SKIM AKREDITASI MAKMAL MALAYSIA (SAMM)
LABORATORY ACCREDITATION SCHEME OF MALAYSIA

STR 1.1 - SPECIFIC TECHNICAL REQUIREMENTS FOR ACCREDITATION OF LABORATORY PERFORMING BIOEFFICACY TESTING OF HOUSEHOLD AND PUBLIC HEALTH PESTICIDES

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(Supplementary to MS ISO/IEC 17025)

MS ISO/IEC 17025

JABATAN STANDARD MALAYSIA
Department of Standards Malaysia

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1 Introduction and scope

This document is intended to describe the specific technical requirement to be adhered by laboratory in the field of biological testing that evaluates the efficacy of product under the category of household and public health pesticides against the target pests.

This document shall be read in conjunction with MS ISO/IEC 17025, *Skim Akreditasi Makmal Malaysia* (SAMM) policies and other relevant requirements published by Department of Standards Malaysia (Standards Malaysia).

The clause numbers in this document correspond to those of MS ISO/IEC 17025 but since not all clauses require additional requirements, the numbering may not be continuous.

Note: The testing of adverse effects of products against non-target organism (e.g. effects of pesticide against honeybee) is under the field of toxicity testing, which is not within the scope of this document.

2 Normative references

The following documents are essential reference to be read together with this document;

i) MS ISO/IEC 17025, with regard to the requirements for a laboratory in provide impartial, confidential and competent biological efficacy testing consistently.

ii) Published standard test method selected for purpose of evaluating the biological efficacy.

iii) SAMM Policy (SP) documents, with regard to the governance of accreditation by Standards Malaysia.

iv) WHO (2010). Guidelines on Public Health Pesticide Management Policy. World Health Organization (WHO). ISBN: 978-92-4-001191-5 (WHO).

v) WHO/FAO (2020). International Code of Conduct on Pesticide Management: Guidance on Management of Household Pesticides. World Health Organization (WHO) and Food & Agriculture Organization of the United Nations (FAO). ISBN: 978-92-4-001191-5 (WHO) and 978-92-5-133401-0 (FAO).

3 Terms and definitions

In addition to the terms and definitions described in the below paragraphs, the documents stated at section 2 are indispensable for referencing of terms, definitions and its application for the purpose of this document.

a) Pest
A living organism that is perceived by human of being nuisance or threat to property or economy or public health significance.

b) Household or public health pesticide
A product that functions to control pest, e.g. mosquitoes, ants, cockroaches, geckos and rats, at indoor or outdoor by a specific way including either by repelling, trapping, attracting, knockdown or killing or in combination. The pest control function could be due to its chemical, biological, mechanical, physical or other properties, or in combination. The product may contain one or a combination of active ingredients of synthetic or natural origin.

Examples of the household and public health pesticide products for non-professional use by general public includes but not limited to anti flea & tick pet collar, rat cage trap, gecko sticky trap, cockroach direct aerosol spray, housefly aerosol space spray, ant residual surface spray, termite bait station, mosquito impregnated net, mosquito larvicidal granule, mosquito topical repellent lotion, mosquito coil, mosquito electric vaporizing mat and liquid.

Examples of the household and public health pesticide products for professional use by pest control operator are suspension concentrate liquid for crawling insect residual surface spray, emulsion concentrate liquid for flying insect thermal fogging space spray, termite's baiting system, bird anti-roosting system and rat's baiting system.

c) Bioefficacy (biological efficacy)
The functional performance of a household or public health pesticide product in controlling a target pest.

4 General requirements

Same as in MS ISO/IEC 17025.

5 Structural requirements

Same as in MS ISO/IEC 17025.

6 Resource requirements

6.1 General

The laboratory shall have sufficient supply of live household pests of susceptible or/and resistant strains.

6.2 Personnel

In reference to clause 6.2.2 of the MS ISO/IEC 17025;

a) The signatory nominated by the laboratory shall have a minimum academic qualification of bachelor's degree related to life science (e.g. biology, zoology, entomology, veterinary, parasitology, biochemistry and biotechnology) with specific knowledge on the biology of the pest that being tested, with at least one year working experience in biological testing of pesticides. The signatory should be knowledgeable on the relevant statistical software needed for the data analysis of the testing.

b) The personnel who handles the pests, including collection, holding, breeding and disposal shall be specifically competent with knowledge on the biology and skill in handling of the pest. The personnel shall be qualified by the laboratory signatory to have adequate knowledge and skill in secure and safe handling of the pest, and capable to identify injured or ill pest, for prompt removal and prevent from being used in the testing.

c) The personnel who handles the pesticide product, including preparation, treatment and disposal, shall be specifically competent with the knowledge on the chemical characteristics of the pesticide product as being documented in the product safety data sheet. The personnel shall be qualified by the laboratory signatory to have adequate knowledge and skill in accurate and safe handling of the specific pesticide product without contamination and deformation/defect.

d) The personnel who observes the biological response of the pest, including during acclimatization, pre-treatment and post-treatment, shall be specifically competent with knowledge on the normal and abnormal biological response of the pest, including sign of intoxication by the pesticide product.

e) The signatory of the laboratory shall qualify that the personnel who undertakes the works as stated at section 6.2b, 6.2c and 6.2d has been specifically competent with knowledge and skills to operate the equipment needed for the work and capable to identify faulty equipment.

f) The laboratory should identify specific record for the monitoring competence of personnel (e.g. staff competency matrix).

6.3 Facilities and environmental conditions

a) In reference to clause 6.3 of the MS ISO/IEC 17025;

i) Pest breeding, holding and disposal

The breeding of pest related to the transmission of infectious disease should require approval from the relevant authorities in accordance with prevailing laws. This document and SAMM accreditation do not exempt or supersedes the regulatory requirements.

The laboratory may colonize on their own or source the pest from supplier in accordance to clause 6.6 MS ISO/IEC 17025. If the laboratory breeds the pest, the laboratory shall establish formal breeding facility, e.g. insectarium and rodent animal house, to ensure the health and pathogen free status. When pest is sourced from a supplier, the laboratory shall ensure, the supply of the pest is accompanied with a document that certifies the pest is healthy and free from pathogen that known to be carried by the pest, relevant to the validity of the test.

The laboratory shall identify and implement measure to prevent escape of the pest from the breeding and holding rooms.

The rooms, areas, containers, cages etc. utilized to breed or hold the pest shall be labelled with pest species and subspecies/ strain. Individual containers or cages shall have additional information on date of hatch/ birth/ emergence, relevant to the validity of the test, whenever suitable to determine the age of the pest.

The breeding and holding system shall be adequately separated between species and subspecies/ strain to prevent inter-species infection and/or cross-breeding and/or mix-breeding. Further the pest shall be segregated by individuals or groups or batches that allows to meet the biological characteristics needed for the bioefficacy test, e.g. life-cycle stage, sex and age.

The laboratory shall reference to published documents to evident the breeding and holding system (e.g. environmental condition, cage dimension, bedding, feeding technique, feed nutrition and faeces removal) for the pest is suitable for healthy growth and does not cause injury or illness or abnormality to the biology of the pest.

The laboratory shall carry out species confirmation of colonized pest periodically.

The laboratory shall determine the acceptance criteria on the fitness of the pests for the intended test at the start of every test and documented in accordance with test method.

A floor layout shall be provided to show the rooms or areas designated for breeding or holding of the pest; and storage of equipment, laboratory wares and consumables that have direct contact with the pest are kept (e.g. cleaned cages,

feeding wick, water, feed or ingredient for feed preparation, breeding media, apparatus for transfer of pest and cleaning of cages), have been isolated from the rooms or areas where the waste (chemical/biological/general) is disposed, chemical substance and pesticide/biopesticide is stored or testing is performed or testing equipment and apparatus are cleaned. The isolation includes the separate ventilation and air conditioning system.

The laboratory shall implement procedure to address the housekeeping, sanitation and pest control particularly the colony housing.

The laboratory shall restrict the access to the laboratory only to authorised personnel.

ii) Experimentation

The pest shall be acclimatized to the environmental condition of the room, test arena or area where the experiment against the pests is to be conducted. Acclimatization may not be applicable for field experimentation against wild pest.

The relevant test arena (e.g. Peet Grady chamber, glass chamber, glass cylinder) shall be prepared in accordance with the requirement of the test method.

The room, test arena or area for experimentation shall be protected against infestation, contamination and/or deterioration.

iii) Biological and chemical waste disposal

Handling and disposal of wastes should be carried out in such a way as not to jeopardize the integrity of the testing. This includes the provision for appropriate collection, storage and disposal facilities, and decontamination and transportation procedures.

6.4 Equipment

a) In reference to clause 6.4.1 of the MS ISO/IEC 17025;

The primary measuring equipment refers instrument utilised in the conduct of the bioefficacy studies, e.g. thermohygrometer, stop watch and weighing scale. While for secondary measuring equipment like aerosol dispenser with timer, its accuracy shall be verified based on calibrated weighing scale.

Example of the reference material refers to certified pesticide active ingredient and standardized pesticide product. It may not be feasible to source pest supply with certification of resistant, thus the laboratory is expected to establish historical data of testing that distinguish between the resistant strain compared to a susceptible strain of insects. While for the susceptible strain of pest, the origin and the susceptibility profile of inbreed colony, at least three consecutive generations shall

be tested using recognised susceptibility diagnostic kit or published scientific method, e.g. insecticide resistance monitoring test kit by World Health Organization (WHO), test kit for the rapid detection of insecticide resistance by Malaysian Institute for Medical Research, WHO test procedures for insecticide resistance monitoring in malaria vector mosquitoes, WHO instructions for determining the susceptibility or resistance of mosquito larvae to insecticides and various scholarly articles in scientific publication.

b) In reference to clause 6.4.4 of the MS ISO/IEC 17025;

The verification of reference material refers to the checking of certificate of analysis (COA) of the supplied reference material to assure the material matches the chemical identification [e.g. Chemical Abstract Service Registry Number (CAS number) or biological identification [e.g. species, strain, colony, source (insectarium/ animal house)], quality (e.g. purity, grade, susceptibility/resistant status) and storage condition at the laboratory as required by the test method or the published standard.

6.5 Metrological traceability

a) In reference to clause 6.5.1 of the MS ISO/IEC 17025;

The metrological traceability is applicable to the primary measuring equipment refers instrument utilised in the conduct of the bioefficacy studies, e.g. thermohygrometer, stop watch and weighing scale.

b) In reference to clause 6.5.2 of the MS ISO/IEC 17025;

Same as in MS ISO/IEC 17025.

c) In reference to clause 6.5.3 of the MS ISO/IEC 17025;

Same as in MS ISO/IEC 17025.

6.6 Externally provided products and services

Same as in MS ISO/IEC 17025.

7 Process requirements

7.1 Review of request, tenders and contracts

a) In reference to clause 7.1.3 of the MS ISO/IEC 17025;

In the event the customer request statement of conformity, the laboratory needs to consider the nature of bioefficacy testing whereby the responses by pest upon

exposure to pesticide product may vary due to biological factors, often standard test methods incorporate comparison with a reference material as part of the testing requirement. The standard method also states the specific statistical tool to be employed in analysing and the interpretation criteria in concluding the outcome of the testing. The statistical tool and interpretation criteria may differ between standard test methods. Thus, the laboratory shall inform to, and agreed by customer the decision rule (statistical tool and interpretation criteria) as specified in the test method that been selected. The statement of conformity to a standard, e.g. Malaysian Standard, shall be issued in accordance with the decision that been jointly agreed by customer and laboratory prior testing.

7.2 Selection, verification and validation of methods

a) In reference to clause 7.2.1 and 7.2.2 of the MS ISO/IEC 17025;

The methods should be compiled and documented and be available to the laboratory staff. Whenever possible, Malaysian Standard (MS) or other International Standard Method should be used. In cases where non-standard methods are adopted, the methods should be experimentally developed and validated with reference similar to standard methods.

Biological test system should be acclimatized to the test environment for an adequate period before the first administration/application of the test or reference items.

All information needed to properly identify the test systems should appear on their housing or containers. Individual test systems that are to be removed from their housing/container during the conduct of the testing should bear appropriate identification, whenever possible.

During use, housing/container for the test systems should be cleaned and sanitized at appropriate intervals. Any material that comes into contact with test system should be free of contaminants at levels that would interfere with the testing.

The laboratory is expected to adopt the latest/current version of the specific test method whenever its published. The laboratory shall advice the customer in the event unable to adopt the latest/current version.

7.3 Sampling

Same as in MS ISO/IEC 17025.

7.4 Handling of test items

a) In reference to clause 7.4.1 and 7.4.2 of the MS ISO/IEC 17025;

There shall be procedures for receipt, retention and disposal of test item. The laboratory must provide an adequate storage system to ensure security of test item and prevention undue deterioration or other damage before and after testing.

To prevent contamination or mix-ups, there should be separate rooms or areas for receipt and storage of the test items and mixing of the test items with a vehicle.

Storage rooms or areas for the test item should be separated from rooms or areas containing the test systems. They should be adequate to preserve identity, concentration, purity, and stability, and ensure safe storage for hazardous substances.

Whenever, only a part or a subsample of the test item is used for the purpose of the testing, the laboratory shall document the process of selection of the part or/and homogenization in performing the subsampling to ensure the selected part or taken subsample represent the whole original test item. It also applies when the test item is diluted for the purpose of the testing.

7.5 Technical records

Same as in MS ISO/IEC 17025.

7.6 Evaluation of measurement uncertainty

Where results are not in numerical values (detected/not detected, pass/fail, positive/negative, visual, tactile, or other qualitative examinations), measurement uncertainty is not required. Nevertheless, the sources of variability, e.g. consistency of reagent, organisms and analyst's interpretation should be identified and demonstrated to be under control.

Where measurement uncertainty is required, the laboratory need to document the procedures and processes on how this is done. The laboratory is required to refer to the current developments in measurement uncertainty requirements.

7.7 Ensuring the validity of results

7.7.1 Activity within the laboratory

The laboratory shall determine the quality control measures in order to monitor the validity of the bioefficacy results. Examples of the quality control measures:

- Comparison of the laboratory historical data of the bioefficacy against the susceptible strain;

- Comparison of the bioefficacy observation between laboratory personnel.

7.7.2 Activity between the laboratories

It is recognised that biological efficacy results are not absolute due to biological, environmental and physical variation. Therefore, laboratories participating in an interlaboratory comparison shall agree to the test method to be employed, reference items and the parameter of the results to be compared. The evaluation of the interlaboratory performance is based on the relative capability of the testing to distinguish results between the reference items without emphasizing the absolute values of the results but provides meaningful results that show the consistency (e.g. similar trend, pattern) between the laboratories.

7.7.3 Same as in MS ISO/IEC 17025.

7.8 Reporting of results

a) In reference to clause 7.8.3 of the ISO/IEC 17025;

In addition to the requirement of the MS ISO/IEC 17025:2017 and SAMM Policies, the test report shall also contain information, data and results as required by the selected bioefficacy standard test method; which shall include the followings that may directly influence the biological evaluation of a pesticide product:

i) Species and subspecies or variety or strain of the pest, together with source of the taxonomic key (author, year) for the identification of the pest species.

ii) The life cycle stage, sex and exact age of the pest selected in the testing.

iii) Laboratory environment including (but not limited to) temperature, relative humidity, time, lighting, etc.

iv) For field testing, additional information on the weather, e.g. cloud, wind and fog.

v) The description whether the pesticide product was diluted before treatment. If diluted, state the concentration, dose/amount applied, name of diluent, storage time and condition before treatment.

When agreed with the customer, the results may be reported in a simplified way. Any information listed above that is not reported to the customer shall be retained and readily available.

b) In reference to clause 7.8.6 of the ISO/IEC 17025;

In the event the customer request statement of conformity, the laboratory shall report on the statement of conformity in accordance with the decision rule (the statistical tool and interpretation criteria) specified by the selected test method.

7.9 Complaint

Same as in MS ISO/IEC 17025.

7.10 Nonconforming work

The procedure is activated when nonconformity detected while testing in-progress, i.e. activities after confirmation of test request until prior issuance of test report.

7.11 Control of data and information management

Same as in MS ISO/IEC 17025.

8 Management system requirements

8.1 Options

Same as in MS ISO/IEC 17025.

8.2 Management system documentation

a) In reference to clause 8.2.1 of the ISO/IEC 17025;

If the laboratory breeds the pest, the laboratory shall establish documented procedure on the instructions for the breeding, holding, handling, transfer and disposal of the pest, and maintenance of the pest breeding facilities. If the pest is out-sourced, the procedure for quarantine and holding shall be documented.

Laboratory shall also document the following procedures:

i) preventing the pest escaping from its breeding, holding, testing and disposal facilities.

ii) preventing intrusion by insects or animals from outside of the laboratory facilities.

iii) preparation of the pesticide sample and equipment/apparatus prior to testing.

iv) conduct of the testing.

v) cleaning of the equipment/apparatus after the testing.

vi) species confirmation of pest is required.

b) In reference to clause 8.2.2 of the ISO/IEC 17025;

If the laboratory breeds pest, the objective for consistent operation shall include the aim of sustaining a stable pest colony that is used for testing. The laboratory shall employ a suitable reference material (see clause 6.4) relevant to the biological efficacy test method to show the consistent outcome of the biological evaluation.

c) In reference to clause 8.2.5 of the ISO/IEC 17025;

The procedures established in section 8.2(a) shall be made available to personnel performing the activities.

8.3 Control of management system documents

Same as in MS ISO/IEC 17025.

8.4 Control of records

Same as in MS ISO/IEC 17025.

8.5 Action to address risks and opportunities

a) In reference to clause 8.5.1 of the ISO/IEC 17025;

The laboratory shall consider the followings as part of risk that causes undesired impact to its operation:

i) pest escapes from its breeding, holding, testing and disposal facilities.

ii) pest of susceptible strain develops resistance to pesticide active ingredient.

b) In reference to clause 8.5.2 of the ISO/IEC 17025;

The laboratory shall plan actions to address the risk stated at section 8.5(a) by implementing the procedures described at section 8.2(a) and evaluate the implementation effectiveness.

c) In reference to clause 8.5.3 of the ISO/IEC 17025;

Whenever the existing implementation leads to non-acceptable level of risks (e.g. moderate and high), the proportional actions of corrective, corrective action and preventive action shall be taken to address the risks.

8.6 Improvement

Same as in MS ISO/IEC 17025.

8.7 Corrective actions

Same as in MS ISO/IEC 17025.

8.8 Internal audits

The internal audits shall include verification of effective implementation and maintenance of the procedures stated at section 8.2(a).

8.9 Management reviews

Same as in MS ISO/IEC 17025.

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