

Developing the interlaboratory comparison testing program for raw milk quality testing within the laboratory network in Thailand

(project proposal)

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1) Background and rationale:

Bureau of Quality Control of Livestock Products (BQCLP) serves as the central networking laboratories in Department of Livestock Development (DLD) and seven Regional Veterinary Research and Development (RVRDC) Centers within Thailand in testing and analyzing the quality of raw milk samples. Raw milk quality is a critical factor in ensuring the safety and nutritional value of dairy products which an essential part of the milk quality and completeness of dairy food. However, the quality of raw milk can vary widely due to differences in farm management practices, animal health and laboratory testing methods across the country. To address this issue, an interlaboratory comparison testing program for raw milk quality would be beneficial to establish a reliable and consistent system for monitoring and improving milk quality in Thailand, this test is the most importance regulation in maintaining the laboratory quality management system (QMS) to meet the standard of ISO/IEC 17025:2017.

Regarding the interlaboratory comparison program will involve networking laboratories responsible for testing raw milk samples from dairy farms and processing facilities by implementing a standardized testing protocol and comparing results among the participating laboratories. It would be helping to identify any discrepancies or inconsistencies in testing methods, lead to more accurate and reliable data on raw milk quality.

Moreover, the program would be provided a platform for knowledge sharing and capacity building among the participating laboratories, allowing them to exchange best practices, troubleshooting issues, and continuously improvement their testing procedures. Developing an interlaboratory comparison testing program for raw milk quality in Thailand would not be only improved the reliability and consistency of milk quality data, but also foster collaboration and knowledge sharing among the participating laboratories, ultimately contributing to the overall enhancement of food safety.

2) Project aim and objectives:

To analyze and compare the results of interlaboratory comparison testing among the participating laboratories in Thailand on raw milk quality testing for fat, protein, solid non-fat and somatic cell count.

To evaluate the performance of individual operator or laboratory staff to ensure that they have competence in the assay performance on raw milk testing.

To enhance the laboratory testing capacity to meet the laboratory quality standard of ISO/IEC 17025:2017 with continuous improvement and maintaining the Quality Management System (QMS).

To meet the achievement of the final report of interlaboratory comparison testing as a final product of this project.

3) Preliminary literature review:

The analysis and comparison of interlaboratory testing results for raw milk in Thailand is crucial for ensuring the competency of laboratory personnel and adherence to international quality standards. This literature review aims to explore the current state of raw milk testing practices, evaluate the performance of laboratory staff and identify opportunities for enhancing laboratory testing capacity to meet ISO/IEC 17025:2017 requirements.

The food safety assurance system in Thailand has been a subject of increasing attention, particularly with regards to the implementation of Good Agricultural Practices standards (Wongsprawmas et al., 2015). In the context of raw milk testing, interlaboratory comparison studies can provide valuable insights into the consistency and reliability of testing results across different laboratories. Studies have shown that Thai farmers have adequate knowledge on food safety measures but some misconceptions still exist regarding recommended practices (Thongpalad et al., 2019).

During 2020-2023, The BQCLP laboratory was participated in the international proficiency testing (PT) scheme organized by QSE GmbH, Germany on somatic cell count, fat, protein and solid non-fat in raw milk (GLLP-SEA Competency 5, short project report, data not published). The results revealed that the Z-score of each year was in the satisfactory level and the comparison results of all PT data demonstrated the similarity results as the reference data of QSE GmbH provider. This meant that the BQCLP laboratory has consistently met the required standards for proficiency testing (PT) over the past four years.

To continue the improvement and maintenance of the robust quality management system, these are essential for enhancing laboratory capacity to meet ISO/IEC 17025:2017 standard. In particular the importance activities of the proficiency testing, on-site assessments and adoption of advanced analytical techniques that are necessary for strengthening the laboratory standard measure to ensure the competency of laboratory personnel and the reliability of test results (Fthenakis, 1995; Tungol et al., 2020; Li et al., 2017; Kumar et al., 2018). It is essential to emphasize the importance of interlaboratory comparison testing, as it plays a critical role in evaluating the accuracy and consistency of test results across different laboratories (Lowry et al., 1951; Glenn, 1983; Gustriansyah et al., 2021). Interlaboratory comparison testing, also known as proficiency testing, involves the distribution of the same sample or set of samples to multiple laboratories, with the goal of assessing the consistency and reliability of their test results (Jenny & Jackson-Tarentino, 2000).

This process enhances confidence in the test outcomes, helps identify potential errors in testing procedures, and leads to improvements in the quality and efficiency of laboratory operations. Proficiency testing is a fundamental aspect of laboratory management systems. It provides insight into measurement processes and allows each lab to compare its test results to those of the most appropriate peer group (Halim, 2013). By identifying discrepancies in test results, interlaboratory comparison testing enables laboratories to investigate the root causes of any discrepancies, such as issues with analytical systems, processes, or personnel training. This information can then be used by the laboratory, device manufacturers, and the proficiency testing program itself to continuously improve their respective products and services (Jenny & Jackson-Tarentino, 2000).

In the past, BQCLP conducted the raw milk quality testing within the DLD laboratories; the results of examination found that the values varied in each laboratory. This discrepancy could not be able to explain or evaluate the real factors of laboratory conditions or others. Hence, to ensure that the laboratories have the same standardized testing measures and good system management operation. BQCLP proposed to organize and develop the interlaboratory comparison testing program for raw milk testing among the networking laboratories within Thailand. This activity will be the pilot project for maintaining a quality management system to meet the standard of ISO/IEC 17025:2017.

4) Methodology:

The Bureau of Quality Control of Livestock Products (BQCLP) under the Department of Livestock Development (DLD) will be working as the organizer for this program. The method used in this inter laboratory comparison (interlab) testing program will be proceeded step by step as the following:

6.1 Assign and inform the networking laboratories who interested and purposed to participating in this program by preparing the official letters, distribute to the head of laboratories within Thailand together with the invitation document including the detail of the program activities and the acceptance document form for head of laboratories signing and replying, then send back to the organizer laboratory at BQCLP.

(detail of invitation letter document no.1, this document is being drafting)

6.2 The organizer laboratory will collect and identify the number of participating laboratories, then make plans for appropriate time schedules on preparation of raw milk samples, testing methods used, duration time for testing and send back all results to the organizer laboratory.

6.3 Prepare the raw milk samples in the big volume, mix well as homogeneously, then aliquot into small tubes, samples code are created and kept at cool temperature. Ten tubes were randomly sampling to test for preliminary results. Homogeneity test is performed before sending and to ensure that the milk samples are well prepared (The acceptance criteria for homogeneity test is determined by comparing the sample standard deviation (Ss) with the standard deviation for proficiency assessment (σ_{pt}) where $Ss \leq 0.3\sigma_{pt}$

indicates that the sample is adequately homogeneous (ISO 13528:2022). The milk samples will be stored in cool temperature in the laboratory, being packed and transported. The process of packing and transportation of samples with safely arrival to the destination laboratories by using the knowledge which has been learnt from GLLP training session #5 Competency 6: Biosafety and Biosecurity by following the working instruction (WI) document on packing and transporting samples to the laboratory under Biosafety and Biosecurity principle. In addition, the creating questionnaires of the participating laboratories are also drafted and attached here in order to study the laboratory conditions, equipment, reagents, environment and laboratory staff. (detail of questionnaire document no.2 and WI on packing and transportation of samples no.3, these documents are being drafting)

6.4 Analysis of testing results, test method uses and interpretation of test results for this interlab program activities are mainly testing milk composition which are somatic cell count. Somatic cell count test by Flow cytometry technique or conventional method according to the method used by the participating laboratories and the results are calculated as cell/ml.

6.5 The record of all raw milk testing results from participating laboratories will be submitted to the organizer laboratory in the suitable limited timeline (see Gantt chart). The management of results are conducted by the organizer who will prepare documents of data sheet recording forms and provide them to all laboratories. These record forms will be attached in the shipping containers when samples are transported to all laboratories for filling all test results with actual data, then send back to the organizer for analyzing and determining the Z- score value, then the infographic also will be built.

The criteria of acceptance value of interlaboratory comparison results are determined by z-score value (ISO/IEC 17043:2010) which is classified into 3 level as follow:

- $|z| \leq 2$ = satisfactory laboratory result
- $2 < |z| < 3$ = questionable laboratory result
- $|z| \geq 3$ = unsatisfactory laboratory result

6.6 The interlaboratory report will be prepared which consists of a summary of analysis results, evaluation laboratory factors with non conforming test results (if any). Providing a suggestion and recommendation which might be useful in enhancing the laboratory capacity testing to meet the laboratory quality standard.

5) Ethical considerations:

The proposed interlaboratory comparison testing program will adhere to strict ethical guidelines to ensure the protection of all participants and the integrity of the data. The selection of participating laboratories will be fair and inclusive, ensuring that no vulnerable or underrepresented groups are excluded without justification. Additionally, the program will implement appropriate data management and confidentiality reports of each laboratory will be put as the laboratory code instead of the laboratory full name to ensure the safeguard privacy, trusting of data protection and sensitive information of the

participating laboratories. The summary report of individual laboratory will be informed by code number only to each laboratory separately but not open for all.

6) Expected outcomes:

The outcome of the interlaboratory comparison testing program will be indicated the raw milk testing results for all laboratories comparing among the laboratories and assigned values by demonstrating as infographics figures. This can be identifying gaps and solving the problems that may have occurred from individual laboratory. Therefore, this program can be used as the standard measure in enhancing the laboratory capability and maintaining the quality management system (QMS) to meet ISO/IEC 17025:2017.

In addition, this program will be able to encourage and implement to the organizer laboratory at BQCLP to expand the number of networking laboratories and propose to apply for the Proficiency Testing (PT) Provider accreditation for ISO/IEC 17043:2023 in future.

7) Strengths and limitations:

Strengths of the proposed project include:

- Establishment of a comprehensive and standardized framework for raw milk quality testing in Thailand
- Strengthening of the technical competence and confidence of participating laboratories
- Potential for the program to serve as a model for similar initiatives in other sectors or regions

Limitations of the proposed project include:

- Potential challenges in securing the full participation and commitment of all targeted laboratories
- Limited funding and resources available for the implementation and long-term sustainability of the program
- Potential resistance from some stakeholders to the adoption of new testing protocols and standards

8) Time table (Gantt chart):

No.	Activities	2024			2025			
		Nov	Dec	Jan	Feb	Mar	Apr	May
1	1.1 Review literatures and study the PT or interlab procedure, overview, outline and draft proposal 1.2 Sourcing of materials used for the interlab program							
2	Draft official letter to survey the interesting laboratories to participate in the interlab program.							
3	3.1 Prepare the invitation letters and participation acceptance form sends to participating laboratories. (document no.1) 3.2 Create a draft questionnaire (document no.2) 3.3 Create a draft working instruction (WI) on packing and transportation samples (document no.3)							
4	4.1 Prepare interlab samples, code number of samples and number of participating laboratories. 4.2 Pretest of interlab samples by organizer before distributing to the participating laboratories.							
5	5.1 Packing and transportation of interlab samples to participating laboratories. 5.2 Providing the strong shipping container and other related materials. 5.3 provide the document of working instruction for packing and transporting the samples with safely arrival to the destination laboratories 5.4 Attach others relevant documents including questionnaires and data sheets of record form put into the shipping container.							
6	6.1 Testing and determining of interlab samples by each laboratory. 6.2 Submission of interlab results to the organizer.							
7	Analysis results and prepare summary report by Organizer							
8	Submission the final report of interlaboratory comparison testing with feedback and recommendation to all laboratories, this is an end product of this project.							

9) Resources required:

- Good quality of materials related to sample packaging with waterproof or leaking and appropriate strong containers for transportation of samples are needed.
- BQCLP annual budget for purchasing an essential materials and some equipment are used for operating this interlab program to meet the target goal.

10) References:

- International Organization for Standardization ISO 13528. (2022). Statistical methods for use in proficiency testing by interlaboratory comparison. Ref. no. ISO 13528:2022 (E).
- International Organization for Standardization ISO/IEC FDIS 17043. (2023). Conformity assessment –
General requirements for the competence of proficiency testing providers. Ref. no. ISO/IEC FDIS 17043:2023 (E).
- International Organization for Standardization ISO/IEC 17025. (2017). General requirement for the
competence of testing and calibration laboratories. Ref. no. ISO/IEC 17025:2017 (E).

1) References:

- International Organization for Standardization ISO 13528. (2022). Statistical methods for use in proficiency testing by interlaboratory comparison. Ref. no. ISO 13528:2022 (E).
- International Organization for Standardization ISO/IEC FDIS 17043. (2023). Conformity assessment –
General requirements for the competence of proficiency testing providers. Ref. no. ISO/IEC FDIS 17043:2023 (E).
- International Organization for Standardization ISO/IEC 17025. (2017). General requirement for the
competence of testing and calibration laboratories. Ref. no. ISO/IEC 17025:2017 (E).
- Fthenakis, G C. (1995). California Mastitis Test and Whiteside Test in diagnosis of subclinical mastitis of dairy ewes. Elsevier BV, 16(3), 271-276.
[https://doi.org/10.1016/0921-4488\(95\)00638-2](https://doi.org/10.1016/0921-4488(95)00638-2)
- Glenn N D. (1983). Replications, Significance Tests and Confidence in Findings in Survey Research, Public Opinion Quarterly. 47(2). SUMMER 1983. 261–269.
<https://doi.org/10.1086/268784>
- Gustriansyah R., Suhandi N., Alie J., Antony F. & Heryati A. 2021. Optimization of laboratory application by utilizing the ISO/IEC 25010 model. IOP Publisher. OP Conf. Ser.: Mater. Sci. Eng. <https://iopscience.iop.org/article/10.1088/1757-899X/1088/1/012067/pdf>.
- Halim, A B. (2013). Proficiency Testing for Monitoring Global Laboratory Performance and Identifying Discordance. Laboratory Medicine. 44(1). Pages e19–e30.
<https://doi.org/10.1309/LMTQ586TDYTAEEXO>
- Jenny R W. & Jackson-Tarentino K Y. (2000). Cause of Unsatisfactory Performance in proficiency testing. Clinical chemistry. 46(1). 88-89.
- Kumar, R., Rana, Y S. & Sharma, A. (2018). Comparative Study of Different Tests for Diagnosis of Sub Clinical Mastitis in Buffaloes. Excellent Publishers, 7(10), 520-528.
<https://doi.org/10.20546/ijcmas.2018.710.057>

- Li, Z., Wen, F., Li, Z., Zheng, N., Jiang, J. & Xu, D. (2017). Simultaneous detection of α -Lactalbumin, β -Lactoglobulin and Lactoferrin in milk by Visualized Microarray. BioMed Central, 17(1). <https://doi.org/10.1186/s12896-017-0387-9>
- Lowry, H., Rosebrough, N J., Farr, A L. & Randall, R J., (1951). Protein measurement with the Folin phenol reagent. [https://www.jbc.org/article/S0021-9258\(19\)52451-6/pdf](https://www.jbc.org/article/S0021-9258(19)52451-6/pdf).
- Thongpalad, K., Kuwornu, J K., Datta, A., Chulakasian, S. & Anal, A K. (2019). On-farm food safety knowledge, attitudes and self-reported practices of layer hen farmers. Emerald Publishing Limited, 121(8), 1912-1925. <https://doi.org/10.1108/bfj-12-2018-0799>
- Tungol, K L S., Primero, J M B. & Villaverde, J F. (2020). Detection of Bovine Mastitis Milk through Somatic Cell Count using Electrical Conductivity Property. <https://doi.org/10.1109/hnicem51456.2020.9400084>
- Wongsprawmas, R., Canavari, M. & Waisarayutt, C. (2015). Food safety assurance system for fresh produce production in Thailand: a review. Codon Publications, 7(1), 73-88. <https://doi.org/10.3920/qas2013.0255>