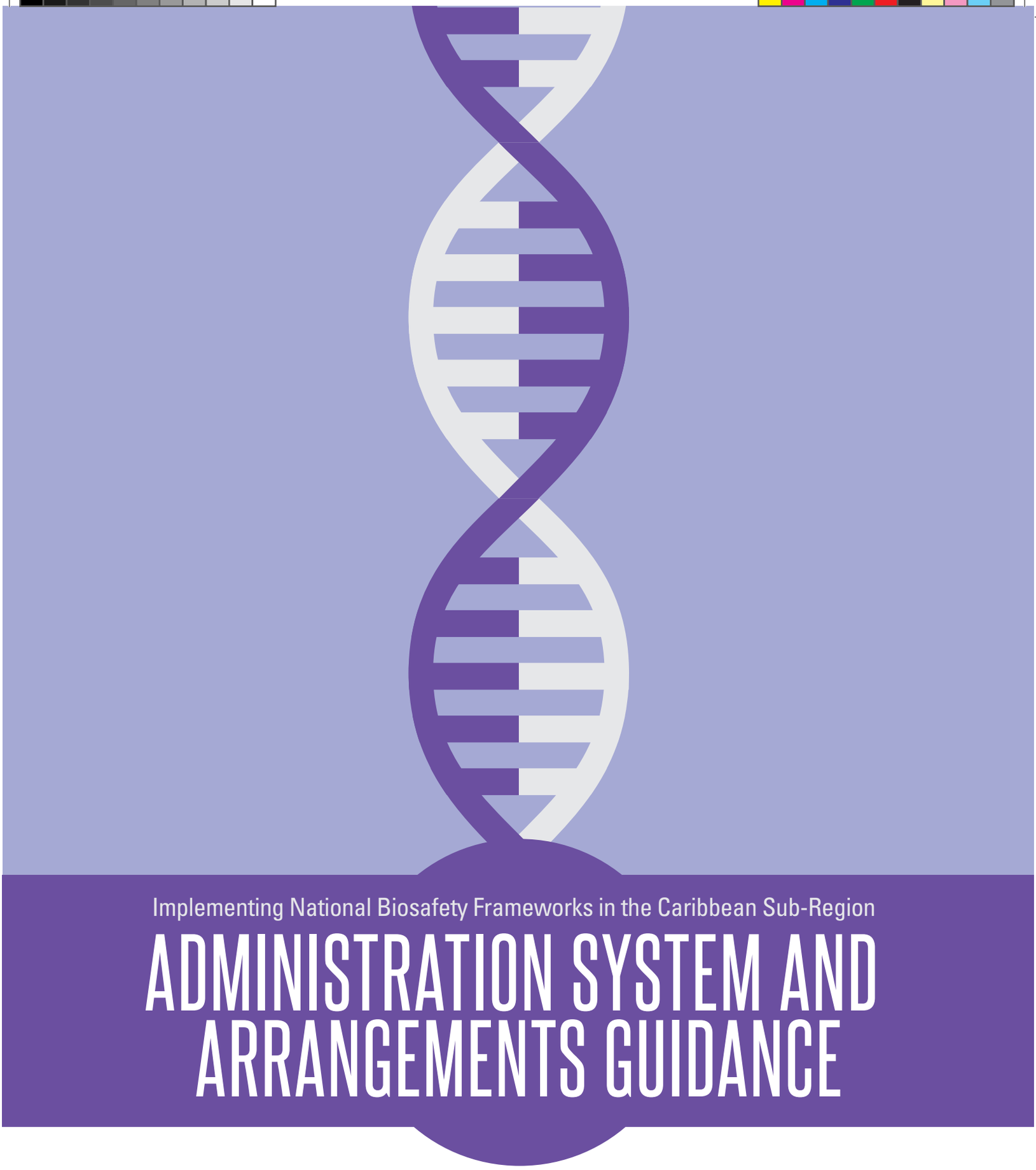

Implementing National Biosafety Frameworks in the Caribbean Sub-Region

ADMINISTRATION SYSTEM AND ARRANGEMENTS GUIDANCE

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EXECUTIVE SUMMARY

This document is a guideline to assist the development and enhancement of an administrative system and associated arrangements for the use of GMOs in the Caribbean region, and includes a reasonable set of administrative approaches and considerations to ensure the safety of human health and the environment, whilst providing the opportunity to access the benefits of biotechnology. These approaches and considerations can be adapted to country-specific legislative and regulatory frameworks as required to align with their specific social and environmental goals.

The development of an administrative system and associated arrangements needs to incorporate consideration of existing biosafety frameworks and their functionality. Further, development needs to be cognisant of the implications and obligations of the Convention on Biological Diversity and the Cartagena Protocol on Biosafety.

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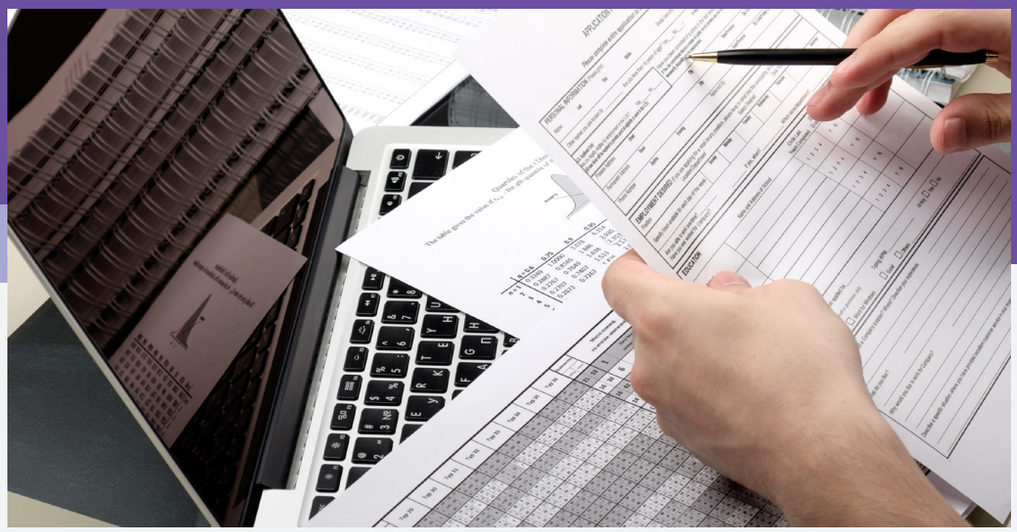

CHAPTER 1: APPLICATION LODGEMENT, PROCESSING OF APPLICATION AND DECISION-MAKING

This Chapter provides a guide for the lodgement of an application, processing of said application, associated procedures and the making of the final decision in relation to the application.

In the recording of the details and stage of the application process, checklists in relation to the required legislative steps, the relevant stage of processing, additional requests for information, recording of evidence that are relevant to the decision-making process, and reasons for the decision are of great assistance (example provided in Appendix 1). The flow diagram from application lodgement, through processing and to decision-making is shown in Appendix 2.

1.1. LODGEMENT OF APPLICATION

The lodgement of an application under biosafety legislation can be made through an electronic lodgement facility or a combination of an electronic lodgement facility and the provision of required documents in hard copies.

1.1.A. FULL ELECTRONIC LODGEMENT

Application forms (example provided in Appendix 3) may be made available from the National Competent Authority (NCA)'s website or another specified website. The applicant may be requested to provide details that include the following:

- The identity and address of the applicant,
- The staff responsible for carrying out the proposed activities involving the genetically modified organism (GMO),
- The type of licence application applied for,
- The proposed use of the GMO,
- The description of the GMO which is the subject of the application,
- The facility to be used or the location of where the activity with the GMO is proposed to occur,
- Proposed controls to safely manage the activity with the GMO,
- The origin of the genetic material introduced into the organism,

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- Any previous use or release of the GMO in the Caribbean region or other country,
- Any risk assessment or approval of the GMO previously granted in the Caribbean region or other country.

The applicant must also certify or provide a declaration that the information provided is accurate, and not false or misleading.

The application form can also be designed to allow for other specific information to be provided. However, the electronic facility must be designed to allow for the lodgement of a significant amount of information on the electronic application form and must have the capacity to store large amounts of information. The electronic system must also be designed in such a way as to ensure the security and integrity of the system.

Information documents such as risk assessment documents, scientific and technical descriptions of the GMO, a description of the technical methodology used to produce the GMO, and associated risk management plan will need to be uploaded with the application form. The NCA must specify the format and form of the document, including requirements for table of contents and pagination. This is important as the electronic facility must be able to read, copy, download and print the document.

On commencing the application process, the system must provide the applicant with a reference number. This reference number will be referred to when paying the application fee and in providing additional information to the NCA during the application process.

During the application process, the applicant will be required to nominate which information is to be considered confidential and the reasons why. A decision will therefore be required as to whether such a claim is justified, and if so, protection granted accordingly.

The electronic lodgement facility must have the capacity to allocate specific "containers"/areas for each application and to be able to disaggregate confidential information from the overall information provided with the application.

In addition, the electronic file must be fully accessible to relevant officers of the NCA, in particular, for the purposes of assessing whether the application process has met all of the jurisdictional pre-conditions under the legislation, and therefore considered as an effective or complete application. This package is then forwarded to the relevant technical advisory committee or authorised officers for further processing and consideration.

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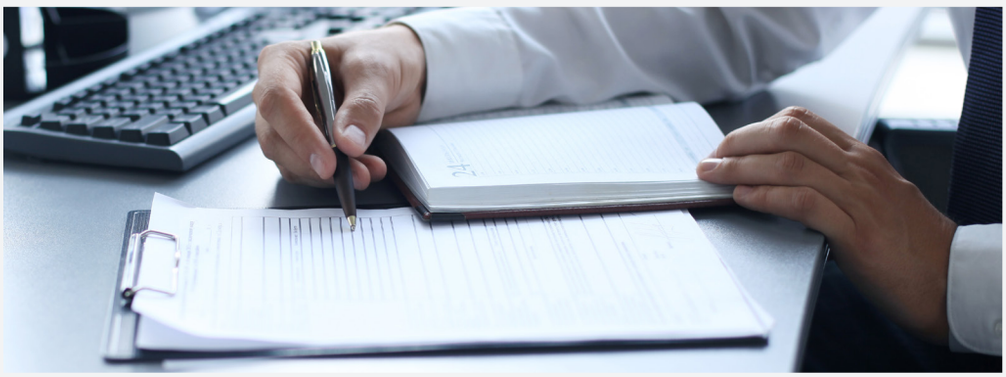
1.1.B. PART ELECTRONIC AND PART HARD COPY LODGEMENT

This system may allow for application forms to be accessible from a nominated website, filled in by the applicant to provide general details about the applicant, and other details as described in section 1(a). The completed application form can be submitted electronically and the applicant provided with a reference number generated electronically once the application is accepted.

The other documents such as a detailed description of the GMO, the characteristic of the GMO and parent organism, the technical methodology, risk assessment document and risk management plan can be lodged as hard copies, with a relevant table of contents and in specified folders with relevant identification. The same reference number must be provided in each of these submissions. As for the full electronic lodgement, the applicant must indicate which of the provided information is to be confidential and the reasons why.

A specified officer will then be responsible for checking the completeness of the information in the application and then forwarding the relevant sections to the technical advisory committee or authorised officers for processing and determination. If this hybrid system is to be used, then a good filing mechanism and robust storage system must be established.



1.1.C. FULL HARD COPY LODGEMENT

This system requires the applicant to provide all information in hard copies. There must be guidance documents to describe how the information is to be presented and how the information is to be grouped/classified. This would also require establishing a robust filing system and storage system.

As above, a specified officer will then be responsible for checking the completeness of the information in the application and then forwarding the relevant sections to the technical advisory committee or authorised officers for processing and determination.

1.2. PAYMENT OF PRESCRIBED FEES

The NCA must specify the process for the payment of prescribed fees. The fees can be paid through electronic transfer to a nominated government account, payment to a credit card account held by the Authority, by cash or by cheque.

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1.3. PUBLIC NOTIFICATION OF RECEIPT OF APPLICATION

Some biosafety legislation requires the publication of a notice indicating the receipt of each application, along with a description of the GMO and its intended use, in the government Gazette and local newspapers for a specified period. This may be for the purpose of inviting public comments or merely for notification purposes.

Legislation requiring that public comments be taken into consideration in decision-making should also outline the necessary requirements and procedures for handling such comments. For those electronic facilities allowing the collection of public comments, a mechanism of assigning them to the correct application (via the allocated reference number) should be incorporated, along with additional security and privacy mechanisms to protect personal and/or confidential information. If the application process is not completely electronic, an assigned officer must ensure that all public comments received are identified, summarised and all documents filed with the correct application.

1.4. SCREENING OF APPLICATION FOR COMPLETENESS - IS IT AN EFFECTIVE OR VALID APPLICATION?

On receipt of the application, an authorised officer (e.g. the Registrar) or the Secretariat to a Committee (e.g. Scientific Advisory Committee) must assess the application for compliance with the legislative requirements (usually referred to as an "assessment for completeness").

Where the application is not complete the relevant authorised officer or Committee Secretariat may request additional information. Again it is important that the request and response to that request (including the details of the request such as the date that the request was sent, the date of receipt of the response and content of the response) are recorded and filed with the relevant application.

When an application is incomplete (taking into consideration the legal requirements) and no response is provided by the applicant within the agreed period, then the application is considered to be ineffective or an invalid application. It would be prudent for the legislation to specify clear pre-condition requirements that the application must meet prior to further processing under the legislation.

Where the application is found to be complete, the whole package of information that is relevant to the particular application is provided to the decision-maker or the technical committee assisting the decision-maker. The applicant needs to be notified that the application is under consideration.

1.5. CONSIDERATION OF THE APPLICATION BY THE NATIONAL COMPETENT AUTHORITY

The legislation may provide that the NCA refer the application to a Technical Advisory Committee or an Advisory Council for consideration. In some Biosafety legislation, the Authority may only request the Committee or Council to review the risk assessment documents as lodged or to undertake a risk assessment process consistent with Annex III of the Cartagena Protocol on Biosafety. All other

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information or documents are assessed by the NCA in making its final decision taking into consideration the criteria set out in the legislation.

1.6. TECHNICAL OR SCIENTIFIC ADVISORY COMMITTEE

The Technical or Advisory Committees established under the Biosafety legislation provide scientific and other technical advice to the NCA. They usually carry out the risk assessment or review risk assessment documents lodged by the applicant. Some examples of Biosafety legislation allow the Committee to request additional information from the applicant or request officers from other government agencies or Ministries to assist in the technical assessment of relevant documents. In addition, some Biosafety legislation also allows the Committee to seek advice from other experts in the field or to form sub-committees.

As Committee members usually have full time employment, it would be useful that a Secretariat be formed or officers of the NCA provide Secretariat services such as recording of deliberations, and final recommendations. The Secretariat must also ensure that the Committee is given the complete application package. Further, the Secretariat must ensure that confidential information is handled appropriately by the Committee and that the information is appropriately identified and not inadvertently released. Moreover, it would also be of great assistance if significant issues are identified and summarised in a brief to the Committee by the Secretariat. This would save time and make deliberations more efficient.

Subject to the requirements of the Biosafety legislation, the Committee or Council may be required to recommend, taking into consideration the criteria and procedures set out in the Biosafety legislation, that a licence or permit be granted, be refused, or be granted subject to conditions.

1.7. OTHER MATTERS

Some Biosafety legislation may require that auditors or other authorised officers inspect facilities and planting areas to be used in the release of GMOs to ensure that they comply with specified requirements and that the activity can be conducted in a manner consistent with specified requirements under the Biosafety legislation. These officers may be required to provide reports to the Technical or Advisory Committee or the NCA.

1.8. DECISION BY THE NATIONAL COMPETENT AUTHORITY

Subject to the requirements and criteria set out in the Biosafety legislation, the NCA may decide to: grant approval in the form or a licence or a permit; refuse to grant approval, or; grant approval subject to conditions.

The NCA must be provided with all of the information lodged with the application, additional information provided by the applicant, copies of public comments if they are to be taken into consideration, and the recommendations or advice by the Technical or Advisory Committee and the reasons for such recommendations. When public comments are to be taken into consideration in the final decision-making, then there is a need to discuss the weight given by the Authority to those comments in coming to the decision. The making of administrative decisions

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under the Biosafety legislation and the provision of a statement of reasons for the decision are discussed in Chapter 2.

Where a licence or permit is granted, the NCA must notify the applicant of the decision to grant the licence and allocate the licence-holder with a licence number. Where the licence or permit is subject to conditions, then the letter of approval must clearly specify the conditions imposed on the licence or permit. The permit or licence must specify the commencement date of the licence or permit, the validity or period covered by the permit or licence, the approved planting areas or facilities, and other requirements set out in the Biosafety legislation applying to that licence or permit. Some legislation provides that the licence or permit issued must be in a prescribed form. Where the licence or permit also grants approval for importation, then a certificate may be provided to the licensee or permit-holder for submission to the Inspector-General or corresponding officer of Customs as a proof that importation or exportation of the GMO has been approved.

A decision refusing the application must provide a statement of reasons (although some legislation is silent on this requirement), and information regarding the appeal or review rights available to the applicant.

1.9. ENTRY OF THE DETAILS OF THE LICENCE IN THE REGISTER

The NCA may establish and maintain a Register of licences and permits, including details of those licences or permits such as location and conditions attached to those licences and permits. The public may be able to access the Register, including details of those licences and permits.

However, the NCA must ensure that the Register is accessible, secure, and has accurate records. In addition, if the Authority has a Register that includes both publicly-available information and information only accessible by the Authority, then the integrity and security of such restricted access information must be preserved.

1.10. APPLICATION FOR REVIEW OR APPEAL WHERE APPLICATION IS REFUSED OR A LICENCE OR PERMIT NOT GRANTED

The applicant may seek a review or appeal against the decision to refuse the application or not to grant a licence or permit. This may be through a merits review tribunal or judicial review. The merits review tribunal may decide to grant the applicant a licence or a permit, or confirm the decision of the NCA. On the other hand, a court may decide that the decision is unlawful and remit the decision to the NCA, ordering the Authority to remake the decision consistent with the legal requirements under the Act and the common law. Alternatively, the court may decide that the decision is lawful and affirm the decision.

If the applicant is successful in relation to the merits review by a Tribunal, then subsections 8 and 9 apply. Similarly, if the remaking of the decision by the NCA results in the granting of a licence or a permit, then subsections 8 and 9 again apply.

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CHAPTER 2: GOOD DECISION-MAKING UNDER BIOSAFETY LEGISLATION

The National Competent Authority will be making decisions under the biosafety legislation. These decisions will affect individuals, the public, companies, other government offices and other organisations.

Good administrative decision making results in gaining the trust and confidence of the public and those entities and persons that are entities and persons that are regulated. Athough individuals and other regulated entities are not prevented from challenging any decision under the Biosafety legislation, good administative decision making ensures that the decision made by the NCA can be successfully defended when challenged in court or merits review Tribunals. It also provides implementation of biosafety policies reflected in the biosafety legislation. Certainty in decision making allows the Authority to focus on its powers and functions, and allocate most of its resources on its activities instead of allocating resources to defend its decisions in courts and tribunals.

The power granted to the NCA relate to important matters of public concern or matters that have a significant effect upon the lives of individual members of the community, the business community, biodiversity and the environment. The NCA is given broad discretion under the Biosafety legislation on how a decision is to be made, but cognisant that the decision must be made consistent with the requirements and legal criteria set out under the biosafety legislation.

The role of the decision maker is to assess the evidence that is available and decide the merits of how the relevant discretion should be exercised. The role of the courts is to ensure that a decision is made within the scope of the decision maker's power: they generally do not look at the findings made by the decision maker but will ensure that the proper processes have been followed in reaching those findings.

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2.1. PRE-CONDITIONS TO THE MAKING OF THE DECISION

Coming to a decision requires the decision-maker, in this case, the NCA, to be satisfied with any preliminary matters or pre-existing facts. These preliminary requirements may include:

(a) That a valid application has been made in the prescribed form,
(b) That prescribed fees have been paid,
(c) Relevant declaration and certification to be attached to the application, and
(d) Relevant information provided with the application, such as the information in relation to the GMO, risk assessment report and risk management plans.

Without a valid application or pre-condition requirements being met, the decision-maker has no jurisdiction or authority to proceed in exercising the relevant power, such as proceeding to make a decision.

Therefore, screening must be made on lodged submissions as to whether they are valid and/or effective applications, before passing on to a technical committee for advice or to the decision-maker to be processed. It would also be prudent to create files containing checklists that indicate: whether pre-conditions have been met; the information provided with the application or on subsequent requests; relevant steps required for decision-making; the dates when those steps have been carried out; when the final decision was made, including the reasons for the decision and names of officers and decision-maker involved in the decision-making.

2.2. AUTHORITY TO EXERCISE THE POWER

Also relevant to the question of authority to make a decision is whether a person or the NCA, or the relevant Minister is authorised to do so:

(a) By the Biosafety legislation itself, that is, the decision-maker is the person identified in the legislation as the repository of the power,
(b) Under a delegation from the person identified in the legislation as the repository of the power,
(c) On the basis of acting as an agent or an authorised person by the person who is the repository of the power or a delegated person.

In some instances, where the NCA is composed of individual officers of different Ministries, or a Board composed of individuals, the decision may be signed by, or be delegated to, the CEO or Chair of such Board. However, it is important that the legislation requirements are reviewed and considered as to whether a delegation or authorisation is specified, and who can delegate and be delegated by the specified decision-maker under the legislation. A person who makes a decision without the appropriate authority or delegation will result in the decision being invalid and of no effect.

2.3. MANDATORY REQUIREMENTS THAT NEED TO BE SATISFIED

The Biosafety legislation may require that, prior to making a decision, the NCA consult the public and specified stakeholders about their views on the particular application. If such consultations are mandatory requirements under the biosafety legislation, the making of a decision without the required consultation will be invalid and of no effect.

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2.4. NATURAL JUSTICE OR PROCEDURAL FAIRNESS

Natural justice or procedural fairness may be part of the common law of the national jurisdiction. A statute such as the Biosafety legislation may specify that before a final decision is made, the applicant is provided with an opportunity to address evidence presented before the decision-maker that is relevant, credible and significant to the decision to be made. Even if not specified in the legislation, it would be good practice to apply the rules of natural justice to ensure that robust decisions are made and to minimise, if possible, court or tribunal reviews of administrative decisions made under the legislation.

The second aspect of the rules of natural justice is "the bias rule". The bias rule requires a decision-maker to have no interest in the matter before them, and for them to be unprejudiced in their approach to the matter. Even though a person may hold the necessary authority to make a decision, if there is a reason that the decision-maker may be biased or may be perceived to be biased in the making of the decision, it may be preferable for the decision to be made by someone else who holds the necessary authority. However, where the decision-maker is a Board or Council, the Board or Council must make sure that members who have a conflict of interest in the decision-making declare those interests and not be further involved. If possible, any issues giving rise to a question of bias must be addressed early and before the final decision-making.

2.5. FACT FINDING AND REVIEW/CONSIDERATION OF EVIDENCE BEFORE THE DECISION-MAKER

2.5.A. MATERIAL FACTS

A statutory power to make a decision usually depends on the existence of certain "material facts". It is necessary to analyse the legislation in order to determine what facts are material to the decision to be made. The legislation itself often sets out factual matters that must be considered. Otherwise, the material facts are implied by considering the scope and purpose of the legislation. For example, the material fact could be adverse effects on the conservation and sustainable use of biological diversity, as well as risks to human health. The NCA guidelines, policies and manuals may provide guidance on how such material facts are to be established for the particular type of decision. As well as material facts, there are also "relevant facts" - facts affecting the assessment of the probability that

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a material fact exists. For example, the Biosafety legislation may require that the risks associated with the release of the GMO to the environment are minimal or negligible or that they can be mitigated by the imposition of conditions on the licence or permit. To make a finding about the material fact, the decision-maker needs to make findings about relevant facts such as consequences and nature of the event that would be considered as minimal, negligible or possible mitigating actions.

2.5.B. EVIDENCE

Evidence is information, documents, and other material that can be used to demonstrate the existence of a fact or the truth of something. Evidence is amenable to testing and evaluation, and can be accepted and rejected when it comes to making findings. In making findings in relation to the facts of issue, they must be based on evidence that is relevant and logically capable of supporting findings. They must not be based on guesswork, preconceptions, suspicions or questionable assumptions.

The type of evidence required to come to a decision may vary, depending on the nature of the required statutory decision. However, the decision that a decision-maker comes to will only be lawful if the evidence reasonably satisfies the requirements or preconditions prescribed by the legislation. If the decision-maker is not satisfied that those factors have been fulfilled, then he/she cannot exercise the power to make the decision.

Evidence must be analysed closely and evaluated to determine whether there is any conflict in relation to a material fact. Note that not all evidence is of equal weight. Assessment and weighing of evidence involves the application of logic, common sense and experience. While administrative law principles mean that all relevant information must be taken into account by the decision-maker, the weight given to any particular piece of information is up to the decision-maker to adjudge.

Note that the weighing of evidence is not a mechanical or mathematical process. Provided that each piece of available evidence has been assessed individually, it is open to the decision-maker to take account of the cumulative weight of evidence for or against the establishment of a fact. Robust scientific evidence, or expert evidence from an international and well-known expert may be given more weight compared to a non-scientific paper or evidence from a lesser-known expert.

2.5.C. WEIGHING OF EVIDENCE

When assessing facts, evidence or other information, it is useful to consider the following:

(a) The relevance of the evidence to the decision to be made,
(b) The source of the evidence - is it from a reliable source?
(c) The credibility of the person providing the information,
(d) The sufficiency of the evidence - is there a need for any further information to satisfy the decision-maker that the legislative requirements have been met;

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(e)The importance of the evidence or other information necessary for the decision to be made.

2.5.D. OFFICERS CAN PROVIDE ASSISTANCE TO THE DECISION-MAKER, INCLUDING VIA BRIEFINGS

The Minister, Parliamentary Secretary, CEO of a Board, or Chair of a Committee is usually involved in a significant number of activities of national interest and if expected to be involved in every decision-making under national legislation, then the whole machinery of government may come to a standstill. In order to address this, Australian courts held that a decision-maker is not required to undertake all of the steps in the decision-making process personally and can rely upon the support of other officers or individuals in collecting, organising and summarising relevant materials.[1]

Decision-making in government usually involves a number of different officers. An officer other than the decision-maker may undertake many of the preliminary tasks that involve receiving an application, assessing its validity, gathering additional evidence and reviewing the relevance of the evidence. The assistance provided by other officers may include briefing the decision-maker in relation to relevant issues, weight of evidence and outcomes from the review of gathered evidence.

A briefing paper or summary paper will generally state the relevant issues for consideration under the legislation and distil the evidence that has been gathered in relation to those issues to be addressed by the decision-maker. The briefing paper must provide an accurate summary of the substance of the documents. It would be necessary to provide decision-makers with copies of any relevant documents, including submissions and representations received from the applicant and other persons. A briefing paper may also make recommendations as to how the relevant power might be exercised, or alternatively, present a neutral evaluation of the relevant issues and available evidence. If the briefing paper recommends that a power be exercised a particular way, the decision-maker must not adopt the recommendation without turning her/his mind to the decision, and must be prepared to depart from the recommendations if she/he is not satisfied that the recommended decision is the correct or preferable decision.

Because the decision-maker must make up her/his own mind, and the decision is ultimately her/his responsibility, an error in the briefing paper or summary may cause the decision made to be affected by the error. If such is the case, the decision will be invalid. It is therefore important that the briefing be accurate and objective.

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[1] *Minister for Aboriginal Affairs v Peko-Wallsend Limited* (1986) 162 CLR 24 at 30; *FAI Limited v Winneke* (1982) 151 CLR 342, at 416; *Norvill v Chapman* (1995) 133 ALR 226.

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2.5.E. DECISION RECORD

Even if there is no obligation to provide reasons for the decision, the decision-maker should make a decision record, in particular, in relation to the assessment of the evidence as discussed above, and place it in the relevant file. The decision record should contain:

- When the application was received,
- Any prescribed period from the legislation in which the final decision must be made,
- What the decision is about, and provide the relevant provision under which the decision is made,
- The identity of the applicant, what type of activity with the GMO the applicant applied for, and when the application was lodged,
- Findings of fact,
- A list of the information, evidence and facts relied upon, including their description, form and source,
- Copies of all evidence, documents, information and representations submitted,
- Weight and significance accorded by the decision-maker on the available evidence,
- The information or evidence that was before the decision-maker,
- The name of the decision-maker,
- The date of the decision.

2.6. PRECAUTIONARY APPROACH CONTAINED IN PRINCIPLE 15 OF THE RIO DECLARATION ON ENVIRONMENT AND DEVELOPMENT

Principle 15 of the Rio Declaration on Environment and Development (Rio Declaration) relevantly provides that:

"In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."

In its preamble, the Cartagena Protocol on Biosafety (the Protocol) reaffirmed the above precautionary approach. Paragraph 6 of Article 10 and paragraph 8 of Article 11 of the Protocol provide that:

".....lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also account risks to human health, shall not prevent the Party from taking a decision as appropriate with regard to the import of that living modified organism intended for a particular purpose set in the application, in order to avoid or minimize such potential."

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Furthermore, Article 15 of the Protocol states that
"risk assessments undertaken pursuant to the Protocol shall be carried out in a scientifically sound manner, in accordance with Annex III to the Protocol and taking into account recognised risk assessment techniques."

It also states that
"the risk assessments shall be based at a minimum, on information provided in accordance with Article 8 and other available scientific evidence in order to identify and evaluate the possible adverse effects of living modified organisms on the conservation and sustainable use of biological diversity, taking also into account risks to human health."

All of these provisions under the Protocol provide support that for those applications where scientific evidence is available to provide full scientific certainty with regard to the risks to the environment and taking into account risks to human health, a decision-maker cannot opt to use the precautionary approach to support its preferred decision. In addition, the Protocol indicates that the risk assessments must be undertaken in a scientifically-sound manner. Significantly, the precautionary approach should only be used where there are threats of serious or irreversible damage and there is lack of full scientific certainty. Use of the precautionary approach contained in Principle 15 of the Rio Declaration to refuse to grant a licence or a permit, in circumstances where the threat is not serious or irreversible, or where there is full scientific certainty supporting the use of a GMO for specified purposes may be considered unlawful and can be successfully challenged in court.

2.7. THE OBLIGATION TO PROVIDE A STATEMENT OF REASONS

The provision of a statement of reasons may be specifically required under the Biosafety legislation. Generally, the statement of reasons in relation to the decision must contain the following:

- The decision,
- The findings on material facts,
- The evidence or other material on which those findings are based,
- The reasons for the decision,
- The name of the decision-maker and source of the power to make the decision,
- The date of the decision,
- The date of effect of the decision,
- Appeal or review rights, if available.

A statement of reason should refer to the provision of the legislation that authorised the decision. It is better to quote rather than summarise the relevant statutory provisions, as well as, the decision reached in relation to those matters. This will avoid legal errors in the application of the provision in question.
The name of the decision-maker should also be made clear, as well as the basis of the person or entity with the legal authority to make a decision.

The findings on material facts are those that support the decision to be made, and the making of the decision or the exercise of the power will depend on the

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existence or non-existence of these facts. Any finding on a fact that relates directly to an applicable criterion for a decision will be a finding on a material fact.

The statement of reasons must refer to the evidence on which each material finding of fact is based and is not sufficient to simply to list all of the documents that were considered in reaching the decision. The statement should refer to the evidence that was considered relevant, credible and significant in relation to each material finding of fact. If there were conflicting evidence, the statement should explain which evidence was preferred and the reasons why.

The statement must also detail all of the steps in the reasoning process that led to the decision. The statement of reasons should enable the applicant or any reader to understand exactly how the decision was reached. In addition, the statement must also go further than merely expressing a conclusion. The statement might relevantly refer to policy statements or guidelines or agency practices.

The statement must also include the date of the decision, the date of effect of the decision and any appeal rights available to the applicant, if the decision is adverse to the applicant's interests.
A good statement of reasons will help avoid unnecessary challenges to decisions and applications for appeals or review. This is because the reasons for the decision will have been clearly articulated in the written statement of reasons, and would enable an accurate assessment of whether a further review of the decision would be justified.

2.8. RECORD-KEEPING

It is good administrative practice to have a record that can form the basis of a statement of reasons, and to make a contemporaneous note of the assessment and weighing of evidence, findings of fact and reasons. In addition, it is also good practice to keep on file all information, documents, and records of oral evidence that were used in decision-making for future references. These records are necessary in case the applicant applies for a review or challenges the decision in a court or tribunal.

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CHAPTER 3: AUDIT AND MONITORING AND OTHER POST-LICENSING ACTIVITIES

Chapter 1 discusses the lodgement of an application, the processing of an application and decision-making. This Chapter discusses what happens after a licence or a permit is granted. Figure 1 below shows the processes and stages involved from the time the application is lodged, to the time a licence or permit is granted, and the requirements with which the licensee or permit-holder is required to comply in order to maintain that licence or permit.

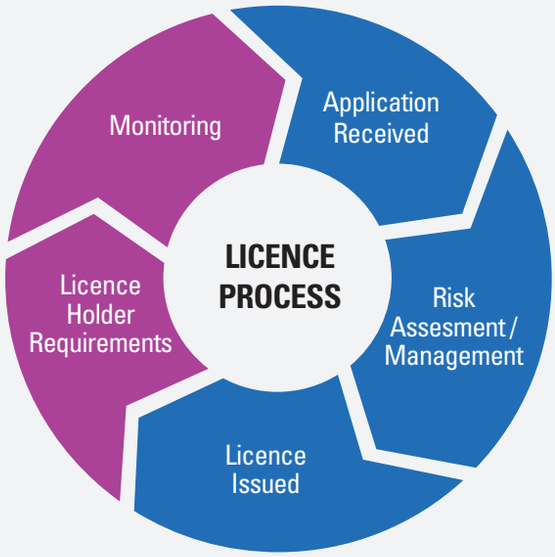

Figure 1. Cyclical stages of the licence process.

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3.1. CONDITIONS WITH WHICH THE LICENSEE OR PERMIT-HOLDER MAY NEED TO COMPLY

The licence or permit granted under the legislation is subject to conditions that need to be continuously complied with by the licensee or permit-holders, including following the conclusion of the licenced activity.

In addition, there are statutory requirements applying to the licence or the permit that must be complied with by the licensee or permit-holder. This includes, for example, the requirement to provide additional information that indicates a risk to the environment or serious adverse effect to human safety after the licence or permit has been granted.
Conditions may be imposed on the licence or permit to allow authorised inspectors to enter the premises of the licensee or permit-holders to monitor compliance with the Act and the Regulations.

The authorised inspector may also inspect, monitor, and audit how conditions on the licence are being implemented by the licence-holder. These conditions may include the following:
(a) The security of the premises,
(b) Agreed disposal mechanisms for the authorised GMOs,
(c) Maintenance of the facilities,
(d) Personnel requirements and qualifications,
(e) Maintenance of the integrity of the trial or activity,
(f) Controls to prevent spread and persistence of the GMO or genetic material,
(g) Compliance with standards, guidelines and policies.

Other monitoring activities could also include monitoring for adverse effects and monitoring to verify or validate processes set out in the risk management plan.

The licences are subject to standard conditions and circumstance specific conditions. Examples of statutory standard conditions and specific conditions are listed in Table 1.

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Table 1. General or statutory conditions of a licence or permit.

General or statutory conditions	Specific details regarding the condition
Monitoring and auditing.	If a person is authorised by a licence to use a GMO, a product of a GMO, or a GMO for feed, food or processing, and a particular condition applies to that particular activity under the licence: ● The licence-holder must allow authorised officers of the NCA, or authorised by the Minister, to enter premises where the activity is occurring to audit or monitor the activity, or the premises in which the regulated activity is being carried out
List of activities that can be carried out under the licence or permit.	The licence does not authorise activities involving the GMO that are otherwise prohibited as a result of the operation of other legislation.
Provision of additional information to the NCA within a specified period, depending on the seriousness of the identified risks to the environment or to public health and safety.	The licence-holder must inform the NCA if they become aware of: ● Additional information as to any identified risks to the health and safety of people, or to the environment associated with the regulated activity, ● Any unintended effects of the regulated activity, ● Any serious adverse effects to people and the environment. These must be reported within 24 hours of their discovery.
To provide additional information if at any time the NCA requests the licensee or permit-holder to collect and provide information about any matter to do with the progress of the regulated activity involving the GMO.	Information such as research, including by way of survey, to verify predictions of the risk assessment, or for any purpose related to risks to public health and the safety of people or to the environment.
Conditions applying to the licensee, contractors, staff and other persons involved in the regulated activities involving the GMO.	Must be a fit and proper person, staff must have relevant educational qualifications, awareness of the conditions of the licence, requirement to carry out monitoring activities, restricted access to premises and security of the premises.

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3.2. INSPECTION AND REVIEW ACTIVITIES

3.2.A. FREQUENCY OF INSPECTIONS

After a licence or permit is granted, specified authorised officers under the legislation should conduct periodic on-site inspection of facilities, planting areas and premises used for GMO-related activities under the licence or permit. The frequency of these inspections may vary depending upon the level of compliance demonstrated at previous inspections and the level of identified risks that the GMO poses to the environment and human beings.

Decisions will need to be made as to when inspections are to be conducted and how frequently. The NCA must take into consideration available human resources in deciding the frequency of inspections or monitoring. There may be regular inspections or reviews that licence-holders are made aware of and notified beforehand. However, unannounced audits or inspections may be conducted, if deemed necessary, to ensure effective compliance.

3.2.B. THE INSPECTION PROCESS

Inspections can be performed by single inspectors or inspection teams. In the case of a team inspection, the team must be led by a Lead Inspector bearing overall responsibility for the inspection.

The Lead Inspector can be supported by appropriately-qualified and experienced inspectors and where required, also by technical specialists acting as technical advisors to the inspectors. Technical specialists bring current specialised knowledge of the activities being inspected and ensure that the inspection provides a relevant and practical review of aspects critical to the regulated activity.

3.2.C. INSPECTION PREPARATION

Inspection preparation involves collection and review of all necessary documents and data relating to the licence, the GMO, and the facility or site being inspected. Preparation for inspection must include the following:

(a) Documents held by the NCA in relation to the licence-holder, the GMO, the facility being inspected, conditions of the licence, authorised activities, and any previous inspections or audit reports and records
(b) Outcomes of any testing, if any, carried out by the NCA or provided to the NCA in relation to the GMO,
(c) Records of regulatory issues or previous non-compliance,
(d) An inspection and monitoring plan and an inspection attendance sheet. The inspection and monitoring plan must be provided to the licence-holder at the start of the inspection and monitoring period.

3.3. CONDUCT OF INSPECTION

3.3.A. INTRODUCTION AND PRE-INSPECTION MEETING

The inspector or inspection team may be accompanied by guides or observers. On arrival at the premises, planting area or facility, the Lead Inspector chairs an opening meeting with the licensee or permit-holder's management team.

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At this meeting:
(a) Members of the inspection team are introduced, including an outline of their roles,
(b) The scope and objectives of the inspection and monitoring are confirmed,
(c) The possible length of the inspection and monitoring period,
(d) The inspection plan and any criteria to be applied during the inspection and monitoring are discussed and confirmed,
(e) A tentative time and date for the closing meeting and any interim meetings of the inspection team and the licence-holder's management are established,
(f) Members of the management team to accompany and provide relevant information are identified, and
(g) The methods and procedures to be used to conduct the inspection are outlined.

The licence-holder must be advised that they will be given sufficient opportunities to respond to potential issues identified.

3.3.B. METHODS OF COLLECTION OF INFORMATION AND EVIDENCE

Inspection evidence is evaluated against the inspection criteria to generate inspection findings. The inspection findings can indicate either compliance or non-compliance with the applicable regulatory requirements and conditions attached to the licence.
Methods to collect information and evidence include:
(a) Interviews of personnel at all levels (if necessary) within the licence-holder organisation,
(b) Observation of activities, including reviewing and evaluating systems and procedures for compliance effectiveness,
(c) Inspection of facilities and planting areas, and recording of compliance/non-compliance against specified conditions,
(d) Review of documents on file,
(e) Taking photocopies of documents or photographs.

3.3.C. CLOSING MEETING

A closing meeting should be held at the end of each inspection to present the inspection findings and conclusions to the licence-holder. All discussed items must be recorded and a copy of the record provided to the attendees of the closing meeting. The Lead Inspector must provide an overview of the inspection and its outcome, and detail any issues identified. Findings of special significance are to be emphasised, particularly those regarded as issues that could result in suspension or revocation of the licence or permit.

3.4. INSPECTION REPORTS

3.4.A. FINALISING THE INSPECTION REPORT

Following the on-site inspections, the inspection team should prepare a report which includes the inspection findings and a summary of the overall compliance of the licence-holder's operations against the requirements under the Act and the Regulations. The inspection report must be signed by the Lead inspector.

3.4.B. THE INSPECTION REPORT

Inspection reports need to be peer-reviewed by a management team of authorised

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auditors of the NCA to ensure consistency, prior to being issued to the licence-holder. During this review, any inspection findings classified as critical, major or other deficiencies and non-conformance must be confirmed in the report.

This report must be provided to the licence-holder within a reasonable time after the inspection. If an agreement or the legislation provides such a period, then the report must be provided within that period.

3.4.C. REVIEW PANEL

A Review Panel may be convened in order to ensure consistency in classifying deficiencies and non-conformity and in ensuing regulatory action, in particular, where the provisional compliance rating is unacceptable. This Review Panel has the task to review the inspection, undertake a risk assessment and prepare recommendations to the NCA for regulatory actions, as applicable.

3.5. INSPECTION CLOSE-OUT

3.5.A. RESPONSE TO THE DEFICIENCIES AND NON-CONFORMITIES BY THE LICENCE-HOLDER

The licence-holder is required to respond to any deficiencies/non-conformities identified in the Inspection Report, and such a response is called a "close-out". The purpose of the close-out process is to ensure that the licence-holder commits to perform appropriate corrective and preventative actions for each identified deficiency or non-conformity within an acceptable period. The licence-holder may also respond to any statements in the report, or comment if they consider a statement to be inaccurate.

Note however, that a subsequent inspection may need to be made to accurately assess whether corrections or corrective actions have actually been implemented by the licence-holder.

3.5.B. CLOSE-OUT LETTER

After all corrections and corrective actions have been reviewed and accepted, the inspection is closed-out by issuing a close-out letter. This letter will refer to the correspondences regarding the required corrections and corrective actions, indicated the final compliance rating assigned to the licence holder as a conclusion to the inspection and refers to any proposed actions in relation to the licence or amendment to conditions imposed on the licence or permit.

3.5.C. INSPECTION DECISIONS

Administrative decisions on the licence or permit, if any, are prepared after the close-out of the inspection. The legal basis of the decision must be included in the close-out letter.

3.6. ENFORCEMENT ACTIONS

Biosafety legislation usually includes provisions for regulatory action in the case where an inspection for the purpose of audit or monitoring demonstrates non-compliance. A licence may be suspended, revoked, varied or new conditions may be imposed. In serious and critical deficiencies, court action may also be commenced, such as prosecution or other appropriate court actions. In deciding the appropriate enforcement action, refer to Chapter 4.

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CHAPTER 4: ENFORCEMENT AND SANCTIONS FRAMEWORK FOR THE IMPLEMENTATION OF THE BIOSAFETY LEGISLATION

A regulatory framework for biosafety-related activities provides rules when there is an expectation of compliance by those being regulated. To promote compliance and deter non-compliance, there must be effective sanctions against non compliance, with a gradation of the level of sanctions addressing non compliance with increasing degrees of seriousness. However, as regulators have limited resources (both human and financial), there is a need to strike a balance between persuasive regulation and egregious sanctions to serious violators.

4.1. INTRODUCTION

This Chapter provides an enforcement framework that the NCA can use when dealing with possible contraventions under the National Biosafety legislation, in accordance with the administrative, criminal and civil sanctions available under that legislation.

Sanctions available under national biosafety legislation usually include:

(a) Administrative sanctions

- Suspension, or revocation of a licence or permit,
- Imposition of new conditions,
- Variation of a licence or permit,
- Imposition of restrictions or prohibition of some, or all, activities authorised by the licence, and
- Orders requesting licensee or permit-holders to cease prohibited activities.

(b) Court-based sanctions

- Criminal sanctions – monetary fines or imprisonment or both,
- Civil sanctions – payment of monetary fines or compensation,
- Injunctions – to stop the prohibited activity.

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However, there are other effective persuasive measures that can be put in place before the Regulator (the NCA) decides to impose administrative or court-based sanctions.

4.2. WHAT IS THE OBJECTIVE OF AN ENFORCEMENT AND COMPLIANCE FRAMEWORK?

A compliance and enforcement framework must:

(a) Achieve the objectives of the national regulatory framework on biosafety for GMOs,

(b) Effectively detect, prevent, if not stop, and manage contraventions of the biosafety legislation and related risks to human health, human safety and the environment,

(c) Maintain compliance with the legislative requirements

- through ongoing assessment of the compliance performance of regulated entities,
- applying a consistent regulatory approach which builds effective compliance performance capacity by regulated parties

(d) where possible, obtain or implement remedies that will undo the harm caused by the contravening conduct,

(e) allow for the imposition of appropriate sanctions in specified circumstances to effectively deter future contraventions.

4.3.PRIORITISATION OF INVESTIGATIONS, AND WHEN ACTIONS NEED TO BE TAKEN

The NCA must exercise its discretion to direct resources to the investigation and resolution of matters that provide the greatest overall benefit for the environment and public health.

4.4. ADMINISTRATIVE VS COURT-BASED SANCTIONS

4.4.A. ADMINISTRATIVE SANCTIONS

Administrative sanctions may be the best effective option in some circumstances to stop the prohibited activity in question, and when the actions associated with the sanction are within the control of the Regulator. They are essentially decisions made by the Regulator against the licensee or permit-holder. Administrative sanctions cannot be made against violators who are not directly regulated by the Regulator e.g. those persons who do not have a licence or permit. In such a case, a court-based sanction may be the only sanction available.

When to impose administrative sanctions?

- When there is evidence of non-compliance with the regulatory requirements,
- When there is evidence of a breach of conditions or regulatory requirements,
- When there is evidence that information provided in support of the application was false or misleading, or provided certifications are incorrect,
- On the basis of evidence before the decision-maker, it appears to the decision-maker that failure to revoke the approval would create an imminent risk of death, serious illness or serious injury, or serious damage to the environment.

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In relation to evidence, strict rules of evidence do not apply. The evidence can be based on information provided by the licence-holder, evidence collected by the agency during monitoring or audit activities, and adverse event reporting and information provided by third parties.

4.4.B. COURT-BASED SANCTIONS

4.4.B.I. CRIMINAL SANCTIONS

Offence provisions are generally characterised by the following:

- Elements of the offence – physical elements *(actus reus)*, mental elements *(mens rea)* unless the offence is one of strict or absolute liability,
- Defences, if any,
- Exemptions,
- Level of penalty or period of imprisonment or both.

In relation to offences, in general:

- The prosecution bears a legal burden of proving every element of an offence,
- The prosecution bears a legal burden of disproving any matter where the defendant has discharged an evidential burden,
- The prosecution must establish the existence of all physical and mental elements "beyond reasonable doubt".

The defendant must raise a reasonable possibility that the defence applies, which the prosecution must then disprove beyond reasonable doubt, otherwise the accused will be acquitted. In addition, a person will not be criminally responsible, due to, for example, incapacity by age, duress, mental impairment, etc.

Before making a decision to prosecute, the agency must consider whether the evidence it has collected can establish the existence of all physical and mental elements beyond reasonable doubt and that there are no defences available to the defendant for it to be acquitted of the offence.

The collection of relevant evidence may take a reasonable amount of time and resources. The prosecution proceedings may also not occur promptly and will be subject to court schedules. The cost of litigation for complex court may be significant.

4.4.B.II. CIVIL PROCEEDINGS

Commencement of proceedings seeking civil sanctions such as injunctions, civil penalties and torts will be dependent on the relevant common law and national court rules.

4.5. OTHER ENFORCEMENT TOOLS

4.5.A. EDUCATION, OUTREACH ADVICE AND PERSUASION

It is advised that the NCA consider the comprehensive use of educational campaigns to provide information and advice to consumers and businesses, and to use persuasion to encourage compliance with the legislation. Prevention

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of a breach of the legislation is preferable to taking action after a breach has occurred. The NCA must also seek to ensure that the public and businesses are aware of their rights and responsibilities under the legislation, through clear and targeted communications.

To do this, measures such as targeted communication and education activities, engaging with the regulated community at the earliest possible stage, and providing timely information and advice is more appropriate. Educational awareness strategies should primarily be used to address activities that have not yet occurred. Outreach consists of targeted and strategic engagement with stakeholder groups to raise awareness and provide information on how to comply with the statutory requirements.

These activities help to raise awareness of the benefits of complying with the legislation, remove barriers to compliance, overcome factors that encourage non-compliance (such as lack of support for, or misunderstanding of the objects of the legislation) and reduce the risk that people will inadvertently take an action that breaches the legislation.

4.5.B. VOLUNTARY INDUSTRY SELF-REGULATION CODES AND SCHEMES

This may include sector-wide initiatives and are generally supportive of the needs of the industry. These schemes may also result in gaining public confidence and trust in the industry. For example, the Australian seed industry has put in place self-regulatory arrangements to ensure that non-GM seeds imported into Australia are not contaminated by GM seeds.

4.6. WHAT IS THE MOST APPROPRIATE ENFORCEMENT RESPONSE OR SANCTION THAT SHOULD BE IMPOSED BY THE NATIONAL COMPETENT AUTHORITY?

To achieve compliance and enforcement objectives, a range of flexible and targeted measures to promote regulation, in addition to sanctions, must be put in place.

A model that may be useful is the Pyramid of Sanctions (Figure 2) developed by John Braithwaite who first argued that compliance is most likely when an agency displays and employs an explicit enforcement pyramid. At the base of the Pyramid of sanctions is the restorative, dialogue for securing compliance with a just law. As one moves up the Pyramid, increasingly demanding interventions are proposed. This shows escalating punitive approaches when dialogue with those being regulated fails.

The regulatory actions involve persuasion as the first attempt to coax compliance, and if unsuccessful, then warning letters or proposals to carry out regulatory sanction, and if they fail:

- Civil penalty,
- Criminal prosecution,
- Shutdown or temporary suspension of licence to operate, and lastly,
- Permanent revocation of the approval of the licence.

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Compliance measures such as communication and educational activities, timely provision of information and advice, persuasion, cooperative assistance and collaboration are recommended to encourage stakeholders to abide by the regulatory requirements.

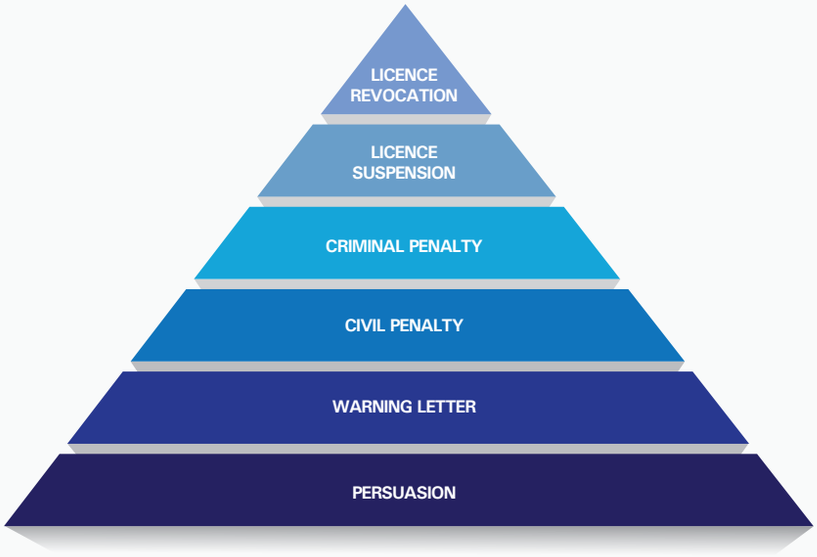

Figure 2. Pyramid of Sanctions (Braithwaite, 1985)

4.7. PRINCIPLES AND APPROACHES IN RELATION TO THE NCA'S ENFORCEMENT RESPONSE

The NCA's enforcement response must be proportionate to the conduct and resulting harm, and the implementation must be governed by the following guiding principles:

(a) Transparency – operates within rigorous corporate governance processes and is able to be reviewed by a range of agencies, including the courts,

(b) Lawful, and within the NCA's power and function,

(c) Confidentiality – investigations are conducted confidentially. No disclosure should be made that may prejudice a person's right to a fair hearing or legal process, impinge upon the privacy or safety of others involved in the investigation or prejudice any past or future action of the authority,

(d) Timeliness – investigative process and resolution of enforcement matters should be conducted as efficiently as possible to avoid costly delays and business uncertainty,

(e) Consistency – the NCA must not make *ad hoc* decisions, and must set its focus clearly to give business certainty concerning its actions,

(f) Fair and impartial – the NCA must seek to strike a balance between voluntary compliance and enforcement while responding to competing interests,

(g) Effective, proportionate and risk-based.

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Note, however that the aim of the regulatory agency to implement the regulatory framework is to establish trust and cooperation with the person/organisation it regulates. Cooperation should be preferred, if possible, to coercion. Prosecution, if possible due to the resources required, should be the last resort and will need to establish the mental elements of the offence (such as intention, recklessness, negligence, etc.).

4.8. WHEN SHOULD A PROSECUTION BE CONSIDERED AND CRIMINAL SANCTIONS CHOSEN AS THE MOST APPROPRIATE RESPONSE?

The NCA may decide to commence prosecution in the following circumstances:

(a) Where the action produced real or potential harm to the community, including the environment, or well-being of individuals within the community,

(b) When the government is committed to such action,

(c) When the public expects that the offence will be dealt with by public court prosecution,

(d) Where the offence is of such a nature or magnitude that it is important to deter potential offenders and prosecution is likely to act as an effective deterrent,

(e) When the defendant has been the subject of previous compliance and enforcement measures,

(f) Where the defendant showed complete disregard of the requirements, and previous administrative or civil responses to contraventions by the defendant of the regulatory requirements have not resulted in compliance.

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END NOTES

Breach of a license condition. A breach of a license condition which has been proven either in court or by way of admission following investigation.

Expert. Advisers appointed by the Regulatory Authority to provide expert advice in order to assist the Authority in the performance of its functions (expert advisers are not committee members).

GMO.Genetically modified organism.

Non-compliance. An inconsistency between an event or state of affairs and the requirements imposed by license accreditation or certification conditions, or any of the requirements of the legislation or regulations.

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APPENDIX 1. CHECKLIST FOR PROCESSING APPLICATIONS

(EXAMPLE DEVELOPED BY PARTICIPANTS DURING A PROJECT WORKSHOP)

Application for field trial under section 25 of the Biosafety Act 2016 Reference number xx

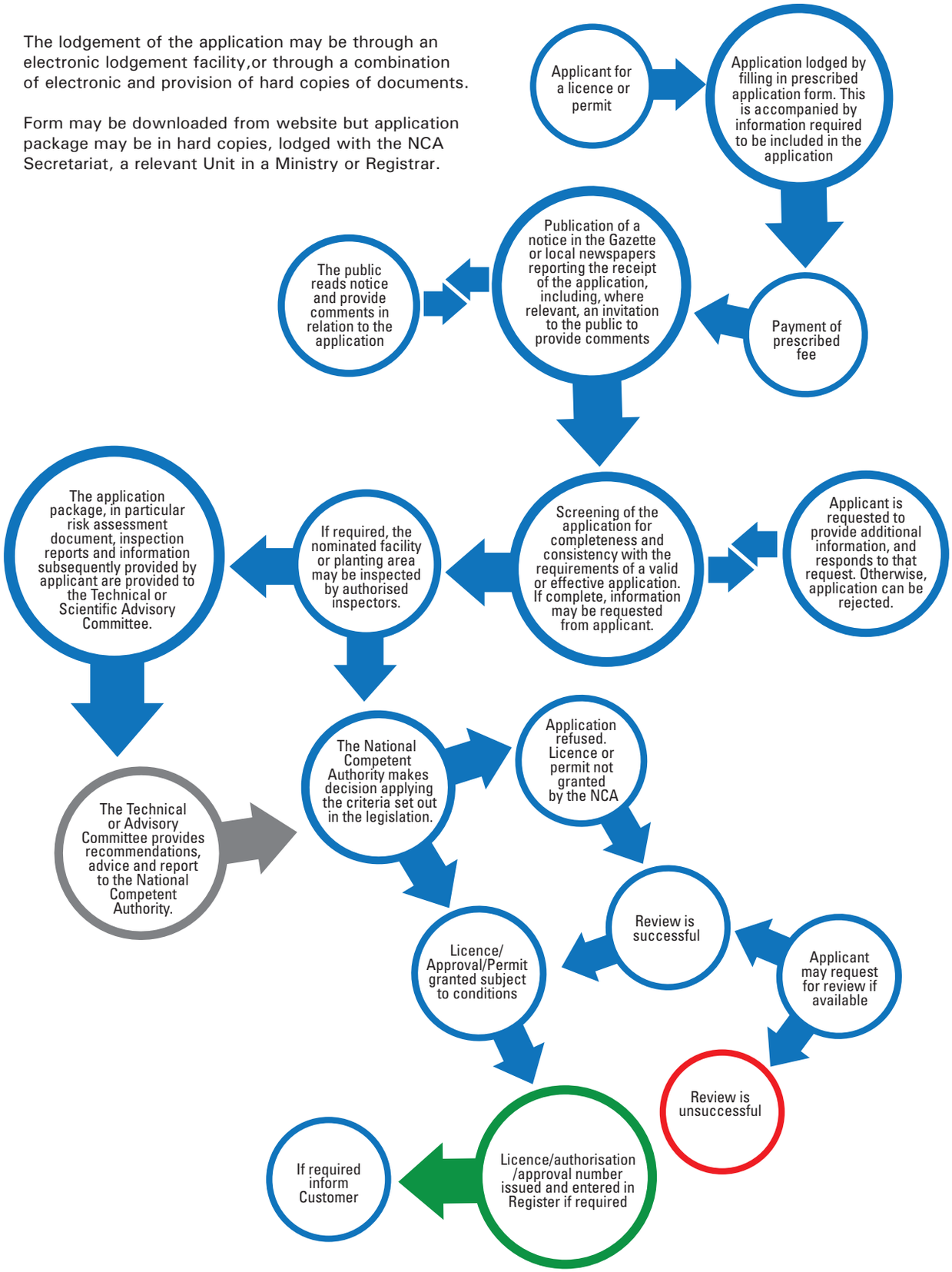
Steps/Process	**Comment**	**Name of recording officer and date**
Application received on xx date	Application contains the following information and application form appropriately filled in	
Application fee	Paid on xx date	
Application screened for completeness	Application complete or not complete If not complete, missing elements listed	
Additional request for information	What type of information requested, when request was sent, and when response was due	
Publication of application in Gazette or local newspaper, invitation for public comments	Date and period of publication, name of local newspaper	
Public comments received	Number of public submissions, names of people who provided submissions and comments, summary of comments	
Inspection of facility or planting area, if required	Date of inspection, name of officers who carried out inspection and results of the inspection	
Application package and summary brief provided to Technical or Advisory Committee	Package of information and list of documents provided, and the date the package and documents were provided to the Committee	
Deliberation and discussion of application by Technical or Advisory committee	Recommendation and record of deliberation by Committee. Date of meeting, list of attendees	
Consideration of the application by the NCA	Decision by the NCA, description of evidence considered, material findings of fact, findings in relation to specified criteria under the legislation. Date of the decision and record of the decision.	
Notification of the applicant	Decision to grant or refuse licence, if approved commencement date of the licence, period of the licence, license number, approved facilities, planting areas and any conditions imposed under the license	
Inclusion of details of license in a Public Register	Details of the license on the Register, and date of publication	
If license was not granted, any appeals or review application made by the applicant	Date of lodgement of appeal or review. Was this a valid appeal or review application? Listing of the tribunal and members dealing with the review	
Review or Appeal decision	Date of application, date of decision and outcome of decision	

This activity was carried out with support from the United Nations Environment Programme (UNEP) and the Global Environment Facility (GEF), under project GFL/2328-2716-4C20, "Regional Project For Implementing National Biosafety Frameworks in the Caribbean Sub-region".

APPENDIX 2. FLOW DIAGRAM OF APPLICATION AND DECISION-MAKING PROCESSES

The lodgement of the application may be through an electronic lodgement facility,or through a combination of electronic and provision of hard copies of documents.

Form may be downloaded from website but application package may be in hard copies, lodged with the NCA Secretariat, a relevant Unit in a Ministry or Registrar.



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APPENDIX 3. APPLICATION FORM FOR THE IMPORT OF A GMO

(EXAMPLE DEVELOPED BY PARTICIPANTS DURING A PROJECT WORKSHOP)

Application form for import of a Genetically Modified Organism for Food, Feed or Prcessing.

Application Number .....

<table>
<tr><td>Name of the Applicant:</td><td>Address of the Applicant:

(Print name, complete address, telephone number of the applicant related to the Restricted Article to be imported)</td><td>Date of Application (DD/MM/YYYY):

Signature:</td></tr>
<tr><td>Name of the Importer:</td><td colspan="2">Address of the Importer:

(Print name, complete address, telephone and fax numbers and electronic address of the importer of the Restricted Article to be imported)</td></tr>
<tr><td>Name of the Exporter:</td><td colspan="2">Address of the Exporter:

(Print name, complete address, telephone and fax numbers and electronic address of the exporter of the Restricted Article to be imported)</td></tr>
<tr><td colspan="3">Genetically Modified Organisms to be Imported for Food, Feed or Processing</td></tr>
</table>

Country of Origin	Common Name of the Product	Scientific Name/Brand	H.S. Code	Description of the Product (Information on the event(s)

Frequency of Importation (monthly or yearly)	Quantity requested	Value	Package size (weight)

Purpose for which the Regulated Article is to be Admitted into St. Lucia (check what is applicable)	Location of the place of destination of the regulated article into St. Lucia	Means of Importation Air: Land: Water:	Point of Entry	Mode of Transportation:
Food ☐ Feed ☐ Processing ☐				

Precautions to be taken to prevent adverse risk to human health and the environment.

FOR OFFICIAL USE ONLY	
Receiving Officer: Print Name Signature	Date received: (DD/MM/YYYY):

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For further information please contact:
Regional Biosafety Project
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