

Guide for the implementation of national biosafety frameworks

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Note to the readers:

The UNEP-GEF Project on *Development* of National Biosafety Frameworks and the UNEP-GEF Projects on *Implementation* of National Biosafety Frameworks are part of UNEP's work on the GEF Initial Strategy on Biosafety, which is aimed at assisting countries to be prepared for the coming into force of the Biosafety Protocol.

As part of the UNEP-GEF Projects on *Implementation* of National Biosafety Frameworks, a number of tools for the implementation of national biosafety frameworks will be developed, such as databases for risk assessment and a comprehensive Guide with practical guidance on:

- regulatory regimes for biosafety,
- handling requests for permits (including systems for administrative processing, risk assessment and decision making),
- enforcement and monitoring for environmental effects, and
- public information and public participation.

The first draft of that Guide is currently under development in collaboration with experts from many countries and national and international organisations. The Guide will be made available on www.unep.ch/biosafety/Implementation in the course of November 2003, and will be regularly updated and further refined.

The document in front of you contains a short version of the current draft of the chapter that deals with regulatory regimes for biosafety. This document is produced with the sole purpose to give a 'flavour' of the approach and level of detail of the Guide to the participants of workshops on regulatory regimes for biosafety that will be held in the period before the Guide will be placed on the UNEP-GEF Biosafety web site.

While work is still ongoing on many of the sections of this chapter we do hope that this short version provides sufficient overview of the approach and level of detail of this chapter of the Guide. Although this document is not yet intended to be used as a guide, your feedback about the approach taken (but not yet about the details, because this chapter is still under revision) is most warmly welcome.

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INTRODUCTION.

A national biosafety framework is a combination of policy, legal, administrative and technical instruments that are set in place to address safety for the environment and human health in relation to modern biotechnology. These frameworks often focus on living modified organisms or, as they are often referred to, genetically modified organisms (GMOs)¹.

Although national biosafety frameworks vary from country to country, they usually contain a number of common components:

- A Government **policy** on biosafety, which is usually part of a broader policy such as policy on biotechnology in general, agricultural production, health care or environmental protection.
- A **regulatory regime for biosafety**, which often is a combination of an Act or Decree, complemented with implementing technical regulations and guidelines.
- A **system to handle notifications or requests for authorisations** for certain activities, such as releases of GMOs into the environment. Such systems typically include administrative functions, risk assessment, decision making and public participation.
- Systems for 'follow up' such as **enforcement and monitoring for environmental effects**. Monitoring is a term used for evaluating actual impacts on the environment and human health, whereas enforcement typically focuses on compliance with the regulatory regime.
- Approaches for **public information and public participation**, i.e. informing and involving stakeholders in the development and implementation of the national biosafety framework.

Establishing an adequate level of biosafety is typically an ongoing, iterative process of developing a draft national biosafety framework, implementing the draft framework, and continuous evaluation and feedback.

In November 2000, the GEF Council approved the GEF Initial Strategy on biosafety, which aims to support countries to prepare for the coming into force of the Cartagena Protocol on Biosafety. Part of the GEF Strategy is the UNEP-GEF Project on Development of National Biosafety Frameworks, which started in June 2001.

In November 2001, the GEF Council approved 12 demonstration projects to support countries with the implementation of their national biosafety frameworks. Two of those projects are coordinated by the World Bank, two by UNDP and eight by UNEP.

The UNEP-GEF demonstration projects on Implementation of National Biosafety Frameworks last on average 3 years, and the budgets range between 500,000 USD and 1,000,000 USD.

¹ Other terms that are often used in this context include: "living modified organisms", "transgenic organisms", "recombinant DNA organisms", "organisms with novel traits". In this document, the term "genetically modified organisms" (GMOs) is used.

Detailed information about the UNEP-GEF projects on Implementation of National Biosafety Frameworks can be found on the UNEP-GEF Biosafety web site (www.unep.ch/biosafety, under ‘Implementation projects’). The UNEP-GEF Biosafety web site also provides information about other of UNEP working on the GEF Initial Strategy on Biosafety, such as the UNEP-GEF Project on Development of National Biosafety Frameworks.

As part of the UNEP-GEF Projects on Implementation of National Biosafety Frameworks, a number of tools for the implementation of national biosafety frameworks will be developed, such as databases for risk assessment and a guidance documents.

This documents aims to provide practical, comprehensive guidance on:

- regulatory regimes for biosafety,
- handling requests for permits,
- enforcement and monitoring for environmental effects, and
- public information and public participation.

This guidance document will be regularly updated and further refined, and new versions will be made available on www.unep.ch/biosafety/Implementation.

This document is developed for the purpose of capacity building and can be used freely for that purpose².

Comments and suggestions about this guidance document are most welcome and can be sent to the Programme Manager of the UNEP-GEF Projects on Implementation of National Biosafety Frameworks at: PietvanderMeer@unep.ch.

² This guidance document builds on a training manual that was developed in the context of the 3 year capacity building “Implementation of National Biosafety Frameworks in pre-accession countries in Central and Eastern Europe” For further information about that CEE project, see: www.biosafety-cee.org, under “MATRA Project”.

CHAPTER 1 - REGULATORY REGIMES FOR BIOSAFETY

Introduction

The objective, scope and structure of regulatory regimes for biosafety vary from country to country.

The objective of some regulatory regimes is exclusively focused on environmental safety, whereas the objectives of other regulatory regimes have broader objectives.

Some regulatory regimes have a narrowly defined scope, such as releases into the environment of GMOs, whereas other regulatory regimes have a more encompassing scope, such as the contained use, release into the environment, placing on the market, and import and export of GMOs and GMO products.

Some countries have made use of their existing regulatory structures, such as a general Environmental Protection Act or Plant protection Act, to regulate biosafety, whereas other countries have adopted new laws specific for biosafety often completed with implementing decrees or regulations, and yet again other countries have for one part of the biosafety framework made use of their existing regulatory structure and for an other part new legislation was developed³.

Each of these approaches has its advantages and disadvantages, and there is no such thing as the perfect 'one size fit all' template for a regulatory regime for biosafety. It very much depends on countries' existing regulatory and administrative structures and practices and its international obligations to decide what an appropriate regulatory regime for biosafety can be.

It requires thorough analysis, in consultation with all stakeholders, of the national developments of biotechnology, of the existing regulatory and administrative structures and practices, and of a countries international obligations before a meaningful choice can be made as to what structure should be given to a countries' regulatory regime for biosafety.

This chapter on general guidance for implementing regulatory regimes does not deal with that type of analysis and consultation, which is typically part of the initial phase of developing a national biosafety framework. The ISNAR briefing paper nr 47 "A Conceptual Framework for Implementing Biosafety: Linking Policy, Capacity and Regulation"⁴ lays some of the ground work for such analysis and consultation, and the ongoing work under the UNEP-GEF Global Project on Development of National Biosafety Frameworks as well as other projects aim at assisting countries in making an informed choice for the regulatory structure.

While not addressing the type of analysis and consultation that normally carried out in the development of a regulatory regime, it is underlined with the strongest emphasis that this analysis and consultation phase is of crucial importance, and that experience shows that simply copying regulatory systems or models usually results in the need of completely redrafting or – worse – unworkable and thereby incredible regulatory regimes.

³ Most of the regulatory regimes for biosafety currently under development consist of a newly developed, framework law specific for biosafety together with implementing decrees or regulations.

⁴ See www.isnar.org.

The starting point of this chapter is thus that an informed choice has been made on the basis of thorough analysis and consultation, and builds on that, by focusing on the type of considerations that are important in further developing and implementing the actual provisions of the regulatory regime.

This chapter addresses the type of considerations and options that are relevant when developing the actual provisions of the regulatory regime, regardless whether use is made of existing regulatory structures or whether a new act on biosafety is developed.

In addition to discussing the type of considerations that played a role in discussing specific provisions, the attached guidance document will also give examples of provisions. It is emphasized, however, that these examples are given as illustrations and not to offer a ‘model to be copied’. Where possible, different examples will be given and discussed.

This chapter is built up as follows:

- **Section 1.1** discusses some **general considerations** in developing and reviewing provisions of regulatory regimes for biosafety.
- **Section 1.2** gives a brief introduction to the **different type of provisions** often found in regulatory regimes for biosafety.
- **Section 1.3** discusses **general provisions** such as objective, scope, definitions, institutional arrangements and general obligations will be discussed.
- **Section 1.4** addresses the **operational provisions** such as provisions on contained use, release, placing on the market.
- In **Section 1.5** a number of topics are discussed that are often called ‘**other provisions and final clauses**’, such as procedural provisions, public information, confidentiality, enforcement, compliance.
- **Section 1.6** discusses a number of **other topics** that some have included in their regulatory regimes, such as socio-economic considerations and ethics.
- **Section 1.7** contains a **glossary of terms**

1.1 General considerations.

In developing, implementing and reviewing regulatory regimes for biosafety, or any law for that matter, a number of general aspects have to be kept in mind continuously.

These aspects include clarity, transparency, consistency, workability, enforceability, and adaptability.

These aspects are briefly discussed below:

Clarity

Regulatory regimes for biosafety have to be clear and unambiguous. This is particularly the case for their objective and scope. For reasons of clarity it is recommended to have clear, separate articles on 1) objective, 2) definitions and 3) scope. (see below for further explanation about these topics).

Transparency.

If the regulatory regime contains a system for permits or authorisations, then transparency requires that the provisions for applying for permits as well as the procedures for handling such applications need to be clear and unambiguous. This means that aspects such as time limits, information that is accessible to the public, and protection of confidential information need to be clearly addressed.

Consistency.

Regulatory regimes need to be internally consistent, as well as consistent with any international agreement to which the country is a party.

As regards internal consistency, draft regulations often show the result of ‘team work by different people’ and as a result different terms are used to refer to the same topic. An example is the mixed use of terms such as GMO, LMO, transgenic organism, recombinant DNA organism, organism obtained through modern biotechnology, etc. It is strongly recommended to review, as a final step of developing draft regulations, the entire legal text for consistent use of terms and approaches.

Ensuring consistency of national biosafety regulations with international agreements and treaties requires examination of the obligations under international treaties such as the Convention on Biological Diversity, the Cartagena Protocol on Biosafety, the WTO, SPS, TBT, the Codex Alimentarius as well as regional agreements such as, where applicable, European Community Directives. For a number of these international agreements, some very useful guides and checklists are available or are under preparation. An example of such a checklist can be found in the documentation produced at the third meeting of the Intergovernmental Committee on the Cartagena Protocol (ICCP3)⁵.

⁵ See www.biodiv.org.

Workability and enforceability.

It may seem obvious and superfluous to state that a regulatory regime needs to be workable and enforceable, but experience shows that this aspect is often forgotten in the complex process of drafting and redrafting regulations. It is, therefore, advisable to make sure that the regulations are implementable. One way of doing this is to test some or all of the rules by applying or analysing them, hypothetically, against a number of ‘real life’ cases before they are adopted.

Adaptability:

Biotechnology and biosafety are rapidly evolving fields, and in order to be effective and efficient, a mechanism for review and rapid adaptation is recommended. For this purpose, countries often opt for a system of a general ‘framework’ law complemented with implementing decrees or regulations, which contain technical details and which can be adapted more rapidly. Another mechanism is a provision requiring regular review and special ‘fast track’ procedures for amending technical provisions.

1.2 Introduction to different types of provisions.

While the structure of the regulatory regime may vary from a comprehensive act with implementing decrees or regulations and guidelines, the actual provisions we find in regulatory regimes can be grouped in three types of provisions:

- General provisions
- Operational provisions
- Other provisions and ‘Final clauses.’

The *general provisions* form the foundation of the regulatory regime, and provide the objective, scope and definitions of the regulatory regime, as well as institutional arrangements (directed at the Government) and general obligations (directed at the ‘regulated community’) that are necessary to get the regulatory regime ‘started’. (see section 1.3)

The *Operational provisions* form the actual ‘heart of the matter’, i.e. the substance of the regulatory framework, such as rules and procedures for contained use and releases of GMOs. (see section 1.4)

The ‘other provisions and final clauses’ is a collection of provisions that provide the ‘fine tuning’ of the regulatory regime, to ensure that it will actually work in practice, and can include (see section 1.4):

- procedural provisions for requests of permits, information requirements, public information, confidentiality and appeal;
- enforcement, compliance, liability
- review mechanism
- entry into force, transition period.

1.3 - General provisions

General provisions of regulatory regimes for biosafety usually include:

- Objective
- Definitions
- Scope
- Institutional arrangements
- General obligations

1.3.1. Objective

The objective provides the basis for the regulatory regime and should be crystal clear. One should bear in mind that the objective also defines the criteria on the basis of which requests for permits or approvals will be evaluated.

The objective of many regulatory regimes for biosafety focus on the protection of the environment (including biodiversity and including humans) in the context of the development and use of GMOs.

In addition to this main objective, some regulations have additional objectives, such as “ensuring food safety”, “ensuring the development of biotechnology” or “ensuring ethical acceptability of the application of biotechnology”.

While there is no fixed rule as to what how broad or narrow the objective of a regulatory regime on biosafety should be, it is important to bear in mind that different objectives are often best addressed in different regulatory regimes, because they require different approaches and methodologies. It is for this reason that in many countries the environmental safety of GMOs is addressed in one regulatory regime, while food safety of GMO food products is addressed in another regulatory regime that addresses food safety in general.

Other product-related aspects, such as seed registration, are usually addressed in yet another regulatory framework. The consequence of this is that the placing on the market of, for example, GMO seeds of crops intended for consumption may require three consents or approvals, i.e. one on the basis of the environmental safety regulation, one on the basis of the food safety regulation and one on the basis of the seed registration regulation.

While some regulatory regimes refer to socio-economic and/or ethical considerations, in other countries those aspects are taken into account in the context of the broader policy debate on the adoption of this new technology rather than in the process of individual approvals for environmental safety or food safety⁶. In some countries there are regulations for an ethical assessment for applications with humans and sometimes animals. The issues of socio-economic and ethical considerations are discussed further in section 1.6.

⁶ See for example page 7 of the ISNAR document “A framework for national biosafety implementation – Linking Policy, Capacity and Regulation”, www.isnar.org

In cases where the regulatory regime is based on an existing regulatory structure, the objective can often be derived from the underlying Act⁷, but in many cases may need to be further specified. In cases where a new Act on biosafety is developed, the objective needs to be specified.

There are several ways of clarifying or specifying the objective of a regulatory regime:

- through a Title,
- through a Preamble,
- through a specific Objective article,
- or a combination of these.

Which of these approaches is followed very much depends on a countries' rules for legislation making and its practices.

Title

As a matter of practice or specific requirement, a title could be long and detailed, trying to specify as much content of the act as possible. In those cases where long titles are common, it is advisable to have also a short 'reference title'. For example, the long title could be "Act to regulate safety in activities relating to modern biotechnology". The short title may simply say "Biosafety Act", or "Act on Safety in Biotechnology". .

Preamble

Many Acts start with a Preamble, depending on the countries' tradition and rules for making legislation. The Preamble is usually not part of the binding rules of the instrument, but can play an important role in providing the policy framework or the intent behind the binding rules in case of disputes arising on the basis of the Act.

A Preamble typically starts with "The Government of, considering", after which a number of points follows, expressing the reasoning and philosophy behind the Act.

The Preamble is in fact often a summary of the Governments policy on biotechnology and biosafety, expressing, for example, that on the one hand biotechnology entails promise for sustainable food production, improved health care and environmental protection, but that on the other hand adequate mechanisms have to put in place to minimise the likelihood of adverse effects on the environment and human health.

Preambles sometimes also address specific aspects, such as the importance of transparency and public information. The Preamble is sometimes also used to clarify the legal basis for the Act and the relationship with other national regulations and international agreements.

⁷ The terms "Law", "Act" and "Bill" usually refer to the same type of legislation, i.e. the legislation that requires the involvement of a parliamentary body. In this document, the term Act is used. See the glossary of terms for further explanation.

Examples of articles on Objective

- “.....*The objective of this Act is to establish a legal framework to regulate activities involving genetically modified organisms with a view to protecting the environment and human health*”
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Note: in this section, different examples will be presented and discussed.

1.3.2. Definitions

In a complex field as biosafety it is advisable to have certain terms and concepts clearly defined in an article with definitions.

The terms to be included in the definition article are terms that are crucial for the understanding and implementation of the regulatory regime, such as ‘GMO’, or ‘release’, as well as terms of which the interpretation used in the regulatory framework may be different from the common use of that term.

It is important to distinguish between an article laying down the definitions and a glossary of terms, which explains some technical terms to a lay audience. Glossaries of terms are usually given in the explanatory notes or guidance notes.

Terms that are not used in the regulatory regime do not need to be defined. Terms that are only used in implementing regulations can be defined in those implementing regulation. It is a general rule of law-making that definitions in implementing regulations cannot divert from definitions in the framework Act on which those implementing regulations are based.

It is strongly advised to ensure consistency of definitions with the definitions used in international agreements that the country is or will be party to. This is not an easy task, because those definitions in different international agreements are not always identical. For example, apart from having a different name, the definition of GMO in the EC Directives is slightly different from the definition of LMO in the Biosafety Protocol.

One very important aspect that has to be kept in mind is the relationship between scope and the definitions. It is important that the interplay between the scope article and the definitions ensure that what is intended to be covered by the regulatory framework is covered and what is not intended to be covered is not covered.

Terms that are usually defined in regulatory regimes for biosafety include: GMO, contained use, release into the environment, placing on the market, risk assessment. While the scope of the regulatory regime may also cover import and export (as it does in this example) there is usually no need to define these terms separately.

Examples of definitions:

For the purpose of this Act and the regulations based on it:

1. *GMO means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology*
2. *Living organism means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids*
3. *Modern biotechnology means the application of:*
 - a. *In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or*
 - b. *Fusion of cells beyond the taxonomic family that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection*
4. *Contained use means any operation with GMOs, undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment*
5. *Release into the environment means any operation with GMOs that is not contained use.*
6. *Placing on the Market means making available to third parties*
7. *Risk Assessment means the evaluation of risks to human health and the environment, whether direct or indirect, immediate or delayed, which an operation with GMOs may pose and which is carried out in accordance with Annex ...*

1.3.3. Scope

An article defining scope is of crucial importance for the functioning of the regulatory framework and needs to be drafted with utmost care.

The scope article describes **which activities** (e.g. contained use and/or releases and/or marketing, and/or import-export) **with which objects** (e.g. GMOs) are covered by the regulatory regime.

Every activity that falls under that description falls under the regulatory regime, unless it is explicitly exempted.

For reasons of transparency and clarity, it is advisable to place scope and exemptions from the scope as much as possible in one article.

Exemptions can take the form of explicit exemptions, such as “GMOs intended for pharmaceutical purposes”, or the form of an enabling provision, allowing the competent authority to exempt in the future certain categories of GMOs of which it is concluded that they do not pose unacceptable risks, comparable to the Biosafety Protocol (Paragraph 4 of Article 7, for example). Although it may not be possible to define exemptions at this point in time, it is often considered advisable to include such an enabling provision in the scope article.

In some countries, contained use, release into the environment, placing on the market and/or import and export are regulated in different laws or regulations, while in other countries one single

regulatory instrument covers all these areas. The choice for which approach to take will depend on the analyses described in the introduction.

NB: For countries in the European Union, the minimum scope of the regulations is clearly expressed by the two European Directives on GMOs, i.e. the Directive on Contained use of genetically modified micro-organisms (98/81/CE) and the Directive on the deliberate release of GMOs into the environment (2001/18/CE). Interestingly, the Directive on contained use is limited to genetically modified micro-organisms while the Directive on release addresses all genetically modified organisms. Regulation of contained use of genetically modified plants and animals is therefore left to the EU member States. All EU Member States have opted to also regulate the contained use of genetically modified plants and animals. The example given below for a scope article covers contained use of all GMOs.

While there is no international obligation to cover contained use, releases, and import and export in one regulatory framework, the example given below does so for illustration purposes. The examples for exemptions are based on the Biosafety Protocol. The third example for an exemption refers to those GMOs that have been authorised for placing on the market. If such GMOs would not be exempted, then there would be a difficult situation where a farmer who wants to use a GMO crop that has been authorised for placing on the market would still need a permit to grow that GMO crop.

Examples of articles on Scope

This Act applies to the contained use, release into the environment, placing on the market, import and export of genetically modified organisms.

Exempted from the provisions of this Act are:

- a. GMOs which are pharmaceuticals for humans that are addressed by relevant international agreements or organisations,*
- b. GMOs or categories of GMOs of which the Competent Authority has, following the procedure laid down in, established that they are not likely to have adverse effects on human health or the environment*
- c. the contained use, deliberate release, placing on the market and import of GMOs as or in products in as far as they are authorised for placing on the market conform Chapter*

Note: in this section, different examples will be presented and discussed.

1.3.4. Institutional arrangements

Competent authorities

The Institutional arrangements lay down the general mandates and responsibilities of Governmental institutions and Government nominated organisations required for the implementation of the regulatory regime .

In case the regulatory framework for biosafety is based on an existing regulatory structure, than often the responsible authorities are already defined in the underlying Act.

Yet, it may be necessary identify specific institutions for specific tasks. To what extent such a sub mandate is possible depends on the underlying regulatory structure.

In case a new Act is established for biosafety, than transparency requires that the Act identifies the competent authority (or authorities) responsible for implementing the Act , e.g. deciding on requests for permits, developing implementing regulations, review of the regime and enforcement. The authority for enforcement is in many countries separate from the authority for issuing permits.

In some regulatory systems, the competent authority responsible for contained use is different from the competent authority responsible for handling requests for permits for release or marketing. In some countries the competent authorities for contained use of GMOs are authorities on the local or provincial level while the authority for releases of GMOs rests at national level .

It is advisable to define which Government Institution has the overall responsibility for the implementation and review of the functioning of the regulatory framework, in as far as specific authorities have not been identified in the other provisions of the Act.

Competent Authority

Example:

Unless otherwise specified in this Act, the authority responsible for the implementation of this Act and the regulations based on it is the [Minister of the Environment] /[Minister of Agriculture] / [Minister of Health] / [Biosafety Board].

Inspectorate

Example:

The authority responsible for the enforcement of the provisions of this Act and the regulations based on it is the [Environmental Inspectorate] /[Agricultural Inspectorate] / [Health Inspectorate].

Advisory body

In the field of biotechnology and biosafety there are, generally speaking, two types of advisory bodies.

Firstly, there are advisory bodies offering *guidance on the overall policy* on biotechnology and biosafety. Such advice often includes a broad array of input, including science, economic development, consumer interests, ethics etc.

Secondly, there are scientific advisory bodies established to *advise on the actual implementation* of a regulatory regime, such as advice on risk assessment and risk management. The tasks of those advisory bodies are usually linked to the objective and scope of the regulatory system, whether it is environmental safety, food safety or otherwise. In some cases, these advisory bodies also have the task to alert the Government or Parliament on broader issues, such as ethical issues, which may be of relevance for the overall policy of the Government on biotechnology development.

The advisory body discussed below is the scientific advisory body established in order to advise the Government in the implementation of the regulatory regime on biosafety.

Establishing an advisory body is not required by any international agreement. Some countries, such as Denmark and the US, do not have separate technical advisory bodies but have the scientific risk assessment carried out by Government institutions. Most countries where biosafety regulations are in place, however, have established a technical advisory body to advise on the implementation of the regulatory system⁸.

Biosafety is a constantly evolving field. It is therefore advisable to keep the provisions on the advisory body general, such as the overall task and to allow technical aspects to be worked out in implementing regulations.

Example - Advisory Committee

x.1. An Advisory Committee on GMOs, hereafter called ‘the Committee’, is hereby established. The task of the committee is to provide technical scientific advice to the authorities charged with the implementation and enforcement of this Act and the regulations based on it.

x.2. The Committee consists of a minimum of [10] and a maximum of [30] members from the following disciplines.....

x.3 The members of the committee are nominated on their personal merit by the [Minister of the Environment] / [Minister of Agriculture] / [Minister of Health] who shall ensure that the relevant scientific disciplines are represented in the Committee.

x.4. Members are nominated for a period of [4] year and their nomination can one time be extended for the same period.

x.4. The Committee will be supported by a Secretariat, provided by the [Minister of the Environment] / [Minister of Agriculture] / [Minister of Health].

x.5 The [Minister of the Environment] / [Minister of Agriculture] / [Minister of Health] shall lay down in a regulation the rules of procedure of the Committee.

x.6. The Committee takes decisions on the basis of normal majority/qualified majority.

x.7. At its first meeting, the Committee will adopt its internal rules of procedure. These rules will be made public.

⁸ See also the ISNAR document “A framework for national biosafety implementation – Linking Policy, Capacity and Regulation”, www.isnar.org.

x.8. The meetings of the Committee are, upon request, open to observers. The Chairman of the Committee can decide that parts of the meeting are not open to the public in cases where either information about persons are discussed or confidential business information is discussed.

1.3.5. General obligations.

These provisions usually contain general obligations in relation to activities that are covered by the regulatory framework.

Such general obligations usually start with a general obligation to ensure that activities are carried out with appropriate safety measures.

An important term here is the word “ensure”. This refers to a instructive for the management of research institutes and companies to establish and maintain an adequate internal system for safety. This provision is based on the notion that while a regulatory framework can lay down general obligations, actual safety can really exist only when there are adequate internal safety systems in the research institutes and in the companies involved.

Internal safety systems include:

- The issuance of internal directives to adequately apply the general safety measures laid down in the regulatory regime, taking into account the specific situation in the organisation involved,
- an internal mechanism for monitoring and controls, including the nomination of biosafety officers or committees and supplying them with adequate guidelines and mandates,
- providing the internal biosafety officers or committees with adequate means and authorities to carry out their task.
- an internal system for keeping an adequate administration of the directives, nominations and mandates given and the way they are implemented.

The general obligations referred to here are usually worked out further in technical regulations or guidelines. Whether regulations or guidelines are the most effective way to further detail these general obligations will depend on the situation. Often a combination of both is used.

It should be remembered that while guidelines are not binding, they still often have some legal consequence, in the sense that a person who followed the guidelines drawn up by or with the consent of the Government can usually claim to have taken appropriate measures.

It should also be remembered that safety is not served by a ‘straight jacket’ of detailed obligations. Which safety measures are the most appropriate depends on many different factors, such as the type of organisms and the type of application, and, therefore, there is a need for fine tuning ‘sur place’.

Example Article - General obligations

x.1. Any person responsible for activities covered by this Act, shall ensure that:

- *such activities are carried out in conformity with the provisions laid down in or established on the basis of this Act,*

- *internal directives are given to adequately apply the general safety measures laid down in or established on the basis of this Act*
- *a mechanism for internal monitoring and controls is established,*
- *an internal system for keeping an adequate administration of directives⁺⁺ , nominations and mandates is created [and the way they are implemented]?,*
- *new scientific information indicating that these activities pose a risk for human health or the environment is reported to the Competent Authority.*

x.2 The Minister shall issue regulations and/or guidelines that further detail the obligations laid down in the previous paragraph. .

1.4 Operational provisions

The operational provisions cover the ‘heart of the matter’, i.e. contain the provisions for the activities that are covered by the regulatory framework.

As was said above, a regulatory framework may cover a whole range of activities, such as contained use, release, placing on the market, import/export of GMOs or only parts of that.

Operational provisions may look very different depending on whether they deal with, for example, contained use of releases, but a close examination of many different systems in the world, shows that in fact the operational provisions have more or less the same structure, regardless whether they apply to contained use, release, placing on the market, import/export.

The operational provisions that usually can be recognised for each of these areas are:

1. an obligation to carry out a risk assessment, prior to an activity
2. an obligation to apply appropriate safety measures,
3. an obligation to request authorisation or notify for certain activities
4. procedures for requests for permits and notifications.

Although these provisions can usually be recognised, there are clear differences in their application for contained use, release, placing on the market, import/export. For example, the obligation to carry out a risk assessment for contained use is often an ‘implicit’ step, because the risk assessment has been done in terms of established rules for assigning containment levels, based on many years of experience with contained use. Based on that same experience, many countries have decided that only certain ‘high risk’ activities actually require authorisations or notification.

For risk assessment of releases and placing on the market, on the other hand, such long standing abundant experience is not widely available, and consequently the obligation to carry out a risk assessment is a key element of the biosafety framework, and – for the same reason – in most countries most or all releases and placing on the market require notification or authorisation.

Although there is no international obligation to cover contained use, release, placing on the market, import/export in one regulatory regime, for completeness, all these topics are discussed in the sections below.

1.4.1. Contained use

Contained use are activities that are carried out in a facility such as a laboratory, an industrial fermenter or a green house, which involves organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment.

The key phrase here is “controlled by specific measures that effectively limit their contact with, and their impact on, the external environment”. The measures required are usually a combination of the physical containment of the facility or installation and work procedures (e.g. good laboratory practices).

Different organisms require different containment measures. Measures required for micro-organisms are different from those for plants or animals. Measures required for large-scale

applications are different from those measures intended for small-scale applications. Measures required for applications in laboratories are different from measures designed for greenhouses or industrial fermentors. And also within different categories of organisms there are differences of required measures, depending on the potential of risk of those organisms.

For micro-organisms, there are 4 internationally used classes of risk, depending on their pathogenicity for humans, animals or plants, whereby class 1 is the class of ‘negligible risk’ and class 4 is ‘high risk’ (including viruses such as small pox and the Ebola virus). Based on these 4 classes, many regulations use 3 or 4 containment levels for genetically modified micro-organisms. It should be remembered that the classes are based on the pathogenic characteristics of the micro-organisms, whereas the containment levels should also take into account the introduced genes.

For plants and animals, there are no such internationally accepted classes. However, also for genetically modified plants and animals there are different containment levels or systems, depending on the type of plant or animal. For example, containment measures for cows will be different from those for fish or insects. And measures for plants that cannot outcross will be different from measures for plants that can outcross.

Turning to developing biosafety regulations for contained use, the first consideration is that the structure of contained use regulations depends on whether they apply to genetically modified micro-organisms or whether they also cover genetically modified plants and/or animals.

As mentioned under “scope”, the examples discussed here will address genetically modified micro-organisms as well as genetically modified plants and animals.

Biosafety regulations for contained use of GMOs usually consist of 2 main elements.

- Firstly, there is an obligation to apply appropriate containment measures, depending on the characteristics of the involved organisms, the characteristics of the introduced or altered genetic material, the characteristics of the application and the characteristics of the receiving environment.

For genetically modified micro-organisms, this usually means the obligation to assess the required containment level (e.g. 1 to 4) and the obligation to apply the safety measures that are required for that level. In most cases the technical details of the assessment and technical details of the different levels are laid down in regulations and/or guidelines. It is advisable to make clear distinctions between classes of organisms and containment levels.

For genetically modified plants and animals, this usually means the obligation to assess the appropriate type of containment (e.g. green house, stable, cages etc), and the obligation to apply appropriate safety measures. In some cases the technical details of the assessment and the technical details of appropriate measures are laid down in regulations and/or guidelines.

- Secondly, in addition to these obligations to identify and apply appropriate safety measures, most regulatory systems contain for certain categories of applications the obligation either to notify the competent authority of planned activities or to obtain permits for certain high risk activities.

There are generally three options for the regulation of contained use activities.

1. the obligation to determine and apply appropriate safety measures and keep records
2. the obligation to notify the Competent Authority of planned activities and to allow a certain period of time to lapse for any reaction by the Competent Authority before proceeding further (plus the obligation to apply appropriate safety measures and keep records)
3. the requisite to obtain a permit before starting planned activities (plus the obligation to apply appropriate safety measures and keep records).

The first option is used for activities that are, based on a case-by-case risk assessment, identified to be in the lowest risk category and the third option for those that are assessed to be in the highest risk category⁹. Regulations for contained use of genetically modified plants and animals require in some countries a notification and in other countries a permit. Which type of obligations will apply for which type of activities depends on the countries' policy for biosafety.

Example - Contained use of genetically modified micro-organisms

Article x.1. Prior to contained use activities with genetically modified micro-organisms, a risk assessment has to be carried in accordance with the specifications in annex..., determining whether the planned activities require containment measures of level 1, level 2, level 3 or level 4, whereby:

- *level 1 is intended for activities with genetically modified micro-organisms that pose negligible risk to human health or the environment*
- *level 2 is intended for activities with genetically modified micro-organisms that pose low risk to human health or the environment*
- *level 3 is intended for activities with genetically modified micro-organisms that pose medium risk to human health or the environment*
- *level 4 is intended for activities with genetically modified micro-organisms that pose high risk to human health or the environment*

Article x.2: The Minister shall establish and regularly update¹⁰:

1. *criteria for the identification of the applicable classes*
2. *criteria for the identification of the applicable levels of containment measures*
3. *containment measures that apply for each of the different levels in laboratories, green houses, animal facilities and large scale installations.*

Article x.3: Prior to the contained use activities with genetically modified micro-organisms of class 2, the Competent Authority has to be notified of the intended activity. Unless the Competent Authority decides otherwise within [60] days after the date of receipt of the notification, the intended activity may proceed in conformity with the obligations laid down in or on the basis of this Act.

⁹ Under the EC Directive for contained use of genetically modified micro-organisms all three options are applied. Activities of the lowest risk level can start immediately, provided appropriate safety measures are applied and records are kept. Activities of 'medium risk' have to be notified to the Competent Authority and there is waiting period. If the Competent Authority does not react within that period, then the activities can start. For the highest risk categories, there is a permit requirement.

¹⁰ Examples of such criteria and containment measures are available in many countries, as well as in EC Directives.

Article x.4: It is forbidden to carry out large scale activities with genetically modified micro-organisms of class 3 and 4 without a written permit issued by the Competent Authority.

Article x.5: the Competent Authority referred to in the previous paragraphs is:

Example - Contained use of genetically modified organisms other than micro-organisms

Article y.1. Prior to contained use activities with genetically modified organisms other than micro-organisms, a risk assessment has to be carried out in accordance with the specifications in annexdetermining the required containment measures.

Article y.2: The Minister shall establish and regularly update:

- *criteria for the identification of the applicable containment measures for genetically modified organisms other than micro-organisms*
- *containment measures that apply in laboratories, green houses, animal facilities and large scale installations for genetically modified organisms other than mirco-organisms.*

Article y.3: Prior to contained use activities with genetically modified organisms other than micro-organisms, the Competent Authority has to be notified of the intended activity. Unless the Competent Authority decides otherwise within [60] days after receipt of the notification, the intended activity may proceed in conformity with the obligations laid down in or on the basis of this Act.

Article y.4: the Competent Authority referred to in the previous paragraphs is:

Example - Procedures

z.1 The information to be included in the notifications referred to in articles x.2. and y.2. is a minimum information as described in Annex

z.2. Within [15] days after receipt of the notification mentioned in article x.2 and y.2, the Competent Authority shall inform the notifier:

- *either that the notification, prima facie, complies with the information requirements, and the date of receipt of the notification, or*
- *that additional information is required and which additional information is required.*

z.3. In case of a notification of intended large scale activities of classes 3 and 4, the Competent Authority will inform the notifier in writing within [60] days:

- *either that the intended activities may proceed and under which conditions, or*
- *that the intended activities may not proceed.*

z.4: The Competent Authority may, on the basis of the evaluation of the notifications submitted on the basis of article x.2. and y.2., request the notifier for additional information. Such a request will clearly identify the requested additional information, and will clearly justify the reasons for the request. In calculating the number of days referred to in articles..... , the number of days the Competent Authority has to wait for additional relevant information shall not be taken into account.

Note: as explained in the note to the readers on the cover page, this document is produced with the sole purpose to give readers a ‘flavour’ of the approach and level of detail of this chapter of the Guide.

Assuming that the previous pages provide a good impression of the approach taken, we suffice at this point to give an overview of the sections that will in any case also be addressed in this chapter of the Guide and which are currently under preparation:

1.4.2 Release into the environment of GMOs other than placing on the market

1.4.3. Placing on the market of GMOs

1.4.4. Import and export of GMOs (including a discussion on LMOs – FFPs)

1.5 ‘other provisions and final clauses’,

- procedural provisions
 - information requirements
 - acknowledgement of receipt
 - timeframes
 - decision making
 - appeal
 - review of decisions
 - simplified procedures
- risk assessment
- risk management
- labelling and accompanying information
- public information, public participation
- international information sharing
- confidentiality of information
- monitoring, new information,
- accidents and emergency measures
- enforcement, compliance, offences, penalties, liability and redress
- implementing regulations and guidelines
- entry into force, transitional arrangements
- review and amendment of the regulatory regime
- annexes

1.6 Other topics

- food safety, seed regist
- socio-economic considerations
- animal health, ethics.

1.7 Glossary of terms