

Calculation Model

ICAR is directly coordinating a proficiency test for milk analyses since 2016.

Nowadays 35 different countries from 5 continents are represented by 72 participant laboratories.

ICAR would now like to improve and expand this service by providing more information with the application of a novel statistical approach starting with a test for the **somatic cell parameter**.

The ICAR/IDF project Reference System for Somatic Cell Counting

<https://www.icar.org/index.php/certifications/milk-analysis-laboratories-certifications/idf-icar-project-on-somatic-cell-counting/> highlighted in these last years, tells us that this parameter requires better equivalence and the quality assurance tools that are adopted nowadays are not sufficient to improve global equivalence for the following reasons:

- The reference method ISO 13366-1 is not very precise and it needs to be implemented
- There is no primary reference material available
- The various existing Proficiency Tests, even if they are ISO 17043 accredited, are not comparable each other because each **PT scheme uses a different matrix, number of samples, sample range and the assigned value is not traceable to a primary reference**.
- The consequence is that the same laboratory that participate in different proficiency tests can obtain, at the same time, completely different performance values !

These aspects produce the picture reported below (Fig 1)

The data could be less scattered if the laboratory can adopt the traceable and modern quality assurance tools

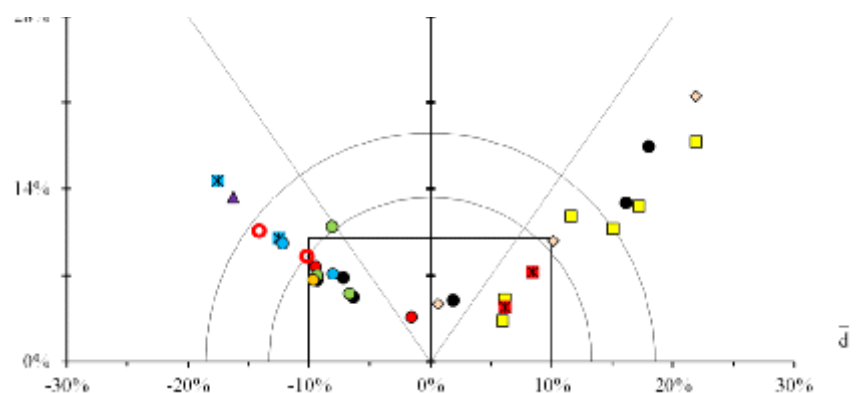


Fig 1. Distribution of the ICAR participant laboratories for the parameter somatic cell. On the x axis is reported the difference from the assigned value on y axis is the standard deviation of difference. Each color represents the reference material used.

ICAR would like to test “**A probabilistic calculation model**” published in 2016 Accred Qual Assur (2016) 21:175–183 DOI 10.1007/s00769-016-1207-y “Probabilistic comparison and assessment of proficiency testing schemes and laboratories in the somatic cell count of raw milk, Thomas F. H. Berger, Werner Luginbul (see publication attached to this email)

The application of this model will allow:

- to qualify the laboratories that participate in different Proficiency test assigning a Quality index **PL (assessing labs)**
- to qualify the Proficiency test provider assigning a Quality index **PQ (assessing PT)**



The obtained quality index will be an “objective assessment criterion” that can be used to promote analytical equivalence and to characterize a primary reference material.

The **comparability of the proficiency tests** and laboratories should ultimately enable the harmonization of the SCC proficiency tests and a better equivalence at a global scale !

ICAR expressed interest to support the proposed *Food Nutrition Security Cloud (FNS-Cloud)* project submitted within the EU Horizon 2020 (H2020) funding programme to the topic Food Cloud demonstrators. In this frame Food cloud demonstrator will purchase the software to test a simulation with the data of ICAR PT, other providers and participants laboratories.

METROFOOD is the platform that manages such pilot tests. About 45.000 € has been allocated for the project. Food cloud will acquire the software (20.000 €) and ICAR services will adapt the model for the somatic cell parameter and charge METROFOOD Project 25.000 € (with expected costs to ICAR of 18.000 €)

MIAMi

Microscope Image Analysis in Milk

Somatic cell counting in milk is relevant in food legislation, payment of raw milk, animal health monitoring and farm management around the globe. It is estimated that a few hundred million measurements are executed on an annual basis. This is done in central milk testing laboratories but the number of on-farm determinations is increasing. The applied routine methods rely merely on flow cytometry and image cytometry. These automated routine methods are linked to the direct microscopic count according to ISO 13366-1|IDF 148-1, which serves as the anchor method. This anchor or reference method has some major drawbacks. It is laborious and has low precision, which is mainly due to the rather subjective interpretation on what is or is not to be counted as a somatic cell. The International Dairy Federation (IDF) and the International Committee for Animal Recording (ICAR) have in recent years created a **reference system for somatic cell counting, RSSCC**

see <https://www.fil-idf.org/idficar-project-group-reference-system-somatic-cell-counting/>

Part of this exercise was the development and production of a primary reference material by the EU Joint Research Centre. A first batch of this **primary reference material** is available since February 2020. It is anticipated that with the adoption of this reference system approach, some major drawbacks will be overcome and global equivalence will be much improved.

However, also with the reference system approach direct microscopic count will remain in its position as anchor/reference method. **One of the suggested alternatives is the application of more modern microscopic techniques that rely on automated microscopy in combination with image analysis.** These techniques offer interesting opportunities for more precise and better standardised total somatic cell counting as well as for differential somatic cell counting.

Milchprüfing Bayern e.V. (mpr) and Qlip B.V. (Qlip) have agreed to jointly invest in the development of **automated microscopy/image analysis as an alternative for the current manual method and to explore its suitability for differential somatic cell counting.**

mpr and Qlip have committed themselves to provide resources for the MIAMi-project:

- Purchase of the required microscopes for their two laboratory locations;



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- Internal expertise and labour for the activities in method development for both total somatic cell counting as well as differential somatic cell counting;
- Development of dedicated image analysis software;
- Communication of the outcome to global standardization bodies like IDF/ISO and ICAR.

At the moment 3 companies are supporting the project:

- Lactotronic
- Page&Pederson
- Foss

With an annual fee of 20.000 €

The project was launched 1st of October 2018 for a running time of maximum 36 months.

Project coordinators are Silvia Orlandini (mpr) and Harrie van den Bijgaart (Qlip). As follow-up of the ICAR/IDF RSSCC ICAR could be interested in the MIAMi project particularly in the development of a modern microscope method to differentiate somatic cell in milk