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DRAFT ZIMBABWE SPECIFICATION FOR

AGRICULTURAL BIOTECHNOLOGY PRODUCTS

This draft is now available for **public comment**. Your views and technical comments on it would be appreciated. If you have no specific comments to make but find it generally acceptable it would be helpful if you would notify us accordingly. Suggestions entailing revisions of the text should indicate the preferred wording using the attached template. The relevant clause number should be quoted against any comment.

All comments should be sent to the Committee Secretary **Ms F Mukwekwerere** at the address shown below.

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PREFACE

This Zimbabwe Standard Specification ZWS 1022:2017 Agricultural biotechnology products, was prepared by Technical Committee FD 002: Genetically Modified Organisms, under the general direction of the Food and Agriculture Standards Council.

This draft standard makes reference to the following publications:

FAO: Status and trends of the conservation and sustainable use of microorganisms in agro-industrial processes, Agricultural remedies registration requirements and procedure document (2013).

Fertilizers, Farm Feed and Remedies Act [*Chap. 18.12*]

National Biotechnology Authority Act [*Chap.14.31*] of 2006

South Africa: Guidelines for the registration of Biopesticides, 2010; Guidelines on the data required for registration of Biological/Biopesticides Remedies in South Africa

Uganda Standard: Biofertilizer-specifications (2014).

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ZIMBABWE SPECIFICATION

FOR

AGRICULTURAL BIOTECHNOLOGY PRODUCTS

INTRODUCTION

An Agricultural biotechnology product (ABP) is a substance which contains living microorganisms and/or components derived thereof which, when applied to seeds, plant surfaces, or soil; promotes growth by increasing the supply or availability of nutrients to the host plant or control plant diseases, pests or weeds.

The use of ABPs has had a number of benefits in agriculture: increasing yield, reducing pest damage, and increasing general productivity among others. ABPs can be grouped depending on their function i.e biofertilizers, biopesticides, bioinsecticides and bioherbicides.

Biofertilizers contain living microorganisms and when applied to seed, plant surfaces, or soil, promotes growth by increasing the supply or availability of nutrients to the host plant.Organisms normally used include; *Rhizobium*, *Azotobacter*, *Azospirillum*, phosphate solubilising bacteria, Mycorrhizal fungi, potassium mobilizing bacteria and zinc solubilising bacteria.

Biopesticides contain preparations of predatory, parasitic organisms, or their pesticidal substances for pest (weeds, insects) control. Viruses, bacteria, protozoa, fungi, and mites and certain plants may be used as bio-pesticides.

Bioherbicides contain preparations of microorganisms (e.g. bacteria, viruses, fungi), certain insects (e.g. parasitic wasps, painted lady butterfly) and/or other organisms that can target specific weeds.
Bioinsecticides contain naturally occurring organisms, and/or their by-products (natural insecticides) that can be employed for the control of insect pests e.g. *Bacillus*, *Baculovirus*, *Coccinellidae* and *Beauveria bassiana*.

The use of ABPs offer potential benefits compared to the use of agrochemicals since they are environmentally friendly, biodegradable, cheaper and tend to have long term benefits. The advent of ABPs is a good agricultural technological innovation as it addresses issues of food security, safety and efficacy.

This standard supports the National Biotechnology Authority of Zimbabwe's regulations and its objective is to ensure that properly evaluated products are placed on the market following set quality criteria while ensuring that farmers use high quality products. This standard will also assist the industry in the manufacture of quality ABPs. This standard will further promote the safe use of ABPs and increase trade thereof.

1. SCOPE

This standard specifies requirements and methods of testing for Agricultural biotechnology products

NOTE. This standard does not apply to chemical-based agricultural products.

2. DEFINITIONS

For the purpose of this draft Zimbabwe Standard, the following definitions shall apply:

2.1 Act. The National Biotechnology Authority Act *[Chapter 14.31]* of 2006.

2.2 Active ingredient. Living agent in an agricultural biotechnology product to which the improvement of the physical condition of soils or aid in plant growth or crop yield or pest control are attributed.

2.3 Agricultural biotechnology products (ABPs). Any product which contains living organisms and/or components thereof which, when applied to seeds, plant surfaces, or soil; promotes growth by increasing the supply or availability of primary nutrients to the host plant, or control plant diseases, insect pests and weeds.

2.4 Authority. The National Biotechnology Authority established under Section 4 of the Act.

2.5 Biofertilizer. A substance which contains living microorganisms which, when applied to seed, plant surfaces, or soil, colonizes the rhizosphere or the interior of the plant and promotes growth by increasing the supply or availability of nutrients to the host plant.

2.6 Biofertilizer. A substance which contains living microorganisms which, when applied to seed, plant surfaces, or soil, colonizes the rhizosphere or the interior of the plant and promotes growth by increasing the supply or availability of nutrients to the host plant.

2.7 Bioherbicide. A preparation made up of microorganisms (e.g. bacteria, viruses, fungi) and certain insects (e.g. parasitic wasps, painted lady butterfly) that can target specific weeds.

2.8 Bioinsecticides. Naturally occurring organisms, and/or their by-products' that can be employed for the control of insect pests.

2.9 Biopesticides. Biological preparations of predatory, parasitic organisms, or their pesticidal substances for pest control.

2.10 Biosafety. Measures that need to be taken up for the prevention of large-scale loss of biological integrity, with a primary focus on both ecology and human health/the containment principles, technologies and practices that are implemented to prevent unintentional exposure to pathogens and toxins, or their accidental release in the environment.

2.11 Efficacy. The ability of an ABP or supplement to fulfil any label claims and to produce a desired or intended result based on the labelled guarantees and directions for use.

2.12 Genetically Modified Organism. An organism the genes or genetic material of which have been modified in a way that does not occur naturally through mating or natural recombination or both, and 'genetic modification' shall have a corresponding meaning

2.13 Ingredient. Any substance, including additives, used in the manufacture or preparation of an ABP and present in the final product although possibly in a modified form.

2.14 Inspection. Conformity evaluation by observation and judgment accompanied as appropriate by measurement, testing, gauging, or documentation.

2.15 Micro-organism. A small living thing that cannot be seen without a microscope. This includes bacteria, fungi, protozoa, microscopic algae, and viruses.

2.16 Product. Agricultural biotechnology product.

3 GENERAL REQUIREMENTS FOR AGRICULTURAL BIOTECHNOLOGY PRODUCTS

All in-use ABPs shall comply with existing regulatory requirements.

The ABPs shall be free from contamination and be presented in a form appropriate to its application.

NOTE. The ABPs can either be in solid (powder or granules), suspension or liquid form.

TABLE 1 – GENERAL REQUIREMENTS FOR BIOFERTILIZERS

Parameter	Source/Limit
Species	Bacteria, fungi, virus, plants and extracts thereof. For the list of approved microbes refer to appendix I
ph	refer to appendix II
Moisture content %m/m in case of carrier based formulations	30 - 40
Size of dried particles	Shall pass through a 0.15-0.212 mm sieve
Concentration	refer to appendix II
Permissible level of contaminant	No contamination at 10^5 dilution
Efficacy level	60 - 100%

TABLE 2 – GENERAL REQUIREMENTS FOR OTHER AGRICULTURAL BIOTECHNOLOGY PRODUCTS (i.e. BIOINSECTICIDES, BIOPESTICIDES AND BIOHERBICIDES)

Parameter	Source/Limit
Species	Bacteria, fungi, virus, plants and extracts thereof. For the list of approved microbes refer to Appendix I
Permissible level of contaminant	No contamination at 10^5 dilution
Efficacy level	60-100%

NOTE. Efficacy and safety data requirements for biologically derived chemicals are similar to those for conventional agricultural products.

NOTE. The species list in this table is not exhaustive and all (Generally Recognized as Safe) GRAS organisms can be used if they meet safety and efficacy criteria based on the views of experts qualified to evaluate such characteristics.

4. SAFETY AND QUALITY CONTROL

The product shall be handled under hygienic conditions and in appropriate premises in order to prevent contamination of the product.

Commercial batches shall be inspected and tested to ensure that they are free from contaminants and records of such shall be retained.

5. PACKAGING AND DISTRIBUTION

ABPs shall be stored, packaged and transported in containers which are safe and suitable for their intended use.

The packaging material shall not impart any toxic substance, undesirable odour to the product or react in any way with the product.

The products shall not be subjected to extremes of temperature and shall be packed in water-proof materials.

6. LABELLING

Labels on ABPs shall be printed in clear and indelible letters and be prominent and legible. They shall be printed in a contrasting colour to that of the background and shall meet the following specific requirements:

a) Name of the product i.e. biofertilizer, biopesticide, bioherbicide or bioinsecticide; a brand name can also accompany the product name.

b) Active ingredient shall appear in close proximity to the name of the product by specifying the genus and species of the microorganism, extract name shall be accompanied by the organism name.

c) The range of crops and / or pests on which the product should be used.

d) Concentration of the active ingredient (e.g. spores/ml or spores/g or cfu/ml or cfu/g or organisms/ml or organisms/g, g/ℓ).

e) Name and address of manufacturer, exporter, packer and/or dispatcher.

f) Batch or code number.

g) Storage conditions and instructions.

h) Date of manufacture.

i) Expiry date.

j) Net content of the product in metric units.

k) Product registration number.

l) Directions for use including application rate, interval, method and frequency of use.

m) Safety precautions.

7. MATERIAL SAFETY DATA SHEETS (MSDS)

All registered agricultural biotechnology products shall have MSDS and must contain the following information:

i) Product and company's identification (local entity's contact information)

ii) Composition/Information on ingredients

iii) Hazards identification

iv) First aid measures

v) Fire fighting measures

vi) Accidental release

vii) Handling and storage

viii) Exposure control/personal protection

ix) Physical and chemical properties

x) Stability and reaction

xi) Toxicological information

xii) Ecological information

xiii) Disposal consideration

xiv) Transportation information

xv) Regulatory information

xvi) Other regulatory information

9. VERIFICATION

Labels pertaining to the genetic modification status shall not be used unless if they can be verified. Verification methods include testing, inspection and audit tracking. Manufacturers who indicate the genetic modification status on labels shall ensure that:

a) they comply with Clause 6 on labelling.

b) they obtain the required information, preferably in documented form and keep it for at least five years.

c) they have well annotated data on the origin of the agricultural biotechnology product and/or ingredient.

d) have a practical plan for identity preservation of the agricultural biotechnology product or ingredient. Plan shall include necessary precautions taken during but not limited to; culturing (microbial), cultivation (plants), harvest, transport, processing and storage.

e) they shall use internationally validated methods for testing for the presence of particular GMOs and sampling methods. Where these do not exist the manufacturer shall propose the most suitable method and this will be validated.

f) Supply information on appropriate methods for sampling, identification and detection of particular GMOs in the agricultural biotechnology product.

g) provide samples of the agricultural biotechnology product that are products of genetic modification.

APPENDIX A – LIST OF SPECIES APPROVED FOR USE IN ABPs

This appendix is forms part of the requirements of this standard

i) *Bacillus* spp.
ii) *Trichoderma* spp.
iii) Yeast
iv) *Pseudomonas*
v) *Lactobacillus*
vi) Photosynthetic bacteria
vii) Nitrogen fixing bacteria
viii) *Bacillus thuringiensis*
ix) *Pseudomonas fluorescens*
x) *Bacillus popilliae*
xi) *Serratia entomophila*
xii) *Verticillium lecanii*
xiii) *Chondrosterum purpureum*
xix) *Metarhizium anisopilae*
xx) *Beauveria bassiana*
xxi) *Paecilomyces fumosoroseus*
xxii) *Cydia pomonella*
xxiii) *Lymantria dispar*
xxiv) *Neodiprion sertifer*
xxv) *Ectomycorrhizae*

NOTE. The species list in this table is not exhaustive and all Generally Recognized as Safe (GRAS) organisms can be used if they meet safety and efficacy criteria based on the views of experts qualified to evaluate such characteristics.

APPENDIX B – PH RANGE FOR BIOFERTILIZERS AND CONCENTRATION OF MICROBES THEREOF

Microbe	**Rhizobium**	**Azotobacter**	**Azospirillum**	**Phosphate solubilising bacteria**	**Mycorrhizal Biofertilizers**	**Potassium Mobilising Bio fertilizers,K MB**	**Zinc Solubilising Bio fertilizers (ZSB)**	**Acetobacter**
Base	Carrier based in form of moist/dry powder or granules or liquid carrier.	Carrier based in form of moist/dry powder or granules or liquid carrier.	Carrier based in form of moist/dry powder or granules or liquid carrier.	Carrier based in form of moist/dry powder or granules or liquid carrier.	Fine powder/ tablets/granules/root biomass mixed with growing substrate	Carrier based in form of moist/dry powder or granules or liquid carrier.	Carrier based in form of moist/dry powder or granules or liquid carrier.	Carrier based in form of moist/dry powder or granules or liquid carrier.
Viable cell count	CFU minimum 5x107 cell/g of powder, carrier material or 1x108 cell/ml of liquid	CFU minimum 5x107 cell/g of powder, carrier material or 1x108 cell/ml of liquid	CFU minimum 5x107 cell/g of powder, carrier material or 1x108 cell/ml of liquid	CFU minimum 5x107 cell/g of powder, carrier material or 1x108 cell/ml of liquid	90% should pass through 250 micron IS sieve powder formulations (60BSS)	CFU minimum 5x107 cell/g of powder, carrier material or 1x108 cell/ml of liquid	CFU minimum 5x107 cell/g of powder, carrier material or 1x108 cell/ml of liquid	CFU minimum 5x107 cell/g of powder, carrier material or 1x108 cell/ml of liquid
Contamination level	None at 105 dilution	None at 105 dilution	None at 105 dilution	None at 105 dilution	None at 105 dilution	None at 105 dilution	None at 105 dilution	None at 105 dilution
pH	6.5 – 7.5	6.5 – 7.5	6.5 – 7.5	6.5 – 7.5 for moist/dry powder granulated carrier based and 5.0 - 7.5 for liquid based	6.0 – 7.5	6.5 – 7.5 for carrier based in form of powder /granules and 5.0 - 7.5 for liquid based	6.5 – 7.5 for carrier based in form of powder/granules and 5.0 - 7.5 for liquid based	5.5 – 6.0 for moist/dry powder and 3.5 - 6.0 for liquid
Particle size in case of carrier based material	All material shall pass through 0.15-0.212 mm IS sieve	All material shall pass through 0.15-0.212 mm IS sieve	All material shall pass through 0.15-0.212 mm IS sieve	All material shall pass through 0.15-0.212 mm IS sieve	Powder material shall pass through 0.15-0.212 mm IS sieve	Powder material shall pass through 0.15-0.212 mm IS sieve	Powder material shall pass through 0.15-0.212 mm IS sieve	All material shall pass through 0.15-0.212 mm IS sieve
Moisture % (max) in carrier based	30-40 %	30-40 %	30-40 %	30-40 %	8 -12 %	30-40 %	30-40 %	30-40 %
Efficiency character	Should show nodulation on all the species listed on the packet	The strain should be capable of fixing at least 10mg of nitrogen per g of sucrose consumed	Formation of white pellicle in semisolid nitrogen free bromothymol blue media	Should have phosphate solubilising capacity in the range of minimum 30% when tested spectrophotometrically	80 infection points in test root/gm of mycorrhizal inoculum used	Minimum 10mm solubilisation zone in prescribed media having at least 3mm thickness	Minimum 10 mm solubilisation zone in prescribed media having at least 3mm thickness	Formulation of yellowish pellicle in semisolid medium N free medium