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

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Vesela Tzeneva & Daniel Schwarz

Leaders of IDF/ICAR Project on Somatic Cell Counting in Milk

Vesela Tzeneva, PhD

Senior Project Manager

Food Safety & Fermentation

NIZO

M: +31 629220548

E: Vesela.Tzeneva@nizo.com

www.nizo.com

Daniel Schwarz, PhD

Dairy Farming Senior Specialist

FOSS

M: +45 2761 6976

E: das@foss.dk

www.fossanalytics.com

Background

- Somatic cell count (SCC) in milk is widely used analysis, e.g. > 500.000.000 cow milk samples/ year world wide
- Indication for monitoring udder health
- Relevant in food quality regulations, milk payment testing, farm management and breeding programmes
- Differences in SCC levels observed around the globe – challenges for trading dairy products

Methods for testing

- Routine instrumental methods (IDF 148-2, ISO 13366-2)
- High throughput – suitable for analysis of large number of samples
- Precision
  - Repeatability
  - Reproducibility
  - **Accuracy**
- Reference method
  - Microscopy (IDF 148-1, ISO 13366-1)

Anchoring of the SCC

- Methodological and precision difference between routine and reference methods (IDF Bulletin from AT S15 to be published soon)
- Results variation among the labs, e.g. seen in ICAR PT
- Need for global reference material for SCC
- Development of primary reference material for SCC
  - Initiative started in 2011 by IDF/ICAR activity
  - Complete in 2020

New Primary reference material for SCC

- EC JRC CRM

(European Commission Joint Research Centre Certified Reference Material)

- Two samples
  - Low SCC ca. 50.000 cells/mL
  - High SCC ca. 1.000.000 cells/mL

- Production
  - ➢ From raw bulk cow's milk to milk powders

  (NIZO, Ede, NL)
  - ➢ Final homogenization, bottling and labelling

  (JRC, Geel, BE)

Material code: ERM-BD001

New Primary reference material for SCC

- Characterisation
  - ➢ (ICAR Proficiency Testing)
    - 16 European and 5 non-European laboratories
    - 19 reference method data sets and 42 routine method data sets were obtained for each material
- Certified values, uncertainties, traceability

Freely available at: Products - ERM-BD001 MILK POWDER (somatic cell count, SCC) - Certified Reference Materials catalogue of the JRC (europa.eu)

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.

- Two certified values are assigned
  - Reference data only
  - Reference data combined with routine data

Application of primary reference material for SCC

- Check on method performance
  - Reference and routine method
  - To verify the correct use and operation of the methods

- Check on calibration settings of routine methods
  - Results from routine methods have to be traceable to a reference → calibration of the routine methods

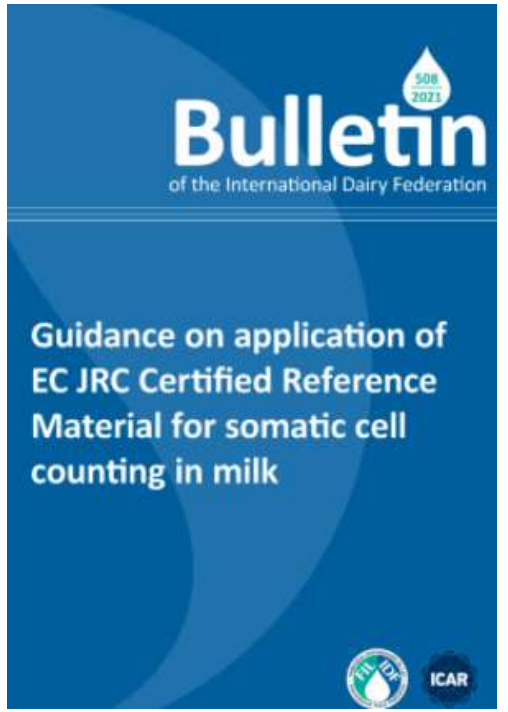
- Assign reference values to Secondary Reference Material

- Use in proficiency testing

Application of primary reference material for SCC

- IDF Bulletin 508/2021
  - Guidance on application of EC JRC CRM for SCC in milk

Freely available at: 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_/



Application of primary reference material for SCC

- Status of implementation around the world:
  - Material adopted in Lithuania, Switzerland
  - Material tested, no transition/adjustment necessary: e.g. Denmark, Germany, UK, USA and Japan
  - Material tested, transition/adjustment necessary: e.g. France, the Netherlands
  - Material under evaluation: Belgium, Canada, New Zealand
  - Material not yet tested: e.g. China

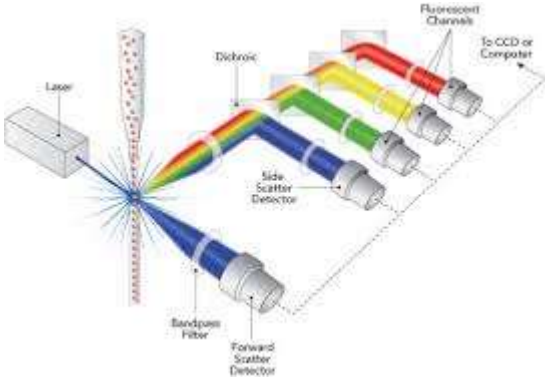
IDF Activities for improved reference method

- MIAMi (MPR (DE)/Qlip (NL) *at al*.)

Microscopic **I**mage **A**nalysis in **Mi**lk

- ANTOINETTE (Agroscope (CH)

DN**A** a**n**d An**t**ib**o**dy Sta**in**ed Total and Diff**e**ren**t**ial Soma**t**ic C**e**ll counting in Milk using Flow Cytometry



Summary

- New primary reference material for somatic cell counting available since spring 2020
- Application of material helps in obtaining global equivalence in somatic cell counting
- IDF Action Team S09 Newsletter for further details

Thank you for the attention

Vesela Tzeneva
Vesela.Tzeneva@nizo.com

Daniel Schwarz
das@foss.dk