

**A BILL FOR**

**An Act of Parliament to regulate biotechnology and biosafety matters and for connected purposes.**

**ENACTED** by the Parliament of Kenya as follows-

**PART I- PRELIMINARY PROVISIONS**

Short title and commencement.

**1.** This Act may be cited as the Biosafety Act 2003 and shall come into operation on such day as the Minister may by notice in the Gazette appoint.

Interpretation.

**2.** In this Act, unless the context otherwise requires-

"applicant" means a person submitting an application pursuant to the provisions of this Act;

"Authority" means the National Biosafety Authority established under section 5 of this Act;

"biotechnology" means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use;

"biosafety" means the avoidance of risk to human health and safety and to the conservation of the environment, as a result of the use for research and commerce of infectious or

genetically modified organisms;

"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;

"genetically modified organism" means an organism that has been transformed by the insertion of one or more genes;

"genetically modified organism register" means such register as may be maintained under section 26;

"placing on the market" means making a genetically modified organism available on a commercial basis;

"Minister" means the Minister for the time being responsible for Science and Technology,

"regulatory agency" means a regulatory agency as set out in the First Schedule to the Act.

Scope of the Act.

**3.** (1) The requirements of this Act are in addition to the requirements imposed by any other Act.

(2) This Act shall not apply to genetically modified organisms that are pharmaceuticals for human use.

Objectives of the Act.

**4.** The objects of the Act are-

(a) In accordance with the precautionary principle, this Act to ensure an adequate level of protection in the field of safe transfer, handling

and use of genetically modified organisms resulting from modern biotechnology that may have an adverse effect on the environment;

- (b) to establish a transparent and predictable process to review and make decisions on such genetically modified organisms and related activities.

## **PART II-ADMINISTRATIVE PROVISIONS**

Establishment of an Authority.

**5(1)** There is hereby established an Authority to be known as the National Biosafety Authority.

(2)The Authority shall be a body corporate with perpetual succession and a common seal and shall in its corporate name be capable of-

- (a) suing and being sued,
- (b) taking, purchasing or otherwise acquiring, holding, charging or disposing of moveable and immovable property
- (c) borrowing and lending money, and
- (d) doing or performing all other things which may lawfully be done or performed by a body corporate.

Composition of Board.

**6.** The Authority shall be managed by a board that shall consist of-

- (a) a chairman who shall be an eminent scientist, appointed by the Minister;

- (b) three other members comprising of experts in each of the following sciences, namely Biotechnology, environmental and social sciences, appointed by the Minister;
- (c) the Permanent Secretary in the Ministry for the time being responsible for Science and Technology or his representative nominated in writing;
- (d) the Permanent Secretary in the ministry for the time being responsible for finance or his representative nominated in writing;
- (e) the Director-General, the National Environmental Management Authority or his representative nominated in writing;
- (f) the Managing Director ,the Kenya Bureau of Standards or his representative nominated in writing;
- (g) the Managing Director, the Kenya Plant Health Inspectorate Services, or his representative nominated in writing;
- (h) the Director, the Department of Veterinary Services or his representative nominated in writing;
- (i) the Secretary, the National Council for Science and Technology.

(2) The chairman and members of the Board shall hold office for a period of three years but shall be eligible for reappointment for a further term of a period not exceeding three years.

(3) The names of all the members of the Board shall be by notice in the Gazette.

Functions of the Authority.

**7. The Authority shall-**

- (a) receive, respond to and make decisions on applications under and in conformity with the Act;
- (b) establish administrative mechanisms to ensure the appropriate handling and storage of documents and data in connection with the processing of applications and other matters covered by the Act;
- (c) promote public awareness and education concerning activities under the Act.

Conduct of business and affairs of the Board.

**8. (1).** The conduct and regulation of the business and affairs of the Board shall be as provided in the Second Schedule to this Act.

(2). Except as provided in the Second Schedule, the Board shall regulate its own procedure and the procedure of any of its committees.

Delegation of powers of the Authority.

**9.** Subject to this Act the Authority may either generally or in any particular case, delegate to any committee of the Board or to any member, officer, employee or agent of the Authority, the exercise of any of the powers of the Authority under the Act.

Remuneration of Board members.

**10.** The Authority shall pay to its Board members, such remuneration, fees or allowances for expenses as it may determine with the approval of the Minister.

The chief executive officer.

**11. (1)** There shall be a Chief Executive Officer of the Authority who shall be appointed by the Board and whose terms and conditions of service shall be determined by the Board in the instrument of appointment.

(2) The Chief Executive Officer shall hold office for a period of five years.

(3) The Chief Executive Officer shall, subject to the directions of the Board be responsible for the day to day management of the affairs of the Authority.

Staff of the Authority.

**12.** The Authority may appoint such officers and other staff as are necessary for the proper discharge of its functions under this Act, upon such terms and conditions of service as the Authority may determine.

Protection from personal liability

**13.** No matter or thing done by a member of the Board or by an officer, employee or agent of the Authority, shall, if the matter or thing is done bona fide for executing the functions, powers or duties of the Authority, render the member, officer, employee or agent personally liable to any action, claim or demand whatsoever.

### **PART III- HANDLING REQUESTS FOR APPROVALS.**

Application for contained use.

**14.** (1) No person shall conduct any contained use activities involving genetically modified organisms without the written approval of the Authority.

(2) The application shall include-

- (a) such details as are set out in the Third Schedule to this Act;
- (b) Any additional information that the applicant may deem necessary to an assesment of the poteential risk and benefits of the requested activity.

Application for introduction  
Into the environment.

**15.** (1) No person shall introduce into the environment a genetically modified organism without the written approval of the Authority.

(2) A person wishing to introduce a genetically modified organism into the environment shall submit to the Authority an application describing the activity for which the approval is sought.

(3) An application to introduce a genetically modified organism into the environment shall include –

- (a) the information set out in the Fourth Schedule to this Act,
- (b) a risk assessment as set out in the Fifth schedule to this Act, and
- (c) any additional information that the applicant may deem necessary to an assessment of the potential risks and benefits of the requested activity.

(4) An application shall include a sworn declaration that the information contained therein is factually correct.

(5) An applicant may withdraw his application at any time prior to the issuance of a final decision by the Authority.

Application to  
import or place  
on the market.

**16.** (1) No person shall-

(a) import; or

(b) place on the market  
a genetically modified organism without a written approval of the Authority.

(2) An application to import or place on the market a genetically modified organism shall include –

(a) the information set out in the Fourth schedule to this Act,

(b) a risk assessment as set out in the Fifth schedule to this Act, and

(c) any additional information that the applicant may deem necessary to an assessment of the potential risks and benefits of the requested activity.

Application to export.

**17.** A person intending to export a genetically modified organism shall provide the Authority with a written advance informed agreement of the competent authority of the importing country.

Genetically modified organisms in transit.

**18. (1)** A person transporting genetically modified organisms through Kenya but such genetically modified organisms are not destined for use in Kenya shall-

(a) Apply for a written approval of such transportation from the Authority;

(b) ensure that the genetically modified organisms are properly packaged and transported in accordance with the regulations and international standards.

(2) An application to transport genetically modified organisms through Kenya shall be as prescribed in the regulations.

Confidential information.

**19. (1)** The Authority shall –



- (a) allow an applicant to identify information provided to the Authority in accordance with the requirements of this Act and any regulations made hereunder, that is to be treated as confidential, with justification for claims of confidentiality to be provided upon request,
- (b) decide whether it accepts as confidential the information designated by the applicant,
- (c) inform the applicant of its rejection of the claim of confidentiality, providing reasons on request, as well as an opportunity for consultation, and
- (d) in the event that an applicant withdraws an application, respect the applicant's claims of confidentiality.

(2) The Authority shall not use confidential information for any purpose not authorized under this Act and shall ensure that such information is protected by any person involved in handling applications under this Act.

Acknowledgement of application

**20.** (1) Upon receipt of the application, the Authority shall screen the application for completeness.

(2) The Authority shall acknowledge in writing, receipt of the application within thirty days of such receipt.

(3) where an application is not complete, the Authority shall request the applicant to submit additional information.

Authority to publish notice

**21.** (1) The Authority shall publish in the Kenya Gazette, notice concerning an application for release into the

environment , for the general information of the public.

(2) Upon request, the Authority may avail to any person portions of any application that do not qualify as confidential information.

Risk assessment  
and risk  
management.

**22.** (1) Where the application has been screened and found to be complete, the Authority shall undertake a risk assessment as set out in the Fifth Schedule to this Act.

(2). Risk assessment shall be carried out taking into account available information concerning any potential exposure to the genetically modified organism.

(3). The Authority shall audit risk assessments submitted by the applicant and shall conduct any additional risk assessment as required.

(4). Upon completion of the risk assessment, the Authority shall make a report giving its decision, justification on the disposition of the application and indicate any measures to be taken to ensure the safe use of the genetically modified organism.

(5). The Authority shall liaise with the appropriate regulatory agency to ensure that measures are in place to manage and control risks identified during the risk assessment process.

Exemption.

**23.** The Authority may exempt genetically modified organisms from certain requirements of sections 14, 15 or 16, where it determines that sufficient experience or information exists to conclude that the genetically modified organisms or activities do not pose a significant risk to the environment.

Determination of the  
application.

**24.** In reaching a final decision, the Authority shall

take into account,

- (a) information submitted by the applicant;
- (b) the risk assessment report;
- (c) relevant comments submitted by the public; and
- (d) socio-economic considerations arising from the impact of the genetically modified organism on the environment.

Communication of decision.

**25.** (1) The Authority shall communicate its final decision to the applicant within one hundred and fifty days of the receipt of the application.

(2). The approval shall clearly set out any specific conditions, related to the approval.

(3). The approval shall be specific to the activity authorized as set out in the decision document.

Authority to maintain a register.

**26.** The Authority shall maintain a register, which shall contain the following information –

- (a) a copy of the application;
- (b) a copy of the risk assessment report;
- (c) a copy of the decision document;
- (d) a copy of the approval; and
- (e) any other information the Authority may deem necessary.

**PART IV- REVIEW AND APPEALS**

Review of approval.

**27.** (1) The Authority may review a decision made under section 24 at any time upon obtaining significant new scientific information indicating that the genetically modified organism or activities involved may adversely affect the human health, plant health, animal health or the environment.

(2) A regulatory agency or an applicant may request the Authority to review its decision under sec. 24 with respect to an activity conducted by the applicant where the applicant considers that -

(a) a change in the circumstance has occurred that may have a material effect on the outcome of the risk assessment upon which the decision was based; or

(b) additional scientific or technical information has become available that may have a material effect on the decision including any conditions, limitations or requirements imposed under an approval.

(3) If upon review the Authority is satisfied that a change is warranted, the Authority shall issue a substitute approval.

(4). The Authority shall make a decision on a review within one hundred and fifty days from the date of notification of the review and shall set out the reasons for the decision.

(5). Where the Authority has the knowledge that an activity poses potential risk to the environment, the Authority shall take immediate action to put necessary measures in place.

(6) The Authority shall give special consideration for review requests from a regulatory agency.

Offence of withholding information.

**28.** Where an applicant withholds information that has become available to him after the approval of his application and the information could change the evaluation of the risk posed by the applicants intended activity, the applicant commits an offence and is liable on conviction to a fine of two million shillings or imprisonment for ten years.

Appeal from decision.

**29.** (1) There is hereby established an Appeals Board, which shall consist of-

(a) a chairman, who shall be an eminent biological scientist, appointed by the Minister;

(b) an advocate with professional qualifications in biotechnology and biosafety matters, appointed by the Minister;

(c) the Chief Executive of the Authority;

(d) two persons, who have qualifications in biotechnology and biosafety management, appointed by the Minister.

(2) All appointments to the Appeals Board shall be by gazette notice issued by the Minister.

(3) The members shall hold office for three years.

(4) Any person who is aggrieved by-

(a) a refusal to grant an approval under this Act,

(b) the imposition of any conditions, on an approval under this Act,

(c) the revocation, suspension or variations of an approval under this Act,

(d) a refusal to treat an application as confidential,

may within thirty days of the decision of the Authority, appeal to the appeals Board in the prescribed manner.

(5) Any person aggrieved by a decision of the Appeals Board may within thirty days of such decision, appeal against such decision to the High court.

(6) The decision of the High court on any appeal under this section shall be final.

## **PART V- DUTIES OF REGULATORY AGENCIES**

Duties of regulatory agencies.

**30.** (1) Regulatory agencies shall, where appropriate, monitor an applicant's activities to ensure that these activities comply with the requirements of this Act and any conditions imposed in connection with the approval under this Act.

(2) Where a regulatory agency becomes aware of any significant new scientific information indicating that approved activities with genetically modified organism's may adversely affect the environment or pose potential risks not previously known, the regulatory agency shall immediately inform the Authority of the new information and of the measures to put in place to ensure the continued safe use of the genetically modified organism.

Unintentional release into the environment.

**31.** (1) A regulatory agency with knowledge of an unintentional or unapproved introduction into the environment of a genetically modified organism, that is likely to have

adverse effects on the environment, shall, within twenty four hours of when the regulatory agency knew of the introduction, notify the Authority of the occurrence.

(2) A notification shall include adequate information for the Authority to undertake a risk assessment.

(3) The Authority in consultation with the regulatory agency shall determine whether any action is necessary to minimize any adverse effect on the environment.

## **PART VI INSPECTION**

Appointment  
of inspectors.

**32.** The Minister shall, by Gazette notice, appoint duly qualified persons to be biosafety inspectors of the Authority, for such jurisdiction units as shall be specified in the notice appointing them.

Powers of  
inspectors.

**33.** (1) A biosafety inspector may, in the performance of his duties under this Act, at all reasonable times and without a warrant –

- (a) enter any premises, facility, vessel or property, which the inspector has reason to believe it is necessary for him to enter, in order to ascertain whether the requirements of this Act or any approval under this Act, are being complied with and may take with him any person duly authorized by the Authority,
- (b) take with him any equipment or material required for any purpose for which the power of entry is being exercised;
- (c) carry out such tests and inspections and make such recordings as may in the circumstances be necessary;

- (d) direct that ,any part of premises which he has power to enter, or anything in such premises ,shall be left undisturbed for so long as is reasonably necessary for the purpose of any test or inspection;
- (e) take appropriate samples of any organisms, articles or substances found in any premises which he has power to enter analysis or any other relevant for this Act;
- (f) in the case of anything found in the premises which he has power to enter, which appears to him to contain genetically modified organisms which have adversely affected or are likely to adversely affect the environment, he may cause it to be dismantled or subjected to any process or test but not so as to damage or destroy it, unless it is necessary.
- (g) require the production of any records, which are required to be kept under this Act.

(2) In exercising his powers under this Act, the biosafety inspector shall suitably identify himself.

## **PART VII - FINANCIAL PROVISIONS**

Funds of the Authority.

- 34.** The funds of the Authority shall comprise –
- (a) such moneys as may be appropriated by Parliament for the purposes of the Authority.
  - (b) such moneys as may accrue to or vest in the Authority in the course of the exercise of its powers or performance of its functions under this Act,



- (c) all moneys from any other source provided for, donated or lent to the Authority.

Investment of funds.

**35.** (1) The Authority may –

- (a) Invest any of its surplus funds in government securities.
- (b) place on deposit with any bank quoted on an approved securities exchange in Kenya as it may determine, any moneys not immediately required for the purpose of the Authority.

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(2) In this section ‘approved securities exchange’ means a securities exchange approved under the capital Markets Authority Act.

Financial year.

**36.** The financial year of the Authority shall be the period of twelve months ending the thirtieth of June in each year.

Annual estimates.

**37.** (1) Before the commencement of each financial year, the Authority shall cause to be prepared estimates of revenue and expenditure of the Authority for that financial year.

(2) The annual estimates shall make provision for all the estimated expenditure of the Authority for the financial year concerned and in particular, shall provide for -

- (a) The payment of salaries, allowances and other charges in respect of the staff of the Authority.
- (b) The payment of pensions, gratuities and other charges in respect of retirement benefits which are payable out of the funds of the Authority

- (c) The acquisition, maintenance, repair and replacement of the equipment and other moveable property of the Authority.

Accounts and audit.

**38.** (1) The annual estimates shall be approved by the Authority before the commencement of the financial year to which they relate. Provided that once approved, the sum provided in the estimates shall not be increased without the prior consent of the Authority.

(2) The Authority shall cause to be kept all proper books and records of account of the income, expenditure, assets and liabilities of the Authority

(3) Within a period of four months from the end of the financial year, the Authority shall submit to the Auditor-General (corporations) the accounts of the Authority together with

- (a) A statement of the income and expenditure of the Authority on the last day of that year.
- (b) A statement of the assets and liabilities of the Authority on the last day of that year.

(4) The accounts of the Authority shall be audited and reported upon in accordance with sections 29 and 30A of the Exchequers and Audit Act, by the Auditor – General (corporations).

(5) The Authority shall inform and keep the public informed of its activities and operations through regular publications and such activities and operations shall be accessible to the public unless there are reasons of commercial confidentiality or security justifying exclusions

**PARTIX – MISCELLANEOUS PROVISIONS**

Minister's power to make regulations.

**39.** The Authority may, with the approval of the Minister, make regulations for the better carrying out of its functions under this Act and in particular for prescribing

- (a) Anything required by this Act to be prescribed;
- (b) Procedures for conducting contained use activities involving genetically modified organisms;
- (c) Procedures for release of genetically modified organisms into the environment;
- (d) Procedures for importation of genetically modified organisms;
- (f) Procedures for exportation of genetically modified organisms;
- (g) Procedures for genetically modified organisms in transit.;
- (h) Procedures for appeals
- (i) Forms to be used for applications for approvals;
- (j) Schedules of fees to cover administrative costs of processing applications and notices.

Offence and penalties.

**40.** Any person who-

- (a) makes contained use of, releases into the environment, places on the market, imports or exports a genetically modified organism without the

approval of the Authority;

- (b) contravenes any conditions attached to an approval under this Act;
- (c) fails to furnish any information as required by this Act;
- (d) uses any confidential information for any purpose not authorized under this Acts;
- (e) uses a genetically modified organism for mischievous or unethical purposes;
- (f) obstructs or fails to assist the Authority or officers of the Authority in the performance of their duties under the Act;

;

(g) contravenes any of the provisions of this act;

commits an offence and is liable to conviction, to a fine not exceeding one million shillings or to imprisonment for three years.

Public awareness  
and participation.

**41.** (1) The Authority shall promote public awareness and education concerning biosafety matters through the publication of this Act and regulations made there under.

(2) The Authority shall publish notices of final decisions concerning all applications.

Liability and  
redress.

**42.** Liability and redress for any damage that occurs, as a result of activities subject to this Act, shall be addressed by applicable laws.

Transitional  
provisions.

**43.** (1) Any application made to the National Council for Science and Technology at the date of the entry into force

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of this Act shall be subject to the provisions of this Act.

(2) An applicant who was granted an approval by the National Council for Science and Technology shall within thirty days of the entry into force of this Act, lodge an application for review under this Act.

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**FIRST SCHEDULE** sec 2

**REGULATORY AGENCIES**

1. Ministry of Health.
2. Department of Veterinary Services.
3. Kenya Bureau Of Standards.
4. Kenya Plant Health Inspectorate Services.
5. Kenya Industrial Property Institute.
6. Kenya Wildlife Service.
7. Pest Control Products Board.
8. NEMA

**SECOND SCHEDULE** sec 8

**PROVISIONS AS TO THE CONDUCT OF BUSINESS AND AFFAIRS OF THE BOARD**

Committees  
and co-opted  
advisors

1(1) The Board shall establish such committees as it may deem appropriate to perform such functions and responsibilities as it shall determine, but all findings of such committees shall be presented to the Board for its consideration and determination.

(2). The Board may at its discretion, at any time and for any length of time, co-opt any person to attend any of its deliberations but such person shall not be entitled to vote on any matter at any meeting of the Board.

Vacation of  
office

2(1) the appointment of a member of the Board other than an ex-officio member shall be terminated by the Minister on any of the following grounds-

- (a). upon the expiry of his appointment,
- (b). upon his death,
- (c). if he is adjudged bankrupt,

(d). if he is sentenced for any offence against any written law to a term of imprisonment of six months or more,

(e). if he is convicted of an offence involving fraud, dishonesty or moral turpitude,

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(f). if he is absent, without permission of the Board from three successive meetings of the Board which he has received notice,

(g). upon notice in writing of his intention to resign his office,

(h). if in the opinion of the Board, he becomes by reason of mental or physical infirmity, incapable of performing his duties as a member of the Board, or

(i). upon the commission of an offence under this Act.

Meeting of Board.

3(1). The Board shall meet at least four times in every financial year.

(2). The chairman shall preside at every meeting of the Board at which he is present, but in his absence, the vice-chairman shall preside and in his absence, the members shall elect one of their number who shall, with respect to that meeting and the business transacted thereat, have all the powers of a chairman.

(3). Unless an unanimous decision is reached, a decision on any matter before the board shall be by a majority of votes of the members present and in the case of an equality of votes, the chairman shall have a casting vote.

(4). The quorum of the transaction of the business of the Board shall be half of the membership of the Board.

Disclosure of interest.

4. if a member of the Board acquires any interest direct or indirect in any application or other matter at which the application or other matter is the subject of consideration by the Board, the member shall at the meeting, disclose the fact to the Board and shall take no part in the consideration or discussion of or vote on any question in respect to the application or the other matter.

Seal of the Board.

5(1). The seal of the Board shall be authenticated by the signature of the chairman and the chief executive officer of the Authority.

(2). In the absence of the chairman, any Board member designated by the chairman for the purpose, may authenticate the seal.

**THE THIRD SCHEDULE** sec 14

**INFORMATION REQUIRED IN APPLICATIONS FOR  
CONTAINED USE**

Application for contained  
use

1. an application to conduct activities with genetically modified organisms under contained use shall be submitted to the Authority at least sixty days before such activities are due to begin.

2. the application shall include -

- (a) the name and contact address of the applicant,
- (b) the location where contained use activities are to be undertaken
- (c) the nature and identity of GMOs to be involved.
- (d) The nature and purpose of the activities including such activities as storing, transporting, producing, processing, disposing or using the GMOs in any other way.
- (e) A description of the containment measures to be provided and the suitability of those measures for the GMOs and activities to be undertaken.
- (f) A description of any potential risks associated with the GMO activities to be undertaken, and
- (g) A description of remedial measures to be undertaken.



**THE FOURTH SCHEDULE** sec 15, 16

**INFORMATION REQUIRED IN APPLICATIONS FOR  
RELEASE, IMPORTATION AND PLACING ON THE MARKET**

1. Name, address and contact details of the exporter.
2. Name, address and contact details of the importer.
3. Name and identity of the genetically modified organism as well as the domestic classification, if any of the Biosafety level of the genetically modified organism in the country of export.
4. Intended date of the transboundary movement.
5. Taxonomic status, common name, point of collection or acquisition and characteristics of the recipient organism or parental organism related to Biosafety.
6. Center of origin and center of genetic diversity if known, of the recipient organism and the parental organism and the description of the habitat where the organism may persist.
7. Taxonomic status, common name, point of collection or acquisition and characteristics of the modification introduced, the technique used and the resulting characteristics of the genetically modified organism.
8. Intended use of the genetically modified organism product thereof.
9. Quantity or volume of the genetically modified organism to be transferred.
10. A risk assessment report.
11. Suggested methods for the safe handling, storage, transport and use.
12. A sworn declaration of the applicant that the above mentioned information is factually correct.

**FIFTH SCHEDULE** sec 15, 16

**RISK ASSESSMENT**

Objective of risk assessment.

1. The objective of the risk assessment is to identify and evaluate the potential adverse effects of genetically modified organisms on the environment.

Use of risk assessment.

2. The risk assessment shall be used by the Authority to make informed decisions regarding genetically modified organisms.

3. The general principles guiding risk assessment are-

(a). Risk assessment shall be carried out in a scientifically sound and transparent manner and may take into account expert advice and guiding principles developed by relevant organisations.

(b). Lack of scientific knowledge or scientific consensus shall not necessarily be interpreted to indicate a particular level of risk, an absence of risk or an acceptable risk.

(c). Risk associated with genetically modified organisms or products thereof, shall be considered in the context of the risks posed by the genetically modified organisms recipient or the parental organisms in the likely potential receiving environment.

Methodology.

4. To fulfil its objective, risk assessment shall entail the following steps-

(a). An identification of any genotype and phenotypic characteristics associated with the genetically modified organisms that may have adverse effects on the environment,

(b). An evaluation of the likelihood of these adverse effects being realized, taking into account the level and the kind of exposure of the likely potential receiving environment of the genetically modified organisms,

(c). An evaluation of the consequences should these effects be realized,

(d). An estimation of the overall risk posed by the genetically modified organisms based on the evaluation of the likelihood and consequences of the identified adverse effects being realized,

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(e). A recommendation as to whether or not the risks are acceptable or manageable, including identification of strategies to manage these risks , and

(f). Where there is uncertainty regarding the level of risk, the Authority may request for further information on the specific issues of concern or may recommend implementing appropriate risk management strategies and monitoring the genetically modified organisms in the receiving environment.

Points to consider

5.Risk assessment shall take into account the relevant technical and scientific details regarding the characteristics of the following subjects-

**(a)recipient organism or parental organism.**

The biological characteristics of the recipient organism or parental organism including taxonomic status, common name, origin, centers of origin and centers of genetic diversity and a description of the habitat where the organism persists

**(b). donor organism**

taxonomic status and common name, source and the relevant biological characteristics of the donor organisms.

**(c). vector**

characteristics of the vector including its identity and the sources of origin and host range.

**(d). insert and characteristics of modification.**

Genetic characteristics of the inserted nucleic acid and the function it specifies and characteristics of the modification introduced.

(e). genetically modified organisms.

identity of the genetically modified organisms and the differences between the biological characteristics of the genetically modified organisms and those of the recipient organism or parental organism.

**(f) detection and identification of** genetically modified organisms.

suggested detection and identification methods and the specificity, sensitivity and reliability.

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**(g). information relating to the intended use.**

Information related to the intended use of the genetically modified organisms including new or changed use compared to the recipient organism or parental organism.

**(h).receiving environment.**

Information on the location, geographical, climatic and ecological characteristics including relevant information on biological diversity and centers of origin of the likely potential receiving environment.