මහජන අදහස් සඳහා ප්‍රමිති කෙටුම්පත
பொதுசனக் கருத்துரைக்கான கட்டளை வரைவு
DRAFT STANDARD FOR PUBLIC COMMENT

(වෙනස්වීමට ඉඩ ඇත. திருத்தத்திற்குட்படக்கூடியது. Liable to alteration)

නිකුත් කළ දිනය
வெளியீட்டுத் திகதி
Date of Issue } 2024-08-23

අදහස් එවියයුතු අවසාන දිනය
அபிப்பிராயங்களை தெவிப்பதற்கான இறுதித்திகதி
Latest Date for Receipt of Comments } 2024-10-23

Draft Sri Lanka Standard
SPECIFICATION FOR BIO PESTICIDES
(DSLS .....: .....)

ජෛව පළිබෝධනාශක සඳහා වූ
ශ්‍රී ලංකා ප්‍රමිති පිරිවිතර කෙටුම්පත
(ශ්‍රීලංප කෙටුම්පත ..... : .....)

අදහස් එවිය යුත්තේ : ශ්‍රී ලංකා ප්‍රමිති ආයතනය, 17, වික්ටෝරියා පෙදෙස, ඇල්විටිගල මාවත, කොළඹ 08.

Comments to be sent to: SRI LANKA STANDARDS INSTITUTION, 17, VICTORIA PLACE, ELVITIGALA MAWATHA, COLOMBO 08.

හැඳින්වීම

මෙම ශ්‍රී ලංකා ප්‍රමිති කෙටුම්පත , ශ්‍රී ලංකා ප්‍රමිති ආයතනය විසින් සකසන ලදුව, සියලුම උද්‍යෝගී අංශ වලට තාක්‍ෂණික විවේචනය සඳහා යවනු ලැබේ.

අදාල අංශ භාර කමිටු මාර්ගයෙන් ආයතනයේ මහා මණ්ඩල වෙත ඉදිරිපත් කිරීමට පෙර , ලැබෙන සියලුම විවේචන ශ්‍රී ලංකා ප්‍රමිති ආයතනය විසින් සලකා බලා අවශ්‍ය වෙතොත් කෙටුම්පත සංශෝධනය කරනු ලැබේ.

මෙම කෙටුම්පතට අදාල යෝජනා හා විවේචන නියමිත දිනට පෙර ලැබෙන්නට සැලැස්වුවහොත් අගය කොට සලකමු. තවද, මෙම කෙටුම්පත පිළිගත හැකි බැව් හැගෙන අය ඒ බව දන්වන්නේ නම් එය ආයතනයට උපකාරි වනු ඇත.

මේ පිළිබඳව එවන සියලුම ලිපි පහත සඳහන් ලිපිනයට එවිය යුතුය.

අධ්‍යක්‍ෂ ජනරාල්
ශ්‍රී ලංකා ප්‍රමිති ආයතනය,
17, වික්ටෝරියා පෙදෙස,
ඇල්විටිගල මාවත,
කොළඹ 08.

xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Introduction

This Draft Sri Lanka Standard has been prepared by the Sri Lanka Standards Institution and is now being circulated for technical comments to all interested parties.

All comments received will be considered by the SLSI and the draft if necessary, before submission to the Council of the Institution through the relevant Divisional Committee for final approval.

The Institution would appreciate any views on this draft which should be sent before the specified date. It would also be helpful if those who find the draft generally acceptable could kindly notify us accordingly.

All Communications should be addressed to:

The Director General
Sri Lanka Standards Institution,
17, Victoria Place,
Elvitigala Mawatha,
Colombo 08.

Draft Sri Lanka Standard
SPECIFICATION FOR BIOPESTICIDES

DSLS :

Gr.

SRI LANKA STANDARDS INSTITUTION
17, Victoria Place,
Elvitigala Mawatha,
Colombo 8,
Sri Lanka.

Draft Sri Lanka Standard
SPECIFICATION FOR BIOPESTICIDES

FOREWORD

This Sri Lanka Standard was approved by the Sectoral Committee on Agriculture and was authorized for adoption and publication as a Sri Lanka Standard by the Council of the Sri Lanka Standards Institution on …….

Biopesticides are pesticides derived from natural materials as animals (biocontrol agents), plants, microorganisms, and certain minerals. They are usually inherently less toxic than conventional pesticides and generally affect only the target pest and closely related organisms. Biopesticides are often decomposed to less harmful substances or deactivated within short period after application to the field. This Standard is to ensure that biopesticides on the market are appropriately tested through the quality criteria provided while ensuring that farmers obtain only certified products and aiding the industry in the manufacture of quality biopesticides. This Standard will also promote the safe use of biopesticides and promote fair trade.

This Standard is subjected to the provisions under the Control of Pesticides Act No. 33 of 1980, the National Environmental Act No. 47 of 1980, the Soil Conservation Act No. 25 of 1951, the Fauna and Flora Protection Ordinance No. 02 of 1937, the Plant Protection Act No. 35 of 1999, and the regulations and amendments framed thereunder, and any other regulatory and statutory requirements wherever applicable.

Guidelines for the determination of compliance of a lot to the requirements of this Standard based on statistical sampling and inspection are given in Appendix **A**.

All values given in this Standard are in SI units.

For the purpose of deciding whether a particular requirement of this Standard is complied with, the final value, observed or calculated, expressing the results of a test shall be rounded off in accordance with **SLS 102**. The number of significant figures to be retained in the rounded off value shall be the same as that of the specified value in this Standard.

In the preparation of this Standard, the valuable assistance derived from the following publications is gratefully acknowledged:

Sri Lankan biopesticides registration guideline
PNS/BAFS 182 Organic biocontrol agents – Microbials and botanicals - Minimum data requirements
US 1577 – Biopesticide - Specification

1 SCOPE

1.1 This Standard specifies the requirements and methods of sampling and tests for biopesticides.

1.2 This Standard does not cover requirements for conventional chemical pesticides and microbial, macrobial, botanical and semiochemical biopesticides derived from or based on genetically modified organisms (GMOs) and pest control agents based on "RNA interference" technology or on "clustered regularly interspaced short palindromic repeats (CRISPR)" or other gene editing techniques and microbial agents for control of vertebrate pests.

2 REFERENCES

SLS	83	SI units and recommendations for use of their multiples and of certain other units
SLS	102	Rules for rounding off numerical values
SLS CEN/TS	17710	Plant biostimulants - Detection of *Listeria monocytogenes*
SLS CEN/TS	17711	Plant biostimulants - Detection of *Vibrio* spp.
SLS CEN/TS	17715	Plant biostimulants – Detection of *Shigella* spp.
SLS CEN/TS	17716	Plant biostimulants - Determination of *Escherichia coli*
SLS CEN/TS	17717	Plant biostimulants - Detection of *Salmonella* spp.

Official methods of Analysis, Association of Official Analytical Chemists (AOAC) 20th Edition, 2016.

3 DEFINITIONS

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

3.1 active ingredient: The part of the product that provides the pesticidal action.

3.2 biopesticide: A substance derived from natural materials, such as microorganisms or plants or certain minerals, and semiochemicals derived from plants and animals.

3.3 botanicals: Compounds and materials naturally derived or extracted from plants that demonstrate ability to manage or control pests and diseases involved in agriculture.

3.4 formulated product (commercial product): Any formulation containing one or more active ingredient and inert materials.

3.5 formulation (recipe): Combination of various ingredients designed to render the (formulated) product useful and effective for the purpose claimed and for the envisaged mode of application.

3.6 metabolites: Products resulting from degradative and biosynthetic reactions taking place within the microorganism or other organisms.

3.7 microbials: Microorganisms that include bacteria, alga, fungi, protozoans, viruses, nematodes, mycoplasma, rickettsia, and any associated metabolites, to which the effects of pest and disease control are attributed.

3.8 Semiochemicals: Substances or mixtures of substances emitted by plants, animals, and other organisms that evoke a behavioural or physiological response in other individuals of the same or other species.

4 TYPES

Biopesticides shall be of the following types:

a) Liquid;
b) Powder; and
c) Granular.

5 REQUIREMENTS

5.1 General requirements

5.1.1 Biopesticides shall be manufactured by a process adhering to Good Manufacturing Practices (GMP) complying with the requirements imposed by the relevant regulatory authorities in Sri Lanka.

5.1.3 The raw materials used in manufacturing biopesticides shall be in accordance with the substances listed in the Appendix **B** of the **SLS 1324**.

5.1.4 The base or carrier material used in the manufacture of the product shall be solid or liquid, be free from contamination and appropriate for the intended purpose.

5.1.5 The product shall be free from any organisms and substances, which would be harmful or potentially injurious to human, animal, plant and other biota, and ecosystems as a whole when used according to the directions provided by the manufacturer.

5.1.5 Biopesticides shall have undergone a complete efficacy assessment.

5.2 Specific requirements

The product shall conform to the requirements given in Table **1**, when tested according to the methods given in Column **4** of the Table **1**.

TABLE 1 -Specific requirements for biopesticides

SI No.	Parameter	Limit	Method of test
i)	pH	6.5 – 7.5	**Appendix C**
ii)	Moisture content, % m/m (For biopesticides produced using solid base material)	10-15	**Appendix D**

5.5 Microbiological limits

The product shall not exceed the limits for microorganisms given in the Table **2** when tested using the methods prescribed in Column **4** of the Table **2.**

TABLE 2 – Microbiological limits for biopesticides

Sl No. (1)	**Test organism** (2)	**Limit** (3)	**Method of test** (4)
	Viable cell count of the active agent (at 25-30°C), cfu/mL or cfu/g, min.		**Appendix B**
i)	Entomopathogenic spp.	1×10^8	
ii)	Tricoderma spp.	2×10^6	
iii)	**Non-target microorganism contamination, at 10^{-5} dilution**	Absent	**Appendix B**
	Pathogenic microorganisms		
iv)	*Salmonella*, per 25 ml or 25 g	Absent	**SLS CEN/TS 17717**
v)	*Escherichia coli*, per 25 ml or 25 g	Absent	**SLS CEN/TS 17716**
vi)	*Vibrio* spp., per 25 ml or 25 g	Absent	**SLS CEN/TS 17711**
vii)	*Listeria monocytogenes*, per 25 ml or 25 g	Absent	**SLS CEN/TS 17710**
viii)	*Shigella*, per 25 ml or 25 g	Absent	**SLS CEN /TS 17715**

5.6 Limits of potentially toxic elements

The product shall not exceed the limits of potentially toxic elements given in Table **3**, when tested as prescribed in Column **4** of the Table **3**.

TABLE 3 - Limits of potentially toxic elements for biopesticides

Sl No. (1)	Elements (2)	Limit, mg/kg (maximum) (3)	Method of test (4)
i)	Arsenic, as As	0.5	**SLS 645: Part 11***
ii)	Cadmium, as Cd	0.5	
iii)	Chromium, as Cr	0.5	
iv)	Lead, as Pb	1.0	
v)	Mercury, as Hg	0.5	
vi)	Nickel, as Ni	0.5	

***NOTE:** *Laboratories may use ICP-MS instead of ICP-OES for detection of potentially toxic elements.*

6 PACKAGING

Biopesticides shall be packed in a well-sealed container which shall not provide deleterious effect on the product from the light, humidity and temperatures.

7 STORAGE

Biopesticides shall be stored in a cool, dark place.

8 MARKING AND/ OR LABELLING

The following shall be marked or labelled legibly and indelibly on each bottle or package:

a) Name of the product as "Biopescticide";
b) Active ingredient shall appear in close proximity to the name of the product by specifying the genus and species of the microorganism; or chemical component
c) A brand name may be used to accompany the product name;
d) Microbial density of microbial biopesticides; (Active Ingredient (AI) content)
e) Name and address of the manufacturer, packer or distributor;
f) Type/nature of carrier; if any
g) Registered trade mark, if any;
h) Batch or code number;
j) Net content in metric units;
l) Date of manufacture;
m) Date of expiry/Best before;
n) Pests or pest spectrum against which the biopesticides is effective;
p) Crops for which it is intended;
q) Rate and method of application;
r) Mode of action:
s) Directions and instructions for use;
t) Storage/disposal instructions; and
u) Safety precautions in handling and application.

9 SAMPLING

Representative samples of the product for ascertaining conformity to the requirements of this Standard shall be drawn as prescribed in Appendix **A**.

10 METHODS OF TEST

10.1 Tests shall be carried out as prescribed in Appendices **B** given in this Standard.

10.2 Unless otherwise specified, quality reagents, chemicals and distilled water shall be used in tests.

APPENDIX A

COMPLIANCE OF A LOT

The sampling scheme given in Appendix **A** shall be applied where compliance of a lot to the requirements of this Standard is to be assessed based on statistical sampling and inspection.

Where compliance with this Standard is to be assured based on manufacturer's control systems coupled with type testing and check tests or any other procedure, appropriate schemes of sampling and inspection should be adopted.

A.1 LOT

All units (packages/ containers) in a single consignment of material belonging to the same batch of manufacture or supply shall constitute a lot. If a consignment consists of different batches of the manufacture the containers of the same batch shall be separated and shall constitute a separate lot.

A.2 GENERAL REQUIREMENTS OF SAMPLING

In drawing, preparing, storing and handling samples, following precautions and directions shall be taken.

A.2.1 The sampling instruments shall be cleaned and dried when use.

A.2.2 When drawing samples for microbiological examination, the sampling instruments shall be sterilized.

A.2.3 Precautions shall be taken to protect the samples; the product being sampled and the sample container from adventitious contamination.

A.2.4 The samples shall be placed in cleaned and dry containers.

A.2.5 Samples shall be drawn from a protected place not exposed to dampness, air, light, dust or soot.

A.2.6 The sample containers need to be filled only up to 80 per cent of the full volume leaving provision for gas exchange.

A.2.7 The sample containers shall be sealed air-tight after filling and marked with necessary details of sampling.

A.3 SCALE OF SAMPLING

A.3.1 Samples shall be tested from each lot separately for ascertaining conformity of material to the requirements of this Standard.

A.4 NUMBER OF TESTS

A.4.1 Each package or container shall be selected as in Clause **A.3.2** shall be inspected at the point of sampling for packaging and marking and/or labelling requirements specified in Clause **7** and **8**.

A.4.2 Each package or container shall be selected as in Clause **A.3.2** and prepared as in Clause **A.3.3** shall be examined for the requirements given in Clause **5.1** and shall be tested for the chemical and physical requirements specified in Clause **5.2** and requirements of potentially toxic elements limits specified in Clause **5.4**.

A.4.3 Specimens selected as in Clause **A.3.4** and **A.3.5** shall be tested for the requirements of biological requirements specified in Clause **5.3**.

A.5 CRITERIA FOR CONFORMITY

A lot shall be declared as conforming to the requirements of this Standard if the following conditions are satisfied.

A.5.1 Each package or container inspected as in Clause **A.4.1** shall satisfies the relevant requirements.

A.5.2 All test specimens tested as in Clause **A.4.2** shall satisfy the relevant and applicable requirements.

A.5.3 All test specimens tested as in Clause **A.4.3** shall satisfy the relevant and applicable requirements.

APPENDIX B

ESTIMATION OF COLONY FORMING UNITS COUNT

B.1 Apparatus

B.1.1 *Pipettes,* Graduated, 1 mL, 10 mL.

B.1.2 *Dilution bottles or test tubes*

B.1.3 *Petri plates,* clear uniform flat-bottomed

B.1.4 *BOD Incubator*

B.2 Preparation of serial dilution

B.2.1 Take 1 g. of product and mix it in 9 mL of sterilized distilled water in a clean and sterilized test tube to make 10-1 dilution (1:10).

B.2.2 Shake well and take 1 mL. of the suspension to 9 mL. of sterile water in a tube to make 10-2 dilution (1:100).

B.2.3 Make four more serial dilutions in the same way to get 10-6 dilution.

B.3 Incubation of plates

B.3.1 Transfer 1 mL. of this suspension to sterile Petri Plates and add 15-20 mL. of sterilized, melted and cooled. selective media.

B.3.2 Rotate the plates gently and allow it to solidify.

B.3.3 Incubate the Perti plates in BOD incubator under the fluorescent illumination at 25 °C ± 2 °C and R.H. at 65% ± 5 % for five to seven days.

B.4 Colony counting

B.4.1 Observe the development of colony and calculate the number of colony unit per gram of the sample as the following formula.

CFU/g = Average number of colonies/dilution factor

APPENDIX C

ESTIMATION OF pH

Take 10 g of sample in 50 mL of glass beaker & mixed with 25 mL of distilled water. pH of the suspension is observed by using the meter.

APPENDIX D

DETERMINATION OF MOISTURE CONTENT BY MASS

D.1 Apparatus

D.1.1 *Beaker*, 50 g. capacity.

D.1.2 *Oven,* maintaining at 103 ± 2 °C

D.2 Procedure

D.2.1 Weigh 5 g sample of product and pour into beaker.

D.2.2 Beaker containing weighed sample is kept in hot air oven at 65 °C for 30 minutes.

D.2.3 After 30 minutes beaker is taken out from oven and again weigh it for determination of mass content.

D.3 Calculation

Moisture content per cent = $\frac{M-m}{M}$ X 100 %

Where,

M- Initial weight of product

m- mass of product found after hot air