②ＡＩＫ－Ｃに関する計画書

JICA/NMIMR COLLABORATION: INFECTIOUS DISEASE PROJECT - VACCINE PREVENTABLE DISEASES RESEARCH

TITLE: EFFICACY TRIAL OF AIK-C MEASLES VACCINE IN THE KASSENA NANKANA DISTRICT OF NORTHERN GHANA

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DURATION

36 MONTHS

FUNDING

JICA

EFFICACY TRIAL OF AIK-C MEASLES VACCINE IN THE KASSENA NANKANA DISTRICT OF NORTHERN GHANA

1.0 INTRODUCTION AND BACKGROUND.

Measles continues to be responsible for approximately one million infant deaths annually, mostly in developing countries despite the availability of potent measles vaccines and the recent increase in worldwide vaccination coverage rates (ref. UNICEF). It has been estimated that measles cases reach approximately 70million each year with a case fatality rate of about 3% and, in some rural areas lacking basic healthcare infrastructure, the case fatality rate has been estimated to be in excess of 30%. Thus, measles, remains one of the most important of the EPI diseases in terms of morbidity and mortality. The recent resurgence of measles in the United States of America, where it was thought to have been eliminated after immunization coverage dropped, emphasizes the need for continuous vigilance and novel approaches to vaccination of children. Although the epidemiology of the disease indicates that older children are being affected more, in areas of very high measles transmission and in outbreak situations, the most vulnerable group includes younger children in whom the current vaccine is not recommended. To prevent the high morbidity and mortality associated with measles in younger children work has focused on the development of new vaccines and novel approaches that would allow immunization of infants before the usually WHO recommended age of vaccination.

It has been estimated that to obtain adequate herd immunity more than 95% of the target population has to be immunized. This rate of immunization is difficult to achieve and maintain. To improve the current low rate of immunization, attempts have been made to identify vaccines that could be given earlier in life in the presence of maternal antibodies. High dose E-Z strain was found to be successful at immunizing infants at a younger age than the Schwarz vaccine. It was, however, later found to be associated with excess mortality in

girls and plans by WHO to recommend the use of this vaccine at 6months in developing countries were shelved. Studies in Togo and elsewhere have demonstrated that AIK-C measles vaccine strain is immunogenic in normal doses in early in life as 4 months and may thus be a suitable candidate for use in early immunization. We have conducted a larger immunogenic trial of AIK-C given at 6 months compared to Schwarz given at 9 months and the results indicate that children are able to mount adequate immunological response to the AIK-C measles vaccine at 6 months of age. Sero conversion rates 3 and 6 months after vaccination with AIK-C measles vaccine was comparable to those seen after vaccination with Schwarz measles vaccine at 9 months (Nkrumah et.al. in press). Preliminary observations of the sero response data for 18 and 36 months after vaccination indicate that the responses are adequate and that sero responses may persist at higher GMTs after immunization when compared to the Schwarz measles vaccine. This study is proposed to study further the effect of AIK-C measles vaccination on measles transmission in the Kassena-Nankana District of northern Ghana.

1.1 Objectives

The aim of this study is to determine the epidemiological impact of immunization with AIK-C measles vaccine at 6 months on measles transmission in the K-N District. The specific objectives are

- To compare the overall child mortality, measles specific mortality and the incidence of measles in an area where children are given AIK-C measles vaccine at 6 months to those of an area where infants receive the routine EPI measles vaccination (Schwarz vaccine at 9 months).
- To determine the immunogenicity (sero response rate) to AIK-C measles vaccination at 6 months and Schwarz at 9 months (in a subset of the study population)
- To document the adverse effects of AIK-C measles vaccine administration, if any

2.0 METHODS

2.1 Study Area.

The study will be conducted in the Kassena-Nankana district of the Upper East Region of Ghana. The district lies within the Guinea Savannah woodland area of Ghana with a mostly rural population of 140,000 excepting those living in the district capital, Navrongo that has a total population of 20,000. It has two main seasons a short wet season from June to October and a long dry season for the rest of the year. The average annual rainfall is 950 mm with mean monthly temperatures ranging from 20°C to 40°C. Settlements are dispersed with no compact villages except in Navrongo town. The district is served by one hospital and three health centers, which provide simple health services from these static centers. In addition limited outreach clinics from these static facilities provide maternal and child health services within the district. Measles is endemic in the district as in other parts of the country. Reported cases of measles over the past 5 years have ranged between 250 and 700 cases a year. Immunization coverage for measles antigen has remained low at below 50% of the 12-23mth age group for the past 2 years. Fig. 1 shows the coverage for measles immunization and the number of measles cases reported in the district over the past 5 years. Data from the district hospital indicate that measles, although it has moved from its position of pre-eminence in the causes of childhood deaths, still accounts for substantial proportion of such deaths by being the 4th most common cause of childhood deaths.

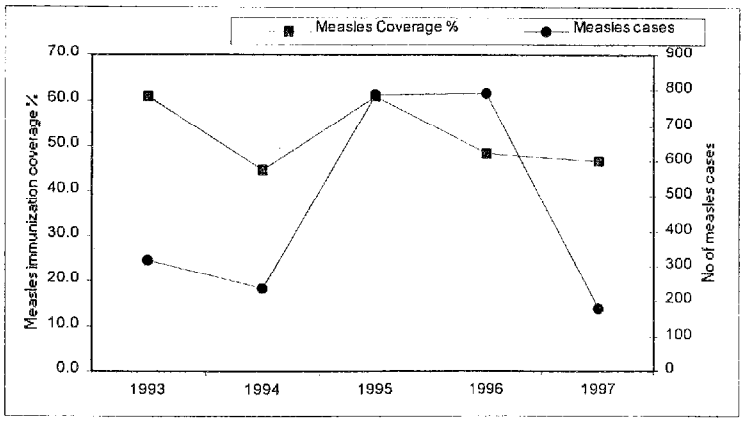

Fig. 1. Measles immunization coverage and the number of measles cases reported in the K-N District from 1993-1997. Source; Kassena-Nankani DHMT reports and data from the NDSS

The entire district population has been regularly surveyed for the past 5 years under the Navrongo Demographic Surveillance System (NDSS). The NDSS involves a 90 day cycle of visits to each compound to update the population census with registration of births, deaths and migrations. It also records pregnancies and their outcome, marriages and their dissolution as well as verbal autopsies for all deaths reported. Results from the NDSS reports for the last 5 years show measles accounts for approximately 3% of childhood deaths. The NDSS data set is linked to the NHRC Geographical Information System (GIS) that allows for spatial analysis of important selected public health outcomes.

2.2 *Study Population*

The study population will be a year's birth cohort identified through the NDSS. This cohort will be chosen both retrospectively and prospectively. The ideal situation would be to follow a birth cohort prospectively, but due to time and logistic constraints, a retrospective cohort of infants aged 6 months and below at the start of the study will be identified to constitute half of the child cohort required. Children delivered within the next six months after the start of the study will be the other half of the birth cohort (see Fig. 2).

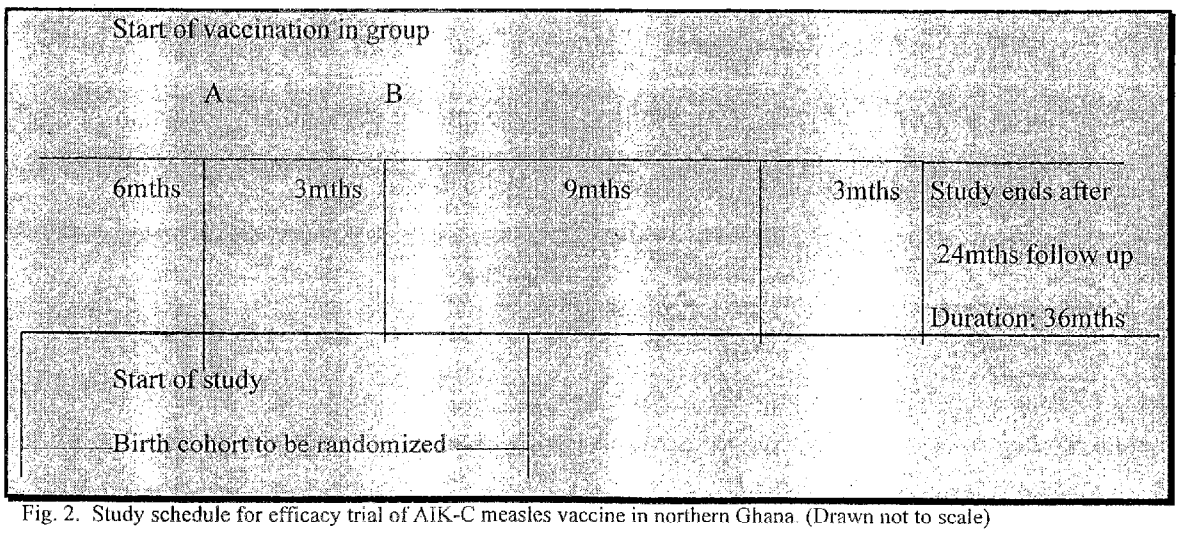

Fig. 2. Study schedule for efficacy trial of AIK-C measles vaccine in northern Ghana. (Drawn not to scale)

2.3 *Study Design*

The study design will be an open randomized community intervention study of the efficacy of

the AIK-C measles vaccine. The Kassena-Nankana district is divided into 5 sub districts, Kassena-Nankana East, Paga, Chiana, South and Navrongo Central. Each sub-district maintains and runs between 10 and 12 outreach centres. The outreach centres have defined catchment areas that are identifiable through the NDSS. The outreach points, corresponding to defined catchment areas will be the units for randomization. Thus, there will be between 50 and 60 outreach areas to randomize. Each point will be randomized into one of two groups, A or B using the NDSS. Infants in areas assigned to group A will receive AIK-C measles vaccine at 6 months and children in areas assigned to group B will receive the usual measles vaccination, Schwarz at 9 months. It is expected to randomize a year's birth cohort this way to receive either AIK-C measles vaccine or Schwarz measles vaccine. The birth cohort will be selected both retrospectively and prospectively. Children aged 6 months in group A at the start of the study, will define the beginning of the birth cohort, that is those born within the previous 6 months. These will be called up for immunization and all infants in group A will subsequently receive measles immunization at 6 months till the end of the observation period (see Fig. 1). Immunization in group B children will follow the normal EPI schedule. Infants included in the data set will be 3 months older than those that receive AIK-C measles vaccination at the time of immunization. Immunization will be undertaken using the EPI outlets available in the district. An approximate total of 4000 children, representing the average annual number of deliveries in the Kassena-Nankana District, will be randomized for the study. Although one year's birth cohort will be the major target group, vaccination will continue in each area according to the randomization schedule till the end of the observation period.

The study will make use of the MOH facilities both for immunization and data capture. However, to improve the quality of data obtained research staff will be attached to the sub-district teams to ensure that the correct vaccine is delivered at the right place. There will also be a tracking team that tracks children who have missed their vaccination appointments to ascertain the reasons. The teams will also assist the sub-district staff in data capture and

recording of outcome events. Children in the birth cohort will be issued with ID cards to facilitate identification and follow up.

2.4 Monitoring for endpoints:

The main outcome variables will be the incidence of overall child mortality, measles specific mortality and measles in the communities. Mortality will be monitored from the routine NDSS and morbidity passively from the district hospital and health centres from the start of the study and will continue for 24 months after recruitment of the main child cohort. Measles specific deaths will be determined through analysis of post mortem questionnaires for all childhood deaths that is already undertaken as part of the NDSS. Measles cases will be identified through a passive case detection via the clinic system. Use of clinic facilities is low in the district, about 30 - 40%. To improve this rate and the yield of cases identified through the clinic system, the trial will offer incentives to mothers to take children with fever and rash to the nearest clinic by picking up the cost of treatment for all measles cases. This is likely to double the rate of utilization.

Clinical diagnosis of measles will be based upon the WHO standard clinical case definition. The criteria for diagnosis of measles will be any child with a generalized maculopapular rash lasting 3 days or more; and fever of at least ?37.5^0 C or and any one of the following: cough, runny nose (coryza), red eyes (conjunctivitis). All cases of suspected measles identified at the health facilities will be confirmed in the laboratory with a measles specific IgM antigen capture assay that will be established in the laboratories of the Noguchi Memorial Institute for Medical Research (NMIMR). The occurrence of other illnesses will also be monitored through a routine audit of hospital and clinic records. Each child will have a permanent ID through the NDSS, which will be used to trace the morbidity visits to the health facilities. Deaths will also be investigated through postmortem questionnaires as is already done to establish the cause of death

Meetings will be held with the regional, district and sub-district health authorities to explain the study and to answer questions related to the study before the study commences. As the study involves a change in the routine vaccination schedule these meetings are deemed very important in order to get all health personnel to understand the reasons for the study and to solicit their participation. The trial will work closely with the District Health Management Team (DHMT) throughout the duration of the study. Random allocation of clusters will be of done in conjunction with the District Health Management team. Meetings will also be held with the communities to explain the study to the population and to seek the consent of the communities. In addition to this mothers of individual infants randomized to receive AIK-C will be free to refuse.

2.5 Immnogenecity study

This part of the study will determine the sero responses of children given AIK-C measles vaccine and the Schwarz measles vaccine in the study area. It will be done on a sub set of the study population. Approximately 150 children in each group will be sampled at 0, 6 and 12 months after immunization and also at the end of the follow up period. Children will be randomly allocated into one of the 4 sampling times at the time of vaccination. At the appointed time these will be visited and a sample of capillary blood (approx. 1ml) obtained by a finger prick. Each selected child will give only one sample of blood. Blood samples will be separated and sera stored at –20 ^{o}C till needed. The plaque neutralization assay will be used to determine measles antibodies in the sera by standard methods. Analysis will be performed in the Virology Unit of NMIMR.

2.6 Data Management and analysis

Data quality will be ensured by routine audit of all questionnaires by field supervisors and data managers. Returns on vaccination will be compiled routinely (monthly) for submission to the district health directorate and the regional health directorate. Copies of the reports will be retained on site at NHRC and a copy sent to NMIMR (Epidemiology Unit). Children who

have missed their vaccination will be followed up and called to have their immunization. Data entry will be done at the computer centre of NHRC. The primary end point will be measles specific /overall child mortality. Primary analysis will be a comparison of measles specific mortality, the incidence of measles, child mortality between the two groups of children.

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BUDGET SUMMARY.

A. PERSONNEL Position	% of time devoted to project /yr.	Budget Requested			
		Year 1	Year 2	Year 3	Year 4
1. Investigators at NMIMR, NHRC & MOH (total 9)					
2. Graduate Research Officer (to server as Research Coordinator)	100%	9600	9600	9600	9600
3. 20 Field Workers	100%	36000	36000	36000	36000
4. Data Entry Clerk	100%	3600	3600	3600	3600
5. Data Manager	20%	2400	2400	2400	2400
Total Personnel		**51600**	**51600**	**51600**	**51600**
B. SUPPLIES					
Total Supplies		**16000**	**16000**	**16000**	**3500**
EQUIPMENT					
Total Equipment		**34200**			
PATIENT COSTS					
Total Patient Costs		**11320**	**11320**	**11320**	
LOCAL TRAVEL					
Total Local Travel		**8060**	**8360**	**8960**	**1000**
OTHER EXPENDITURE					
Total other expenditure		**6500**	**6500**	**6500**	**6500**
GRAND TOTAL		**127680**	**93780**	**94380**	**62600**

BUDGET JUSTIFICATION

Personnel
A study of this nature will require the full attention of dedicated staff at several levels. A core of research staff dedicated to the projected will be employed and stationed at the field site. The Research Coordinator will be in charge of all field operations of the study as well as liasing between the research centre and the District Health Management Team. He will be responsible for the general conduct of the study and supervise the subordinate staff including field workers and data entry clerk. He will be assisted by a core group of 20 field workers and a data entry clerk. A total budget of $51600 USD is requested to pay salaries and other allowances to this core group only. No salary will be paid the investigators at NMIMR, NHRC and Ministry of Health.

Supplies
An annual sum of $16000 USD is requested to procure consumables such as syringes and needles, mediswabs, gloves, laboratory reagents for measles antibody assays and stationery for the study.

Equipment.
The sum of money required under this item will be used to procure necessary equipment such as medical freezers for storage of vaccines at NMIMR and NHRC as well as a fridge for storing samples at NHRC. Motorbikes that will be required to transport field supervisors over the district to ensure the completeness of the information collected are also requested under this item. In addition 2 computers and a printer are required for data capture at NHRC. A total sum of $34200 is requested in the first year.

Patient costs
This item will cover the provision of photo ID cards and immunization cards for the study children and all those immunized as well as snacks for the MOH personnel that will do the immunization at the immunization points. Provision is also made for paying the transport charges of mothers to and from the clinics as well as paying for the cost of hospital fees for the study cohort. An annual sum of $11320 is requested.

Local Travel
This item will cover the provision of fuel and lubricants for the outreach teams as well as maintenance charges of the motorbikes. In addition the transportation charges associated with the meetings of the research team and the local authorities will be paid from this charge.

Other Expenditure.
A charge of $6500 is made to cover partial support of the NDSS and communication charges at NHRC and NMIMR. The support for the NDSS is requested to help maintain the core activity of the Navrongo Centre that will be used to obtain data on the outcome variables from the study. The amount requested is approximately 5% of the annual cost of running that surveillance over the past 3 years and does not compare with what would have been spent to collect the information from scratch.

BUDGET.

A. PERSONNEL Position	% of time devoted to project /yr.	Budget Requested			
		Year 1	Year 2	Year 3	Year 4
1. Investigators at NMIMR, NHRC & MOH (total 9)					
2. Graduate Research Officer (to server as Research Coordinator)	100%	9600	9600	9600	9600
3. 20 Field Workers	100%	36000	36000	36000	36000
4. Data Entry Clerk	100%	3600	3600	3600	3600
5. Data Manager	20%	2400	2400	2400	2400
Total Personnel		**51600**	**51600**	**51600**	**51600**
B. SUPPLIES					
Vaccines AIK-C (2500 doses per year from Kitasato Institute) Schwarz (2500 doses per year from MOH /UNICEF) Yellow Fever Vaccine (2500 doses per year from MOH)					
Syringes (2ml) 10000 /yr; Needles (23G) 10000 /yr; Cotton Wool; Medi Swabs (10000 /yr; Spirit, etc		5000	5000	5000	
Lab supplies for HI and IgM assays; (approx. 500 samples for HI/yr and 200 clinical cases for IgM /yr)		7500	7500	7500	
Stationery		3000	2500	2500	3000
Computing supplies		500	500	500	500
Total Supplies		**16000**	**16000**	**16000**	**3500**
EQUIPMENT					
2 Medical Freezers (-40°C, with automatic temp. recording) 1 Medium size and 1 large size 1 Refrigerator /Freezer		 6000 4000 750			
6 Motorbikes		18000			
2 Computers		3500			
1 Printer		500			
60 Vaccine Carriers		1200			
Freezer Packs		250			
Total Equipment		**34200**			
PATIENT COSTS					
Photo ID Cards for study cohort (4000 children)		2000	2000	2000	
Snacks for outreach teams		5520	5520	5520	
Immunization cards (12000)		800	800	800	
Transport charges for mothers to and from clinics		3000	3000	3000	
Total Patient Costs		**11320**	**11320**	**11320**	
LOCAL TRAVEL					
Fuel for outreach teams		5760	5760	5760	
Running costs of motorbikes		300	600	1200	
Twice yearly meetings of the investigators		1000	1000	1000	
Quarterly review meetings of the sub district teams, DHMT and research team		1000	1000	1000	1000
Total Local Travel		**8060**	**8360**	**8960**	**1000**
OTHER EXPENDITURE					
Partial Support for NDSS (5% of total)		5000	5000	5000	5000
Communication		1500	1500	1500	1500
Total other expenditure		**6500**	**6500**	**6500**	**6500**
GRAND TOTAL		**127680**	**93780**	**94380**	**62600**

③麻疹の免疫不全とアポトーシス

JICA INFECTIOUS DISEASES PROJECT

i. Vaccine Preventable Diseases

Title: IMMUNE DYSFUNCTION AND APOPTOSIS IN MEASLES INFECTION

Subjects
30 – 40 cases of measles infection in children
10-20 children immunized with measles vaccine
10-20 healthy controls
Measles cases will come form 37 Military Hospital and La Polyclinic
Immunization cases from Ashiaman and 37 Military Hospital
Controls will come from 37 Military Hospital

Methods
Flow cytometry for phenotying T cells. Will include markers of B cells and T cells(Helper/inducer cells), suppressor/cytotoxic cells, NK cells, activated and naïve cells.
Antibodies include CD3, CD4. CD8, CD19, CD25, CD16, CD45, CD95, TCR gamma delta.
All from Dako or any other source. Catalogues available.
Whole blood will be used. Plasma cytokines and cytokines in culture supernatants will be measured.
Co-cultures of PBMC and B95a for detection of virus.
Measles virus antibody measurements
Storage of PBMC from samples for IL-12 detection by RT-PCR

Equipment
The Becton-Dickinson FACSTATION computer attachment for the existing FACScan. This comes with the Cell Quest Software. Can be ordered through BD at Becton Dickinson, Belgium. Telephone number (32) 53-720211 and Fax (32) 53-720450(Will make initial contact for pro-forma invoice.

Freezer(-80°C), Sanyo. Order can be placed locally.

Liquid nitrogen facilities are available. Cell separation facilities are also available.

BD Akanmori

④ガーナ国Biosafety Guideline策定審議会開催案内

Tel: 666049/662013
Fax: 666828
Our Ref: MEST/SCR/042/02/V.2

REPUBLIC OF GHANA

Ministry of Environment, Science & Technology
P. O. Box M.232
Accra

Your Ref:

December 1, 19 98

INVITATION TO PARTICIPATE IN NATIONAL WORKSHOP ON BIOSAFETY

I wish to invite you to participate in the National Workshop on Biosafety being organised under the joint sponsorship of the Ministry of Environment, Science and Technology and the Ghana Institute of Biology.

The details for the Workshop are as follows:

Date	:	Thursday December 3, 1998
Time	:	8.30 am
Venue	:	Conference Room, Science and Technology Policy Research Institute (STEPRI), CSIR, located behind Golden Tulip Hotel.

Please find attached a copy of the relevant document for the Workshop. Kindly bring it along to the Workshop.

Counting on your usual cooperation.

E. P. D. BARNES
CHIEF DIRECTOR
For : MINISTER

DISTRIBUTION

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M. O. F. A.
Pokuasi

⑤ガーナ国Biosafety Guideline (Draft)

-DRAFT-

Guidelines on Biosafety for Ghana

Ministry of Environment, Science and Technology

Contents:

GUIDELINES ON BIOSAFETY FOR GHANA *,**

Introduction

Biotechnology has been recognised in Ghana to offer great potential for increasing agricultural output and ensure food security as well as improving human health. Biotechnology helps in generating products relevant to agriculture, human and animal health, industry, and the environment.
Traditional biotechnology has been practised for centuries in our society in industries such as brewing and fermentation. Modern biotechnology, however, includes, *inter alia* technologies such as cell and tissue culture, monoclonal antibodies, and recombinant DNA (rDNA) or genetic engineering techniques.
The increased precision and shorter time required in producing results with modern biotechnology make these new techniques particularly attractive.

Genetics engineering has introduced a new dimension to biotechnology. With this technology, scientists can recombine DNA from different organisms, given rise to genetically modified organisms (GMOs). Organisms that have been produced using the recombinant DNA technique, the genome of the organism has been modified. The results of this modification need to be assessed for risks to humanity or the environment before the organism can be freely released or deployed. The issues of public and environmental safety concerning biotechnology product or application must be carefully considered.

The potential influence of modern biotechnology in our lives is far-reaching and the variety and number of products that can be released into the environment is high. Developing countries like Ghana can derive tremendous benefits from these techniques of biotechnology. It is therefore important that Ghana devises appropriate regulatory guidelines to ensure that the products are safe. The guidelines must afford protection to individuals, the community and the environment by minimizing potential hazards associated with new application of genetic engineering.

* In developing these guidelines for biosafety for Ghana, use has been made of documents listed in Annex 1.

** In view of the rapid changes occuring in biotechnology, it is necessary that this document should be reviewed from time to time.

An international biosafety information network and advisory service already exists to provide help the information currently available includes a general framework and guidelines that can ensure the safe application of the GMOs in research, development, trade, and utilization.

Background

The need to establish National Biosafety Guidelines is in consonance with the National Environment Action Plan (NEAP). The NEAP defines the scope for environmental intervention in Ghana. It sets out a policy and strategy for managing Ghana's environmental resources on the basis of a sustainable development approach. The plan provides for a coherent technical, institutional and legal framework necessary for intervention. A National Biosafety Guidelines is in this vein.
The first major step in fulfilling the obligations in the handling of biotechnology and the distribution of its benefits that are stipulated in the International Convention on Biological Diversity Biosafety systems are intended to protect the entire environment of which biodiversity is a component. With the Government's commitment to ensuring safe environment it is advisable to:

a) Develop guidelines, standards, codes of practice and monitoring capabilities for both research and development (R&D) and prerelease assessment of the risk associated with release into the environment of GMOs.

b) Develop a sound scientific database, upon which risk assessment and evaluation of products can be made.

c) Provide guidelines to ensure safety of developers and end-users of biotechnology products.

d) Promote the development and enforcement of regulations in harmony with national priorities and international approaches.

e) Foster a favorable climate for developing and accelerating innovations and for adopting sustainable biotechnology products and processes.

Objectives

The National Biosafety Guidelines will promote opportunities for the application of innovative biotechnology products. The guidelines will be broad-based and adaptable to new knowledge and advances in biotechnology, focusing on: the characteristics and risk of biotechnology products used in agricultural, medical/pharmaceutical, and industrial production. The review process for efficiency and effectiveness of the products as well as safety in terms of public health and the environment; and integration of the release process of biotechnology products into the overall regulatory system that governs the release of new products.

Utilization of GMOs in research and development, as well as industrial production processes, should ensure public and environmental safety, with particular attention paid to accident prevention, containment, and waste disposal. The need to prevent accidents is even more imperative as released organisms could easily reproduce in the environment and spread into neighbouring countries. In view of these, there is need for a program for the safe development of biotechnology. Equally necessary are measures for risk evaluation and reduction in all operations, as well as the prescription of appropriate conditions for the use of biotechnology and its products since the nature and scale of risks' are currently fully known. Biotechnology processes and GMOs can be suitability of installations and equipment where such processes are carried out, and the control of the different operations should be subject to nationally approved, specific guidelines.

These guidelines shall cover the following:

a) Genetically engineered microorganisms
b) Genetic transformation of plants and animals
c) rDNA technology in vaccine and pharmaceutical products development.
d) Large-scale production and deliberate or accidental release of microorganisms, plants animals, and products derived from rDNA technology.

e) Appropriate measures to avoid adverse effects on human health and the environment, which might arise from the deliberate or accidental release of GMOs.

f) Provision of a foundation for a scientifically based process of risk assessment for the development and authorization of release of specific GMOs. This assessment will be part of continuing R&D, evaluation, and commercialization of organisms with novel characteristics.

h) Creation of awareness within the public of the benefits of biotechnology.

Risk Assessment

Safety considerations in the applications of biotechnology are imperative since possible risks in R&D involving recombinant DNA modified microorganisms, plants, and animals have been recognised.

a) risk/safety assessment of a GMO should be based on the nature of the GMO and the environment into which it will be introduced and not on the method by which it was modified. In essence, key aspects of risk assessment should include the factors affecting the survival, reproduction, and dissemination of the GMOs in the environment, the stability of the organism in terms of genetic traits, its capability to transfer genetic material, and routes of potential dissemination. Other important considerations include methods for the detection, identification, and monitoring of the organism and for detecting transfer of the donated DNA to other organisms; and the relevant attributes of the site where the GMOs will be used.

b) In risk and safety assessments of GMOs experience elsewhere can help in determining the degree of confinement or containment,

c) Possible types of risks to be assessed on GMOs, for example, in agricultural biotechnology, are

i) potential for the plants to become weeds;

ii) likely toxicity of plants and plant materials;

iii) potential pathogenicity of microorganisms:

iv) potential for animals to become pests:

v) potential for other hazards to human beings, plants and animals:

vi) potential for environmental hazards.

d) Field testing: There is a long history of utility and safety in the use of plants and microorganisms. Society has benefited from the use of genetically modified microorganisms and plants, and field testing is essential to increase our knowledge of the relative safety or risk of large-scale use of GMOs and to determine their potential utility.

For field-testing of genetically modified microorganisms, risk can be minimized or eliminated by adopting good development practice to confine the introduced microorganisms to the target environment.

In all cases involving microorganisms, plants and animals, the following should be taken into consideration:

i) Vector-host specificity and stability;

ii) potential for vector "leakage" into unintended hosts in the environment;

iii) nature and ease of possible recombination and spread of such vectors.

e) Familiarity: "Familiar" does not necessarily mean "safe". Rather, to be familiar with the elements of an introduction means to have enough information to be able to judge its safety or risk. Microorganisms have been suggested according to the following criteria.

i) Is sufficient knowledge available concerning the properties of the organism and the environment into which it may be introduced?
ii) Can we confine or control the organisms effectively?

iii) What are the probable effects on the environment, should the introduced organism or genetic trait persist longer than intended or spread to non-target environments and organisms?

Other information required for risk assessment include:

iv) identity of the GMO and specific genetic modification included in the GMO; e.g., DNA sequence, copy number, plasmid border integrity, and pedigree information for traditionally bred offspring of previously assessed GMOs;

v) phenotypic expression of the GMO with various forms of life, including identification of anticipated or observed specific relative differences of the GMO compared with its counterpart and interactions with other forms of life;

vi) potential interactions of the GMO with various forms of life, including identification of anticipated or observed specific relative differences of the GMO compared with its counterpart and interaction with other forms of life;

vii) other potential environmental impact; e.g., potential excessive population increase in the environment, competitive advantage of the GMO in relation to the unmodified form, identification and description of the target organisms, anticipated mechanism and result of interaction between the GMO and target organism, likelihood of post-release shift in biological interaction or host range, other potentially significant interaction with the environment (e.g., effect on non-target organisms), and impact on population levels and on other organisms (e.g., prey, hosts, symbionts, predators, parasites and pathogens).

When the familiarity standard for a plant or microorganism is such that there is reasonable assurance that the organism and the other conditions of an introduction are essentially similar to known introductions, and when those have proven to present negligible risk; the introduction is assumed to be suitable for field testing, according to established practice. The familiarity criterion is central to the suggested evaluation framework. It permits decision makers to draw on past experience in introducing plants and microorganisms into the environment, and it provides for flexibility. As field tests are performed, information will continue to accumulate about the organisms, their phenotypic expression, familiar enough to require minimal oversight.

When knowledge of the type of modification, the species being modified, or the target environment is insufficient to meet the familiarity criterion, the proposed introduction must be evaluated according to whether the organism can be confined or controlled, as well as the potential effects of a failure to confine or control it. This defines the relative safety or risk of the introduction.

f) Level of risk: In evaluating the potential risks associated with GMOs and new technologies, the appropriate questions are:

i) What are the relative risks of the new technologies compared with the risks of the existing technologies?

ii) What are the potential risks of overregulation or failing to fully develop new technologies?

iii) How are risk determinations incorporated in cost and benefit evaluations?

The aim is not necessarily to achieve zero risk. Concerns over potential risks of introducing GMOs should not lead to too stringent and expensive regulations which can impede development of new technologies that can lead to exciting new and beneficial organisms and products.

Risk Management

For each planned GMO release, the authority should ensure that there is compliance with the safety conditions which were developed from the results of the risk assessment. That should include appropriate control procedures, and procedures for terminating the experiment and disposing of wastes.

Once action is complete on risk assessment, adequate regulatory action should be taken to ensure appropriate risk management, including the following:

a) Contained use and practice: Good laboratory practice, good occupational safety and hygiene (see annex 2), as well as well qualified and competent personnel, are prerequisites for biotechnology.

b) GMO use and release:

There must be

i) judicious choice of DNA vector and host to ensure that vector infectivity is host-specific and controls host vector survival in the external environment.

ii) appropriate containment for the microorganisms, plants, and animal system being manipulated which reflects the expected risk level of the GMO.

c) Additional action is called for as follows.

i) Appropriate authorities at the national or institutional level should oversee the introduction of GMOs. One or more authorities may be appropriate to cover specific areas; e.g., foods, pesticides, pharmaceuticals, agriculture, among others.

ii) Risk assessment and management should be carried out by competent bodies. It may be necessary to seek expertise from outside the particular country. However, ultimate decisions must rest with the country.

iii) Case-by-case evaluation should be the rule based on the premise that the risk of a particular application cannot be determined theoretically, but only empirically.

iv) For field testing, genetically modified plants, which exhibit traits that are unfamiliar in the unmodified plant will require careful evaluation in small-scale field tests, where plants which exhibit undesirable phenotypes can be destroyed.

v) Step-by-step analysis should progress from controlled trials to less controlled and/or larger geographical trials based on acceptable results from prior tests.

NATIONAL BIOSAFETY COMMITTEE (NBC)

For purpose the of safe management of biotechnology activities, including research, development, introductions and use of GMOs, Ghana, like other countries, needs to establish a National Biosafety Committee (NBC).

Subcommittees could be established by the NBC for sectoral interest such as agriculture, health, industry, and environment.

Membership

Membership of NBC should comprise the following:

a) Scientists
   - Biologist (1)
   - Environmentalist (1)
   - Physical Scientist (1)
   - Social Scientist (1)

b) Relevant ministries/agencies
   - Ministry of Agriculture (1)
   - Ministry of Environment, Science and Technology (1)
   - Ministry of Industry (1)
   - Ghana Standards Board (1)
   - Environmental Protection Agency (1)

c) Community

Public Sector (1)
Organized Private Sector (1)

d) The Ministry of Environment, Science and Technology will provide secretariat. The chairman should be appointed from among the members.

Tenure

Members of NBC should serve for three years in the first instance and are eligible for re-appointment for second term only.

Responsibilities of NBC

a) Formulate policy and procedures at the national level;

b) Provide technical advice.

Specific functions of the NBC

In recognition of the need to provide advice to government agencies on the assessment of the risks and benefits associated with the production and/or application of GMOs and other biological materials produced in laboratories, the NBC shall.

a) Establish and review, as necessary, guidelines for both physical and biological containment and/or control procedures, appropriate to the level of assessed risk involved in relevant research, development, and application activities.

b) Consult with relevant government agencies and other organizations as appropriate;

c) submit an annual report to the Ministry of Environment, Science and Technology and also report within 15 days on any accidents or any breaches of the guidelines cited in (a) above and on other relevant matters referred to it;

d) Establish contact and maintain liaison with appropriate monitoring bodies in other countries and with international organizations;

e) Advise, if appropriate, on the training of personnel with regard to safety procedures;

f) Collect and disseminate information relevant to the above, having due regard to the special circumstances relating to proprietary information;

g) Maintain an inventory of laboratories with physical and human capacities to conduct research in rDNA; also create a database of experiences in the releases of GMOs in the country;

h) Establish and oversee the work of scientific subcommittees, whose guidelines follow and whose role and function include not only participation in the foregoing items (b), (c), (d), (f), and (g), but also all research performed under contained laboratory conditions.

The National Biosafety Technical subCommittees:

These subcommittees shall be formed in one each of the various disciplines (e.g. agriculture, health, industry, environment) to support the work of the NBC. The subcommittees shall enter into discussion directly with those scientists and institutions working on biotechnology and with fund-granting bodies in order to determine the conditions under which research should be conducted.

The subcommittees shall:

a) Review proposals for research and recommend the conditions under which experiments should be conducted, or whether work should not be undertaken.

b) Provide technical advice to the NBC and contribute to its functions in relation to laboratory-contained research.

Relationship of NBC with Regulatory Bodies

The NBC will have to deal with bodies having responsibilities for:

a) Assessment and regulation of in-country research:

In this connection, the NBC shall set out required guidelines for laboratory and field research while establishing necessary structures and responsibilities to ensure their implementation by the relevant organizations in the country.

In Ghana, the Biotechnology and Nuclear Agriculture Research Institute, which is pursuing research in diverse areas of biotechnology may be used to regulate the products of modern biotechnology.

b) Assessment of safety of imported and exported biotechnology products:

Relevant regulatory authorities shall have the responsibilities for importation and exportation of biotechnology products. The NBC is expected to play an active advisory role with these agencies, by assisting in assessing the adequacy of the tests carried out in the product's country of origin or of the adequacy of tests carried out on products of biotechnology to be exported.

c) Assessment of environmental effects of biotechnology products:

NBC should cooperate with and aid EPA to develop up-to-date tests for monitoring the effects of biotechnology products in the environment.

INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)

All institutions in Ghana, both private and public (e.g., research institutes, universities and polytechnics, international research institutes, industrial research and development units which plan to undertake biotechnology research and/or development), must each establish an institutional biosafety committee (IBC), which will be responsible to, and cooperate with, the NBC.

Actions and Responsibilities of Institutions

Responsibilities of the institution will include:

a) Establishment of guidelines for biotechnology research, which should be subject to review in line with developments in that field.

b) Establishment of an institutional biosafety committee (IBC). Where a critical mass of scientists to constitute the IBC is not available, the institution may jointly form one committee with other institutions, or rely on the IBC of another institution;

c) Assistance to Chief Investigator responsible for research to make sure that the research is conducted in accordance with established guidelines;

d) Appointment of a biosafety officer who will monitor and advise on biosafety issues on a day-to-day basis.

e) Establishment of provisions to make available to the public information on experiments conducted at the institution, subject to established guidelines, unless it contains confidential business information or unless its disclosure is prohibited by law, and to make available a general description of information withheld;

f) Assurance that the IBC reports promptly to the NBC any significant problems with implementation of established guidelines;

g) Assurance that the IBC reports to the NBC within 15 days any research related accidents that have resulted or could result in human illness, in unanticipated plant or animal disease, or in the escape of organisms under study from the intended confinement.

Composition of the IBC

The IBC should include:

a) Five members, including the biosafety officer, so selected that as a group, they have experience and expertise for evaluation of the biosafety and environmental effects of biotechnology research, including the use of rDNA techniques;

b) Two members not affiliated with the institution but knowledgeable in biotechnology, and representing the interests of the community; such as

i) members of government public health or environmental agencies,

ii) persons active in human, plant or animal health concerns,

iii) persons active in environmental concerns.

The membership of IBC under categories (i), (ii), and (iii) does not imply affiliation with the institution.

Functions of the IBC

The terms of reference of IBC are to:

a) Consult with and seek approvals from the NBC;

b) Implement the recommendations of the NBC;

c) Establish and implement policies that provide for the safe conduct of biotechnology research and ensure compliance with applicable guidelines;

d) Review and endorse applications from Chief Investigators;

e) Create and maintain a central reference file and library of catalogs, books, articles, newsletters, and other communications as a source of advice and reference, including such items as the availability of safety equipment, the availability and level of biological containment for various host vector systems, suitable training of personnel, and data on the potential biohazards associated with certain technologies;

f) Develop a safety and operations manual and assist Chief Investigators in the required staff training;

g) Certify the safety of facilities, procedures, and practices and ensure that the level of training and expertise of the personnel involved have been reviewed and approved;

h) Review all biotechnology research conducted and sponsored by the institution for compliance with established guidelines. In effect, IBC should establish a program of inspections to ensure that the physical containment facilities and field trials continue to meet requirements and that other procedures and practices specified in the guidelines are followed;

i) Maintain a list of Chief Investigators, project supervisors, and other supervisors approved by the IBC as competent to perform supervisory duties for particular projects;

j) Maintain individual records and files of individual research projects;

k) Investigate and report promptly to the NBC all accidents and unexplained absences and illness;

l) Provide an annual report to the NBC.

Activities of IBC

The IBC of an institution may also review and approve biotechnology research conducted or sponsored by another institution that cannot establish its own. Every effort should be made to promote cooperation between Chief Investigators and the IBCs. The IBC is encouraged to invite the Chief Investigators to attend its meetings and provide detailed information on the proposed project so that a clear, definitive, and defensible decision can be made.

Scientific review by the IBC of biotechnology research outside the laboratory should consider, but not limited to, the following topics:

a) Identification, taxonomy, source, molecular biology, and relevant ecological characteristics of the modified relative to the non-modified organism; its construction; its capacity for genetic transfer, stability and expression; and the source, nature, and function of any inserted DNA sequence;

b) Data related to any anticipated effects of the modified organism on the environment and other associated organisms in experiments that simulate trial conditions;

c) Methods of detection and limits or sensitivity of sampling techniques, periodicity of sampling, and types of data to be obtained;

d) Physical, biological, and other confinement incorporated in the experiments;

e) Survival, replication, and dissemination characteristics of the modified organism by wind, water, soil, mobile organisms, etc., and methods of application;

f) Identification and taxonomy of the target organism, the anticipated mechanism of action of the modified organism on the target organism, and results of the interaction between the released organism and the target organism (if the modified organism has a target organism);

g) Monitoring procedure, transportation of biological materials, and termination plans for the field test;

h) Site characteristics and design, including diagrams of the experimental location and the immediate surroundings;

i) Contingency plans for emergency termination;

j) Access restrictions and security measures for the areas(s) in which the tests will be performed.

Once a project involving biotechnology research has been reviewed and approved by the IBC, the project should be monitored periodically by IBC.

Biosafety Officer

Terms of reference/responsibilities of the biosafety officer include:

a) Familiarity with the biosafety requirements for the rDNA work and facilities, and ability to check and advise on biosafety issues on day-to-day basis;

b) Sufficient independence and authority to ensure that biosafety is not compromised by other considerations;

c) Appointment as a member of the IBC;

d) Provision of a report which should form part of the IBC's annual report to the NBC.

Responsibilities of the Researcher or Chief Investigator

The Researcher or Chief Investigator, as an agent of an institution, is responsible for conducting biotechnology research in a safe manner and in compliance with the appropriate research guidelines and all applicable regulations.

The responsibilities include the following:

a) Ensure that experiments, for which the Chief Investigator is responsible, are covered by institutional and national guidelines;

b) Instruction and training of staff in the practices and techniques to maximize safety and in procedures for dealing with regulations;

c) Provision of prompt reports to the IBC on any significant problems with implementation of relevant guidelines and regulations;

d) Provision of reports to the IBC on any research-related accidents that have resulted or could result in human illness, in unanticipated plant or animal disease, or in the escape of organisms under study from the intended confinement.

e) Non-initiation or modification of biotechnology research requiring prior approval of the IBC;

f) Compliance with applicable shipping requirements regarding human, plant, and animal health protection and policies, permit requirements, and containment conditions for possession of certain organisms.

2. Level of Safety Determination

In addition to the foregoing, the researcher should make an initial determination of the condition for research and the appropriate level of safety as follows:

a) Determine the level of safety concern for the unmodified organisms on a scale of 1 (lowest concern) to 5 (highest concern);

b) Determine the effect of the genetic modification on safety (i.e., whether it increases, decreases, or has no effect on safety);

c) Determine/specify the level of safety concern for the modified organism on a scale from 1 (lowest concern) to (highest concern);

d) Determine the confinement level appropriate to the particular level of safety concern for the modified organism and develop a safety protocol to meet this level of confinement.

3. Proposals by the Chief Investigator

The Chief Investigator shall remain in contact with the IBC as the research progresses. In submitting research proposals, the Chief Investigator should:

a) Make the initial determination of the required confinement level in line with the relevant guidelines or regulations;

b) Select the appropriate practices and techniques to be used in the research;

c) Submit the initial research protocol and subsequent changes to the IBC for review or action.

4. Other Considerations

a) The Chief Investigator should take the following into account, in connection with environmental introduction of GMOs:

i) characteristics of the organism(s) used, including the introduced gene, genetic materials and gene products;

ii) characteristics of the site and the surrounding environment;

iii) appropriate conditions of the release, including confinement, control, mitigation, and disposal procedures as appropriate;

b) The Chief Investigator is responsible for conducting evaluations of potential risks at appropriate stages of research and development of an organism, prior to its formal review or assessment.

c) Records should be properly kept and maintained on all activities involving GMOs (documentation should include the description and location of each activity, protocols for carrying them out, the results, monitoring data, and any other pertinent information);

d) The Chief Investigator should notify and obtained approval, from the NBC through the IBC, prior to the conduct of an activity involving the release of GMOs;

e) The Chief Investigator should disclose all relevant information on previous approvals and refusal of all trials in subsequent proposals or submissions to the IBC.

Annex 1

REFERENCES

1. Voluntary Code of Conduct for the Release of Organisms into the Environment . Prepared by the UNIDO Secretariat for the Informal UNIDO/WHO/FAO Working Group on Biosafety (July 1991).

2. The Safe Application of Biotechnology in Agriculture and the Environment. G.J. Persley, L.V. Giddings, and C. Juma (1992). The World Bank/International Service for National Agricultural Research (ISNAR).

3. Agricultural Biotechnology. Introduction to Field Testing, March 1990. H. Graham Purchase and David R. Mackenzie, Editors. Office of Agricultural Biotechnology, U.S. Department of Agriculture.

4. Guidelines for Research Involving Planning Introduction into the Environment of Genetically Modified Organisms. Guidelines Recommended to USDA by the Agricultural, Biotechnology Research Advisory Committee, 3-4 Dec., 1991.

5. Recombinant DNA Safety Considerations. Safety Considerations for Industrial, Agricultural and Environmental Applications of Organisms derived from Recombinant DNA techniques. Organization for Economic Cooperation and Development (OECD), 1986.

6. BIOTASK/ISNAR Seminar, Biotechnology Policy-and the CGIAR: Draft summary of discussion on biosafety (1991).

7. Canada: Regulation of Agricultural Products of Biotechnology.

8. Canada: Proposed Assessment Criteria for Determining Environmental Safety of Genetically Modified Plants.

9. India: Recombinant DNA Safety Guidelines and Regulations.

10. Biosafety: A Report on Regulatory Approaches for the Deliberate Release of Genetically-engineered Organisms. CIIFAD, Cornell Univ., Ithaca, N.Y. 1993. pp.67.

Annex 2

GOOD LABORATORY PRACTICES

Laboratory Hygiene

Never do direct mouth pipetting of infectious or toxic fluids; use a pipette.

Plug pipettes with cotton wool.

Do not blow infectious material out of pipettes.

Do not prepare mixtures of infectious material by bubbling expiratory air through the liquid with a pipette.

Use an alcohol-moistened pledget around the stopper and needle when removing a syringe and needle from a rubber-stoppered vaccine bottle.

Use only needle-locking hypodermic syringes. Avoid using syringes whenever possible.

Expel excess fluid and bubbles from a syringe vertically into a cotton pledget moistened with disinfectant, or into a small bottle of cotton.

Before and after infecting an animal, swab the site of injection with a disinfectant.

Sterilize discarded pipettes and syringes in the where they were first placed after use.

Before centrifuging, inspect tubes for cracks. Inspect the inside of the trunnion cup for rough walls caused by erosion or adhering matter. Carefully remove all bits of glass from the rubber cushion. A germicidal solution added between the tube and the trunnion cup not only disinfects the surfaces of both these, but also provides and excellent cushion against shocks that otherwise might break the tubes.

Use centrifuge trunnion cups with screw caps or equivalent.

Avoid decanting centrifuge tubes; if you must do so, afterwards wipe off the outer rim with a disinfectant. Avoid filling the tube to the point where the rim becomes wet with culture.

Wrap a lyophilized-culture vial with disinfectant-wetted cotton before breaking the vial. Wear gloves.

Never leave a discarded tray of infected material unattended.

Sterilize all contaminated discarded material.
Periodically, clean out the deep-freeze and the dry-ice chest in which cultures are stored, to remove broken ampoules or tubes. Use rubber gloves and respiratory protection during the cleaning.

Handle diagnostic serum specimens carrying a risk of infectious hepatitis with rubber gloves.

Develop the habit of keeping your hands away form your mouth, nose, eyes, and face. This may prevent self-inoculation.

Avoid smoking, eating, and drinking in the laboratory.

Make special precautionary arrangements to avoid respiratory, oral, intra-nasal, and intratracheal inoculation of infectious material.

Give preference to operating rooms gowns that fasten at the back.

Evaluate the extent to which the hands may become contaminated with some agents and operations, remember that forceps or rubber gloves are available.

Wear broth cultures in a manner that avoids wetting the plug or cap.

Aerosol Minimization.

Because of their insidious nature, aerosols pose special problems in that the laboratory worker may be unwillingly exposed. Procedures which can produce aerosols include:

grinding
blending
sonicating
resuspending packed cells or viruses
inserting hot loop into a culture
forceful ejection of fluid from a pipette or syringe
centrifugation
flaming an inoculation loop so that it splatters
opening a tube containing a lyophilized agent
releasing the vacuum on a freeze-dryer
opening a tube within which the air pressure may differ from that of the room, such as may occur when the tube is opened at a temperature different from that at which it was sealed.

Annex 3

GLOSSARY

Accident. Any incident involving a significant and unintended release of genetically modified organisms in the course of their contained use, which could present an immediate or delayed hazard to human health or the environment;

Biosafety. The policies and procedures adopted to ensure the environmentally safe applications of modern biotechnology in medicine, agriculture, and the environment, and to avoid endangering public health or environmental safety.

Biotechnology. Any technique that uses living organisms or substances from these organism to make or modify a product, to improve plants or animals, or to develop microorganisms for specific uses.

Cell. The smallest component of life A membrane-bound protoplasmic body capable of carrying on all essential life processes. A single-cell unit is a complex collection of molecules with many different activities.

Confinement/Containment. Measures to limit the interaction of the regulated organisms with the environment or with human. Procedures include but are not limited to isolation from related species, destruction of residues, and sterilization using, physical, chemical and/or biological barriers to limit their contact with the general population and the environment.

Deliberate release. Any intentional introduction into the environment of a GMO or a combination of GMOs without provisions for containment, such as physical barriers or a combination of physical barriers together with chemical and/or biological barriers used to limit their contact with the general population and the environment.

Environment. Components of the earth, including air, land, water, all layers of the atmosphere, all organic and inorganic matter and living organisms, and all interacting natural systems that include components referred to above. Includes the natural and managed ecosystems, including agricultural ecosystems.

Environmental Release. The controlled, intentional testing of genetically engineered living organisms, outside of a confinement structure.

Environment Risk Assessment. The evaluation of the risk to human health and the environment (which includes plant and animals) connected with the release of GMOs or products containing GMOs.

Gene. The fundamental physical and functional unit of heredity; the portion of a DNA molecule that is made up of an ordered sequence of nucleotide base pairs that produce a specific products or have an assigned function.

Genetic engineering. Technologies (including rDNA technologies) used to isolate genes from an organism, manipulate them in the laboratory, and insert them into another organism.

Genetically modified organism (GMO). An organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.

Notification. The presentation of documents containing the requisite information to the competent authorities of a national state. The person making the presentation shall be referred to as the notifier.

Organism. Any biological entity capable of replication or of transferring genetic material

Phenotype. The physical appearance of an organism as distinguished from its genetic constitution (genotype)

Products. A preparation consisting of, or containing, a GMO or a combination of GMOs, which is placed on the market.

Shipping. Movement of materials which includes transportation, exchange, introduction, acquisition and transfer.

Tissue culture. The propagation of tissue removed from organisms in a laboratory environment that has strict sterility, temperature, and nutrient requirements.

Transformation. Introduction and assimilation of DNA by one organism from another.

Use. The deliberate application of product which has been placed on the market. The persons carrying out this use shall be referred to as users.

Proposed Regulation

1. Scope and Objectives

To protect what
biodiversity (conservation and sustainable use
human health, socio economic well-being
c) environment
d) others such as food safety, food quality?

To protect from

a) LMOs, products thereof, that may have adverse effects;
b) potential risks from these (known/unknown)
Then classify these organisms in groups and provide in annex (easily amended)

When to protect

a) during research and development
b) handling, use and transfer
c) deliberate or unintentional release
d) commercialisation – import/export
e) gene therapy and others

Which organisms to exclude

a) non-viable organisms?
b) extracts from LMOs?
c) is it necessary to mention organisms and activities to be excluded?
d) give power to National Authority to exclude where appropriate.
e) any domestic law for biological resources, R&D, food safety can be mentioned?

Also Art. 1 and 3 in Protocol.

2. Definitions/Use of terms/Legal definitions

As much as possible terms used in CBD, Protocol, UNEP Guidelines and/or existing regulations must be used.

3. National authorities, other bodies and functions

a) Ministry responsible
b) National Biosafety Committee/competent national authority
c) National focal point (individual or institution)
d) Institutional Biosafety Committee

Their functions, powers, duties, financial aspects

4. Elements for Preamble

Source from Protocol preamble; UNEP guidelines.

5. General obligations/procedures/principles

a) the basis for general procedure are in UNEP guidelines
b) statement must be kept short with reference to Annexes
c) a decision has be made whether to include all or some of the following
    - R&D
    - contained use
    - small scale environmental release
    - large scale environmental release
    - import (first and subsequent)
    - export
d) is it necessary to distinguish between microorganisms, plants and animals?
e) emergency response
f) note must be taken of provisions in existing laws on R&D of biological resources, toxic substances, waste, quarantine

6. Notification

a) elaborate on notification procedures taking into account risk posed by the organisms.
b) consideration must be given to the type of information required at every step of the process including confidential information

7. Review process and authorization

a) there should be an elaboration on review process
b) should we foresee simplified procedure?

8. Provisions on risk assessment and management

a) general description in UNEP guidelines
b) model of provisions in Protocol
c) annexes relating to RAM in UNEP & Protocol
d) consideration must be given to the issue of insufficient capacity - possible regional and international cooperation is needed

9. Liability and redress; compliance requirement, inspection

a) need to define damages and level of damage or offence in legal terms
b) need to define penalties commensurate to offence/damage
c) need to identify responsibility of those involved
d) need to develop provisions that are feasible realistic

10. Labelling, packaging and transport

a) should we just refer to international guidelines for import and export, and to domestic law
b) should we just state that NBC/competent national authority will define guidelines
c) should we include products on the market?
d) also take into consideration domestic and regional laws eg. ECOWAS, OAU

11. Information exchange or sharing

How to handle secrecy

12. Intellectual property rights

a) is it needed in regulation or should we refer to existing law
b) what about other rights such as breeders rights and farmers rights?

13. Capacity building

a) how do we include this in a domestic regulatio
b) include promotion of the private sector

14. International cooperation

a) Should we include it in the regulation or just in the preamble?

15. Public awareness and participation

Should specify who is responsible for ensuring public awareness and participation

Constraints Restricting Development of National Regulations

(Lack of national regulatory framework
(Finances
(Lack of confidence in decision makers
(Multiplicity of actors (public & private)
(Lack of technical expertise
(Lack of coordination among stakeholders
(Apprehension about regulation

IMPLEMENTATION: The Greatest hurdle?

Risk assessment and Risk Management are the integral part or the continuum that constitutes a capacity to successfully implement biosafety programs.

COST CATEGORIES

Biosafety capacity building

(Guideline/regulation development
(Regulation implementation
(Harmonization

Requirements

(Training (eg. Technical, RA/RM)
(Information collection, storage, retrieval
(Monitoring programs

CONCLUTION

A regulatory framework that:

(is not too restrictive, not too bureaucratic, not too costly and not too burdensome
(is at the intersection of science, policy & reg.
(takes into account realistic safety(no zero risk
costs
(is flexible, ie evolving with science
(promote biotechnology
(others: transparent, participatory, promote confidence.