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forestry & fisheries
Department:
Agriculture, Forestry and Fisheries
REPUBLIC OF SOUTH AFRICA

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APPLICATION FOR GENERAL RELEASE OF GENETICALLY MODIFIED ORGANISMS (GMOs) IN SOUTH AFRICA

This application template is primarily intended for applications dealing with genetically modified (GM) plants

Applicants are advised to review guidelines available on the Department of Agriculture, Forestry and Fisheries (DAFF) website (www.daff.gov.za) to assist in the completion of the application

IMPORTANT: All the data required to assess the application should be included in the application dossier. Applicants should not refer to in-house generated results or data that are not part of the application dossier.

PART I

1. APPLICANT

1.1 Name of applicant

1.2 Address of applicant

2. BRIEF DESCRIPTION OF THE GM PLANT/PRODUCT

Provide a brief description of the plant, the intended function(s) of the genetic modification(s), and the GM trait(s) of the plant.

3. CHARACTERISTICS OF THE HOST OR UNMODIFIED RECIPIENT ORGANISM

3.1 Specific and common names of the recipient or parental organism or plant

3.2 Natural habitat, geographic distribution, geographic origin, and centres for diversity. Provide details on the type of environment and the geographical areas for which the plant is suited.

3.3 Reproduction:

3.3.1 Provide detailed information on the mode(s) of reproduction.

3.3.2 Provide information on specific factors affecting reproduction.

3.3.3 For pollen spread, identify pollinating agents and the distances to which pollen is known to spread.

3.3.4 Provide information on the generation time.

3.4 Sexually compatible species:

3.4.1 Provide information on cultivated species, their distribution, and proximity to general release areas.

3.4.2 Give details of wild species and their distribution and proximity to general release areas.

3.4.3 Identify any plants in the area of general release that may become cross-pollinated with the host plant.

3.5 Survivability in the environment:

3.5.1 Provide details on structures produced by the plant for survival or dormancy.

3.5.2 Provide information on specific factors affecting survivability.

3.6 Dissemination in the environment:

3.6.1 Provide details on how the plant may disseminate in the environment

3.6.2 Provide information on specific factors affecting dissemination.

3.7 Provide information on how the plant is usually utilised in agriculture, forestry, medicine, or other areas.

4. GENERAL RELEASE

4.1 When will general release be implemented?

4.2 Where will general release take place?

4.3 Detail the type of environment and the geographical areas for which the plant is suited.

4.4 Who will undertake the general release?

4.5 Estimate the amount of production of the GM plant within South Africa per annum, or the amount of viable plant product to be imported into South Africa per annum.

4.6 Give a description of the intended use of the GMO and / or derived product. Indicate if the derived products are for food / feed or industrial use.

4.7 Identify the parts of the plant to be used for the product, the type of product, and the use of the product as well as the market sector in which the product may be marketed.

4.8 Provide information on the proposed labelling of the product for marketing. Please refer also to the Consumer Act, 2008 (No. 68 of 2008) and other relevant Acts for guidance on labelling requirements.

4.9 State whether the benefits of the product are available in any other non-GM form. If so, state why the GM form should be approved for general release when other, non-modified products are available.

5. BRIEF SUMMARY OF FIELD TRIALS UNDERTAKEN

5.1 Submit a list of previously authorised activities undertaken by the applicant with the GMO in:

(a) South Africa.

(b) Other countries.

Your answers to (a) and (b) should include information on the country, year, location and the authority from which permission was obtained to run the field trials.

5.2 Provide a scientific summary on the field performance of the GM plant, including a scientific explanation of the efficacy of the introduced trait for each of the previously authorised activities listed in 5.1.

6. INSERTED NUCLEIC ACID SEQUENCES AND THE GM ORGANISM OR PLANT

6.1 Provide a description of the methods used for genetic modification and, in cases where vectors were used, describe the nature and source of the vectors used.

6.2 Provide detailed information on the genetic construct and the region intended for insertion, including the source of donor DNA and the size and intended function of each constituent fragment of the region intended for insertion. Use maps and tables as appropriate. Provide information on any change in the ability of the GMO, which is the focus of this application, to transfer genetic material to bacteria, plants, or other organisms.

6.3 Provide information on the sequences actually inserted or deleted in the GM plant:

6.3.1 The copy number of all inserts, both complete and partial.

6.3.2 In the case of deletion(s), the size and function of the deleted region(s).

6.3.3 Location(s) of insert(s) (nucleus, chloroplasts, mitochondria, or maintained in non-integrated form), and the molecular methods used for determination of the location(s).

6.3.4 The organisation of the inserted genetic material at the insertion site.

6.4 Describe the trait(s) and characteristics which have been introduced or modified:

6.4.1 Identify all inserted sequences and genes in the GM plant.

6.4.2 Describe the gene products that are derived from the inserted genes.

6.4.3 Describe the biological activity associated with the inserted sequences.

6.4.4 In the case of insect tolerance traits, what level of reduction in crop damage caused by the major insect pests may growers of the GM plant in South Africa expect? The level of reduction in damage should be discussed relative to conventional (non-GM) counterparts.

6.5 Provide information on the expression of the inserted sequences:

6.5.1 State whether expression is constitutive or inducible. In the case of inducible expression, discuss the induction conditions.

6.5.2 Provide information on the rate and level of expression of the products of the inserted sequences or inserted genes and the sensitivity of the measurement of the rate and level.

6.5.3 Provide information on the expression of the products of the inserted sequences or inserted genes in different plant tissues. For stacked events, provide data on the expression of the inserted sequences relative to that in the parental GM events.

6.6 Provide protocols for the detection of the inserted sequences or inserted genes in other plants in the environment including sensitivity, reliability and specificity of the techniques.

6.7 Provide information on the genetic stability of the inserted sequences.

6.8 Provide information on the phenotypic stability of the GM plant.

6.9 Provide information on how the GM plant differs from the recipient plant in:

6.9.1 General agronomic traits.

6.9.2 Reproduction.

6.9.3 Dissemination, including persistence and invasiveness.

6.9.4 Survivability.

6.9.5 Other.

7. RESISTANCE DEVELOPMENT

7.1 Detail whether any component of the environment can develop resistance to any of the foreign gene products in the GM plant.

7.2 Highlight the occurrence of resistance in previous field trials / general releases or in the literature for plants containing the same or similar genes.

7.3 Detail what methods are available to minimise the risk of resistance developing in the environment.

8. HUMAN AND ANIMAL HEALTH

8.1 State whether the GM plant or its products will enter human or animal food chains.

8.2 Provide information on the anticipated intake or the extent of exposure to the GM plant or its products.

8.3 Toxicology:

8.3.1 Detail the results of experiments undertaken to determine the toxicity to humans and animals of the newly expressed proteins (including antibiotic markers) or new constituents other than proteins.

8.4 Allergenicity:

8.4.1 What are the common/major allergens present in the recipient organism before modification?

8.4.2 Detail the results of experiments undertaken to determine the allergenicity of the newly expressed gene products (including antibiotic markers) to humans and animals.

8.4.3 What evidence is there that the genetic modification described in this application did not result in over-expression of the possible allergens indicated in 8.4.1, i.e. is the expression of the possible allergens in the non-GM counterpart substantially equivalent to that in the GM organism?

8.4.4 Detail the results of experiments undertaken to determine the allergenicty of whole GM food or GM feed.

8.5 If the newly expressed gene products are toxic or allergenic in any way, detail how the general release will be managed to prevent contact with animals or humans that will lead to discomfort or toxicity.

8.6 Compositional analysis and feeding studies

(The Appendix contains guidance for the completion of section 8.6)

8.6.1 Compositional analysis.

Detail the results of compositional analyses, and highlight any changes in natural food and feed constituents, including toxicants, metabolites and anti-nutritional factors.

8.6.2 Feeding studies

(a) Detail the results of nutritional performance or comparison studies.

(b) Detail the results of toxicological studies undertaken with the GM crop (whole GM food and/or GM feed).

8.7 What are the implications of the proposed activity with regard to the health and safety of the workers, cleaning personnel and any other person that will be directly or indirectly involved in the activity? Please take into consideration the provisions of the Occupational Health and Safety Act, 1993 (Act No. 85 of 1993 as amended by Act No. 181 of 1993) (and accompanying regulations) and indicate the proposed health and safety measures that would be applied.

9. ENVIRONMENTAL IMPACT AND PROTECTION

9.1 Pollination and reproduction:

9.1.1 Identify any plants in the area of general release that may become cross-pollinated with the GM pollen (see 3.4.3).

9.1.2 How do seeds of the GM plant interact with the environment and what long term effects will the seed likely have on the environment.

9.1.3 In the case of vegetative reproduction, describe methods to be used to limit vegetative spread of the GM plant into the environment.

9.2 Detail any effects, especially long-term, that the general release of the GM plant is likely to have on the biotic and abiotic components of the environment. Information on the impact on non-target organisms should be provided.

9.3 Provide data and information on ecosystems that could be affected by use of the plant or its products.

9.4 Specify what effect the general release of the GM plant will have on biodiversity.

9.5 If the foreign genes give rise to crops tolerant to agrochemicals, provide information on the registration of the agrochemicals to be used on the crop.

9.6 Submit an evaluation of the foreseeable impacts, in particular any pathogenic and ecologically disruptive impacts.

10. SOCIO-ECONOMIC IMPACTS

10.1 Specify what, if any, positive or negative socio-economic impacts the GM plant will have on communities in the proposed regions of release. The information may include but is not limited to information on the impact on the following:

(a) Income, competitiveness or economic markets.

(b) Food security.

(c) Access to genetics and other natural resources previously available.

(d) Cultural traditions, knowledge and practices.

(e) The continued existence and range of diversity of the biological resources.

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11. RISK MANAGEMENT AND POST MARKET MONITORING PLAN

11.1 Please indicate any risk management measures that users of this trait will have to adhere to with regard to commercial planting and use.

11.2 Please specify an environmental monitoring plan (approach, strategy, method and analysis) which encompasses but is not limited to the following:

(i) Spread, including vegetative spread, of GM plants.

(ii) Environmental impact and protection (focusing on issues such as weed and insect resistance management; direct and indirect impacts on non-target organisms).

(iii) Pathogenic and ecological impacts.

(iv) Effects on human and animal health.

(v) Impacts of the cultivation, management and harvesting techniques specific to the GMO.

(vi) Also refer to requirements in terms of the Environmental Risk Assessment Framework for Genetically Modified Organisms.

12. COMPLETE THE AFFIDAVIT. The affidavit is an inseparable part of the application form.

PART II

COMMON FORMAT FOR RISK ASSESSMENT

(In accordance with Annex III of the Cartagena Protocol on Biosafety)

	Risk assessment details	
1.	Country Taking Decision:	South Africa
2.	Title:	<Text entry>
3.	Contact details:	<Standard contact address details: name, function (job title/designation), organization, address, phone, fax, email, website>
	LMO information	
4.	Name and identity of the living modified organism:	<Text entry – Identity of the living modified organism, and the differences between the biological characteristic of living modified organism and those of the recipient organism or parental organisms>
5.	Unique identification of the living modified organism:	<Text entry>
6.	Transformation event:	<Text entry>

7.	Introduced or Modified Traits:	Choose the trait from the following list: <u>A. Abiotic environmental tolerance</u> - Altered photoperiod sensitivity - Cold or heat tolerance - Drought or water tolerance - Other abiotic environmental tolerance <u>B. Altered growth, development and product quality</u> - Altered ripening or flowering - Colouration - Fertility restoration - Growth rate or yield - Male sterility - Nutritional composition (incl. allergenicity) - Other growth, development and product quality - Selectable marker genes and reporter genes - Uptake or degradation of environmental pollutants **Chemical tolerance** - Herbicide tolerance - Other chemical tolerance **Medical products** - Animal vaccines - Development of transplant organs - Other medical products - Production of pharmaceuticals **Pest resistance** - Bacterial resistance - Fungus resistance - Insect resistance - Nematode resistance - Other pest resistance - Virus resistance and <text entry for other, not on the list>
8.	Techniques used for modification:	<Controlled vocabulary for common techniques - Please select techniques used for the transformation: plasmid carried by *Agrobacterium tumefaciens*, biolistic methods, breeding, electric shock (poration), osmotic shock> *and* <text entry – for other, not on the list>
9.	Description of gene modification:	<Text entry>
		Characteristics of modification
10.	Vector characteristics (Annex III.9(c)):	<Text entry - Characteristics of the vector, should include its identity, if any, and its source or origin, and its host range >
11.	Insert or inserts (Annex III.9(d)):	<Text entry - Genetic characteristics of the inserted nucleic acid and the function it specifies, and/or characteristics of the modification introduced>

Recipient organism or parental organisms (Annex III.9(a)):	
12. Taxonomic name/status of recipient organism or parental organisms:	<Controlled vocabulary: agreed international standards> *and* <text entry – for other, not on the list>
13. Common name of recipient organism or parental organisms:	<Controlled vocabulary with thesaurus> *and* <text entry – for other, not on the list>
14. Point of collection or acquisition of recipient or parental organisms:	<Text entry >
15. Characteristics of recipient organism or parental organisms related to biosafety:	<Text entry >
16. Centre(s) of origin of recipient organism or parental organisms:	<Text entry - Describe the exact location and give geographical coordinates>
17. Centres of genetic diversity, if known, of recipient organism or parental organisms:	<Text entry - Describe the exact location and give geographical coordinates>
18. Habitats where the recipient organism or parental organisms may persist or proliferate:	<Text entry - Description of the habitat where the organisms may persist or proliferate>
Donor organism or organisms (Annex III.9(b)):	
19. Taxonomic name/status of donor organism(s)	<Controlled vocabulary: agreed international standards> and <text entry for other, not on the list>
20. Common name of donor organism(s):	<Controlled vocabulary with thesaurus> and <text entry for other, not on the list>
21. Point of collection or acquisition of donor organism(s):	<Text entry - the exact location and geographical coordinates>
22. Characteristics of donor organism(s) related to biosafety:	<Text entry - Relevant biological characteristics of donor organisms>

Intended use and receiving environment	
23. Intended use of the LMO (Annex III 9(g)):	<Text entry - Information relating to the intended use of the living modified organism, including new or changed use compared to the recipient organism or parental organisms>
24. Receiving environment (Annex III.9(h)):	<Text entry - Information on the location, geographical, climatic and ecological characteristics, including relevant information on biological diversity and centres of origin of the likely potential receiving environment>
Risk assessment summary	
25. Detection/Identification method of the LMO (Annex III.9(f)):	<Text entry - Suggested detection and identification methods and their specificity, sensitivity and reliability>
26. Evaluation of the likelihood of adverse effects (Annex III.8(b)):	<Text entry - An evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism>
27. Evaluation of the consequences (Annex III.8(c)):	<Text entry - An evaluation of the consequences should these adverse effects be realized>
28. Overall risk (Annex III.8(d)):	<Text entry - An estimation of the overall risk posed by the living modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realized>
29. Recommendation (Annex III.8(e)):	<Text entry - A recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks>
30. Actions to address uncertainty regarding the level of risk (Annex III.8(f)):	<Text entry - details about any further information that has been requested where there is uncertainty regarding the level of risk, as well as any information on risk management strategies and/or monitoring of the LMO in the receiving environment>
Additional information	
31. Availability of detailed risk assessment information:	<Text entry - Please indicate whether more details on the risk assessment are available and how they can be accessed>
32. Any other relevant information:	< Text entry - any other information that is relevant to the risk assessment. e.g. information of non CBI nature that was included in the original application but is not included in this form>
33. Attach document:	*Not applicable to applicant*<Specific types of entry: option to choose a file from the local source and 'upload' a copy to the BCH server>
34. Notes:	<Text entry>

AFFIDAVIT/STATEMENT

(to be completed in the presence of a Commissioner of Oaths)

I…….

ID Number……. Age ……..

Residing address …….

Working address ……..

Tel ……..(w) ……(h) ……(cell)

Declare under oath in English / confirm in English –

……
……
……
……

I am familiar with, and understand the contents of this declaration. I have no objection/have objection to taking the prescribed oath. I consider the prescribed oath as binding to my conscience.

Place: …….. Date: ……..

Time: ……

Signature: ……

I certify that the above statement was taken from me and that the deponent has acknowledge that he/she knows and understands the contents of the statement. The statement was sworn to/affirmed before me and deponents signature/mark/thumb print was placed thereon in my presence.

At: …… on …… at ……

……..
Commissioner of Oaths
(details to be provided on physical and postal address e.g. stamp of police station)

……
Force number/Rank/Name – print

Directions for the applicant:

(This page must be excluded from the documents submitted to the Registrar's office)

- Please complete all relevant sections of the questionnaire CLEARLY.
- Please provide 1 original and 15 copies (9 additional copies if application for a crop with no previous general release approval) of the application with confidential information for use by the regulatory bodies appointed in terms of the Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997).

  Please confirm with the Office of the Registrar with regard to submission of electronic applications
- Please provide an additional hard copy and electronic version of the application containing no confidential information. Non-Confidential Business Information (Non-CBI) copy - this is your application where you have deleted any information that you regard as confidential business information. Please take note that you must make reference to the specific section of the Promotion of Access to Information Act, 2000 whenever you "delete" information in this application. This copy must be clearly marked NON-CONFIDENTIAL, and will be made available for public scrutiny and placed on the website of the Department. This copy of the application must be submitted to the Registrar one day after the placing of the public notices.
- Please provide an electronic and hard copy of a risk assessment conducted in accordance with Annex III of the Cartagena Protocol on Biosafety and in the format prescribed below.
- Please conduct a public notification in accordance with Regulation 6 of the GMO Act, and making use of the guideline document available on the website of the department. Copies of the public notification must be submitted with the application.
- Please submit all relevant documentation to the Registrar at the address indicated in the application form.
- The appropriate fee stipulated under the GMO Act must accompany the application. Please note that the Registrar's office does not accept cash.

APPENDIX

Guidance for section 8.6 (compositional analysis and feeding studies)

1. Compositional data should be provided for the GM crop (including stacked events) under consideration in the application.
2. For both compositional analyses and feeding studies, provide clear information on:
    a. the choice of non-GM comparators,
    b. the production of material for the comparative assessments, including locations, replicates and growing seasons, and
    c. the baselines used for consideration of natural variations.
3. For all stacked event applications that include a complete, stand-alone risk assessment package for the stacked event, there is no expectation that data will be provided for the parental GM events.
4. For stacked events that contain RSA-approved parental GM events and a parental GM event that has not yet been approved in the RSA, the safety assessment of the stacked event may take into consideration the demonstrated safety of the parental GM events (i.e. a data bridging approach may be used); however, detailed safety assessments, including feeding and toxicological studies, would be expected for the unapproved GM event in the stack. Alternatively, a full risk assessment package may be submitted for the stacked event under consideration. For either approach, agronomic/phenotypic, expression and compositional data for the stacked event are expected. The expression levels of the inserted sequences relative to those in the parental GM events need to be taken into consideration (see also 6.5.3).
5. For all stacked event applications that do not include a complete risk assessment package for the stacked event (e.g. prior RSA approval for parental GM events is used to argue that feeding studies are not required; see point 4 above), the full safety assessment package for each parental GM event needs to be included in the application dossier.
6. For stacked events in general: in the event that the compositional analyses show that there are statistically significant differences of biological relevance between the stacked event and the non-GM comparators, further safety assessments, including feeding and toxicological studies, of the stacked event under consideration would be expected.

7. Lower-level stack applications: in the event that compositional analyses show that there are not statistically significant differences of biological relevance between a lower-level stack (e.g. AxBxC) and both a previously RSA-approved higher-level stack (e.g. AxBxCxD) and non-GM comparators, then the need for further safety assessments should be considered on a case-by-case basis. However, in all such applications, the full risk assessment package (including expression and feeding studies) for each parental GM event needs to be included in the application dossier. In these types of applications, the expression levels of the inserted sequences relative to those in the parental GM events need to be taken into consideration (see also 6.5.3).

8. For all newly assessed single events: besides compositional data, further detailed safety assessments, including feeding and toxicological studies, for the GM crop under consideration are expected.

9. Compositional analyses and feeding studies should be done using widely-accepted industry standards or guidelines (e.g. OECD or WHO guidelines).