United Nations

UNEP

Environment Programme

Republic of Ghana

Global Environment Facility

GEF

Guidelines on Public Participation, Information Sharing and Access to Justice with Respect to Genetically Modified Organisms

The guideline on "Public Participation, Information Sharings and Access to Justice with respect to Genetically Modified Organisms in Ghana" was prepared with financial support from the UNEP-GEF Project on "Development of National Biosafety Frameworks".

The guideline was prepared by the following:

Prof. Eric C. Quaye – University of Cape Coast, Cape Coast

Prof. George Y. P. Klu, Biotechnology & Nuclear Agric. Research Institute

Prof. Josephine Nketsia-Tabiri, Biotechnology & Nuclear Agric. Research Institute

Dr. Musheibu Mohammed-Alfa, Food & Drugs Board

Mr. E. K. Jack-Vesper Suglo, Plant Protection & Regulatory Services Directorate

Mr. Alex Owusu-Biney, Biotechnology & Nuclear Agric. Research Institute

Published by:

UNEP-GEF	United Nations Environment Program – Global Environment Facility
NBC	National Biosafety Committee
BNARI	Biotechnology & Nuclear Agriculture Research Institute

Copyright:

MES The Ministry for Environment & Science

Reproduction of this publication for educational or other non-commercial purposes is authorized without prior written permission form the copyright holder provided the source is fully acknowledged.

Editors: Alex Owusu-Biney, Eric C. Quaye & Josephine Nketsia-Tabiri

ISBN: 9988-8275-1-2

ACKNOWLEDGEMENT

This guideline is a guidance document to assist scientists and reviewers in risk assessment involving Genetically Modified Organisms in Ghana. The document has evolved through consultation and review by several stakeholders. We would like to take opportunity to acknowledge the support received from the National Biosafety Committee and several individuals and institutions in the development of this guideline. We however accept responsibility for any omissions in the drafting of this guidance document.

It is our fervent hope that this document will assist biotechnology activities in Ghana.

Table of Contents

I. OBJECTIVE **4**

II. INTRODUCTION **4**

III. PUBLIC PARTICIPATION IN DECISION-MAKING ON SPECIFIC 6ACTIVITIES WITH GMOS SCOPE **:** **6**

PUBLIC NOTICE AND ACCESS TO INFORMATION RELEVANT TO PUBLIC PARTICIPATION 7

PROCESS FOR PUBLIC PARTICIPATION AND DECISION-MAKING 9

IV. ACCESS TO ENVIRONMENTAL INFORMATION ON GMOS, COLLECTION AND DISSEMINATION OF INFORMATION ON ACTIVITIES WITH GMOS. SCOPE THIS CHAPTER OF THE GUIDELINES DEALS WITH THE BROADER AND MORE GENERAL ACCESS TO INFORMATION FOR THE PUBLIC IN THE CONTEXT OF ACTIVITIES WITH GMOS. THE GUIDELINES COVER INFORMATION ON - (A) DEL IBERATE RELEASES OF GMOS; (B) PLACING ON THE MARKET OF GMOS AS OR IN PRODUCTS; (C) CONTAINED USES OF GMOS. (D) TRANSBOUNDARY MOVEMENT 11

COLLECTION AND DISSEMINATION OF INFORMATION ON GMOS BY THE NATIONAL BIOSAFETY AUTHORITY 12

V. ACCESS TO JUSTICE **13**

VI. IMPLEMENTATION OF THE GUIDELINES **14**

ANNEX I USE OF TERMS **15**

ANNEX II RECOMMENDED CONTENTS OF THE PUBLIC NOTICE **16**

ANNEX III INFORMATION RECOMMENDED FOR A PUBLIC PARTICIPATION PROCESS 17

ANNEX IV POSSIBLE WAYS FOR THE NATIONAL BIOSAFETY AUTHORITY TO MAKE INFORMATION AVAILABLE TO THE PUBLIC **18**

ANNEX V **19**

POSSIBLE CONTENTS OF PUBLICLY ACCESSIBLE LISTS, REGISTERS OR FILES ON ACTIVITIES WITH GMOS ESTABLISHED AND MAINTAINED BY THE NATIONAL BIOSAFETY AUTHORITY **19**

ANNEX VI REGULATORY AGENCIES **R22**

Guidelines on Public Participation, Information Sharing and Access to Justice with Respect to Genetically Modified Organisms

The various terms used in these Guidelines, such as GMO, are defined in Annex 1.
The following Guidelines are hereby adopted.

I. OBJECTIVE

The objective of these Guidelines is to:

(a) Facilitate and give guidance to the practical application of the provisions of the Cartagena Protocol on Biosafety and the National Biosafety Framework Law relevant to GMOs;

l

(b) Encourage the development of methodologies to access information, public participation and access to justice with respect to GMOs;

(c) Stimulate open, transparent, efficient and accountable decision-making on activities with GMOs, thereby fostering good practices for public participation in decision-making that may go beyond the scope of these guidelines; and

(d) Promote and facilitate public awareness, education and participation in decision-making on activities involving GMOs.

II. INTRODUCTION

Public awareness of and participation in issues that have the potential to affect society in one way or the other have become an integral part of the democratic process, especially in relation to good governance. Decision-making is no longer the prerogative of only the three arms of government; civil society now has a unique and critical role to play. Indeed, the general public has the right to know, access information and comment on issues that have social, cultural, economic and political implications for the well being of the populace.

Biotechnology, and its corollary, biosafety, is one such issue that requires the full awareness and participation of the public in its application in the country. This is because, as useful as biotechnology is as a tool in agriculture and health-related research, among others, scientists recognize that the deliberate release of GMOs into the environment and the accidental release of GMOs from certain types of contained use may have significant adverse effects on the environment, and pose risks to human health. This is enough justification for the need for transparency and public participation in decision-making on GMOs. The end results, hopefully, will be to provide consumers with adequate information on products consisting of or containing GMOs to enable them to make informed environmental choices. The ultimate goal is to build public confidence in decision-making on the use of GMOs.

The important role of the public in the deployment of LMOs[1] is spelt out in Article 23 of the Cartagena Protocol. Article 23 (2) requires that the public is consulted in the decision-making process regarding LMOs and the results of the decision are also made public while respecting confidential information. In the light of this, there is urgent need to innovative and practical methods for making information accessible to the public. Public education on genetic technologies and LMOs must also be intensified. The processes of educating the people must provide opportunities for the public to freely exchange information thus promoting active participation in decision-making.

It is against this backdrop that the following guidelines have been provided. The guidelines provide a non-legally binding and voluntary framework that emphasizes good practices involving the uses of and specific activities with GMOs. They are also without prejudice to any other differentiated guidance at the national level.

[1] LMOs and GMOs means the same and is used interchangeable in the guideline. Please refer to Annex 1

III. PUBLIC PARTICIPATION IN DECISION-MAKING ON SPECIFIC ACTIVITIES WITH GMOs

SCOPE

In principle, public participation should be provided for in decision-making procedures in all three areas of GMO applications, and adapted to the specific requirements of these decision-making procedures and uses:

a. Deliberate release;
b. Placing on the market;
c. Contained use.

This does not mean that public participation processes should be applied to all decision-making procedures in these areas. The following two paragraphs aim to give guidance on which decision-making procedures should generally be subject to public participation.

Public participation as described in paragraphs 1 to 14 should be provided for as appropriate in the following GMO-related decision-making procedures:

(a) First-time deliberate release into the environment of GMOs in any new location;
(b) First-time placing on the market of GMOs not exclusively intended for research or for culture collections;
(c) Procedures for determining whether sufficient experience has been obtained with respect to deliberate releases of certain GMOs in certain ecosystems and simplified procedures could therefore be followed;

(d) The contained use of GMOs in a specific installation where in the event of an accident there would be a risk of serious damage to the environment and/or human health and therefore suitable contingency/emergency plans are foreseen.

The following general criteria should be considered when deciding if a specific case should be subject to public participation or not:

(a) The type of GMO (host organism, genetic modification, unique identification code and transformation event);
(b) The intended use;
(c) The characteristics of the potentially affected environment;
(d) The level of experience obtained with the GMO and intended use in question with respect to risks to the environment and/or human health;
(e) Any proposal for simplified procedures in the decision-making procedure on the basis of experience;
(f) For genetically modified micro-organisms, the risk category (if any);
(g) First-time or subsequent application;
(h) The scale of use, if applicable;
(i) Any planned containment or other risk management measure, if applicable;
(j) The significance of any adverse affects on the environment and/or human health that could result from the unintended release of the GMO or from a lack of appropriate risk management measures;

Public notice and access to information relevant to public participation

Providing adequate public notice of a specific planned activity with GMOs within the scope of this chapter of the Guidelines should be the first step in the public participation process. The nature and contents of the public notice will vary, depending *inter alia* on the type of the planned activity (e.g. contained use, deliberate release, placing on the market). The following paragraphs provide examples of good practice and should be applied in a flexible manner.

1. The public concerned should be informed, either by public notice or individually as appropriate, early in the decision-making procedure, and in adequate, timely and effective manner of the aspects described in Annex II.

2. The National Biosafety Authority should find effective means to inform the public concerned about the proposed activity with GMOs, for example through notices;

   (a) In the official government gazette;
   (b) In appropriate national, regional or local newspapers; radio & TV stations
   (c) Through notices to the District Assembly in the proximity of the facility or site where the proposed activity (contained use or deliberate release) with GMOs is intended to take place and other traditional modes of communication including the beating of the gong;
   (d) On their Internet site; and/or
   (e) On any existing national or regional biosafety clearing-house.

3. In addition to notifying the public concerned according to paragraphs 1 and 2 above, the National Biosafety Authority should provide opportunities for members of the public concerned to seek and obtain information relevant to the decision-making procedure so that they can participate in an informed manner.

4. Without prejudice to their right to refuse to disclose certain confidential information in accordance with the Right to Information Bill 2003, the information which should be publicly accessible includes, where appropriate, the elements described in Annex III. In this context, Annexes I, II and III to the Cartagena Protocol on Biosafety may also be useful sources of information. The National Biosafety Authority should give the public access to the information that they possess and that is available at the time of the public participation.

5. The National Biosafety Authority may give the public access to the relevant information for examination by publicly disclosing this information:

   (a) At national, regional and, where applicable, local governmental or public premises, such as libraries, in the proximity of the facility or the site where the contained use or the deliberate release of GMOs into the environment will take

place; and/or

(b) On their Internet site/or the National Biosafety Clearing House

6. The National Biosafety Authority should provide public access to information for examination free of charge and endeavour to supply copies of information free of charge in response to requests from the public. However, a reasonable charge for supplying the information requested may be made following procedures outlined in the Right to Information Bill 2003. In such cases the National Biosafety Authority should make available a schedule of charges which may be levied, indicating the circumstances in which they may be levied or waived and when the supply of information is condition on the advance payment of such a charge.

Process for public participation and decision-making

The public participation processes should provide for early participation, when all options are open and effective public participation can take place. The following paragraphs provide examples of good practice for processes for public participation and should be applied in a flexible manner.

7. The public participation processes should include reasonable time frames for the different phases, taking into account any legally binding time frames as spelt out in the National Biosafety Framework. Sufficient time should be allowed for informing the public and also for the public to prepare and participate effectively during the decision-making on certain specific activities with GMOs.

8. The National Biosafety Authority should ensure that potential notifiers or applicants identify the public concerned, enter into discussions and provide information regarding the objectives of their application before notifying or applying for a consent or permit for certain specific activities with GMOs.

9. Public participation processes should allow the public to submit, in writing or, as appropriate, at a public hearing or inquiry (with the notifier or applicant), any comments, information, analysis or opinions in relation to the proposed activity with GMOs.

10. The National Biosafety Authority should ensure that in the decision, due account is taken of the outcome of the public participation. This should, where appropriate and feasible, include an analysis of the comments and a description of the reasons for taking or not taking them into account in the (draft) decision.

11. When the National Biosafety Authority has taken a decision on a proposed specific activity with GMOs, the public should be promptly informed of the decision, e.g. through notices:

(a) In the official government gazette;

(b) In national, regional and, where applicable, local newspapers, radio and television in the proximity of the facility or the site where the contained use or the deliberate release of GMOs into the environment will take place;

(c) On the National Biosafety Authority's Internet site (e.g. in cases of placing on the market); and/or

(d) On any existing national, regional or international biosafety clearing-house.

12. The National Biosafety Authority should make publicly accessible the text of the decision and the reasons and considerations on which the decision is based, together with, where appropriate, a description indicating how due account has been taken of the outcome of the public participation. This can be done by making the information available, for example:

(a) At national, regional and where appropriate, local governmental or public premises, such as libraries, offices of the District Assemblies or community centres in the proximity of the facility or the site where the contained use or the

deliberate release of GMOs into the environment will take place;

(b) On their Internet site.

13. The National Biosafety Authority should consider, when deciding on whether to renew a consent or permit after it has expired, if paragraphs 7 to 12 above should be applied *mutatis mutandis* and where appropriate. In a similar way this could be done when the National Biosafety Authority reconsiders and updates the operating conditions for a specific activity with GMOs on the basis of new information on the potential significant effects on the environment and/or human health.

14. In order to improve public knowledge, public participation and awareness of activities involving GMOs, the National Biosafety Authority should explore mechanisms and measures such as consensus conferences, public hearings, round-table discussions, stakeholder dialogues, citizens' juries and community meetings facilitated by traditional leaders and local opinion leaders on issues relating to, for example, the risk assessment and risk management of GMOs.

IV. ACCESS TO ENVIRONMENTAL INFORMATION ON GMOS, COLLECTION AND DISSEMINATION OF INFORMATION ON ACTIVITIES WITH GMOS.

Scope

This chapter of the Guidelines deals with the broader and more general access to information for the public in the context of activities with GMOs. The Guidelines cover information on -

(a) Deliberate releases of GMOs;

(b) Placing on the market of GMOs as or in products;

(c) Contained uses of GMOs.

(d) Transboundary movement

recognizing that the need for the provision of information on products from GMOs, which do not necessarily contain the GMO as such, should be addressed through additional regulations when the need arises.

Collection and dissemination of information on GMOs by the National Biosafety Authority

In addition to the information requirements for notification of the public in the context of public participation in decision-making, the National Biosafety Authority may collect and disseminate further information on GMO activities which can be made accessible to the public.

15. The National Biosafety Authority should:
    (a) Maintain and update information on activities with GMOs, e.g. via registers and databases through the Biosafety Clearing House;
    (b) Establish mandatory systems to facilitate adequate flow of information about proposed and existing activities with GMOs;
    (c) In the event of any imminent threat to the environment and/or human health of activities with GMOs, disseminate immediately and without delay to members of the public who may be affected, all information they hold, and which could enable the public to take measures to mitigate harm arising from the threat.

16. The National Biosafety Authority should have transparent ways of making information on activities with GMOs available to the public and effectively accessible, *inter alia,* by the ways described in Annex IV.

17. The publicly accessible lists, registers or files established and maintained by the National Biosafety Authority as described in paragraph 16 above and Annex IV should contain, *inter alia,* the information on activities with GMOs listed in Annex V.

18. The National Biosafety Authority should establish and maintain an up-to-date list of web sites which are considered to be examples of good practice in this area.

19. At regular intervals not exceeding in principle three years, the National Biosafety Authority should publish and disseminate reports on the experience gained with activities with GMOs, including any results of monitoring their effects on the environment and/or human health, such reports should also include possible implications for the risk assessment and risk management of further activities with GMOs. Information on deregulated products based on current information should be made available to the public.

20. The National Biosafety Authority should develop mechanisms to ensure that sufficient information on products consisting of GMOs or containing GMOs is made available to the public in a manner which enables consumers to make informed environmental and consumer choices about such products. Activities and progress in other forums, such as the Cartagena Protocol, the *Codex Alimentarius* and WTO, should be taken into account.

21. One such mechanism is the labeling of products consisting of or containing GMOs or the provision of relevant accompanying documentation in particular for bulk quantities at any stage of the production and distribution chain.

22. The notifiers or applicants for activities with GMOs having a significant impact on the environment are encouraged to inform the public regularly of the environmental impact of such activities.

V. ACCESS TO JUSTICE

The implementation of the provisions of these Guidelines shall be effected through a legally binding framework, the National Biosafety Framework Law, which provides for access to justice as required, including, where appropriate appeals against decisions of the

NBA, first to the Board and finally the Courts with respect to GMO activities that fall within the scope of these Guidelines.

VI. IMPLEMENTATION OF THE GUIDELINES

23. The National Biosafety Authority, to the extent possible and where appropriate, shall seek assistance to build capacity for the practical implementation of these Guidelines.

24. The National Biosafety Authority shall monitor and keep under review the implementation of these Guidelines after every three years.

25. The need for and the possible substance of proposals for further refinement and amendment of the Guidelines, as may be necessary, as well as proposals for complementing the Guidelines with more detailed guidance (such as detailed handbooks) shall be further assessed and, if need be, acted upon by the National Biosafety Authority.

26. The Regulatory Agencies listed in Annex VI shall, through their mandates. assist the National Biosafety Authority in the implementation of these Guidelines.

Annex I

USE OF TERMS

1. Unless otherwise stated, the terms 'National Biosafety Authority', 'environmental information', 'public' and 'public concerned' shall have the meanings given to them in the Cartagena Protocol on Biosafety and the National Biosafety Bill.

2. For the purpose of these Guidelines, the following terms based on existing international and regional documents, such as the Cartagena Protocol on Biosafety are employed:

   (a) 'Genetically modified organism' (GMO) or Living Modified Organisms (LMOs) means any organisms with the exception of human beings that possesses a novel combination of genetic material obtained through the use of modern biotechnology;

   (b) 'Modern biotechnology' means the application of:
   In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles; or Fusion of cells beyond the taxonomic family,

   (c) 'Micro-organism' means any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, including viruses, viroids, animal and plant cells in culture;

   (d) 'Deliberate release' is defined as any intentional introduction into the environment of a GMO or a combination of GMOs for which no specific containment measures are used to limit their contact with and to provide a high level of safety for the general population and the environment;

   (e) 'Placing of GMOs on the market' is defined as making GMOs available to third parties, whether in return for payment or free of charge;

   (f) 'Contained use' means any activity, undertaken within a facility, installation or other physical structure, which involves genetically

modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment;

(g) 'Accident' shall mean any incident involving a significant and unintended release of GMOs in the course of their contained use which could present an immediate or delayed hazard to the environment and/or human health.

3. Where reference is made to human health, this refers to aspects of human health which are linked to the use of a GMO and its intended or unintended release into the environment.

Annex II

RECOMMENDED CONTENTS OF THE PUBLIC NOTICE DESCRIBED IN PARAGRAPH 1

The following information shall be actively notified to the public concerned in the context of the decision-making procedures referred to in chapter III:

(a) The proposed activity and the application on which a decision will be taken;

(b) The type of decision which is being taken (e.g. a decision on whether to grant a permit for the import of a GMO, a deliberate release, etc.);

(c) The National Competent Authority responsible for making the decision;

(d) The envisaged process, including, as and when this information can be provided:

(i) The commencement of the process;

(ii) The opportunities for the public to participate (these can vary depending on the case: e.g. examination of the dossier and/or draft decision, possibility for written comments, participation in any public hearing);

(iii) The time and venue of any planned public hearing;

(iv) The National Biosafety Authority or any other official body from

which relevant information can be obtained and where the relevant information has been deposited for examination by the public;

(v) The National Biosafety Authority or any other official body to which comments or questions can be submitted and the time schedule for the transmittal of comments or questions; and

(vi) An indication of what environmental information relevant to the proposed activity with the GMOs is available, e.g. a notification dossier; and

(e) Any other information that the National Biosafety Authority considers appropriate.

Annex III

INFORMATION RECOMMENDED TO BE AVAILABLE WITHIN A PUBLIC PARTICIPATION PROCESS

In addition to the information items listed in annex II, the following information should be available to the public in the context of the decision-making procedures referred to in chapter III:

(a) A general description of the GMOs; including the common, scientific, and technical name, the unique identification code and transformation event;

(b) The name and address of the notifier or applicant;

(c) The purpose of the proposed activity with the GMOs;

(d) Experience obtained with deliberate releases into the environment of certain GMOs;

(e) In the case of a proposal for simplified procedures for deliberate releases of certain GMOs into the environment, experience obtained with deliberate releases into the environment of those GMOs;

(f) The location of the site where the proposed deliberate release of the GMOs into the environment will take place (depending on the legal and

administrative practice in a country this can vary between the description of the exact plot, the land register or the local community); the intended uses of the GMOs; an environmental risk assessment including a description of the potential effects on the environment and/or human health; a description of the measures, if any, to limit potentially adverse effects on the environment and/or human health; a description of the plan for monitoring the effects on the environment and/or human health; a description of the measures, if any, to treat waste arising from the deliberate release of the GMOs; a description of any emergency response plan;

(g) The location of the facility where the contained use of GMOs under the scope of this chapter of the Guidelines will take place, and a description of the specific containment measures; a description of the expected waste of the GMOs and its treatment; a description of any emergency response plan and the possibility for its implementation

(h) A non-technical summary of the above; and

(i) The main reports and advice issued by expert committees or advisory bodies to the National Biosafety Authority, in accordance with national legislation.

Annex IV

POSSIBLE WAYS FOR THE NATIONAL BIOSAFETY AUTHORITY TO MAKE INFORMATION ON GMOs AVAILABLE TO THE PUBLIC

(a) Providing sufficient information to the public about the type and scope of information on activities with GMOs that they hold, the basic terms and conditions under which such information is made available and accessible, and the process by which it can be obtained. This can be done through Internet sites or regular publications;

(b) Establishing and maintaining practical arrangements, such as: (i) publicly accessible lists, registers or files; (ii) requiring officials to support the public in seeking access to information; and (iii) the identification of points of contact;

(c) Providing access to the information on activities with GMOs contained in publicly accessible lists, registers or files free of charge; and

(d) The lists, registers or files with publicly accessible information on activities with GMOs may be available at national, regional and/or local governmental or public premises, as appropriate, and progressively on their Internet sites.

Annex V

POSSIBLE CONTENTS OF PUBLICLY ACCESSIBLE LISTS, REGISTERS OR FILES ON ACTIVITIES WITH GMOs ESTABLISHED AND MAINTAINED BY THE NATIONAL BIOSAFETY AUTHORITY

The contents of this annex are not meant to duplicate existing national obligations or any obligations under other international organizations and instruments, such as the Biosafety Clearing House or other international and regional databases. It is meant as a checklist, which should be applied in a flexible manner according to the specific activity with the GMO. If parts or all of these aspects are dealt with in an existing national or regional register/database/web site, no new mechanism needs to be established. Parts of this paragraph are already listed in Annex III (containing the possible information according to paragraph 4) and are not meant as duplication but have to be seen as complementary to each other. Please observe the different scopes of chapters III and IV of these Guidelines and therefore of Annexes III and IV. The National Biosafety sAuthority should take measures within the framework of their legislation for the purpose of disseminating, *inter alia,* the information items listed in subparagraphs (a) to (d).

(a) Legislation and policy documents on activities with GMOs prepared at

various levels (local, national, regional and international). This may include a description and, where applicable, the actual texts of legal and policy frameworks related to GMOs and contact point(s) for further information;

(b) Legislation and policy documents on public information and public participation in decision-making at various levels (national, regional or international);

(c) International treaties, conventions and agreements relevant to activities with GMOs, such as the Convention on Biological Diversity and the Cartagena Protocol on Biosafety;

(d) Other significant international documents on regulatory approaches and the risk assessment of GMOs by international organizations, such as the Food and Agriculture Organization of the United Nations, the World Health Organization and their *Codex Alimentarius Commission*, the United Nations Industrial Development Organization, International Plant Protection Convention, *Office Internationale des Epizooties* and the Organization for Economic Co-operation and Development;

(e) A non-technical explanation of the types of activities with GMOs regulated by national, regional and international legislation

(f) A list of GMOs which have gained approval for placing on the market within the country including contact points and links to Internet sites for further information on the risk assessments of these GMOs; this may include a list of GMOs which have been approved for food use, feed use or any other use within the country, and the requirements for product information;

(g) (i) Notifications of and/or applications for certain contained uses of GMOs; (ii) a (summary of the) risk assessment; and (iii) any decisions on such applications made by the National Biosafety Authority;

(h) (i) Notifications of and/or applications for deliberate releases of GMOs into the environment; (ii) a (summary of the) risk assessment; and (iii) decisions made by the National Biosafety Authority;

(i) Non-technical summaries of applications for deliberate releases of GMOs

into the environment and decisions made by the National Biosafety Authority;

(j) Experience obtained with deliberate releases into the environment of certain GMOs, in particular those for which simplified authorization procedures are proposed;

(k) Information on methods of protection if any risk arises for the environment and/or human health;

(l) New information relevant to the risk assessment that may become available whilst the notification of or application for a specific activity with GMOs is under consideration by the National Biosafety Authority;

(m) The advice on a notification or application for a specific activity with GMOs of any expert committee or advisory body to the National Biosafety Authority;

(n) Decisions to grant or refuse consent or permit for a proposed specific activity with GMOs;

(o) Any limitations and/or conditions attached to any consent or permit granted, including the reasons of the National Biosafety Authority for attaching limitations and/or conditions;

(p) Significant new information on a specific activity with GMOs for which a consent or permit has previously been granted subsequently notified to the National Biosafety Authority and which may have an influence on the risk assessment;

(q) Information on the effects of deliberate releases of GMOs into the environment, including information on the results of the monitoring of their effects on the environment and/or human health, and its implications for any further deliberate releases; information on the monitoring of products containing or consisting of GMOs which have been placed on the market;

(r) Decisions taken by the National Biosafety Authority to revoke or to vary limitations and conditions attached to a consent or permit granted;

(s) Information on the advance informed agreements on Living Modified Organisms (LMOs) imported into the country as foreseen by the Cartagena

Protocol on Biosafety to the Convention on Biological Diversity (reference should be made to the Biosafety Clearing House of the Cartagena Protocol);

(t) Information shared by the National Biosafety Authority of different countries, if a deliberate release of GMOs into the environment will take place in more than one country;

(u) Information on sites of deliberate releases of GMOs and, where appropriate, places where GMOs are grown commercially. This may be information specifying the actual plot, the land register or the local community; and

(v) Contact points to obtain further information from the National Biosafety Authority.

ANNEX VI

REGULATORY AGENCIES

1. Customs, Excise & Preventive Services (Ports and Frontiers Handling – Export & Importation Laws – Act 623)
2. Environmental Protection Agency (Act 490, Act 528)
3. Fisheries Directorate (Fisheries Act – Act 625)
4. Food and Drugs Board (PNDCL 305B, Act 523, LI 1541,)
5. Plant Protection and Regulatory Services Directorate (Act 307, NRCD 100, Act 528)
6. Veterinary Services Directorate (Cap 247, Act 83)
7. District and Metropolitan Assemblies (Act 462)

s