BIOSAFETY (MANAGEMENT OF BIOTECHNOLOGY) REGULATIONS, 2007

LEGISLATIVE INSTRUMENT 1887

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IN EXERCISE of the powers conferred on the Board by subsection (1) of section 25 of the Council for Scientific and Industrial Research Act, 1996 (Act 521) these Regulations, with approval of the Minister, are made this 30th day of November, 2007.

Institutional arrangements

The National Focal Point

1. (1) The National Biosafety Committee

(a) is the National Focal Point on biosafety,

(b) is responsible for liaison with the Secretariat of the Convention on Biological Diversity for the administrative functions required under the Cartegena Protocol on Biosafety, which Protocol is set out in the First Schedule;

(c) is the Committee on biosafety in Ghana,

(d) is responsible for the functions pursuant of the Cartagena Protocol on Biosafety and related technical matters,

(e) shall ensure that laboratory and field work with genetically modified organisms and their products conform to the national biosafety guidelines set out in the Second Schedule.

(2) The National Biosafety Committee may

(a) certify the institutional biosafety committees to undertake laboratory and field trials and monitoring functions for certain levels of classified risks to be issued periodically through guidelines;

(b) provide assistance to the institutional biosafety committees and advise on the various notification and assessment forms, biosafety guidelines and any other relevant documents;

(c) prepare and provide to the institutional biosafety committees, the various notification and assessment forms, biosafety guidelines and any other relevant documents;

(d) suggest practical alternatives to high-risk laboratory procedures;

(e) inform the various institutions engaged in genetic manipulation work about new developments in biosafety so as to avoid exposure of laboratory personnel, the community or the environment to undue risks;

(f) co-ordinate efforts between the relevant Government agencies and private organizations to maintain safety levels in biotechnological work and to prepare them for biological emergencies;

(g) certify high-level laboratories, green and animal houses intended for in high-risk work, for which purpose the committee on request by the institution, and at the earliest convenience, and with assistance from the technical advisory

subcommittee will in inspect the facility, issue certification or recommend additional precautions where necessary;

(h) inspect high-level laboratories and containment facilities on a regular basis through the designated regulatory agencies, for which purpose an inspectorate established by the Committee, whose functions are set out in the Third Schedule, may inspect laboratories and facilities of physical containment levels at any time subsequent to certification without prior notice;;

(i) inspect systems, equipment, vessels and instruments governing ambient biosafety level in genetic manipulation laboratories; and

(j) protect and restrict access to information of commercial significance not in the public domain that researchers have provided in project proposals which, on the written proposals submitted, researchers may be permitted to mark as "Commercial-In-Confidence."

Implementation roles

2. (1) The implementation of biosafety practices in genetic engineering and biotechnological work shall be supervised by

(a) the National Biosafety Committee,

(b) the regulatory agencies referred to in the Sixth Schedule,

(c) the relevant institutional biosafety committees, and

(d) the Principal Investigator.

(2) The authorities specified in sub regulation (1) though retaining their different functions

(a) shall pursue the common objective of enforcing and preserving the integrity and the intent of the Guidelines, and

(b) shall ensure adherence to the Guidelines for the safety of personnel, the community and the environment.

(3) Where there is a non-compliance with the prescribed biosafety measures, whether deliberate or unintentional, the authority which accorded the approval,

(a) may stop the work on issuing a show cause notice and requesting proper investigation through the relevant institutional biosafety committee, or

(b) may prescribe additional safety measures or conditions or the Committee may intervene in any other manner through the relevant institutional biosafety committee.

Powers of National Biosafety Committee

3. (1) The National Biosafety Committee

(a) may, in addition to the Guidelines set out in the Second Schedule, adopt any other Regulations or Guidelines compatible with its functions to ensure the safety of the population both animal and human and their environment;

(b) may stop a project through the relevant institutional biosafety committee after establishing that further continuation of the project is unsafe to the personnel, the community and the environment; and

(c) approve deregulation of regulated materials for free movement and commercial release on the recommendation of the relevant institutional biosafety committee.

(2) In the performance of its functions under these Regulations, the Committee may co-opt additional members, form sub-committees and adopt any other measures which may facilitate its work.

The technical advisory sub-committee

4. (1) The National Biosafety Committee shall appoint a technical advisory sub-committee, in addition to any other sub-committees that it may appoint, the composition of which shall be determined by the Council.

(2) The functions of the technical advisory subcommittee are set out in the Fourth Schedule.

(3) In appointing the technical advisory sub-committee, the Committee, to achieve its mandate, shall endeavour to draw on various disciplines.

(4) A member of the Committee shall be the chairman of the technical advisory sub-committee.

(5) The tenure of office of members of the technical advisory sub-committee is renewable on a yearly basis.

(6) The additional operational procedures of the sub-committee shall be as provided in the national guidelines.

The institutional biosafety committee

5. (1) Institutions and organizations, public or private engaged, or with the intent to engage, in the purchase, construction, propagation or field release of genetically modified organisms or their products shall each establish an institutional biosafety committee and support the needs and demands of the committee to enable it perform its functions efficiently.

(2) An institutional biosafety committee shall include representatives from cognate organizations or institutions in its membership.

(3) Institutions and organizations, particularly those engaged in industrial grade or other large-scale work, may recruit a biosafety officer to work in conjunction with the various institutional biosafety committees.

(4) Small research institutions, which may encounter difficulties in constituting an independent institutional biosafety committee, may request any other institutional biosafety committee to help monitor and supervise the biosafety aspects of their work,

(5) Agreements under sub regulation (4) shall be entered into between the parties involved, and the Committee shall be notified of the proceedings.

(6) A representative of the institution requesting assistance shall maintain close ties with, or serve as a member on, the supporting institutional biosafety committee.

Certification of the institutional biosafety committee

6. (1) The Committee shall formally endorse each institutional biosafety committee.

(2) For the purposes of sub-regulation (1), the completed notification forms of the committee, detailing the academic and professional history, faculty and qualifications of each member appointed to the committee shall contain information relating to

(a) members of the institutional biosafety committee,

(b) the designated biosafety officer, where applicable,

(c) a list of the current projects indicating the risk assessment category,

(d) a list of the laboratories approved or nucleic acid work indicating the category of containment, and

(e) a list of the institution's green and animal houses, certified and intended for work with transgenic species, indicating category of containment.

Composition of the institutional biosafety committee

7. An institutional biosafety committee shall include

(a) the biosafety officer and four other members selected because of their experience and expertise for the evaluation of the biosafety and environmental effects of biotechnology research, including the manipulation of nucleic acids,

(b) two members who are not affiliated with the institution but are knowledgeable in biotechnology and representing the interest of the community such as

(i) members of government, public health or environmental agencies,

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

(iii) persons active in environmental concerns, and who do not require a previous affiliation with the institution.

Functions of the institutional biosafety committee

8. (1) In order to enforce the Guidelines issued by the Committee, an institutional biosafety committee shall report infractions to the institutional head or to the Committee and recommend the relevant authority to stop a project if its continuation under the existing circumstance, is a threat to the public, the environment or to laboratory personnel.

(2) An institutional biosafety committee shall

(a) monitor the regulated work under progress within the institution and counsel the proponents on issues of biosafety and on compliance with national guidelines on a regular basis, or as requested;

(b) determine additional biosafeguards and draft supplementary operating instructions for work at the institution, in line with and addressing the specific risks and concerns uncovered;

(c) evaluate the qualification of researchers involved in biotechnological projects and assess whether each retains a thorough understanding of good laboratory practices necessary for the supervision of students, assistants, technicians and junior personnel;

(d) assist research in undertaking risk assessment and organize training programmes;

(f) set apart time for researchers and for laboratory and field personnel to approach the committee with questions, disputes or concerns;

(g) maintain and update a directory of the personnel engaged in activities at every biosafety level, and instruct new personnel on the correct laboratory or field practices, emergency procedures and equipment operation at the relevant level;

(h) where appropriate, serve as a gateway for the flow of information, ideas and opinions between the Committee and the research teams.

(3) To ensure that laboratory genetic manipulation work within the institution conforms to these Regulations and the Guidelines, the institutional biosafety committee shall

(a) assess the projects referred to the committee, and on the basis of the information provided and the risks forecast determine under which category of work the proposals fall and whether to endorse the work proposed;

(b) maintain records of approved project proposals for laboratory genetic manipulation work, including notification for project exemption and the committee's assessment;

(c) forward summaries of the project proposals submitted for notification, and the committee's assessments, to the Committee for records and information or for review and recommendation in the case of proposals for risk assessment as specified in the Second Schedule.

(d) undertake risk assessment, in co-operation with the research teams as necessary to determine the appropriate containment and biosafety conditions, operating procedures and emergency safeguards for risk assessment as specified in the Second Schedule, and for the housing, storage or movement of regulated material and also for the waste;

(e) in convention with the research teams, specify contingency plans after undertaking risk assessments and reviewing project proposals;

(f) enforce, with particular emphasis on risk work, the recommendations and ensure that the comments of the Authority have been acknowledged and promptly addressed;

(g) inspect and certify, before use in genetic manipulation work, the appropriate level laboratories, conventional animal houses, plant glass houses, and quarantine and medical facilities for infected animals, for which the Committee with the advice of the technical advisory sub-committee will be responsible for certification of higher-level laboratories only;

(h) facilitate the preparation of dossiers for submission to the Committee for the conduct of confined field trials and the commercial release of genetically modified organisms;

(i) monitor and assay the containment feature, and the working conditions within the laboratories, of plant glass houses and animal houses supporting the institution's work, to ensure that the various facilities are maintained at the standards and requirements outlined in the Second Schedule for laboratory and field work.

The biosafety officer

9. (1) An institution or organization involved in genetic manipulation work shall appoint a biosafety officer to the institutional biosafety committee.

(2) An institution affiliated to a committee which committee does not have the services of a biosafety officer may opt to transfer the responsibility of securing a biosafety officer over to the institutional biosafety committee.

(3) A larger institution contracting the services of multiple biosafety officers, shall designate one representative for the purposes of the training and instruction of personnel.

(4) The biosafety officer in conjunction with the institutional biosafety committee shall review the operating procedures and biosafety records, and assess the integrity of containment facilities and safety equipment or utilities.

(5) Further guidance for the benefit of the biosafety officer are provided in the Guidelines.

Principal investigator

10. (1) A trained scientist with thorough understanding of the codes, regulations and laws applicable to genetic engineering and biotechnological work and exhibits an appreciation for the biosafety concerns shall be appointed as the principal investigator.

(2) As the officer-in-charge, the responsibilities of the principal investigator include the initial stages of originating proposals and obtaining approval of the institutional biosafety committee, where necessary.

(3) For laboratory genetic manipulation work, the project supervisor shall assess the nature of the research and determine whether the work proposed falls within the scope of the Guidelines.

(4) Where there is an uncertainty or a doubt the matter shall be addressed by submitting a detailed proposal of the experimental condition to the institutional biosafety committee for endorsement or clearance before work is carried out.

(5) Where the work is regulated under the guidelines, the project supervisor shall submit a completed project proposal form, including requests for exempts status to the supervising institutional biosafety committee for consideration and recommendations and inform the committee of any notable intents such as plans to import regulated material.

(6) Laboratory work may begin after authorization from the institutional biosafety committee and directed by the committee, and the project supervisor may be required to provide additional details of the research for evaluation and monitoring activities of the institutional biosafety committee.

(7) The project supervisor shall enforce the provisions, and adhere to the intent, of the Guidelines throughout the duration of a research work, with special emphasis on

(a) the submission of new project proposals to the institutional biosafety committee for consideration and recommendation before adopting radical operating procedures or substantially changing the parameters of the work, especially

approaches to physical and biological containment, which may introduce novel risk, delimit new biosafety levels or warrant change of classification;

(b) establishing and maintaining working conditions appropriate to the level of biosafety as approved and advised by the institutional biosafety committee and, in the case of risk work in accordance with the recommendations of the Committee;

(c) ensuring that student, junior personnel, technician, co-investigators and any other person entering controlled areas realize the nature and degree of the risks involved and that those persons have been properly instructed on applicable codes of conduct;

(d) co-operating closely with the institutional biosafety committee and the biosafety officer in carrying out various safety tests for instance, inspection of containment facilities;

(e) reporting to the institutional biosafety committee the personnel developments, including unusual illnesses, to the committee;

(f) relaying to the institutional biosafety committee details of the contingences and the emergency procedures instigated to deal with these incidents.

Relationship between the various committees and the Committee

11. (1) Works described as "no risk", "minimal risk", and "low risk" works including laboratory work and field trials shall be assessed, evaluated and granted permission by the institutional biosafety committee.

(2) The risk work, that is, laboratory and field trials shall be evaluated, and granted permission, by the Committee.

(3) The works which do not have prior history of risk assessment and the requests for deregulation and commercial releases of genetically modified organisms and their products shall be decided by of the Committee with the advice of the technical advisory sub-committee.

(4) The relevant institutional biosafety committee shall notify the Committee of the clearance granted and lodged with the national depository for the biotechnological projects.

(5) Further guidance are provided in the Guidelines.

Handling and application for permit

12. (1) Where an application is formally submitted to the National Biosafety Committee, it shall be recorded and a tracking number assigned to the dossier so as to systematically keep track of the request and of the status of administrative and technical progress through the national system.

(2) A reviewer shall be assigned to the dossier in consultation with the technical advisory subcommittee.

(3) The tracking numbers shall be kept in the National Biosafety Committee database for progress control to make the information readily available both within the Government and to various stakeholders.

(4) The electronic database enables the information to be easily searched, and can be integrated into any other aspects of providing information, helping in the transmission of information to any other database, such as the Biosafety Clearing House of the Cartagena Protocol on Biosafety.

(5) The format for the tracking numbers shall be outlined in the Guidelines database.

(6) Where an application is properly recorded, the request itself shall be handled in a number of steps:

(a) the first step, which is an administrative step is screening for completeness, that is, checking whether the request complies with legally required information;

(b) where it is concluded that the request is in compliance with the information requirements, a risk assessment shall be carried out as a scientific process, based on the best available, and up to date, scientific knowledge and data;

(c) the risk assessment shall be carried out by the technical advisory subcommittee through technical advisory panels based on particular requests considering the functions of the committee as set out in the Fourth Schedule;

(d) based on the results of the risk assessment and, where applicable, comments received from the public and any other socio-economic consideration, the National Biosafety Committee shall take a decision which shall be communicated to the applicant in the form of a decision document;

(e) the key elements for determination and communication of the decision are set out in the Fifth Schedule.

Monitoring and enforcement

13. (1) The National Biosafety Committee is the executive body for the overall monitoring, risk management and commercial release of the regulated materials.

(2) The monitoring and inspection functions shall be performed by the regulatory agencies referred to the Sixth Schedule.

(3) The inspectorate functions shall be performed by the identified regulatory agencies and certified inspectors as specified in the Fifth Schedule.

(4) The monitoring and inspection functions shall be performed first by the relevant institutional biosafety committee.

(5) The institutional biosafety committee shall serve, in part, as a conduit for the flow of information between the researcher and the Committee, forwarding proposals, assessments and recommendations to the Committee.

(6) An institutional biosafety committee shall receive applications, propose measures for improvement and for laboratory set-up as well as planned release and effectively monitor any of those matters.

(7) Information or any other data that needs to be submitted to the National Biosafety Committee shall be sent through the institutional biosafety committee.

(8) The second tier of monitoring and enforcement shall be performed by the Committee through the regulatory agencies and any designated individuals or companies through the inspectorate functions.

(9) The principal investigator and researcher are responsible subject to the approval of the institutional biosafety committee, to the community in the monitoring and implementation of laboratory work.

(10) Further guidelines shall be given through the development of guidelines on monitoring and enforcement including inspection manuals.

Public awareness, participation and education

14. (1) The Committee shall to develop procedures to engage the public through education and awareness, through the issuance of public participation and regulatory guidelines and strategies on public engagement.

(2) The Committee shall promote awareness, participation and education of the public and those conducting activities concerning biosafety matters through the publication and dissemination these Regulations and the Guidelines as well as guidance documents and any other material aimed at improving understanding of biosafety and related authorization an notification requirements.

(3) The Committee shall publish, on a regular basis,

(a) notices concerning proposals on exemptions and simplified procedures, and

(b) proposed decisions on applications and petitions filed pursuant to applications for intentional introduction into the environment.

(4) On a request made by any person the Committee shall make available to that person portions of an application or petition which does not qualify as confidential information.

(5) A person may submit a written comment on a proposed decision for an application for placing genetically modified organisms on the market or a petition for an exemption within sixty days from the date the notice is posted.

(6) The comments shall be considered as part of the decision-making process.

(7) A comment received by the Committee and a response to the comment shall be made available to the public on request.

(8) The Committee shall publish notices of final decision concerning the applications or petitions and notices concerning the final resolution of compliance in cases involving non-compliance with any of the provisions of these Regulations.

(9) The Committee shall establish and maintain a registry of

(a) genetically modified organisms for which authorization is granted by the Committee including whether the organization has been authorized for placing them on the market; and

(b) genetically modified organisms and activities which are exempted or subject to simplified procedures as determined by the Council.

(10) The Regulations shall, in accordance with clause (7) of article 11 of the Constitution be laid before Parliament and during the period of twenty one days allowed, a person may submit written comments to the relevant parliamentary committee.

(11) The comments shall be considered as part of the regulatory process.

(12) the comments received by the Committee and the response shall be made available to the public on request.

The Biosafety Clearing House and information

15. (1) The Committee is responsible for the management of the National Biosafety Clearing House and for that purpose the Committee may request any other agency to manage that obligation on its behalf.

(2) The applicant or the Committee, shall inform the National Biosafety Clearing House of a notification, decision or an activity that is required to be made or conducted under these Regulations.

(3) In addition to sub regulations (1) and (2)

(a) the Committee shall notify the National Biosafety Clearing House that the Committee's domestic regulation shall apply to the importation of genetically modified organisms to the area of national jurisdiction of Ghana;

(b) the Committee shall provide the National Biosafety Clearing House with

(i) a copy of these Regulations including the amendments to the Regulations, decisions made pursuant to the Regulations and any other legislation and national guidelines of relevance to the implementation of the Cartagena Protocol or the management of genetically modified organisms;

(ii) the summaries of risk assessments generated pursuant to these Regulations;

(iii) the final decision regarding the importation or intentional introduction in the environment of genetically modified organisms;

(iv) the reports concerning national implementation of the Cartagena Protocol in accordance with the Protocol;

(v) a copy of the decision describing the changes to the previous decision and the reasons for the decision within thirty days; and

(vi) any other information required under the Cartagena Protocol or any other international agreement concerning the subject matter dealt with under these Regulations.

(c) where the Committee takes a final decision regarding domestic use, including placing on the market, of a genetically modified organism that may be subject to export for direct use as food or feed or for processing, it shall ensure that information concerning the authorization of that organism as specified in the Seventh Schedule is provided to the National Biosafety Clearing House established under the Cartagena Protocol within fifteen days of taking the decision.

Procedures

Contained use and confined field trials

16. The Committee shall provide additional guidance including specific protocols on a case by case basis as regards contained used and field trials.

Importation

17. In addition to these Regulations, further guidance will be given through the issuance of periodic guidelines in respect of the importation of GMOs.

Transit

18. (1) An applicant handling products in transit shall inform the National Biosafety Committee prior to the transshipment across the borders of Ghana.

(2) The products shall be transported on agreed terms and conditions specified by the Committee, and the instrument of agreement shall designate a specific entry point manned by a certified regulatory officer.

(3) The products shall be accompanied by an officer from the Customs, Excise and Preventive Service in collaboration with the designated regulatory agency officials to ensure safe transport across the border.

(4) Further guidance on the transit of genetically modified organisms shall be given through the guidelines.

(5) A foreign entity which intends to import a genetically modified organism or a product containing a genetically modified organism, destined to countries of the region, conducting the transit through Ghana, shall obtain a transit authorization from the National Biosafety Committee, the application for which shall contain

(a) the authorization, by the recipient country, for the importation,

(b) the contingency plan in case of an accident,

(c) the terms of liability and means of redress on the part of the Government of the recipient country, and

(d) the anticipated date of the movement across the borders of Ghana and the respective entry locations.

(6) The documents referred in sub-regulation (5) shall be submitted to the Committee fifteen working days prior to the cargo's departure from the exporting country.

(7) The merchandize in transit shall be transported in properly sealed containers.

(8) Further guidance shall be given in the Guidelines.

Appeals

19. (1) An applicant who is aggrieved by a decision of the National Biosafety Committee may appeal to the appeals board of the Committee on procedural or substantive grounds.

(2) The appeals board shall decide an appeal within a reasonable time, not exceeding sixty days, and shall communicate its decision and the reasons for the decision in writing to the Committee and to the applicant.

(3) An applicant who is aggrieved by a decision of the appeals board or who does not receive a response within the time frame stated in subregulation (2) may appeal to the High Court for an appropriate order or for an order for the appropriate response.

Forms

20. [Comment (F3): L Reference forms in the biosafety guidelines, and the role of the NBA to give additional guidance when the need arises]

Fees

21. (1) The fees that are payable pursuant to these Regulations shall be determined by the Committee in consultation with the regulatory agencies.

(2) In determining the fees, the Committee shall consider the cost of processing by the Committee, the cost of inspection and any other relevant factors to cover the cost of an agent from any of the regulatory agencies.

Further guidelines

22. In addition to the Second Schedule further guidelines shall be provided to facilitate the work of the Committee.

Use of memorandum of understanding

23. (1) In the performance of its functions, the Committee on the coming into force of these Regulations may enter into an agreement through a memorandum of understanding with the five designated regulatory agencies for the biosafety coordination system.

(2) The memorandum shall spell out clearly the areas of operation and roles expected and the financial arrangements related to the execution of the role.

Food safety

24. In collaboration with the Food and Drugs Board, the Committee may issue Guidelines in respect of Food Safety.

Confidential business information

25. (1) The Committee shall

(a) permit an applicant to identify information provided to the Committee in accordance with these Regulations, including information contained in a notification, an application or any other written submission, that is to be treated as confidential, with justification for claims of confidentiality to be provided on request;

(b) decide whether it accepts as confidential the information designated by the applicant;

(c) inform the applicant, prior to a disclosure of information identified by the applicant as confidential, of its rejection of the claim of confidentiality providing reasons on request as well as an opportunity for consultation and for an internal review of the decision prior to disclosure; and

(d) respect, in the event that an applicant withdraws or has withdrawn an application,

(i) the applicant's claims of confidentiality, including claims for information which the Committee shall neither use nor permit the use of confidential,

(ii) information accepted as confidential for a purpose not specifically authorized under these Regulations, except with the written consent of the applicant

and shall ensure that the information is protected by the persons involved in handling or reviewing applications or any other written submission under these Regulations.

(2) Without prejudice to paragraph *(a)* of subregulation (1), the Committee shall not consider as confidential

(a) the name and address of the applicant,

(b) a general description of the genetically modified organism,

(c) a summary of the risk assessments performed on the genetically modified organism, and

(d) any methods and plants for emergency response.

Socio-economic consideration

26. The Committee shall give further guidance in the form of Guidelines in line with the national priorities and sustainable development agenda in the area of the socio-economic development of the country.

Cessation orders

27. (1) The National Biosafety Committee may issue an order for the immediate cessation of an activity covered by an authorisation or which has been the subject of a notification, for the immediate imposition of additional risk management measure with respect to that activity, if the Committee determines that there is an imminent danger posed to the conservation and sustainable use of biological diversity, taking into account the risk to human and animal health, on the basis of

(a) one or more tests conducted and evaluated in a manner consistent with accepted scientific procedures, or

(b) any other validated scientific evidence.

(2) The Committee may issue a cessation other on the failure of an operator to demonstrate substantial compliance, after a reasonable period of time, with an order issued under these Regulations, or with respect to an authorization granted or a notification submitted under these Regulations when there exists a material infringement of a provision of these Regulations.

(3) An order issued under this regulation shall be withdrawn once the Committee determines that sufficient information exists to permit the activity to resume or to resume in the absence of additional risk management measures without posing a significant risk to the conservation and sustainable use of biological diversity, taking into account the risks to human and animal health.

Safety standards

28. Safety standards shall, in addition to the Second Schedule, be issued by the Committee in collaboration of the appropriate authority.

Liabilities and redress

Strict liability and redress

29. (1) A person who imports, transits, makes contained or confined use of, releases or places on the market, a genetically modified organism, is strictly liable for a harm caused by the organism and is bound to fully compensate a person detrimentally affected by the release, transit, use or placement on the market of the genetically modified organism.

(2) A person responsible for an activity which results in a damage, an injury or a loss, as well as the provider, supplier or developer of the genetically modified organism is strictly liable.

(3) Where two or more persons are responsible for the damage, injury or loss, the liability is joint and several.

(4) In the case of harm to the environment or biological diversity, compensation shall include the cost of reinstatement, rehabilitation or clean-up measures which are actually incurred and, where applicable, the costs of the preventive measures.

(5) Liability under this regulation extends to harm or damage caused directly or indirectly by the genetically modified organism to the economy, the social, the cultural practices, the livelihood, and the indigenous knowledge systems of technologies of a community.

(6) Harm under sub regulation (5) includes disruption or damage to production systems, agricultural systems, reduction in yields, soil contamination, damage to the biological mass, and damage to the economy of an area or community.

(7) An action in respect of the harm caused by a genetically modified organism lapses only after a reasonable period from the date on which the affected person or the community could reasonably be expected to have learnt of the harm, taking due account of

(a) the time the harm may take to manifest itself, and

(b) the time that it may reasonably take to correlate the harm with the genetically modified organism, considering the situation or circumstances of the person or the community affected.

(8) A person or group of persons may bring a claim and seek redress in respect of the breach or threatened breach of a provision of these Regulations,

(a) in that person's or group of persons' interest,

(b) in the interest of, or on behalf of, a person who is, for practical reasons, unable to institute the proceedings,

(c) in the interest, or on behalf of a group or class of persons whose interests are affected,

(d) in the public interest, or

(e) in the interest of protecting the environment or biological diversity.

(9) Costs shall not be awarded against a person mentioned in sub-regulation (8) who fails in an action which was reasonably instituted out of concern for the public interest or in the interest of protecting the environment or biological diversity.

Labeling

30. The Committee, in consultation with the appropriate authorities, shall issue guidelines in respect of labeling.

Interpretation

31. In these Regulations, unless the context otherwise requires,

"Cartagena Protocol" means the Cartagena Protocol on Biosafety and set out as the First Schedule;

"Committee" means the National Biosafety Committee established by the Minister responsible for Science;

"genetically modified organism" includes the products of genetically modified organisms and living modified organisms and the products of living modified organisms;

"Guidelines" includes the National Biosafety Guidelines set out in the Second Schedule and the Regulation or Guidelines adopted by the Committee under regulation 3;

"regulatory agency" means any of the agencies specified in the Sixth Schedule.

Transitional provisions

32. An application pending at the date of the coming into force of these Regulations is subject to these Regulations.

(2) An application for approval shall be made in accordance with these Regulations for an import, contained or confined use, release, or placing on the market of a genetically modified organism that has already been carried out prior to the coming into force of these Regulations.

(3) An application in terms of sub regulation (2) shall be submitted to the Committee within a time limit to be determined by the Committee.

(4) Where the application has been made within the prescribed time limit, the activity in respect of which the application is made may continue until a decision is made by the Committee.