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GENERAL PROTOCOL

Introduction

The Proficiency Testing Centre (PTC), Pesticide Management Division (PMD) of National Institute of Plant Health Management (NIPHM), Hyderabad, India has been accredited in accordance with the standard ISO/IEC 17043:2010 (Conformity Assessment-General Requirements for Proficiency Testing) as Proficiency Testing Provider in the Field of Chemical Testing, by National Accreditation Board for Testing and Calibration Laboratories, an autonomous body under the Department for Promotion of Industry and Internal Trade, India.

This protocol contains general procedures for Proficiency Testing (PT) Schemes organized by the Proficiency Testing Centre for *pesticide residues in Water, Fruits, Vegetables, Cereals and Pulses and Pesticide Analysis in Pesticide Technical and Pesticide Formulation samples.*

These Proficiency Testing schemes are open for all accredited laboratories and laboratories willing to go for accreditation as per ISO/IEC 17025:2017.

Objectives and Details

The aim of these PTs is to obtain information regarding the quality, accuracy and comparability of the data generated by Pesticide Residues Testing and Pesticide Formulation Testing Laboratories.

Participating laboratories will be provided with an assessment of their analytical performance and the reliability of their data – compared to the other participating laboratories.

Criteria to be met for participation

It is mandatory to all the Pesticide Residue Testing Laboratories working under central sector scheme "Monitoring of Pesticide Residues at National Level" and involved in analysis of above samples as per the plan decided by the MPRNL scheme to participate in PT schemes on pesticide residues.

As per the directives of Government of India, It is mandatory for all regulatory State Pesticide Testing Laboratory (SPTL), Regional Pesticide Testing Laboratory (RPTL) and Central Insecticide Laboratory (CIL) working in India to participate in PT schemes.

Confidentiality arrangements

All information supplied by a participant to the PTC is treated as confidential. Each participant will be given unique ID (Laboratory code) for individual PT round. This will be shared to only respective participant at the time of dispatch of report.





Consent from participants

As per the regulatory requirements results of PT rounds will be shared with Government of India, State Government, Regulatory Authorities and NABL. The results of MPRNL Network labs will be shared with project coordinator, MPRNL.

Services from External Providers

There are no external activities in PTC related to testing and PT conduction. But transportation of the samples will be done through the competent external service provider.

Communication

The official language used in NIPHM-PTC is English. Communication between participating laboratories during the test on matters concerning this PT exercise is not permitted. Proficiency Testing Centre has procedures to enable the participants to appeal against the evaluation of their performance in a proficiency testing scheme.

Announcement / Invitation Letter

The announcement of the individual PT Program or Scheme will be issued at least 2 months before the distribution of PT Item.

The Distribution of PT item to all the participant laboratories will be done as per the PT Plan. However, if there is any request from any other participant laboratory after the distribution of actual PT item, then a written consent or mail is taken from the laboratory that they are willing to send the result before the closing date.

The announcement will be published on the NIPHM website and additionally distributed via e- mail to the interested laboratory (which has already submitted the details to NIPHM).

The announcement will contain an invitation letter, details on how to participate and where to find additional-related documents, as well as some preliminary information on the specific protocol such as the tentative calendar, the name of the commodity expected to be used, and the tentative Target Pesticide List.

Mode of Payment

Partcipation fees is available with Plan of PT scheme on NIPHM Website. Participant can pay the fees through Demand Draft in the name of National Institute of Plant Health Management Payable at Hyderabad.

or through Online:

1. Name of the Beneficiary : NIPHM COLLECT ACCOUNT

2. Name of the Bank : State Bank of India

3. Branch : Rajendranagar, Hyderabad - 500030,

Telangana

4. IFSC : SBIN0020074 5. Bank A/C No. : 40373518076

6. UPI Transaction : https://niphm.gov.in/general/niphm.sbi.pdf





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Target Analyte / Product List

This list contains Product and or analytes to be analyzed, is available with Plan of PT scheme on NIPHM Website.

Instruction for Participants

For each PT, an instruction for participant will be sent along with the PT Item. This instruction will contain general instructions including handling and storage of PT items, formats used for acknowledgement of receipt of PT item, format for reporting the result, Contact details of PT Coordinator.

This instruction also contains willingness of participatory laboratory regarding sharing the PT results with interested parties.

General procedures for reporting results

Laboratories are responsible for reporting their results to the PTC within the stipulated deadlines. Laboratories should not leave any column unattended. Need to fill the column either with result or write as not detected / below detection level / not analyzed / not participated or equivalent wording. The results should be submitted in three decimal places for PRA and two decimal places for PFA. Each laboratory must report only one result for each of the analytes detected in the Test Items, using the analytical procedure(s) that they would routinely use for each compound for monitoring purposes. Use appropriate units of measurement as specified in the instruction sheet.

In case of pesticide residue analysis for fruits, vegetables, cereals and pulses, one test item will be treated with pesticides (Spiked) and the other one is left untreated (Blank). Both test items have to be analyzed by the laboratories and any pesticide detected in them shall be reported. Blank (control) sample will be provided for Quality Control purpose (Ex. Recovery study and Calibration purpose). In case of water, only one water sample (Spiked) will be given to participants.

In case of pesticide formulation analysis, individual samples will be sent to individual laboratory with tentative range. Participant laboratories require reporting appropriate result. In some cases PT items are prepared synthetically in the laboratory in the range which is not normally available in the market.

Complaints regarding PT items that are distributed and are subsequently found damaged or contaminated and unsuitable for performance evaluation will be clearly verified. The request from participant laboratories are verified based on document evidence sent through mail or post and after due verification, sample will be resent to the participant laboratories.

Methodology information

All laboratories are requested to provide information on the analytical method(s) they have used.





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Estimation of Assigned value:

In order to minimize the influence of out-lying results on the statistical evaluation, the assigned value is estimated using robust statistics as described in ISO 13528:2015 [Consensus Value from Participants, Consensus values from expert laboratories, Reference Value, Certified Reference Value and Formulation].

Estimation of Standard Deviation for Proficiency Assessment (SDPA):

In case of Residue Analysis, standard deviation for Proficiency Assessment will be calculated using Fit-For Purpose Relative Standard Deviation (FFP-RSD) approach. The FFP-RSD is set at 25% of Assigned value based on the experience.

In case of Pesticide Formulation Analysis, the value of Standard Deviation for Proficiency Assessment (σ_{pt}) determines on the basis of predictive models of the appropriate form of the Horwitz equation as described in ISO 13528:2015.

However, NIPHM-PT organizer also reserves the right to employ other approaches on a caseby-case basis considering analytical difficulties and experience gained from previous proficiency tests.

Evaluation of Participant Performance

A) z scores: It has been calculated for all the participants using the assigned value and standard deviation stated above using following formula.

B) z' scores

If the criteria for acceptability of assigned value in terms of standard uncertainty of assigned value is not passing i.e. $u(x_{pt})$, $> 0.3 \sigma_{pt}$, then uncertainty of assigned value is taken into account while estimating the performance score in terms of z' score.

z' score = $\frac{\text{(Lab Value - Assigned Value)}}{\sqrt{(SDPA)^2 + (Standard Uncertainity of Assigned value)^2}}$

where, SDPA or σ_{pt} : Standard Deviation for Proficiency Assessment x_{pt} : Standard Uncertainty of Assigned value





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Publication of results

The PTC-PMD-NIPHM will publish a preliminary report, containing participant results and tentative z / z' score values for all parameters in the test sample, within 2 months from the sample dispatch.

The Final Report will be published after the PTC-Panel has discussed the results. The final report may be published up to 3 months after the deadline for results submission.

Complaint / Appeal

PTC has a set procedure for complaint / appeal from the PT participants in case any sort of irregularities observed by the participant during the period of the current PT. Under such situation, the participants can put their complaint or appeal to the PTC in the prescribed format attached herewith.

Feedback

After the distribution of the final report, participating laboratories will be given the opportunity to give their feedback to the organizer and make suggestions for future improvements.

Laboratory Rights

After the preliminary Report has been sent, the laboratories will have the right to communicate any discrepancy of their result evaluation in written form. Any detected errors in the preliminary report should also be reported to the organizer. The organizer, in consultation with PTC management, will decide upon any re-evaluation and will give a corresponding explanation.

Participant can appeal against the evaluation of their performance in PT Scheme. PTC has procedure to clarify participant doubt regarding evaluation of their performance in the given PT scheme.

Disclaimer

The PTC - Panel of NIPHM retains the right to change any parts of this PTC – General Protocol based on new scientific or technical information. Any changes will be communicated in due course through website or mail.

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