Implementation of the new certified reference material for somatic cell counting in milk

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Abstract

This study is sought to provide an overview on the implementation of the new certified reference material for somatic cell counting in milk, which was launched in 2020.

Milk somatic cell count (SCC) is a widely used indicator for monitoring the udder health of several mammalian species and is relevant in food quality regulations, milk payment testing, farm management and breeding programmes. Joint efforts of International Dairy Federation (IDF), the International Committee for Animal Recording (ICAR) and EC JRC resulted in the development and release of a new certified reference material. The availability of this new material allows better global equivalence in somatic cell counting in milk, which is a challenge today.

The newly available reference material has been tested in numerous countries around the globe. In some cases, an adjustment/re-anchoring of current SCC level would not be necessary, whereas it would be in others. Examples for both scenarios including evaluation of the impact of the transition on the results will be demonstrated. Suggestions for handling of possible transition issues in case of re-anchoring the current SCC level will be discussed. Further details and examples will be given on other possible applications of the certified reference material such as verification/ adjustment of calibration settings of routine methods, assigning reference values to secondary reference materials, and usage in proficiency tests.

In conclusion, seeking global equivalence in somatic cell counting first countries already re-anchored their SCC level with more countries/laboratories to follow. These real-life examples are highly valuable to further promote the usage of the new reference material and help to establish procedures for its application.

Keywords: SCC, reference material, equivalence

Introduction

Somatic cell count (SCC) in milk is a widely used analysis and the number of tests done worldwide is estimated to be >500.000.000 per year. SCC test results from individual cow milk samples are used for udder health monitoring and management and breeding purposes. Beyond that, SCC result from bulk tank milk samples are relevant in food quality regulations and milk payment. A challenge in the industry is different SCC levels around the world as can be seen based on, for example, ICAR Proficiency Test results. These differences, in turn, lead to challenges in terms of trading dairy products.

New certified reference material for Somatic Cell Counting

A joint project team of experts from the International Dairy Federation (IDF) and ICAR together with the European Commission Joint Research Centre have developed a new certified reference material for somatic cell counting. The official name of the material is "EC JRC CRM® ERM-BD001" and it can be ordered here: https://crm.jrc.ec.europa.eu/p/ERM-BD001

The material consists of two samples. One sample has a low SCC of about 50,000 cells/mL and the second one has a high SCC of about 1,000,000 cells/mL (Figure 1). The samples are produced based on bulk tank cow milk. Milk cells are preserved through spray drying and samples are afterwards homogenized, bottled, and labelled.

The two samples are produced from raw bulk cow's milk which has been powdered by spray drying at NIZO in the Netherlands. The homogenization of the samples, bottling and labelling was performed by the Joint Research Centre in Belgium.

Application of the new primary reference material

The primary reference material for somatic cell counting can be applied in different ways in laboratories. When reference and/or routine methods are operational at your laboratory the primary reference material can be used to check the performance of the methods. This way the correctness of the two methods can be verified and when necessary adjusted.

Another way to apply the primary reference material could be to check on the calibration settings of the routine methods. When the routine method is calibrated with the primary reference material, the obtained results will be traceable to the reference results.

	Cell concentration	
	Certified value [3] [cells/mL]	Uncertainty [4] [cells/mL]
Somatic cell count (SCC) [1]	1202000	121000
Somatic cell count (SCC) [2]	1166000	79000

[1] As defined in ISO 13366-1. The certified value is the mean value of 13 accepted data sets obtained from ISO 13366-1-compliant measurements.

[2] As defined in ISO 13366-1 and ISO 13366-2. The certified value is the mean value of 13 accepted data sets obtained from ISO 13366-1-compliant measurements and 13 randomly selected data sets out of 32 accepted data sets obtained from ISO 13366-2-compliant measurements.

[3] Certified values are values that fulfil the highest standards of accuracy and represent the unweighted mean value of the means of accepted sets of data, each set being obtained in a different laboratory and with methods of determination referred to in footnotes 1 and 2. The certified value and its uncertainty are traceable to the International System of units (SI).

[4] The uncertainty of the certified value is the expanded uncertainty with a coverage factor $k = 2$ corresponding to a level of confidence of about 95 % estimated in accordance with ISO/IEC Guide 98-3, Guide to the Expression of Uncertainty in Measurement (GUM:1995), ISO, 2008.

Figure 1. Somatic cell count levels of the two samples included in the EC JRC CRM ERM-BD001 as illustrated on the Certificate of Analysis.

Another application of the primary reference material is to assign values to secondary reference materials. In practice, the routine instruments for somatic cell counting are often calibrated by using secondary reference materials produces by difference providers. When the values assigned to these secondary reference materials are based on primary reference material, the alignment of the results, consecutively obtained with the routine methods in different laboratories will be ensured.

Last, the primary reference can be used in a proficiency test, where the results obtained at the same time from different laboratories and with difference methods are compared. Including the primary reference materials in proficiency testing schemes allows for a proper comparison of the methods and the laboratories performance.

A webinar entitled "Development and application of a certified reference material for somatic cell counting in milk" to introduce the reference material and elaborate on its application was conducted in December 2020. A recorded version of the full webinar and pdf-copies of the presentations are available here: https://www.icar.org/index.php/technical-bodies/sub-committees/milk-analysis-sub-committee-landing-page/webinar-3-december-2020-on-development-and-application-of-a-certified-reference-material-for-somatic-cell-counting-in-milk/

The new reference material including examples on its application are also described in detail in the recently published IDF Bulletin 508/2021, which is available for free download here: https://store.fil-idf.org/product/bulletin-of-the-idf-n-508-2021-guidance-on-application-of-ec-jrc-certified-reference-material-for-somatic-cell-counting-in-milk/

Status on implementation of the new certified reference material around the world

We conducted a small survey to learn more about the actual status on the implementation of the new SCC certified reference material and observed that different countries are mainly in four different phases of the implementation:

1. Material tested and adopted - in Lithuania and Switzerland.
2. Material not tested so far – In countries such as China and Chile the new material has not yet been tested so far. Among other reasons, the shipment of the SCC reference material was not possible due to COVID 19 restrictions.
3. Material tested, no need for adjustment of SCC level – The new primary SCC reference material has been tested and it was observed that the current SCC level and the SCC level of the primary reference material are well in alignment. Thus, it was concluded that no adjustment of SCC counting levels is needed. Nevertheless, the new primary SCC material is considered a valuable product because it opens up the possibility to monitor SCC counting levels on a regular basis (e.g. once every quarter) and verify correctness. This situation applies to many countries around the world, e.g. Denmark, Germany, Italy, Japan, New Zealand, UK, USA. A dialogue on using the new primary SCC reference material as an official and mandatory material has been initiated with the respective authorities in Japan and USA. Below a case report for this implementation phase coming from Germany.
4. Material tested, need for adjustment of SCC level – The test of the new primary SCC reference material revealed that the current SCC level requires some adjustment. Following this finding, the respective laboratories started to initiate the dialogue with their stakeholders and agreed upon a strategy for transition of SCC levels. Regular application of the new SCC reference material is seen as highly valuable in the transition period and thereafter. This situation applies to, e.g. Canada, France, Israel, and the Netherlands and is further described in below case report from the Netherlands.

It is common practise in most milk testing laboratories around the globe to work with secondary SCC reference material. In this context, we would like to recommend that secondary SCC reference materials are to be checked for alignment with the new primary reference material and that customers of secondary reference materials ask their providers for such alignment checks.

Conclusions

Equivalence in SCC levels around the world has been a challenge for many years. A joint IDF/ICAR project team developed and launched a new primary reference material for somatic cell counting. The application of this material can help to obtain global equivalence in somatic cell counting.