

# REGULATORY BEST PRACTICE IN THE SOUTH AFRICAN CONTEXT

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DEPARTMENT OF AGRICULTURE, FORESTRY AND FISHERIES



agriculture,  
forestry & fisheries

Department:  
Agriculture, Forestry and Fisheries  
REPUBLIC OF SOUTH AFRICA

# INTRODUCTION

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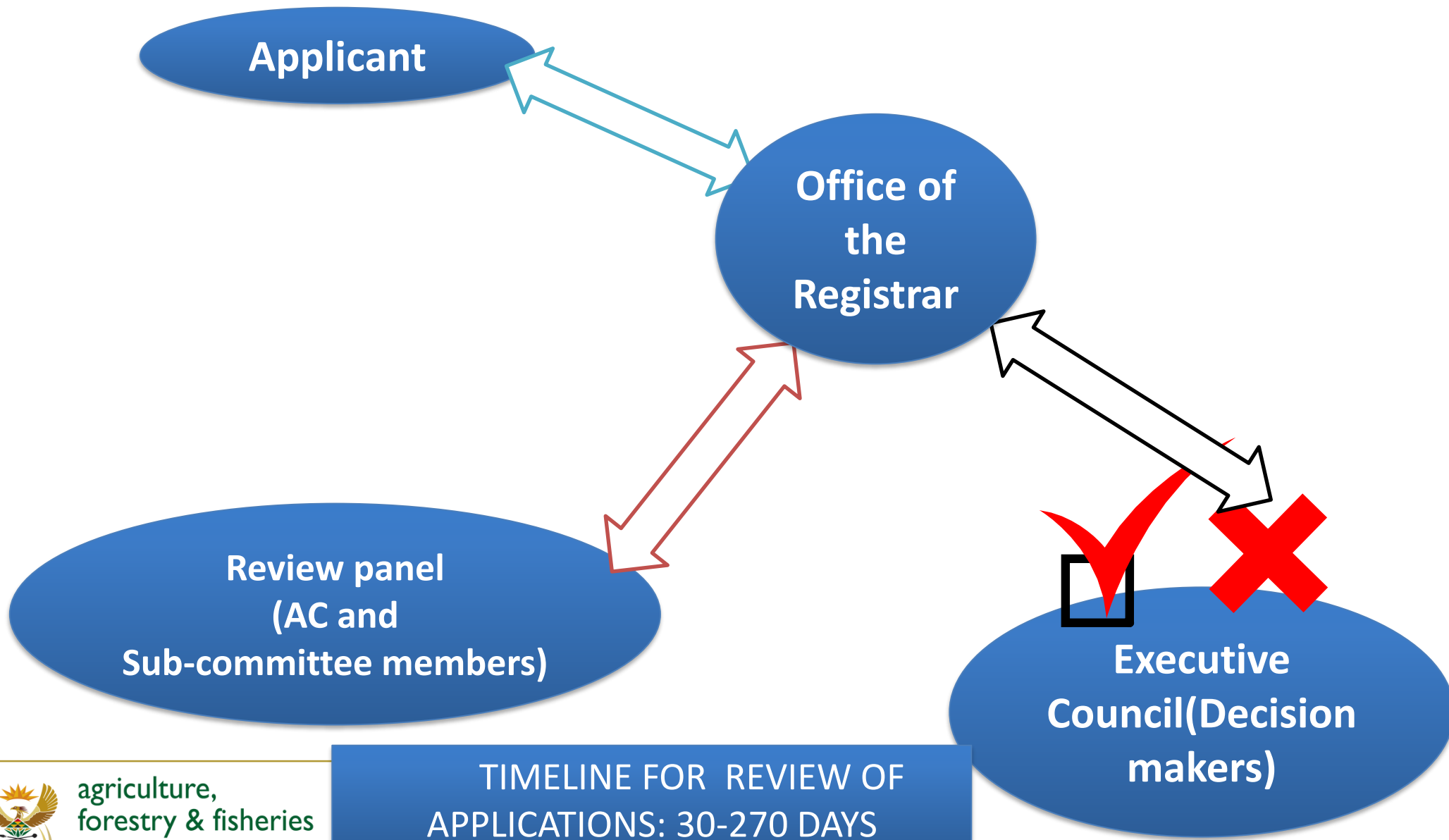
□ Overview of the requirements and recommendations for:

- Facility
- Contained use
- Trial release
- Commodity clearance
- General release

□ Ensure compliance



# OVERVIEW OF THE ASSESSMENT PROCESS



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TIMELINE FOR REVIEW OF  
APPLICATIONS: 30-270 DAYS

## REGISTRAR: COMPLIANT APPLICATIONS

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- Latest application form: reviewed as per AC recommendations
- Applicable fees: Tariffs 01 April each year
- Labelling of Confidential Business Information vs NON-Confidential Information
- Incomplete application forms
- Copy paste from previous applications
- Number of copies submitted



## ADVISORY COMMITTEE: RISK ASSESSMENT

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- Comprehensive risk assessment data: For each application
- Data on stacked events and not on individual events
- Scientific references cited in the application
- Data supported by scientific evidence
- Good quality images



## FACILITY REGISTRATION

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### Type of facilities:

- Laboratories/glasshouses
- Growth rooms
- Seed storage

### Detailed information on the facility:

- Description of the facility
- Containment level
- Map identifying the location of the facility
- Reasons for restricted access
- Waste management



## CONTAINED USE

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### Activities:

- Trait development
- Feeding studies
- Expression levels of the gene

### Detailed information on the activity:

- Detection protocols
- Evidence for genetic stability (e.g. Southern blot or PCR analyses)



## FIELD TRIAL RELEASE

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### Activities:

- Generate local performance data: 2-3 seasons
- Introgression in locally adapted germplasm

### Clear objectives of the proposed trial

### Detailed information on the experimental methodology

### Information on the trial site:

- Actual site co-ordinates, map and size
- Isolation distances e.g. proximity of the trial site to surface water, protected areas etc





## FIELD TRIAL RELEASE

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### Genetic information:

- Evidence on genetic stability and copy number (e.g. Southern blot or PCR analyses)
- Information on any adverse effects e.g., allergenicity, toxicology, and weediness (unmodified host and GM counterpart)
- Table and/or map of the genetic construct with all elements and their nucleotide positions and orientation

### Information on any effects on non-target organisms

### Comprehensive yield data (for each trial site)



## COMMODITY CLEARANCE

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### Activity:

- Food/feed safety data

### Comprehensive reports and results from the studies conducted:

- Data for each trial site
- Data from controls used under the current experimental conditions (not historical control data)
- Reasonable sample size



## GENERAL RELEASE

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### Activities:

- Field trial data
- Food/feed Safety data

Evidence on genetic stability and copy number for at least two generations

Field trial data for at least two seasons

Compositional data analyses for individual trial sites

Statistically analysed field trial data



## OBLIGATIONS OF THE APPLICANT

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- Public notices as prescribed
  
- Responses to public comments where applicable
  
- Submission of additional information if and when requested
  
- Compliance to permit conditions
  
- Submission of annual reports



## OTHER STAKEHOLDERS

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### DAFF inspection services

- Inspections (permit conditions)
- Report submitted to OoR
- Non-compliance reported to EC

### Appeal Board

- Appointed by Minister of Agriculture, Forestry and Fisheries
- Recommendation to Minister
- Final decision by Minister



# CONTACT DETAILS OF OoR

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## **Administration of the GMO Act**

Registrar of the GMO Act:

Ms Nompumelelo Mkhonza

Tel: 012 319 6382

Email: [NompumeleloM@daff.gov.za](mailto:NompumeleloM@daff.gov.za)

## **Commodity clearance/General release/Trial release of GMOs**

Biosafety Officer:

Mr Sello Mokhothu

Tel: 012 319 6033

Email: [SelloMok@daff.gov.za](mailto:SelloMok@daff.gov.za)

## **GMO status certificates, Imports, Exports and commodity use of GMOs**

Biosafety Control Officer:

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# Thank you



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