

agriculture, forestry & fisheries

Department: Agriculture, Forestry and Fisheries **REPUBLIC OF SOUTH AFRICA**

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GUIDELINE FOR SUBMISSION OF ANNUAL REPORTS IN TERMS OF THE GENETICALLY MODIFED ORGANISMS ACT, 1997

A. INTRODUCTION

The purpose of the document is to provide guidance for permit holders with regards to drafting and submission of annual reports.

B. PURPOSE OF THE ANNUAL REPORT

The purpose of the annual report is to provide information to the regulators on performance of the activities carried out by the permit holder.

The following information must be included:

1. **PERMIT HOLDER**

- The name and the physical address of the local permit holder
- Permit number and date:
- Submission date of the report:

2. SUMMARY OF THE REPORT

• Provide a summary of the purpose, methodology, results and conclusion.

3. OBJECTIVE/S

• Provide a purpose of the activity

4. MATERIALS AND METHODS

- Any deviations from the information submitted in the application e.g, trial site/size and provide reasons thereof.
- Description of the experiments conducted

• Detailed treatment of the samples

5. RESULTS AND DISCUSSION

- The results should be in relation to the purpose of the activity
- Provide information on the performance of the GMO with respect to the introduced trait; e.g., for insect resistance crops, did the crop provide sufficient protection against the target pest?
- Discuss discrepancies; if results were unexpected explain why.
- 6. ADDITIONAL INFORMATION FOR COMMODITY CLEARANCE AND GENERAL RELEASE AS APPLICABLE: (this section should include details of post-market monitoring)
 - Detailed data from the insect resistance management and integrated pest management programs; e.g. cases of which farmers had to use chemical insecticides on insect resistant crop due to unacceptable infestation or damage levels, detailed information on the compliance by farmers regarding the non-spraying of the 5% refuge area)
 - Detailed data on the monitoring of planting regime e.g. early detection of increased of insect resistance, educational programmes
 - In depth data on the performance and efficacy of the GMO e.g. what was the level of increased yield or drought tolerance and was it robust at every site.
 - Information on the stewardship program e.g. educational material and training.
 - Information regarding any unanticipated adverse effects arising from the handling and use of the GMO.
 - If any unanticipated adverse effects are detected, the likely impact to humans and communities.
 - Information on who benefits from the technology e.g. gender of growers.

7. CONCLUSION

• Provide any other relevant information.

C. SUBMISSION OF ANNUAL REPORTS

Permit holders must submit an annual report to the Office of the Registrar (OoR) within 90 days of expiry date of permit.

D. ASSESSMENT OF THE ANNUAL REPORT

- The OoR will assess the reports for:
 - a. compliance to the permit conditions
 - b. performance of GMO in relation to the purpose of the activities
 - c. stewardship activities
- The OoR will provide feedback to the permit holder within 60 days of submission of the report.

N.B This document is solely a guideline and does not preclude the Executive Council, or the Office of the Registrar to request additional information in line with the permit conditions.