

DEPARTMENT OF AGRICULTURE

Directorate Genetic Resources Private Bag X973, Pretoria, 0001, South Africa Tel: 27 12 319 6536; Fax: 27 12 319 6329 E-mail: SMGRM@nda.agric.za

TERMS OF REFERENCE FOR SUB-COMMITTEES TO ASSIST THE ADVISORY COMMITTEE IN TERMS OF SECTION 11(2) OF THE GENETICALLY MODIFIED ORGANISMS ACT, 1997

Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997)

May 2004

CONTENTS

FAGE

1.	Scope		2
2.	Criteria for appointment		2
	2.1	Appointment as member to the sub-committees	2
	2.2	Sub-committees appointed to conduct a review	3
3.	Term of appointment		3
4.	Capacity building		4
5.	Time	frame for reviews	4
6.	Distri	ibution of documents	4
7.	Conflict of interest		5
8.	Confidentiality		5
9.	Remuneration		5

1. Scope

The sub-committees to the Advisory Committee is appointed in terms of Section 11(2) of the Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997).

The functions of the sub-committees are to assist the Advisory Committee in reviewing applications received by the Registrar, therefore to assist the Advisory Committee in performing the functions listed in Section 11(1) of the Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997). Additionally, the sub-committees will deal with specific matters that are beyond the expertise of the Advisory Committee.

In the event that the Advisory Committee needs more clarification on a specific application, the sub-committees appointed to the specific application may be invited to attend the meeting where the relevant application will be discussed. Members of the sub-committees do not form part of the quorum and may therefore not participate in the decision making.

2. Criteria for appointment

2.1 Appointment as member of the Sub-Committees

Members of the sub-committees should include additional expertise to that provided for by the members of the Advisory Committee. This will ensure that the sub-committee serves as a source or pool of expertise that may be called upon by the Advisory Committee when required.

The sub-committee members in the pool shall be selected and nominated by the Advisory Committee, in collaboration with the Executive Council, on the basis of their special expertise in matters relevant to the GMO Act, 1997. Not more than 50 scientists shall be appointed. The Registrar will, upon the recommendation of the Advisory Committee, send official appointment letters to each member.

Additional to the members appointed to the sub-committees, the Advisory Committee may, on its own accord or upon recommendation by the Executive Council, invite written comments of any knowledgeable person (e.g. farmer) to address certain issues within a review. These individuals may also, upon recommendation by the Advisory Committee, be appointed as a member of the sub-committees.

In the event that expertise regarding a specific aspect is not available in South Africa, members of the sub-committee may, upon recommendation by the chairperson of the specific review, consult with international experts. These individuals may also, upon recommendation by the Advisory Committee, be appointed as a member of the sub-committees.

2.2 Sub-committees appointed to conduct a review

To assist the Advisory Committee in reviewing applications for activities with GMO's, a sub-committee will be appointed for each application. More than one sub-committee may be appointed for each review. Each sub-committee will review the application within its own scope. E.g. an environmental safety assessment sub-committee reviews the application with regard to environmental impact and a food safety assessment sub-committee reviews the application with regard to food and feed safety. In light of capacity, a sub-committee may also include expertise to conduct more than one type of assessment, such as both environmental and food and feed safety. Other sub-committees as required by the Advisory Committee or Executive Council, may be appointed to assist in the evaluation of a particular assessment.

Members of all appointed sub-committees to a specific review will report back to the review chairperson.

If the need arise, the chairperson of any review committee, with the consent of the chairperson of the Advisory Committee, may request a meeting to address certain concerns, between the members of the review committee and the applicant in the case of general release applications.

It is the responsibility of the chairperson of a review to ensure that the relevant expertise required for the review is present on the review committee. If expertise in a certain field is required, but cannot be fulfilled by the current members of the sub-committee pool, the chairperson should indicate the situation to the Registrar (in writing), nominate a preferred expert for the review and request the Registrar to appoint the expert for the particular review. The chairperson may not make use of experts that have not been appointed by the Registrar, as these individuals will not be remunerated.

The review chairperson must address al concerns raised by each member within the review committee, and give a clear indication to the Registrar on questions that should be addressed to the applicant. Once the review chairperson has submitted the final recommendation document, the review chairperson will copy the document to each reviewer within the sub-committee. The review chairperson is also responsible to provide feedback to the review committee on the decision taken by the Executive Council.

3. Term of appointment

The members of the sub-committees as referred to in Section 2.1 are appointed for a period of three years. A member of the sub-committees whose period of service has expired shall be eligible for reappointment. Appointment of the sub-committees to review a certain application will be adhoc; i.e. members appointed will be determined by the expertise required for review of the application.

4. Capacity Building

In the interest of capacity building, members of the sub-committees may, upon recommendation of the Executive Council, be nominated to participate on international bodies. The Council would further make recommendations to the relevant international body regarding the nominated scientist. All invitations and nominations to participate internationally should be channelled through the Registrar's office.

Scientists participating in this manner must commit to capacity building in SA in whatever way the Council feels necessary, and share the experience gained in such undertakings with members of both the Advisory Committee and Executive Council.

5. Timeframe for reviews

Members of the sub-committees have a period of three weeks to conduct an assessment of the application received. On completion of the review, the reviewer must submit a report to the review chairperson indicating all aspects assessed during the review.

Each member of the sub-committee must keep within the timeframe allocated to him or her by the review chairperson. If the member is unable to keep within the timeframe, the member must contact the chairperson of the review committee immediately.

6. Distribution of documents

All documents relevant for the evaluation of a certain application will be sent via courier to each reviewer and the review chairperson. The review chairperson shall, on confirmation of the availability of the sub-committee members to conduct the review, contact the Registrar's office to arrange for a courier service to distribute the documentation to the relevant sub-committee members.

Upon receipt of additional information from the applicant, this information will be directly forwarded to the sub-committees, via courier, from the Registrar's office. The review chairperson will be notified in advance of these proceedings.

In the event that clarity on certain issues with regard to the application can only be resolved through direct communication with the applicant, the reviewchairperson may, after notification to the Registrar, contact the applicant directly (via phone, e-mail, or meeting). On completion of the review, the sub-committee members should send their comments/recommendations to the review chairperson, who will compile a final report to be submitted to the Registrar.

7. Conflict of interest

According to Section 13 of the GMO Act, a person appointed to the subcommittees shall, immediately recuse himself or herself as a member of the subcommittees if a subject matter is reviewed in which he or she has any direct or indirect interest or if, for any other reason, there is or there is likely to be a conflict of interest as a result of his or her participation in the proceedings of the sub-committees.

8. Confidentiality

According to Section 18 of the Genetically Modified Organisms Act, 1997, no member of the sub-committees shall disclose any information acquired by him or her through the exercise or the performance of his or her duties in terms of the GMO Act.

Once finality on an application has been reached through a decision of the Council, or if the applicant withdraws the application, each member of the subcommittee will destroy all relevant documentation in relation to the application in an effective manner.

Each appointed member of the sub-committees shall sign a Deed of Confidentiality. The signed Deeds of Confidentiality will be collected by the Registrar and placed on a register administered by the Registrar's office.

9. Remuneration

The members of the sub-committees shall be, in terms of Section 12(1) of the GMO Act paid such remuneration as determined by the Minister of Agriculture and Land Affairs, in concurrence with the Minister of Finance.

The sub-committees shall be remunerated on the same basis as the members of the Advisory Committee. Payment will therefore be done adhoc, i.e. no work no pay. Hours spent (as indicated below) by the sub-committees on relevant matters of an application should be recorded and submitted via the review chairperson to the Registrar's office.

The Registrar will make direct payments to the sub-committees on a quarterly basis. No review will be paid until a decision on the application has been made by the Executive Council.

The average amount of hours paid for a certain review will be as follow -

- (a) Assessment of an application for contained use:
 - Member: 4 hours
 - Review chairperson: 5 hours
- (b) Assessment of an application for trial release:
 - Member: 8 hours
 - Review chairperson: 9 hours
- (c) Assessment of an application for general release/commodity clearance:
 - Member: 12 hours
 - Review chairperson: 13 hours