2.htm

3.2.1 Format of approval and rejection documents

The format of the approval document is stipulated by the regulatory regime. In some countries permits are issued with or without compulsory risk management conditions, and rejection letters are issued if an activity is not approved. The CPB requires that the reasons for rejection are given to enable the applicant to modify their activity for a further submission.[32]

Other countries use existing approval instruments, such as letters of approval. The appending of risk management conditions and reasons for rejection are common to most approval documents.

Information commonly used in decision documents includes:

- A summary of the process used for the review;
- A summary of the application;
- A summary of the scientific risk assessment review;
- A biosafety recommendation, including conditions for reducing risk;
- A summary of input received from the public;
- A summary of issues discussed in decision making;
- The decision with risk management conditions or reasons for rejection, where appropriate;
- A list of the proposed inspections; and
- A list of people (with titles and expertise) on the risk assessment and decision-making bodies.

Not all countries use all of this information; specific requirements are usually detailed in national regulations.

A final decision made on an application should provide details of what is granted to the applicant. The decision may not necessarily grant exactly what the applicant is requesting, but may apply conditions such as time limits, geographical location, and other specific restrictions, or request field trials before any further use is authorized. Most decisions are therefore conditional, with the requirements for risk management appended to the approval, or the reasons for refusal detailed in the rejection letter. The review process frequently leads to a revision of the proposed risk management conditions so that the activity that is approved may differ from that proposed in the application. As reviewers and applicants become more familiar with the risk management of specific GMOs, subsequent decisions may contain fewer modifications to the proposed activity.

3.3 Biosafety Clearing House

The CPB has specific obligations regarding information sharing. The Biosafety Clearing House[33] has been established to facilitate access to the regulatory requirements of other countries, the decisions taken by other countries on specific GMOs, and the expertise available for risk assessment. Parties are required to add their biosafety contact points, copies of laws, regulations and guidelines when they ratify the CPB. In addition, parties are given specific obligations to register decisions on transboundary movement and intentional release of GMOs to the BCH within certain time frames (see Table 1).

Parties making decisions on LMOs intended for placing in the market or for direct use as food or feed, or for processing, must inform the Biosafety Clearing House.[34] This decision is then available to other importers, and could be used to approve identical GMO imports, where this is allowed by national regulations.

According to the CPB a failure to communicate a decision on the import of a GMO shall not imply consent or refusal. However, it is a task of the administrative office to establish a mechanism for dissemination of information to relevant agencies on decisions communicated through the BCH by other Parties.

[32] Article 10
[33] www.biodiv.org/bch/
[34] Article 11 (1)



As such, the administrative officers of any NBF will be responsible for keeping the country's information on the BCH up-to-date and accurate. UNEP-GEF is providing funding to assist developing countries to acquire the electronic resources and the training to carry out these obligations with minimal fuss and expenditure.[35]

The CPB encourages parties to make the information on the BCH available to the general public to ensure public access to information and to build public awareness about biosafety. The information on this database is largely government-generated documents in response to applications for permission to carry out activities with GMOs. In addition, there is information on national and regional biosafety frameworks, capacity building projects and needs, a roster of experts used in development of regulations and risk assessment. The applicant's data is not placed on the BCH.

The specific requirements for information input into the BCH are listed in the Annex to CBD CoP-MoP Decision BS-1/3 [36] (also see Annex I of the toolkit module 3(i) on "Developing the Regulatory Regime"). These include:

- Any relevant existing laws, regulations or guidelines, including those applicable to the approval of LMOs-FFP; and any bilateral, regional or multilateral agreements or arrangements.[37]
- Cases in which import may take place at the same time as the movement is notified.[38]
- Imports of LMOs exempted from the AIA procedures.[39]
- If domestic regulations shall apply with respect to specific imports.[40]
- A point of contact for receiving information from other States on unintentional transboundary movements.[41]
- Summaries of risk assessments or environmental reviews of LMOs generated by regulatory processes.[42]
- Final decisions concerning the import or release of LMOs.
- Implementation reports.[43]
- Information concerning cases of illegal transboundary movements.[44]

If there is a lack of access to the Biosafety Clearing-House, then hard copies of any notifications should be provided to the Secretariat of the Convention on Biological Diversity (SCBD).

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[35] http://www.unep.ch/biosafety/BCH.htm
[36] Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety, Decision BS I/3, Annex
[37] Articles 20(3)(a)-(b), 11(5), 14(2); 24
[38] Article 13(1)(a)
[39] Article 13(1)(b)
[40] Article 14(4)
[41] Article 17(2)
[42] Article 20(3)(c)-(e)
[43] Article 33
[44] Article 25(3)

4. Monitoring, inspections and enforcement

4.1 Introduction

For the purpose of this toolkit the term "*monitoring*" describes the scientific collection of biosafety data to support the scientific basis for biosafety decisions. It also describes the systematic measurement of the effects of GMOs over time.[45] The aim of GMO monitoring is to identify direct, indirect, immediate, delayed, or unforeseeable harmful effects that GMOs and their application might cause to the environment, and human health. The data obtained by such monitoring measures will, among others, be used to impose conditions, or to maintain, renew, or withdraw an approval for placing a GMO on the market.

The term "*inspection*" describes the check for compliance with biosafety conditions for activities with GMOs. This may include the review and investigation of facilities, materials and documents related to GMOs. Not all activities will require monitoring plans. Where they are deemed necessary, careful consideration by the regulators of the data needed, and how it will be used, is essential for the monitoring to be useful.

After an approval or consent is given and the proposed activity has started, the mechanism of "monitoring and inspections" begins.

Monitoring may be carried out by a competent agency identified in the NBF or by the applicant, who submits the data to the regulator for review. Inspections are used to monitor compliance and are usually carried out by the biosafety regulators. In both instances regulatory requirements for monitoring and inspections should be clearly laid out in the decision documents (section 3.2) for each GM activity.

The scientific advisors may revise risk management conditions and specify these in their recommendations. They may also identify key times when inspections are needed. This is important when the level of inspections rises to a point where not all activities can be inspected at every stage. The inspectors set priorities for inspections based on the recommendations of the scientific advisors. The priorities usually reflect the level of risk posed by a specific activity as a whole, or at a specific time in the activity.

The **objectives of monitoring** are to:

- **Evaluate** or verify results and assumptions arising from previous research and evaluation of risks;
- **Gather information** with a view to future assessments; and
- **Survey for unintended impacts** on the environment and human health.

The **purpose of inspections** is to ensure compliance with the conditions set out in decision documents or approvals, and also to ascertain whether the agreed risk management strategies are adhered to. One of the functions of the National Biosafety Authority is to provide and update inspection and guidance manuals to assist in the inspectorate functions for GMOs.

Enforcement follows identification of non-compliance. Most corrections of non-compliance are initiated by the regulators, and for more serious violations, law enforcement officers may be needed. How countries deal with enforcement is detailed in their regulatory regime.

4.2 Monitoring

Monitoring is a term used for different activities, varying from general surveillance to a detailed, case-specific monitoring plan, including methodologies of sampling, testing and analysis.[46]

Monitoring can be defined as the systematic measurement of variables and processes over time and assumes that as a result of the risk assessment there are specific reasons for collection of such data. Whether or not these 'specific' monitoring plans are required depends on the results of the risk assessment. This is usually decided on a case-by-case basis. Case-specific monitoring of a potential effect should be required and performed only if it is concluded that there is a reasonable chance that the monitoring can contribute to confirmation or dismissal of assumptions made during the risk assessment.

There are two different types of monitoring associated with the testing and release of GMOs:

1. Compulsory monitoring which is required by the regulators and is intended to confirm any assumptions made in the risk assessment; and
2. Voluntary monitoring which is undertaken by the applicant in order to provide further information for their own purposes.

4.2.1 Who decides what should be monitored?

Where monitoring is required as a condition of an approval, the regulators need to understand the implications of this request to ensure that useful information is generated from the research. It is usually the responsibility of the scientific advisors to set plans and parameters for monitoring and to evaluate the data that is gathered. These details are part of the safety recommendation document submitted by the scientific reviewers. They need to identify clearly what needs to be monitored, how this should be done, and what the data will be used for.

Effective monitoring requires that appropriate methodology is available prior to the commencement of monitoring programmes, and advisors need to be clear in what they are looking for from the monitoring, how they want it to be done and what value they hope to get from the data.

[45] EU Guidance notes on monitoring -
[46] This distinction can be found the monitoring provisions in EU Directive 2001/18/EC.



4.2.2 Designing an effective monitoring strategy

Where risk assessment indicates the need for monitoring, the following points should be considered as part of the monitoring strategy

- Identification of the potential effects to be monitored as indicated from the risk assessment.
- Background information pertaining to the particular GMO.
- Baseline status of the receiving environment.
- Timeframe and frequency of data collection.
- Assignment of responsibilities.

Where risk assessment indicates the need for monitoring, the following points should be considered for the monitoring methodology:

- Identification of the relevant parameters to be monitored, as indicated by the risk assessment.
- Place and area to be used for the monitoring
- Approaches for sampling and analysis.

Where risk assessment indicates the need for monitoring, the design of the monitoring plan should:

- Be undertaken on a case-by-case basis;
- Take into account the characteristics of the GMO, the type and scale of the activity and the conditions of the release site;
- Incorporate specific monitoring provisions focusing on adverse effects identified in the risk assessment, and general surveillance for unanticipated adverse effects;
- Be carried out for a period of time long enough to detect immediate or delayed effects which were identified in the risk assessment;
- Make use of established routine surveillance practices where appropriate;
- Identify who (applicant, users) will carry out the various monitoring tasks and who is responsible for ensuring that the monitoring plan is carried out;
- Ensure that data are analysed and used in determining future risk management strategies;
- Ensure that there is a route by which the applicant and the competent authority will be informed of any observed adverse effects;
- Provide appropriate remedial measures to use if significant adverse effect is noted; and
- Provide feedback mechanisms during the monitoring to enable the process to be stopped or modified if inadequate data is being generated from the methodology.

More detailed information on monitoring methodology is given in Annex I.

4.2.3 Reporting requirements

For all the types of activities with GMOs (contained, confined, restricted or unrestricted) there may be some need to determine when and what to monitor, and how to evaluate the data. This process identifies who would undertake the monitoring and evaluation and who would receive the reports arising from monitoring programme. Generally it is the function of the administrators to ensure that the reports are received and reviewed by the scientific advisory body at predetermined times before, during, or after the release.

Since GMOs and activities differ, it is not possible to give generic methods for monitoring, but specified data should be collected, analysed and submitted back to the biosafety officers for consideration in future risk assessments. Such information should assist the applicant and the regulators in developing safer programmes of release.

The outcomes of compulsory monitoring can be the establishment of new risk management conditions for a particular GMO in a specific release environment.

EXAMPLES OF REPORTING REQUIREMENTS

In **Mexico**, applicants monitor experimental crops based on the requirements of the Secretariat of Agriculture. In semi-commercial sowing like Bt cotton, the applicant engages researchers from training or research centers to monitor resistance to insects and to report the results of this monitoring to the Secretariat of Agriculture.

In **South Africa,** pollen flow and pollen viability studies on maize were used to justify the reduction in isolation distances needed around field trial experiments with this GMO in its local release environment. The data were collected by the applicants over several seasons, and in several release environments. The data were reported in the activity reports and reviewed by the scientific advisors.

In **New Zealand**, reporting requirements are imposed on a case-by-case basis and are part of the decision. Any reports arising are reviewed for compliance with controls imposed by the decision.

4.3 Inspections

Risk management procedures are generally proposed by the applicant, then reviewed and possibly changed by the scientific advisors. The conditions of any GM activity are appended to the approval documents and used by inspectors to check for compliance. The administration officers in the biosafety office are responsible for triggering inspections.

The inspectors submit inspection reports that are reviewed by the administrators and follow up actions are initiated as needed. In most instances, the applicant must supply an activity report at the end of an approved activity; compliance or alterations to risk management procedures are recorded in this document. In some cases, evaluating the effectiveness of risk management procedures may form part of a monitoring programme that functions before, during, and even after an approved GM activity.

Inspecting applicants' performance in complying with risk management conditions gives regulators a fair indication of how responsible an applicant is. Non-compliance may lead to stricter conditions for future applications, or even to a refusal for further approvals. Applicants can lobby for less stringent risk management conditions in future applications by complying diligently with risk management conditions and collecting data on their effectiveness.

Countries need to establish sustainable mechanisms for inspecting GMO activities. Development of an inspection check list helps to keep the inspection on track and focused. The inspection should include a discussion with the biosafety office at the outset and at the end to clarify issues and address minor problems. A report of the inspection should be submitted within a specified time after the inspection to both the regulators and the facility. The report should clearly indicate actions that need to be taken at the facility and timeframes within which these are to be done.

The negotiation of regional agreement may facilitate the sustainability of inspection services for GMOs.

4.3.1 Training inspectors

Most countries identify and train inspectors from existing regulatory agencies to undertake biosafety inspections. Regulatory agencies in departments of agriculture, customs, health and environment often have inspectorates to carry out inspections for these agencies, with inspectors who already have legal training and inspection rights. These inspectors would need training in biosafety and genetic modification to equip them with inspection of GM activities.

EXAMPLES OF INSPECTION PRACTICES

In the **Philippines** plant health inspectors are used to inspect field trials with GM plants.

In **South Africa**, agricultural inspectors are used to inspect field trials.

In **New Zealand**, for all new organisms including GMOs, the Ministry of Agriculture and Forestry (MAF) is the enforcement agency for controls imposed by ERMA New Zealand. MAF inspectors have expertise for inspection, monitoring, and enforcement of ERMA New Zealand controls.

In **Estonia**, the Environmental Inspectorate under Ministry of the Environment is responsible for surveillance of deliberate release and marketing of GMOs or products containing or consisting of GMOs; Veterinary and Food Board under Ministry of Agriculture and Health Protection Inspectorate is responsible for surveillance of novel food (including genetically modified food); Plant Production Inspectorate under Ministry of Agriculture is responsible for surveillance of use of seeds and plant propagation material; Veterinary and Food Board, Environmental Inspectorate and Policy Board are responsible for surveillance of conducting tests with animals; Labour Inspectorate under Ministry of Social Affairs is responsible for surveillance of contained use of genetically modified micro-organisms (GMMs); the Consumer Protection Board is responsible for checking the proper labelling of the products at retail level.

In **Zimbabwe** biosafety administrators delegate inspections to the applicant who is required to report on the inspections in their activity report. The Biosafety Board members visit trials to verify that inspections are being undertaken.

Some countries train special biosafety officers as legal inspectors. Some countries use scientists to undertake biosafety inspections of contained facilities and field trials.

Biosafety inspectors need four types of skills: legal, technical organisational, and personal:

- The **legal skills** usually come through legal training and qualification as officers of law in the country.
- The **technical skills** include a good understanding of ecology, general biology, molecular biotechnology and gene transfer, a willingness to read scientific literature critically and a good understanding of what is needed to run a biotechnology laboratory and testing facilities.
- Good **organisational skills** are the most critical for effective performance. The biosafety inspector must develop processes and systems that enable him/her to cope with increasing numbers of approvals. A slow increase in issued approvals will give inspectors an opportunity to understand their role and to streamline and prioritise their time and procedures.
- In addition to these skills, inspectors would also require **personal qualities** that would give them credibility to do their job. These qualities include trustworthiness, non-corruptibility, good conduct, a willingness to take oaths of duty, a high work ethic, and good interpersonal skills. The regulatory authority may also require a disclosure of possible conflict of interests.



The day-to-day activities of an inspector could include inspection of facilities, imports, shipments, field trials, commercial field releases, as well as the follow up of reports of non-compliance and the ongoing review of GM activities in the country. Inspections of imports and facilities are greatly assisted by proper planning and preparation. Pre-visit preparation includes an understanding of the facility, its GM activities and the staff arrangements. This requires a review of the literature and reports related to each facility and a notification of the inspection, except in exceptional circumstances.

On-the-job training for biosafety inspectors means that regulators and scientific advisors may need to work closely with new biosafety inspectors until the process and procedures are well understood by them. At this point the biosafety administrators can develop inspection guidelines so that the inspectors can proceed without accompaniment. Bearing in mind that the number of GMO trials is usually small at the start, and grows relatively slowly, it is seldom necessary to have a large inspectorate for the implementation of the NBF.

4.4 Enforcement

The inspections may be carried out under several legal instruments. These are usually outlined in the regulatory regime [47] and may or may not make specific mention of GMOs, how they are regulated and how compliance is checked and enforced.

Many countries have an existing administrative law that sets regulations for carrying out inspections and dealing with non-compliance. Existing criminal law establishes how evidence and statements of non-compliance are taken and how legal actions proceed once non-compliance has been identified.

4.4.1 Legal authority for enforcement

The legal authority for enforcement is determined by the national laws. These may be existing laws left unchanged, or amended to deal specifically with GMOs. Some biosafety frameworks may include additional or specific enforcement clauses for GMO activities. This subject is dealt with in more detail in 5.2.12 of the first part of this toolkit module on the regulatory regime.

4.4.2 Administrative tasks

When the inspectors or regulators become aware of an infringement they need to take action immediately. Many infringements are unintended and easily corrected. The corrections need to be implemented quickly to maintain safety levels and the credibility of the system.

Where an infringement cannot be quickly or easily corrected, the activity may need to be stopped until the corrections can be implemented to the satisfaction of the regulators. Most regulatory regimes provide for this and the process must follow the legal requirements. In extreme cases where the infringement may have resulted in harm, or the negligence is deemed unacceptable, the enforcement agency may wish to prosecute the applicant. Prosecution is usually carried out under the country's existing legal system.

4.4.3 Roles and responsibilities

The responsibility for enforcement falls primarily on the enforcement agency. These officers will rely on the biosafety administrators and inspectors for evidence to support any legal action that is taken. The biosafety administrators need to provide documentation to support an infringement claim. These documents may include:

- the approval document with the conditions clearly stated;
- the inspection reports identifying the infringement;
- an assessment of the impact of the infringement with respect to safety; and
- an assessment of the impact of the infringement with respect to safety;
- any evidence seized or collected to support the claim, such as soil or plant analyses, photographs, signed statements, etc..

Administrative officers and inspectors may be called as witnesses during the prosecution proceedings.

[47] See toolkit module for Phase 3, Part (i).

5. Conclusion

5.1 When is an administrative system for biosafety final?

Countries preparing their NBFs need to be aware that the development of an administrative system for biosafety is, in many ways, a work in continuous progress. Biotechnology is a rapidly evolving field in which new issues and activities are constantly emerging, and governments have to be able to deal with changes in their national priorities and in public concerns. An administrative system is best designed to evolve according to changing circumstances and/or demand. For example, in many countries, it may take many applications per year to justify a stand-alone biosafety administration office as in most instances the submission of applications starts slowly, and builds up until more staff and resources are needed.

The development of an administrative system is, therefore, an ongoing, iterative exercise, and the feedback from the actual implementation of the NBF gives a country an opportunity to ensure that the NBF is able to respond to changing needs, priorities and circumstances. In developing and implementing their NBF, countries need to make sure that they have some means for gathering information on how the NBF systems work in practice, what problems are arising, and how the NBF responds to changing circumstances. This could be done, for example, through the institutions involved in the administrative system for biosafety, through a national committee on biosafety or biotechnology, or an auditor general's office that is responsible for reviewing the operations of government. Feedback from the regulators and applicants, as well as the general public, will indicate how well the administrative is working in practice.

EXAMPLES OF REVIEWS OF ADMINISTRATIVE SYSTEMS

Australia implemented an interim biosafety process through cooperation between The Ministry of Science and Technology, the Industrial Biosafety Committee and the Genetic Manipulation Advisory Committee. This process functioned until the current national biosafety framework was developed and implemented.

South Africa implemented an interim process linked to the regulation of import approvals for living organisms. After three years the process justified a part-time administrative officer focusing on biosafety. After 7 years the process justified a full-time biosafety officer. When the GMO Act was implemented after 10 years, the staff increased to 3 administrators dealing with about 50 applications a year. Currently the staff consists of 5 officers issuing about 250 applications per year.

In **New Zealand**, central government's independent agency the Environmental Risk Management Authority (ERMA New Zealand) is responsible for dealing with all new organisms (including GMOs) applications to import, develop, field test, conditionally release, or release without controls.
(refer to http://www.ermanz.govt.nz)

In this regard, it is important to get some of the basic aspects of the regulatory regime and administrative system clearly defined from the start. These include: a) a clear definition of the objective of the regime, b) the importance of definitions which in turn prescribe the scope and the applicability of the regime and will be central to any legal interpretation of the regime, and c) the authority under which the regime is implemented. This is very important when dealing with multiple centres of responsibility.

5.2 What are the most useful qualities of an administrative system for biosafety?

Once a country has developed its NBF, how can it ensure that the component systems work well in practice, and are responsive to changing needs, priorities and circumstances? The following questions are useful for determining the most useful qualities of an administrative system:

- **Clarity** – Is it clear what processes and procedures apply to GMOs, GM derived products and activities involving GMOs? Will users of the system – be they government, the public, or applicants – understand how the administrative system works? Is a clear message or consistent instructions being communicated through a country's policy, laws, websites, employees, messages to the media, etc.?

- **Transparency** - Is the system transparent? Can applicants and others stakeholders find out and understand how the administrative system works? Is it possible to follow the decision-making process from the initial filing of an application through to the final decision?

- **Consistency** – Are terms and definitions used in the administrative system in a consistent manner?

- **Practicality** - Is the system as designed a workable one for the problem in question? Can this idea work in practice as well as on paper? Are the resources available to implement this system? Do the stakeholders understand the system? Are they willing to comply with it or will it create enforcement problems?

- **Authority** - What sorts of authority are required to implement the administrative system procedures? For example, the authority to inspect private property or the authority to request test data from an applicant. Does the government department or institution that is being charged with implementing this system actually have the authority to implement it?

- **Participation** – Is the system participatory? Are there mechanisms for all interested stakeholders to participate in the decision process? Is public participation allowed at various stages in the decision-making process?
- **Effectiveness** – Does the administrative system achieve its objective?



- **Predictability** – How predictable is the administrative system? Has it been designed in such a way that applicants and other stakeholders can expect the administrative system to work in a predictable manner? Is it clear to applicants and other stakeholders who is responsible for taking decisions and on what basis? Are the time frames, for example, clear and definite?

- **Enforceability** - Do the resources exist to carry out this enforcement? Is enforcement likely to be a problem or will there be willing compliance? Can there be non-governmental enforcement through the help of industry and/or the public? What sort of training will be needed if existing enforcement mechanisms are to be used?

- **Adaptability** - How adaptable does the system need to be? How adaptable is it? Will changes be difficult, costly, or confusing? Are the elements that will most likely need changing relatively easy to change?

Useful sources of background information

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Annex 1: monitoring methodology[48]

Monitoring may be deemed necessary at some stages in GMO development and use. This is usually the case where data are needed to help verify biosafety assumptions and decision making. When planning a monitoring programme it is necessary to establish a common methodology to carry out the environmental risk assessment based on independent scientific advice. It is also important to establish common objectives for the monitoring of GMOs after their deliberate release or after placing a GMO or products of GMOs in the market. Monitoring of potential cumulative long-term effects should be considered as a compulsory part of monitoring plans. The objective of a monitoring plan is to:

- confirm that any assumption regarding the occurrence and impact of potential adverse effects of the GMO or its use in the environmental risk assessment are correct, and
- identify the occurrence of adverse effects of the GMO or its use on human health or the environment which were not anticipated in the environmental risk assessment.

Critical data requirements needed before trial

Obtain data which identify the status quo of the host species or organism in the release environment and determine whether facilities are available with adequate specifications for the required containment. It is necessary to monitor the arrangements for producing the GMO in quantity; transporting it to site and accounting for transported organisms.

Data requirements needed during trial include:

- potential of gene flow to sexually compatible species.
- efficiency of containment facilities.
- capacity of the organism to survive in the receiving environment.
- products of expression of introduced genes.
- phenotypic and genotypic stability.
- pathogenicity to other organisms.
- potential for other environmental effects, such as release of exudates into the soil.
- potential for harm to humans.
- extent of horizontal gene transfer.
- evaluation of data and whether these are answering the questions.

It will be necessary to assess the methods for monitoring the presence of GMOs or transferred genetic material beyond the primary site. An important component of monitoring is an ongoing evaluation of the data as it is collected. Many times, data has proven to be unhelpful and modifications were needed to monitoring plans to ensure useful data at the end of the monitoring period. Regular evaluation of data helps prevent a complete waste of monitoring resources.

Monitoring during release

Monitoring during release aims to assess the efficacy of any risk management safeguards applied to the release. This should detect whether there is any risk of harm, caused for example by introgression with potential recipients. For example, if the presence of available pollen recipients within the dispersal area is required for risk to exist, their number should be kept below the level at which harm might occur.

The frequency of monitoring should take into account the growth rate and stage of maturity of relevant plants. Monitoring data obtained during and after the release from such voluntary experiments to test survival could help address the uncertainty. A more precise risk assessment could then be made for a subsequent release proposal, and consequently, could allow risk management safeguards to be reduced or tightened.

The primary purpose of monitoring during the release is to assess the practical efficacy of adopted safeguards. The risk assessment should have identified the safeguards (risk management) required to reduce any risks to an acceptable level. The frequency and extent of monitoring during the release should be adequate to ensure that any safeguards applied are effective.

Monitoring can, where appropriate, be carried out during the course of site visits made for other purposes, such as ensuring there is satisfactory agronomic management of the crop. It is essential, however, that sampling regimes are realistic.

It is possible that, despite a thorough risk assessment, unforeseen events will still occur. The monitoring regime may or may not be able to detect whether this is the case. If an unforeseen effect is detected, its significance should be assessed. If there is a significant adverse impact on the environment, pre-planned emergency control will be required.

[47] Adapted from the SAGENE Guidelines, 1998. South African Committee for Genetic Experimentation.

Data requirements needed after trial

- Determine whether the trial was properly implemented;
- Determine whether the aim of the trial was achieved;
- Determine whether there were any adverse effects;
- The survival and dissemination characteristics of the organism were as expected.

Post release monitoring

Monitoring after general release approval is necessary where the risk assessment identifies that continuous presence of the released GM plant or gene presents risk of harm. Post-release monitoring will concentrate on confirming the removal of the released plants. Where appropriate, monitoring should concentrate on detecting and controlling any volunteer plants arising from the release. In some cases there may be uncertainty regarding the risk of harm from continued presence of an organism, especially over the long term. Post-release monitoring should be designed to provide data to enable the uncertainty to be resolved. Factors to be taken into account include:

- Seasonal effects, such as flowering and likely germination times;
- Post-trial treatment of the release site; and
- Longevity of seed or tubers in soil.

Post-release monitoring of a trial site may be useful where it gives basic data on, for example, the longevity of propagules. In general, where flowering creates a risk of harm, e.g. by gene spread, monitoring visits should be planned to coincide with potential flowering times of volunteer plants. If volunteer plants do occur and subsequently flower, the dispersal area should be monitored for potential pollen recipients, or their offspring. Any such plants found should be destroyed. Monitoring information could indicate how long transgenic plants could continue to appear (and hence indicate the likely duration of post-release monitoring). Estimates of survival times for volunteers should take into account the effects of the volunteer control practices applied to the site. In all cases, the extent and duration of the monitoring should be sufficient to prevent or minimise damage to the environment over the longer term as a consequence of the release. Monitoring should concentrate on ascertaining and demonstrating that the safeguards put into place are effective. Monitoring should concentrate on the release plot, plus the dispersal area identified in the pre-release survey, and relevant species within the area. Methodology used in monitoring may include:

- Site visit and evaluation missions (teams);
- Review of reports from the applicant;
- Interviews;
- Surveillance and inspections.

Many methods can be used to monitor plants released into the field. These vary from simple, traditional methods to the most modern and complex. The following aspects need to be taken into consideration in this respect.

- The choice of monitoring methods will depend upon the purpose for which the monitoring is done: if the monitoring is done to demonstrate that there is minimal risk of harm to the environment during the release experiment, then methods of appropriate scope and sensitivity should be used.
- The validity of any one method, or combination of methods, depends partially upon the ease and accuracy of identification of the introduced plants, and their propagules or pollen.
- Identification should ideally be by means of easily recognisable phenotypic or genetic characteristics
- The choice of monitoring method(s) should be appropriate to the degree of sensitivity of detection required: monitoring methods should be accurate, reliable and operable. There should be a balance between sensitivity and practicality.
- Ideally, marker characteristics that are cheap and easy to identify would be the most suitable for assessing the spread of the organism or introgression of genetic markers.
- Direct observation of the trial site forms the basis of all monitoring methods. Regular and methodical inspection of the site and data recording will often provide much useful monitoring information. The frequency of inspection of the site before, during and after the completion (termination) of the experiment will depend on the estimated risk.
- For monitoring by direct observation, the released plant should, where possible, be easily and unequivocally identifiable. Any identifying character should be stably inherited and expressed, and clearly different from the equivalent characters displayed by local crops and feral populations of the same species.
- Direction sampling of the atmosphere (for pollen), or soil (for seeds or vegetative organs) can be used to monitor dispersal. Physical sampling methods are most useful if the pollen or seed are morphologically quite uniform, and distinct from those produced by non-transgenic varieties. For example, a marker that produced a distinctive seed coat colour could be easily detectable.
- There may be a risk that one or more of the inserted genes can spread to either nearby crop plants, volunteers, or pollen-compatible weedy relatives. If so, the choice of monitoring method should enable detection of events of this type. Detection of the presence of the inserted gene in a recipient plant may be by means of various biological methods.
- One such method may assess the presence of a gene by examining potential recipients for signs of the presence of the gene, for example, herbicide tolerance.
- An example of another method would be if possibly unrelated (i.e. non-transgenic) morphological characteristics of the transgenic plant (such as flower colour, leaf morphology, seed shape and colour) are transmitted to recipients. Such events can be interpreted to presume flow of the inserted gene.
- Trap plants (of the same species as the plant to be released) can be used to detect the spread of pollen from the experimental plants. Transfer can be inferred from analysis of seeds or progeny of the trap plants. Male-sterile varieties may be particularly useful for this purpose.



- Other characteristics that may be suitable for monitoring purposes include pest susceptibility; biochemical characteristics or end-products of the gene product (for example, allozyme analysis, carbohydrate analysis), and DNA characteristics, including RFLP mapping and PCR amplification.

Reporting requirements

For most field trials there is some need to determine when and what to monitor and how to evaluate the data. This process identifies who would undertake the monitoring and evaluation and who would receive the reports arising from monitoring programme. Since GMOs and activities differ from each other, it is not possible to give generic methods for monitoring, but specified data should be collected, analysed and submitted back to the biosafety officers for consideration in future risk assessments. Such information would assist the applicant and the regulators in developing safer programmes of release.

Guidelines for designing a monitoring plan

The design of the monitoring plan should:

- Be undertaken on a case-by-case basis,
- Take into account the characteristics of the GMO, the type and scale of the activity and the conditions of the release site,
- Incorporate specific monitoring focusing on adverse effects identified in the risk assessment and general surveillance for unanticipated adverse effects,
- Be carried out for sufficient time to detect immediate or delayed effects which were identified in the risk assessment,
- Make use of established routine surveillance practices where appropriate,
- Identify who (applicant, users) will carry out the various monitoring tasks and who is responsible for ensuring that the monitoring plan is carried out,
- Ensure that data are analysed and used in determining future risk management strategies,
- Ensure that there is a route by which the applicant and the competent authority will be informed of any observed adverse effects
- Provide appropriate remedial measures to use if significant adverse effect is noted.
- Provide an early opportunity to review the data and determine whether the data is useful or the methodology needs to be modified to obtain more valuable information.