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NATIONAL BIOSAFETY FRAMEWORK FOR GHANA - ADMINISTRATIVE GUIDELINES

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1.0: INTRODUCTION

A National Biosafety Framework (NBF) is a combination of policy, legal, administrative and technical instruments that is set in place to address safety for the environment and human health in the context of modern biotechnology. These frameworks often focus on "Living Modified Organisms" (LMOs)[1] in the area of transboundary movement.

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

- A Government **policy on biosafety,** often part of a broader policy on biotechnology.
- A **regulatory system** set in place to address safety in the field of modern biotechnology. This includes laws, guidelines and regulations to guide practices in modern biotechnology.
- A **mechanism to handle requests for permits** for certain activities, such as releases of GMOs into the environment.
- A **mechanism for monitoring and inspections.**
- A **system to provide information** to stakeholders about the national biosafety framework.

The Ghanaian biosafety framework is made up of the following:

- A Government **policy on biosafety,** often part often part of a broader policy on biotechnology. The current policy direction to the framework is in the National Science & Technology Policy which states "innovative and modern technologies including biotechnology shall be harnessed to address problems in agriculture, health and industry. The policy direction is further strengthened by the constitutional obligation to promote agriculture and industry and at the same time ensure protection of the environment and our natural resources (Art. 36, 41).

[1] Other terms that are often used in this context include: "genetically modified organisms (GMOs)", "transgenic organisms", "recombinant DNA organisms", "organisms with novel traits". In our Ghanaian context, LMOs and GMOs may be used interchangeably.

- A regulatory system set in place to address safety in the field of modern biotechnology. This includes a Biosafety Bill, a National Biosafety Guidelines and regulations/guidelines to be made periodically to guide practices in modern biotechnology.

- An Administrative system to handle requests for permits for certain activities, such as releases of GMOs which is the focus of this guidance document.

- A decision making system that includes risk assessment and management for the release of GMOs. A guidance document on "Risk Assessment of GMOs in Ghana" has been developed to assist in the decision making process.

- Mechanisms for public participation and information sharing. A guidance document on "Public Participation, Information Sharing and Access to Justice with Respect to Genetically Modified Organisms".

1.1 Institutional Arrangements

National Focal Point

The National Biosafety Authority shall be the National Focal Point on Biosafety. The Authority shall be responsible for liaison with the Secretariat of the Convention on Biological Diversity for the administrative functions required under the Cartagena Protocol on Biosafety.

Competent National Authority

The National Biosafety Authority shall be the Competent National Authority on Biosafety in Ghana. The Authority shall be responsible for all functions pursuant on the Cartagena Protocol on Biosafety and related technical matters.

2.0: REGULATORY SYSTEMS FOR BIOSAFETY

2.1 Introduction

Regulatory systems for biosafety vary from country to country. Some countries have made use of existing regulatory systems to regulate biosafety, whereas other countries have adopted new regulatory systems specific for biosafety. Each of these approaches has its advantages and disadvantages[2].

The structure and content of a regulatory system for biosafety depends on a country's legislative and administrative system, the countries' policy on biosafety and the countries' international obligations.

Most of the recently developed regulatory systems consist of a newly developed, specific biosafety framework law together with implementing decrees or regulations. The general trend these days is to use a coordinated regulatory regime to manage modern biotechnology activities. The Ghanaian Biosafety Regulatory system is a coordinated framework with a coordinating agency, the National Biosafety Authority, whilst monitoring and enforcement issues shall be handled by the existing regulatory agencies.

3.0: HANDLING AN APPLICATION FOR PERMIT[3] (Administrative & Risk Assessment Requirements)

Before an application for a permit is formally submitted to the National Biosafety Authority[4], there should be informal consultations between the applicant and the competent authority, to ensure that the request contains the required information.

[2] See for further elaboration and guidance about the choice for a regulatory system the ISNAR document "A framework for national biosafety implementation – Linking Policy, Capacity and Regulation", www.isnar.org.

[3] In different countries different terms are used, such as "request", "application" or "notification".

[4] The National Biosafety Authority is the Competent National Authority on all issues on LMOs and matters pursuant to the national obligations to the Cartagena Protocol on Biosafety.

In different countries different terms are used, such as “request”, “application” or “notification”. In the Ghanaian context the term “application” shall be used. An application will consist of a letter signed by the legal person that submits the request, and an accompanying dossier.

Once an application is formally submitted to the National Biosafety Authority, it shall be recorded and a tracking number is assigned to the dossier. A reviewer shall be assigned to the dossier in consultation with the Technical Advisory Committee. Assigning a dossier a tracking number is useful to systematically keep track of the requests and of the status of administrative and technical progress through the national system. The tracking numbers shall be kept in the National Biosafety database for progress control to make the information readily available both within the government and to various stakeholders. This electronic database enables the information to be easily searched. It can be integrated into other aspects of providing information. It also helps in the transmission of information to other databases, such as the Biosafety Clearing House of the Cartagena Protocol on Biosafety. The format for the tracking numbers are outlined in the National Biosafety Guidelines.

Once an application has been properly recorded, the request itself shall be handled in a number of steps:

a. The first step is **screening for completeness**, i.e. checking whether the request complies with legally required information; this is mainly an administrative step.

b. Once it is concluded that the request is in compliance with the information requirements: a **risk assessment** is carried out. This is a scientific process, based on the best available and up to date scientific knowledge and data. This step is addressed under Section 3.2.

   Risk assessment shall be carried out by the Technical Advisory Body through technical advisory panels based on particular requests.

c. Based on the results of the risk assessment and, where applicable, comments received from the public and any other socio-economic considerations, a **decision** is made by the

National Biosafety Authority and communicated to the applicant in the form of a decision document. This is usually also the phase in which public participation takes place, where applicable. The key elements for determination and communication of decision are spelt out in sections 21 – 22 of the Biosafety Bill.

3.1 Screening for completeness (Administrative Requirements)

Before screening for completeness, it is advised to check two procedural aspects of the regulatory system:

- The legal information requirements for applications
- The formal "start" of the actual procedure.

Information requirements for applications will be addressed below.

It is important to note when the procedure of handling requests starts and the time period within which a decision has to be made. These procedural steps are spelt out in the Biosafety Bill and the Biosafety Guidelines.

Screening an application for completeness involves a number of steps:

1. The process starts with examining what the application implies. Is it clear who the applicant is and what the request is, i.e. who wants to do what, when and where?

2. This is then followed by the question whether the activities for which a permit is requested actually **require** a permit.

3. Once it has been established who wants to do what and where, and that the involved activities require a permit, then the question arises whether the application complies with the **information requirements** laid down in the regulatory system.

Information requirements include the following:

- **Administrative data**, such as name and contact information of the applicant;
- **Technical information**, which describes the GMO (e.g. the plant species, the genetic constructs used and resultant phenotype), the type of activity and the receiving environment. This information should be sufficient to **begin** the risk assessment. Details are spelt out in the National Biosafety Guidelines and the Guidelines on Risk Assessment of GMOs in Ghana. While conducting the risk assessment, it may be necessary to request additional information or clarification of information provided with the original request.

These details are spelt out in the second and third schedules of the Biosafety Bill.

Examples of lists of information requirements can be found in:

- Biosafety Protocol on Biosafety, Annexes I and II [5]
- EC Directive 2001/18/EC, Annex III[6]

Periodic 'checklists' shall be released as guidance to assist both the applicant and the Biosafety Authority in the evaluation for completeness of both administrative and technical information. The National Biosafety Authority shall periodically make such checklists and other guidance documents available to the public.

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).

[5] http://www.biodiv.org/biosafety/protocol.asp
[6] http://europa.eu.int/eur-lex/en/archive/2001/l_10620010417en.html

When an application does not fulfil the information requirements, additional information shall be requested from the applicant. In such situations, often the procedural 'clock' stops 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 for by the assessor through the National Biosafety Authority. Requests for additional information can be made during the entire process, i.e. during the screening for completeness as well as during the risk assessment process.

For reasons of transparency, requests for additional information need to be in writing and as specific as possible and must be clearly justified. In this respect, it is important to distinguish as much as possible between 'need to know' and 'nice to know'. Assessors should bear in mind that it is only useful to ask for additional information, if it is clear what will be done with the additional information in the next steps of the risk assessment.

As soon as it has been established that an application complies with the information requirements, a number of administrative steps shall be taken:

- the applicant shall be informed that the request complies with the information requirements and that the procedure for handling or risk assessment has commenced;
- the application and any accompanying information will then be sent to the technical advisory committee with a request for a risk assessment of the proposed activity;
- the request shall be publicly announced without the confidential information through the electronic and print media and the web site of the National Biosafety Authority.

There is a natural overlap in "Screening for Completeness" and "Risk Assessment" with respect to technical information. Technical information requirements depend on the nature of the application. An Application to place on the market usually contains more information than a request to conduct a confined field test (Refer to the section on handling of applications for approval in the Biosafety Bill.

3.2 Risk Assessment

Introduction

Risk assessment[7] in the field of biosafety is a scientific process used to identify and evaluate the impacts that activities with GMOs may have on the environment, including humans.

Risk assessments can be carried out by those who plan or carry out the activities with GMOs as well as by authorities with responsibilities regarding such activities.

To provide a meaningful tool for decision making, risk assessment needs to be carried out in a scientifically sound and transparent manner, and needs to make use of the best up to date scientific knowledge and experience

Although the details of a risk assessment vary from case to case, the overall methodology followed in doing a risk assessment for GMOs usually involves a number of systematic steps.

An outline of this overall methodology can also be found in a variety documents, including:

- Guidelines on Risk Assessment of GMOs in Ghana
- UNEP International Technical Guidelines for Safety in Biotechnology[8],
- the Biosafety Protocol (Annex III), and
- EC Directive 2001/18/EEC (Annex II).

As these documents show, the steps taken in a risk assessment are:

1. Identification of potential adverse effects[9] on the environment and human health.
2. An estimation of the likelihood of these adverse effects being realized.
3. An evaluation of risks based on the evaluation of the likelihood and of the consequences of the identified adverse effects being realized.

[7] In certain documents, such as the EC Directives, the term "environmental risk assessment" is used. See also Art. 15 & Annex III of the Cartagena Protocol on Biosafety).
[8] http://www.unep.org/unep/program/natres/biodiv/irb/unepgds.htm
[9] In some countries and documents the terms "potential harm" or "hazard" are used

4. Consideration whether any identified risks are acceptable or manageable, including where appropriate, an identification of risk management strategies.
5. Assessment of the overall potential environmental impact.

In addressing these steps, account is taken of the relevant characteristics of:

- the recipient organism[10],
- the inserted genes and other inserted sequences[11],
- the resulting GMO,
- the application (e.g. small scale field trial or marketing)
- the receiving environment,
- the existing situation, including consideration of the use of the non modified recipient organism.

3.2.1 *Administrative Processes related to initiation of Risk Assessment on Applications*

The methodology described above is applied in practice in countries where biosafety frameworks have been in place for many years.

The administrative approach to risk assessment includes the following:

1. preparation of a cover note on the application and the dossier
2. the actual risk assessment.

Preparation of a cover note

As a first step in the risk assessment it is useful to 'set the scene' of the assessment by listing on a cover note:

- the name of the applicant

[10] In some documents the term "host organism" is used. Both these terms refer to the organism in which genetic material from a donor organism is introduced.
[11] With the term 'other inserted sequences', reference is made to *inter alia* a) open reading frames (ORFs) coding for proteins (i.e. that encode a protein in the host from which the sequence has been derived), b) promoter, terminator and enhancer sequences, c) sequences that code for RNA transcripts that are not functional in translation, e.g. anti-sense RNA.

- the type of application (e.g. field trials under controlled conditions or a commercial release,
- the name of the recipient organism, including whether the recipient organisms can cross fertilise with wild flora/fauna and/or with cultivated crops in the case of plants in the receiving environment,
- the inserted genes or sequences.

The last part of the cover note is a list of the inserted or modified genes and sequences, and – where known - the corresponding traits for which these genes code or may code. What is important at this stage is to get a complete list of any inserted genes or sequences, regardless of whether the genes are actually expressed in the plant, animal etc.

It is recommended to note the pages of the application on which relevant information is found or in other sources of information used by the risk assessor. Assessors should be aware that in some application the relevant information about inserted genes may be given in different places. Applicants should be urged to concentrate similar types of information as much as possible in one part of the request.

Experience shows that the use of such a 'cover note' facilitates the risk assessment and in fact the overall handling of a request.

The actual risk assessment

Once the main elements of the request are included in a cover note, the actual risk assessment can start.

The risk assessment starts in a systematic way whereby for each of the inserted genes and sequences the questions described above are addressed:

1. Identification of potential adverse effects.
2. An estimation of the likelihood of these adverse effects being realized.
3. An evaluation of the identified risks.
4. Consideration of risk management

After this systematic 'gene by gene' assessment, a broader and more 'holistic' approach follows, whereby the potential impacts of the genes together are evaluated with a view to an assessment of possible synergistic effects.

Finally, the overall environmental impacts are evaluated by placing any identified risks in the context of risks posed by the non-modified recipients.

These steps are discussed below.

While these steps offer a systematic tool for risk assessment, it should not be forgotten that in the different steps of the risk assessment in this field there may be elements of uncertainty.

3.2.1.1 Identification of potential adverse effects

The risk assessment process starts with the identification of potential adverse effects that will be considered in the risk assessment.

This is done in a systematic way by looking for each of the inserted genes or sequences at what genetic material has been introduced, by examining the resulting changes in the plant metabolism and any resulting new or changed traits (phenotype), taking into account that gene products through their interaction with the physiology of the host may cause multiple traits that may differ from the traits in the host organism.

Unlike risk assessments for chemicals, there is not yet a fixed 'cookbook recipe' for the identification of potential adverse effects related to a gene or sequence. Whether or not a particular gene or sequence may have the potential to cause adverse effects depends on the characteristics of the gene, of the gene product, of any resulting changes in the phenotype, of the receiving environment and of the type of application.

To assist in the process of identifying potential adverse effects, the following questions must be addressed:

- Can the inserted gene/sequence cause the recipient plants to become more persistent in agricultural habitats or more invasive in natural habitats (weediness), with the related potential adverse effects of changes in management of weeds and/or changes on population level in natural populations; this could be the case when the inserted gene or sequence confers to a selective advantage or changes in survivability or dispersal.
- Can the inserted gene/sequence cause the recipient plant to be toxic and/or allergenic to humans or animals,
- Can the inserted gene/sequence cause changes in susceptibility of the recipient plant or – after outcrossing of other plants, to pathogens, which in turn can cause the dissemination of infectious diseases and/or creating new reservoirs or vectors,
- Can the inserted gene/sequence cause negative effects on populations of non-target organisms, including indirect effects on population level of, where applicable, predators, competitors, herbivores, symbionts, parasites and pathogens,
- Can the inserted gene/sequence cause unintended effects on the target organisms (e.g. resistance development),
- Can the inserted gene/sequence result in a change in management of the genetically modified crop plant that has a negative impact on the environment,
- Can the inserted gene/sequence cause changes in biogeochemical processes,
- Can the inserted gene/sequence cause other unintended side effects, such as:
    - the potential reduced effectiveness of an antibiotic used in medicine as a result of horizontal transfer of antibiotic-resistance genes,
    - the development of new virus strains due to the introduction of viral sequences in a plant genome and possible recombination of genetic material,
    - potential insertion effects.

In this stage of the risk assessment it is important to consider the type of potential adverse effect(s) that are scientifically conceivable, depending on the characteristics of the gene involved, regardless whether it is likely that this effect actually would occur in the proposed application. The question of likelihood will be addressed in the next stage of the risk assessment.

In the process of identifying potential adverse effects it should also be remembered that such effects can be direct, indirect, immediate and delayed effects[12].

Adverse effects may occur directly or indirectly through mechanisms such as:

- the spread of the GMO(s) in the environment,
- the transfer of the inserted genetic material to other organisms,
- phenotypic or genotypic instability,
- interactions with other organisms,
- changes in management, such as agricultural practices.

When a certain potential adverse effect is considered in the risk assessment, transparency requires that the 'scenario' is described through which this potential adverse effects might occur, i.e. the causal steps that could end in the adverse effect. The scenario starts with a trigger: what is the scientific reason to assume that a certain adverse effect may occur. The scenario should show the chain of causal events that may lead to its occurrence. As with all scenario writing, this is a creative process, which requires scientific imagination.

It is also important to formulate clearly which potential adverse effect is being considered. For example, just mentioning 'horizontal gene transfer' of an antibiotic resistance gene does not clarify the potential adverse effect the assessor is focusing on. Transparency is helped by clarifying that, for example, the assessor has in mind the potential adverse effect of reduced effectiveness of an antibiotic used in medicine as a result of horizontal transfer of antibiotic-resistance genes to pathogenic micro-organisms. Sometimes it may be useful to indicate whether the adverse effect, would it occur, is deemed to be severe or low.

[12] For example, Directive 2001/18/EC describes these terms as follows:

– "direct effects" refers to primary effects on human health or the environment which are a result of the GMO itself and which do not occur through a causal chain of events;
– "indirect effects" refers to effects on human health or the environment occurring through a causal chain of events, through mechanisms such as interactions with other organisms, transfer of genetic material, or changes in use or management. Observations of indirect effects are likely to be delayed;
– "immediate effects" refers to effects on human health or the environment which are observed during the period of the release of the GMO. Immediate effects may be direct or indirect;
– "delayed effects" refers to effects on human health or the environment which may not be observed during the period of the release of the GMO but become apparent as a direct or indirect effect either at a later stage or after termination of the release.

Although assessments are done on a 'case by case' basis, information and analyses from previous assessments can be very useful.

There are many sources of existing knowledge and experience, such as

- decision documents of earlier cases, which can be found on the web sites described under section 5.3;
- search engines such as the SWISS-PROT/TrEMBL Full text search (http://www.expasy.ch/cgi-bin/sprot-search-ful) and the ICGEB database on risk assessment (http://www.icgeb.trieste.it/biosafety/rasm.html)
- OECD consensus documents on traits (http://www1.oecd.org/ehs/cd.htm)

It is strongly recommended that risk assessment should be done in a systematic way, focusing on each of the gene or sequences separately, and listing for each gene or sequence any potential adverse effect or effects that the assessor wishes to consider in the risk assessment.

3.2.1.2 Estimation of likelihood

Once a potential adverse effect has been identified for consideration in the risk assessment, the next step in the risk assessment is the estimation of the likelihood that the identified potential adverse effects will actually occur in the proposed application.

This stage follows the same, systematic approach. For each of the identified potential adverse effects of each of the inserted genes or sequences, an estimation should be made of that particular potential adverse effect actually occurring in the proposed application.

Here the term 'estimation' is chosen, because - given the 'nature of nature' – exact numbers of the frequency with which something will happening in nature can rarely be given. Therefore terms are used such as likely, unlikely and negligible or effectively zero (or 'zero' for that matter, but many scientists are uncomfortable using the term 'zero' in the context of risk assessment).

The likelihood of a certain inserted gene or sequence of actually having a potential adverse effect is influenced by many different factors, such as:

- The characteristics of the inserted gene. For example, a gene that is not involved in toxicity of the donor organism, is very unlikely to cause the recipient organism to be toxic. On the other hand, it is likely that a gene product that is known to be toxic for one insect, such as the endotoxins produced by *Bacillus thurigiensis,* is also toxic for other closely related insects. Assumptions related to toxicity or allergenicity can usually be verified with the information presented in the application or dossier, such as feeding studies.
- The characteristics of the recipient organism. For example, the potential for outcrossing with wild relatives is negligible for sterile plants or in regions where no relatives exist, but is likely for fertile plants in an environment where wild relatives are present in the environment.
- The characteristics of the size or the scale of the application. For example, the likelihood of a genetically modified plant with a certain 'built-in' pesticide resulting in the development of resistance by the target organism, is negligible in a small-scale field trial, but can be quite likely in a commercial application if no resistance management is applied.

There are a number of tools that can provide useful information on the characteristics of recipient organisms, such as:

- The OECD consensus documents on the biology of plants (http://www1.oecd.org/ehs/cd.htm),
- 'Botanical Files'.
- Files on the biology of several crop species (see www.aphis.usda.gov/ppq/biotech)

In cases where the estimation of the likelihood does not result in the conclusion 'negligible' or 'effectively zero', the risk assessment continues with the next step described under section 3.2.1.3.

As was said above, in risk assessment in this field there may be elements of uncertainty. This is particularly the case in the step that deals with an estimation of the likelihood.

In cases where the estimation of the likelihood does not result in a clear conclusion, it is sometimes recommendable to proceed with the next step of the assessment by assuming a certain effect will occur. For example, rather than spending much time and effort to determine the frequency of outcrossing, it is assumed that if the plant can outcross then it will outcross. The attention is then focused on the next step in the risk assessment, i.e. what are the potential consequences of such transfer.

Another example is the assessment of the possible transfer of antibiotic resistance genes from plant material to microbial organisms. In case there is no scientific consensus about the likelihood of the transfer from plant material to micro-organisms, then it may help to continue the risk assessment by asking what the consequence would be if such transfer would occur.

3.2.1.3 Evaluation of the identified risks

In the cases where a potential adverse effect has been identified and the estimation of the likelihood did not lead to the conclusion 'negligible' or 'effectively zero', the risk assessment proceeds to the next step, i.e. the evaluation of that particular risk.

Note that at this point the term used is 'risk' instead of 'potential adverse effect'. Risk is the combination of a potential adverse effect and the likelihood of it occurring.

Here too, it is recommended to follow the same systematic approach as before, i.e. for each of the identified risks (i.e. the cases where the likelihood of an identified potential adverse effect is not negligible or effectively zero) of each of the inserted genes or sequences, an evaluation is made of the actual consequence it may have.

Here it is important to differentiate between risks related to human health and risks related to the environment.

Key issues in risks to human health are toxicity and allergenicity. For toxicity, tests are available.

For allergenicity, a particular risk assessment is required, because allergenicity can usually only be scored by patients that have the allergenic reaction[13]. For an evaluation of the potential consequence of possible toxicity or allergenicity, the type of application is taken into account. For applications, such as small scale field trials whereby the material resulting from the field trial is not consumed by humans or animals, toxicity and allergenicity would generally be of no consequence. For large scale and market releases, toxicity and allergenicity would be of a consequence and therefore needs to be addressed. It is for this reason that in requests for market approvals, usually the results of toxicity and allergenicity tests are included. Assessors should bear in mind that there is a difference in looking at toxicity in terms of food safety, whereby it is assumed that large quantities may be consumed frequently (i.e. scenarios in which even low levels of toxicity may have a consequence) and toxicity in the context of environmental safety, whereby the focus is on effects of incidental consumption.

Evaluating the impacts that the introduction of a genetically modified plant may have on the environment is less straightforward for a number of reasons: Firstly, the different type of effects that can be considered differ strongly, such as weediness, susceptibility to diseases, effects on non-target organisms, effects on target organisms, changes in agricultural management etc. Secondly, agricultural and natural ecosystems are very dynamic systems in which many changes occur constantly. Thirdly, every agricultural activity has an impact on the environment in which it takes place. For example a simple agricultural practice such as ploughing, has a severe impact on the soil organisms such as worms, insects, bacteria and fungi, because of the exposure to air and UV light. However, due to natural processes such as migration, these impacts are usually restored quickly.

In order to evaluate the possible consequences of the introduction of a GMO in the context of these dynamic processes, the concept of "base line" plays an important role.

The assessment of the transfer of antibiotic resistance genes from plant material to microbial organisms can serve to illustrate this. Apart from the discussion whether or not it is likely that

[13] See also http://www.who.int/fsf/GMfood/Consultation_Jan2001/report20.pdf made after the 2nd Joint FAO/WHO Consultation on Foods Derived from Biotechnology, Allergenicity of Genetically Modified Foods, 22-25 January 2001, Rome, Italy

such genes present in decaying plant material can be taken up by bacteria in such a way that the gene will still function in the bacterium, one could assess what the consequence would be.

For this purpose it is important to know what the baseline is, i.e. what is the existing presence of antibiotic resistance genes in the soil population? It is known that certain antibiotic resistance genes, such as kanamycin resistance, are so abundantly present in the environment that any – theoretical – addition would make no measurable difference, i.e. would be of no consequence. Some other antibiotic resistance genes, on the other hand are not present in the environment at such high numbers, so in those cases a (hypothetical) transfer of antibiotic genes could have a measurable consequence. This example illustrates that the assessment of the presence of antibiotic resistance genes can not be done in a generic way, but depends on the type of antibiotic resistance involved.

3.2.1.4 Consideration of appropriate risk management strategies

In the previous step of the risk assessment, it is evaluated whether the introduction of a GMO would have a measurable adverse impact in the background of the baseline of the existing situation.

In cases where this question is answered with "yes", the risk assessment continues with the next phase, which is a consideration whether the identified risk is acceptable or manageable[14], i.e. a consideration of appropriate risk assessment strategies[15].

It should be underlined here that it is important to be aware that the term "acceptable" plays a role twice in the evaluation of a proposed activity with GMOs, but in a different way. Firstly, it plays a role in this phase of the risk assessment, when it is considered what kind of risk management strategies would be appropriate. Secondly it plays a role in the final decision making, when an identified risk for the environment or human health is compared and weighed against any potential benefits that the proposed activity may have for the environment or human health.

[14] See for example Annex III of the Biosafety Protocol
[15] See for example Annex II of Directive 2001/18.

In this phase of the risk assessment, the question is addressed whether there are risks identified that require additional risk management measures and, if so, a risk management strategy is defined.

It is recommended to conduct this step too in the systematic, "gene by gene" and "potential adverse effect by potential adverse effect" way a as described before.

For cases where a risk management strategy has been identified, the risk assessment "loops back" to the earlier steps in the risk assessment to check whether the proposed risk management strategies sufficiently reduce the likelihood or the consequence.

This is why risk assessment is often called an "iterative process".
There are many different strategies for risk management of genetically modified plants, including reproductive isolation by removing of flowers, use of isolation distances or border rows and reduction of the size or duration of an application. Annex 5 of the UNEP International Technical Guidelines on Safety in Biotechnology gives examples of risk management strategies.

3.2.1.5 Assessment of the overall potential impact, conclusion

After the systematic 'gene by gene' assessment described in the previous steps, a broader and more 'holistic' approach follows, whereby firstly the potential adverse effects of the genes together are evaluated with a view to possible synergistic effects. Finally, the overall environmental impacts are evaluated by placing any identified risks in the context of risks posed by the non-modified recipients and by taking into account any beneficial effects the proposed activities with GMOs may have on human health or the environment.

Synergistic effects
New traits may enhance or suppress each other. This may have effects on the overall behaviour of the genetically modified plant.

This is why after the systematic 'gene by gene approach' two more questions are considered in the risk assessment, focusing on the GMO 'as a whole'.

The first question is whether the introduced genes or traits have characteristics which may enhance the effect of the GMO in the environment. For example, a plant with one newly introduced abiotic stress resistance, such as drought resistance, may behave differently than a plant with several different abiotic stress resistances. Whether this is the case depends on the type of traits introduced and on the biochemical pathways involved.

The second question is how the GMO behaves in practice. For this part of the assessment, data obtained from greenhouses, field trials and placing on the market in other countries are often included in the request.

Assessors should be aware that while the GMOs that have been developed to date are usually relatively 'simple' constructs with one or sometimes two new traits, it may be expected that more complex cases will be offered for assessment in the near future.

Overall environmental impact

In the last step of the risk assessment, the overall environmental impact is evaluated. Note that at this point there is a change in terminology. While in the previous steps the focus was on potential "adverse effects", in this last step the focus is on the "overall environmental impact", i.e. consideration and comparison of potential adverse effects as potential beneficial effects on the environment. This is done by placing any risks identified in the context of risks posed by the non-modified recipients and by taking into account any beneficial effects the proposed activities with GMOs may have on human health or the environment.

The risk assessment usually ends with a summary or a conclusion. It should be underlined that this is not the same as the final decision. The summary or conclusion will "spell out" the type of risks that the proposed activity with GMOs may have, including, where appropriate, proposed risk management strategies. The summary also describes any potential beneficial effects the proposed activity with GMOs may have on the environment or human health.

It is usually up to the decision makers to "weigh" these potential risks and potential benefits.

3.3 Decision Making

Introduction

Which decision the competent authority can or must make, depends entirely on the underlying regulatory system.

Decisions are usually based on the results of the scientific risk assessment, relevant comments submitted by the public and socio-economic considerations arising from the impact of the GMOs on the environment.

The question as to which decision has to be made in a particular case is the prerogative of the National Biosafety Authority within the framework of the National Biosafety Legislation and in the context of our international obligations.

Decision documents

Generally speaking, the decision can be to allow, with or without conditions, or to deny a permit or approval for the requested activity.

It should be noted that in many legal systems, the terms 'permits' and 'approvals ' have different meanings and legal consequences. With 'permit' usually reference is made to a permission to a legal or natural person to carry out certain activities. This permission is limited to that particular person. A drivers' licence is an example of a permit. 'Approvals' are often used in the sense of 'product approvals'. Product approvals are usually not given to a legal person but are more 'attached' to a certain product. After a product approval has been granted, then others do not require a permit to buy, sell or use that product as long as the product is used according to the conditions of the product approval.

The form of decision documents varies from country to country. Some decision documents are relatively short, whereas other decision documents include a detailed report of the risk assessment and the decision making process.

Despite differences in the level of detail, the decision document shall contain the following elements:

a. A summary of the application
b. A description of the procedure followed, including the solicitation of advice and comments from the pubic, and the reaction of the competent authority to the input received.
c. A summary of the risk assessment carried out, based on the approach described before.
d. Socio-economic considerations arising from the impact of the genetically modified organisms on the environment
e. The final decision, which can be to allow, with or without conditions, the requested activity or to not to allow.

4.0: MONITORING AND INSPECTIONS

Introduction

After a permit or consent is given and the proposed activity has started, usually a mechanism of "monitoring and inspections" begins.

Monitoring is usually carried out by the person responsible for the activities, whereas inspection and enforcement is be done by the National Biosafety Authority (NBA) through the regulatory agencies as spelt out in fifth schedule of the Biosafety Bill and the Institutional Biosafety Committees as spelt out in Part I of the National Biosafety Guidelines.

The National Biosafety Authority (NBA), set-up under the Biosafety Bill shall act as the executive body for the overall monitoring, risk management and commercial release of all regulated materials. As per the law, monitoring and inspection functions shall be handled by the regulatory agencies as listed below:

1. Food & Drugs Board – Food Safety and related Matters
2. Plant Protection & Regulatory Services – Plant Health and Related Matters
3. Veterinary Services Department – Animal Health and Related Matters

4. Environmental Protection Agency – Environmental Releases and Related Matters
5. Customs & Preventive Services – Port and Frontiers Handling of GMOs in collaboration with the other agencies listed above

The National Biosafety Guidelines suggest two tiers for monitoring and implementation**.** The monitoring and inspection will be done **first** by the Institutional Biosafety Committee (IBC) **which is** important and occupies a pivotal position **in laboratory work involving LMOs**. The IBC serves, in part, as a conduit for the flow of information between the researchers and the NBA, forwarding proposals, assessments and recommendations.

The Institutional Biosafety Committee will receive applications, propose measures for laboratory set-up as well as plan release and effectively monitor them. All information/data that needs to be submitted to the National Biosafety Authority will have to go through the IBC, which therefore, must consist of people adequately qualified to understand the associated risks and evaluate them accordingly.

The 2nd Tier of monitoring and enforcement shall be handled by the NBA through the regulatory agencies and any designated individuals or companies through the inspectorate functions as spelt out in section 33 of the Biosafety Framework Law.

Lastly, the Principal Investigator and researchers are responsible to themselves and to the community in the monitoring and implementation of laboratory work but are required to seek approval from the IBC.

The objective of monitoring is:

- to evaluate or verify results and assumptions arising from previous research and evaluation of risks,
- to gather information with a view to future assessments, and
- to survey for unintended impacts on the environment and human health.

The purpose of inspections is to ensure compliance with the conditions set in decision documents or permits and also to ascertain whether the agreed risk management strategies are adhered to. Periodic inspection and guidance manuals shall be released by the National Biosafety Authority to assist in the inspectorate functions related to GMOs.

Monitoring and general surveillance

Monitoring is a term used for different activities, varying from general surveillance to a detailed monitoring plan, including methodologies of sampling, testing and analysis[16].

General surveillance is typically directed to gathering information about unexpected effects and events, and often makes use of established routine surveillance practises such as monitoring of agricultural cultivars or plant protection products.

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 upon on 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.

Effective monitoring requires that appropriate methodology is available prior to the commencement of monitoring programmes.

Monitoring plans usually contain three sections, namely;

1. Monitoring strategy
2. Monitoring methodology
3. Analysis, reporting, review

[16] This distinction can, for example be found in the monitoring provisions in Directive 2001/18/EC

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 visits/inspections
- Assignment of responsibilities.

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
- Approaches for sampling and analysis.

5.0: PUBLIC INFORMATION AND PUBLIC PARTICIPATION

Introduction

The efficacy and efficiency of any legal system depends to a large extent on the information that is made available about that system and about its implementation. The need to inform stakeholders[17] is not only a 'matter of fact', it is also reflected in a number of international and national agreements such as the Biosafety Protocol, the Right to Information Bill (2003) and the Constitution of the Republic of Ghana.

Information about a legal system is usually made available in the form of general information, guidance documents and application forms. Information about applications that are currently being handled or have been handled shall be made available through the electronic and print media and the Authority's web site. Additional details on public information and participation

[17] With "stakeholders" reference is made to those who may be, directly or indirectly, affected by the legislation, e.g. companies, research institutes and universities, as well as the general public and NGOs.

are spelt out in the "Guidelines on Public Participation, Information Sharing and Access to Justice with Respect to Genetically Modified Organisms" and section 41 of the Biosafety Bill.

One of the key rules of public participation that should be addressed is that once a Government has decided that certain decisions are subject to public participation – in whatever form – then every comment brought in by the public should be taken seriously and worked out in a transparent manner.

5.1 Providing general information

The National Biosafety Authority shall produce brochures and develop web sites with general information about that framework and opportunities for the general public to access the National Biosafety Clearing House.

Those brochures and web sites shall offer information about:

- The general policy of the Government with respect to modern biotechnology and biosafety.
- The purpose and scope of the biosafety regulations
- Applicable procedures including procedures for decision making and the rules for public information and public participation.
- Possibilities to obtain further information.
- The status of GM approvals and activities in the country.

An attempt has been made to provide a guidance document referred to above to assist the Ghanaian public with all the key procedures to participate in the decision processes related to GMOs.

The following web sites also provide useful information on public engagement practices in other jurisdictions.

The web sites include the following:

- UK: http://www.defra.gov.uk/environment/acre/index.htm
- Belgium: http://biosafety.ihe.be/
- Netherlands: http://www.rivm.nl/csr/ (choose option "Genetically Modified Organisms Bureau")
- Hungary: The Hungarian Biosafety Home page (http://www.biosafety.hu/)
- United States:
    - Unified Homepage - overview of the coordinated biosafety regulatory framework)
      (http: www.nbii.gov; http://www.aphis.usda.gov/biotech/OECD/usregs.htm)
    - Internet home page for APHIS biotechnology
      (http://www.aphis.usda.gov/ppq/biotech/)
    - APHIS REGULATIONS (http://www.aphis.usda.gov/biotech/7cfr340.html)
- Canada: Canadian Food Inspection Agency, Plant Health and Production Division, Plant Biosafety Office (http://www.cfia-acia.agr.ca/english/plaveg/pbo/pbobbve.shtml),

Web sites of other countries can be found via the OECD Biotrack On Line and BINAS web site (www.oecd.org/ehs/service.htm and http://binas.unido.org/binas/). Web sites of Central and Eastern European (CEE) countries can be found through the CEE regional biosafety web site (www.biosafety.hu/CEE). Additional information can be found on the Biosafety Clearing House of the Convention on Biological Diversity (www.bch.biodiv.org)

5.2 Guidance documents and application formats

In addition to supplying general information about the National Biosafety Framework and its related guidelines/regulations, the National Biosafety Authority shall provide specific guidance documents or application formats for permits. Examples of such formats have been included in Part II and III of the National Biosafety Guidelines. Attempts shall be made to update these formats with current information as and when necessary. These updates shall be made available to the public. The guidance documents shall explain which procedures apply in which cases and what the information requirements are. These guidance documents and application formats shall be made available in hard copy and on the Authority's website. Eventually bilingual application formats shall be made available.

Examples of guidance notes from other jurisdictions can be found at the following web sites:

- UK: http://www.defra.gov.uk/environment/index.htm
- Netherlands: http://www.rivm.nl/csr/ (choose Genetically Modified Organisms Bureau)
- United States:
    - APHIS example of how to submit a notification letter to APHIS for importation or interstate movement to a contained facility or to conduct a field trial. (http://www.aphis.usda.gov/biotech/usergdn.html)
    - Additional Guidance for Notification Submissions (http://www.aphis.usda.gov/biotech/nottips.html)
    - Petitioning APHIS for a Determination of Nonregulated Status (http://www.aphis.usda.gov/biotech/petguide.html

5.3 Providing information about applications and permits

Information about applications that have been handled and/or are currently being handled shall be made available through the electronic and the print media and the authority's web sites.

Hard copies of the requests, without the confidential commercial information, are made available for interested people and organisations in places, such as the libraries, offices of the District Assemblies and community centres or can be requested from the National Biosafety Authority. Examples of web sites in other countries with such information can be found on:

- UK:
    - Index of Public Register Entries for applications to market GMOs under EC Directive 90/220/EEC (http://www.defra.gov.uk/environment/acre/pdf/market.pdf)
    - UK GMO Public Register Index: List of applications received by the Secretary of State of UK to release Genetically Modified Organisms to the environment as part of experimental trial (http://www.defra.gov.uk/environment/acre/pdf/exper.pdf)
- Netherlands: http://www.rivm.nl/csr/ (choose Genetically Modified Organisms Bureau)
- The Hungarian Biosafety Home page (www.biosafety.hu).

- US:
    - Permits to release and petitions for deregulation (a step towards commercialisation) for plant pests, plants and veterinary biologics (http://www.aphis.usda.gov/biotech/status.html)
    - Field Release Database online: ISB Environmental Releases Database, which contains information on applications for field tests of GMOs (http://www.nbiap.vt.edu/cfdocs/fieldtests1.cfm)
    - Petitions granted for Determination of Nonregulated Status http://www.unep.org/unep/program/natres/biodiv/irb/unepgds.htm
    - Decision documents for Determinations of Nonregulated Status http://www.aphis.usda.gov/biotech/dec_docs/
- Canada: Status of Regulated Plants with Novel Traits (PNTs) in Canada: Environmental Release, Novel Livestock Feed Use, Variety Registration and Novel Food Use (http://www.inspection.gc.ca/english/plaveg/pbo/pntvcne.shtml)