APPLICATION OF EC JRC CERTIFIED REFERENCE MATERIAL WITH SOMATIC CELL COUNTING IN MILK

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Application of the EC JRC Certified Reference Material (CRM)

Transition from current anchoring systems

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Guidance on application of EC JRC Certified Reference Material for somatic cell counting in milk

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Background

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 (IDF, 2008). In February 2020 the EC Joint Research Centre (EC JRC) launched a new certified reference material (CRM ERM®-BD001) for somatic cell counting in milk. The launch is one of the tangible outcomes of a close cooperation of the International Dairy Federation (IDF), the International Committee for Animal Recording (ICAR) and EC JRC in developing solutions and tools to promote a better global equivalence in somatic cell counting in milk.

+ Excel template for calculations on ICAR website

APPLICATION OF EC JRC CRM

A “gold standard” to:

- Check on method performance
- Check on calibration settings of routine methods
- Assign reference values to Secondary Reference Materials (SRMs)
- Use in proficiency testing

ICAR

. CHECK ON METHOD PERFORMANCE

For reference method users and routine method users

To verify whether their method operates correctly

After checking the basic functioning of the method*

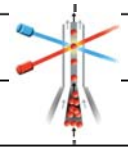
Using appropriate reference value with EC JRC CRM and related uncertainty information

Check whether difference between mean measured value and stated reference value is smaller than expanded uncertainty: $\Delta \leq U$

*Checks on reference method functioning:

- Dimensions of microsc field
- Repeatability

(see ISO 13366-1|IDF 14

Certified value [cells/mL]		Uncert [cells
64000		80
1202000		121
62000		60
1166000		790

. CHECKING/ADJUSTING CALIBRATION SETTINGS OF ROUTINE METHODS

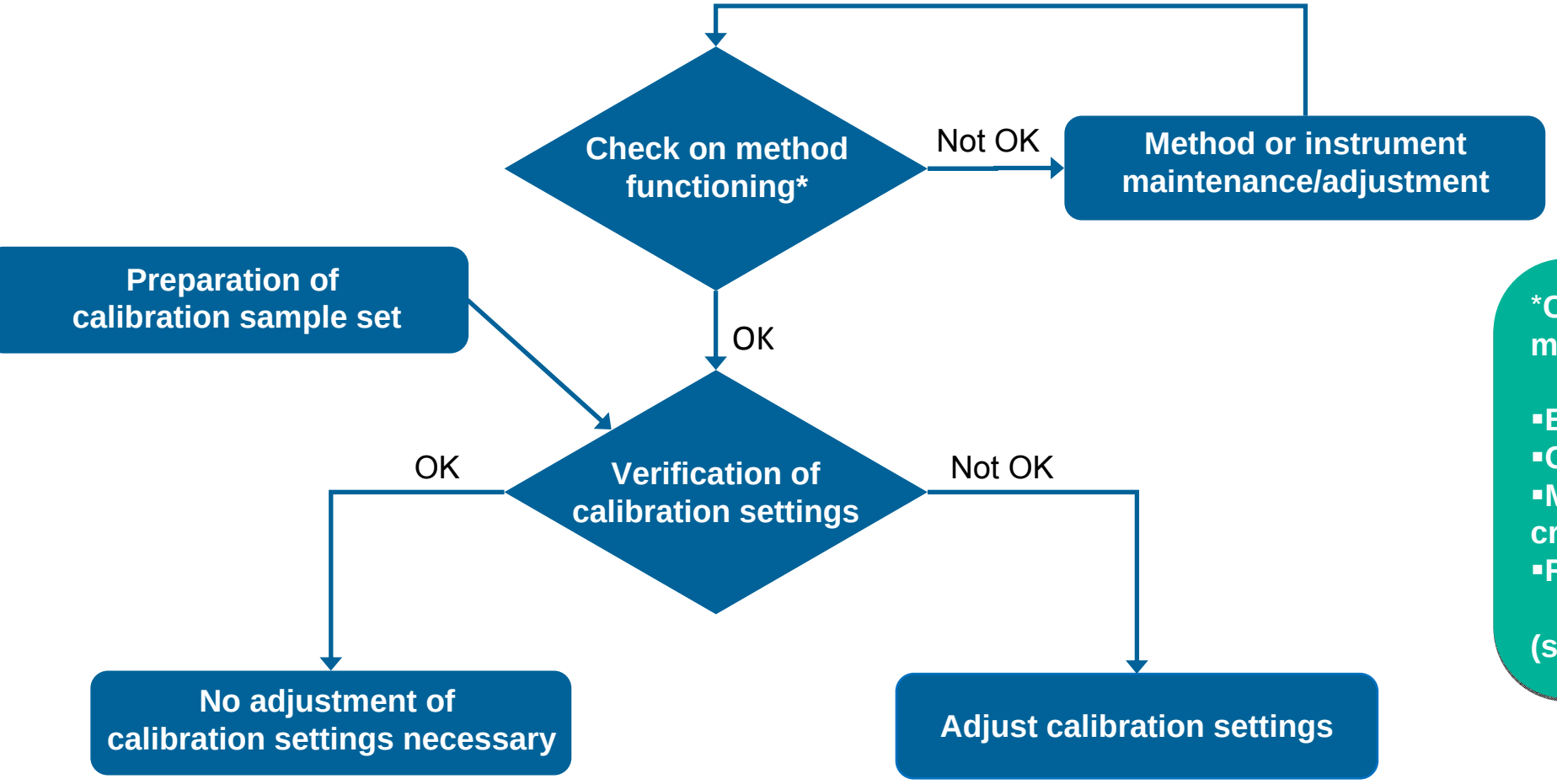
ISO 13366-1|IDF 148-1. Milk – Enumeration of somatic cells – Part 1: Microscopic method (Reference method)

ISO 13366-2|IDF 148-2. Milk – Enumeration of somatic cells – Part 2: Guidance on the operation of fluoro-opto-electronic counte

Results with a routine method
have to be traceable to a reference

Calibration and calibration maintenance of routine methods

LOWCHART FOR CHECKING/ADJUSTING CALIBRATION SETTINGS OF ROUTINE METHODS



*Checks on routine method functioning:

- Blank checks
- Carry over
- Method-specific critical aspects
- Repeatability

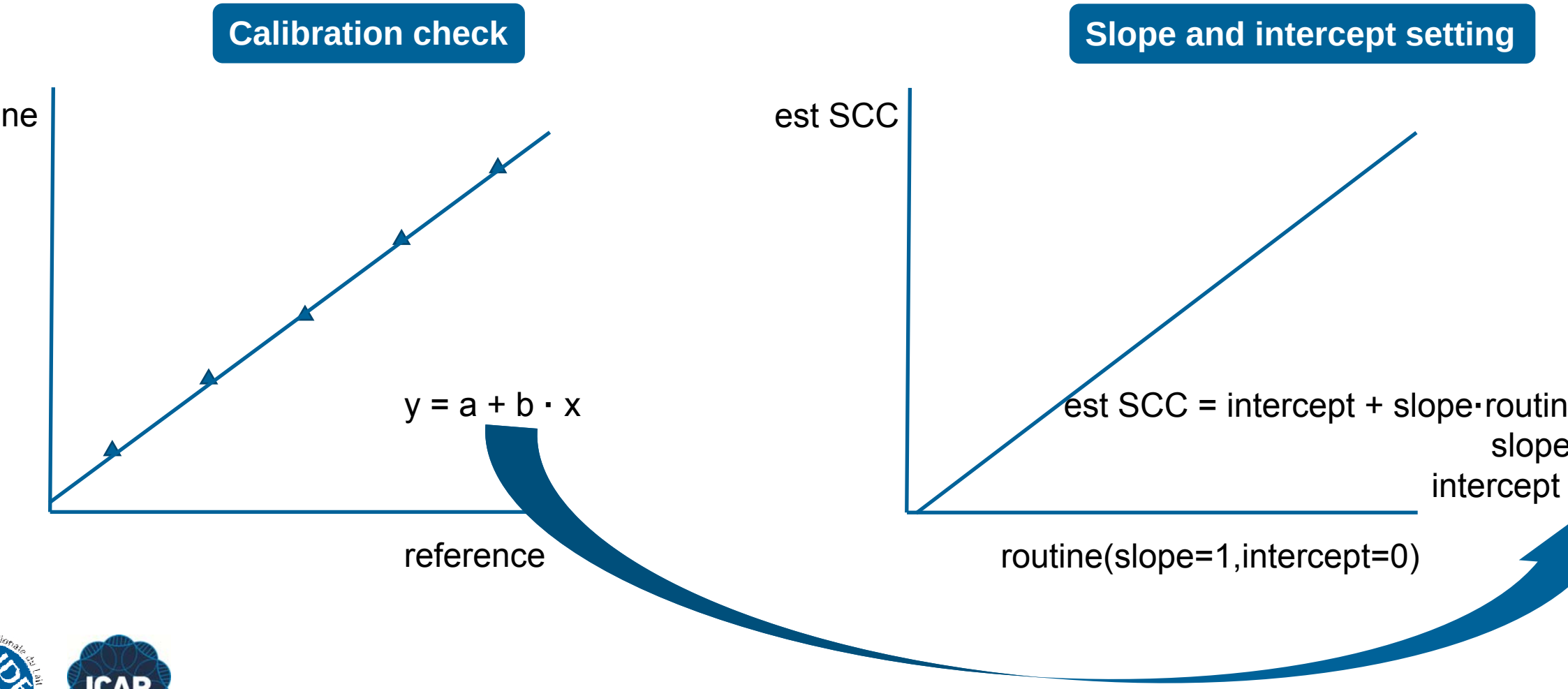
(see ISO 13366-2|IDF 148

PREPARATION OF CALIBRATION SAMPLE SET

Use both EC JRC CRMs to prepare calibration sample set:

- Reconstitute in water according to EC JRC instructions
  - Sample low with 62 000 cells/mL
  - Sample high with 1 166 000 cells/mL
- Preparation of calibration sample set by mixing sample low and sample high in different ratios: 4:0 – 3:1 – 2:2 – 1:3 – 0:4
- Corresponding reference values to be calculated
- Sample set with five equidistant reference values

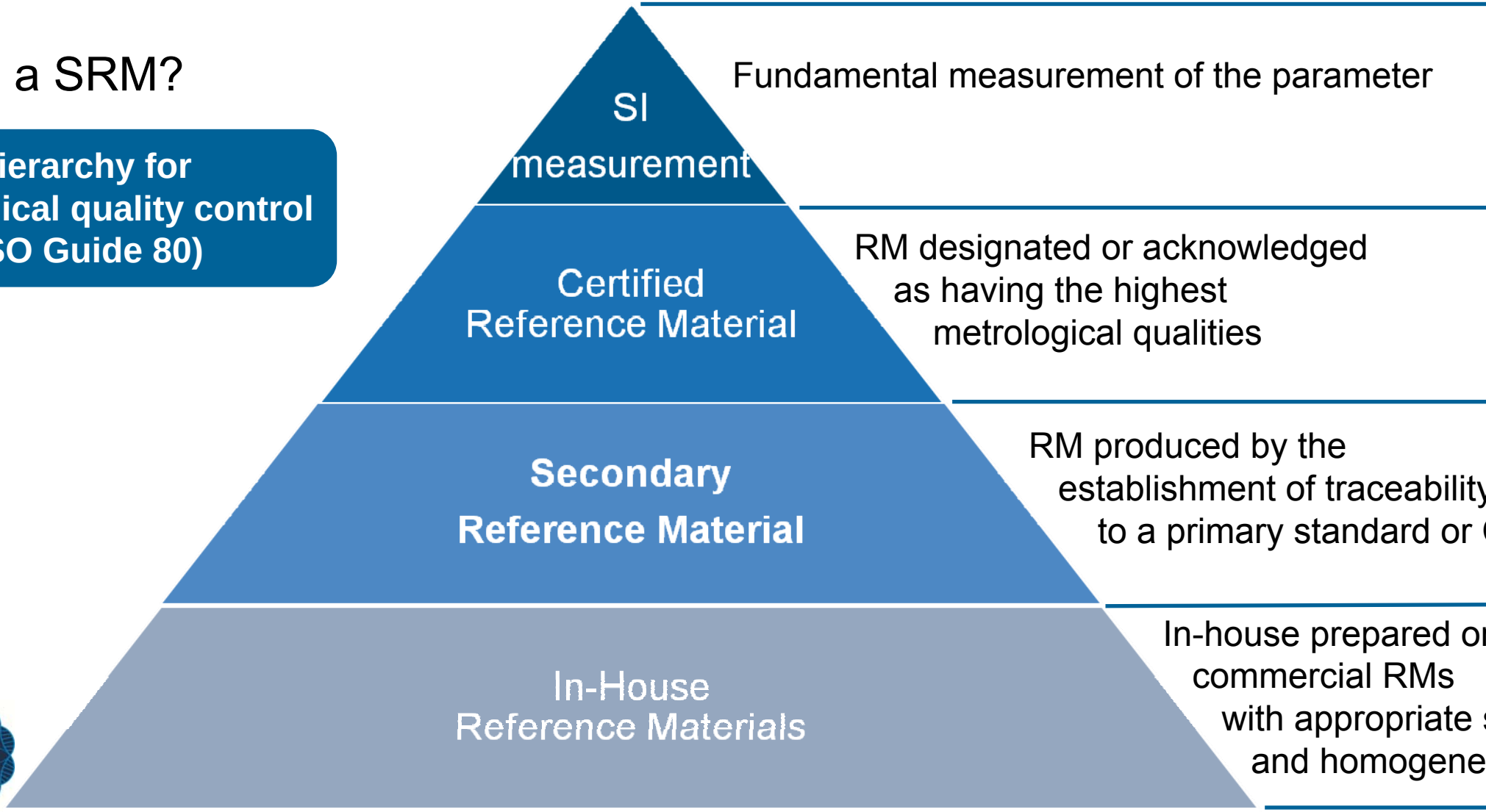
ROM CALIBRATION CHECK
TO SLOPE AND INTERCEPT ADJUSTMENT



. ASSIGNING REFERENCE VALUES TO SECONDARY REFERENCE MATERIALS (SRM)

What is a SRM?

Hierarchy for metrological quality control (ISO Guide 80)



ASSIGNING REFERENCE VALUES TO SECONDARY REFERENCE MATERIALS (SRM)

Advised procedure in brief:

- Prepare material suitable to serve as SRM (see ISO 13366-2|IDF 148-2)
- Analyse a CRM and the SRM with about same cell count levels pairwise (n>15 pairs) with a precise method under repeatability conditions
- From the average of the pairwise differences and the CRM reference value
  ➔ SRM reference value
- From the uncertainties of the CRM and pairwise differences
  ➔ uncertainty with SRM reference value

Kuselman, I., Weisman, A. & Wegscheider, W.
Traceable property values of in-house reference materials. Accred Qual Assur 7 p 12

. USE IN OF EC JRC CRM IN PROFICIENCY TESTING

Proficiency testing = comparing measuring results between laborato

Including EC JRC CRM (or a SRM) in PT schemes allows to compa

- between laboratories
- against “gold standard”
- in time

with next speaker…..

ANCHORING OF ROUTINE SOMATIC CELL COUNTING
OUTCOME IDF/ICAR QUESTIONNAIRE 2011)

No Certified Reference Material (‘gold standard’) available

Application of various SRMs,
globally coming from more than 20 suppliers

Relying on instrument manufacturer settings and checks through proficiency testing

Adjusting calibrations based on results in proficiency testing

omatic cell counting is a big ship, sailing with many anchors

POSSIBLE ISSUES WITH RE-ANCHORING

Being:

robust and stable,

well characterised,

representative in behavior,

affordable,

he EC JRC CRM is now there to serve dairy stakeholders around the globe
s the “common anchor” for somatic cell counting in milk…..

….but re-anchoring may in places cause a significant shift in counting levels.

STAKEHOLDERS IN SOMATIC CELL COUNTING

- Competent authorities
- Laboratories
- Farmers
- Veterinarians
- Milk collectors and processors
- Breeding organisations
- Instrument manufacturers
- Providers of secondary reference materials (SRM)
- Providers of proficiency testing services

ASPECTS TO CONSIDER WITH RE-ANCHORING

Extent of the expected shift in counts

Need for reassessment of limits/targets
(milk payment, udder health programs)

Secure interlinkage between past data and future data

Consequences for laboratory protocols

Consequences in laboratory proficiency testing

Timing of the transition (when, in one step or in multiple steps?)

Communication to stakeholders

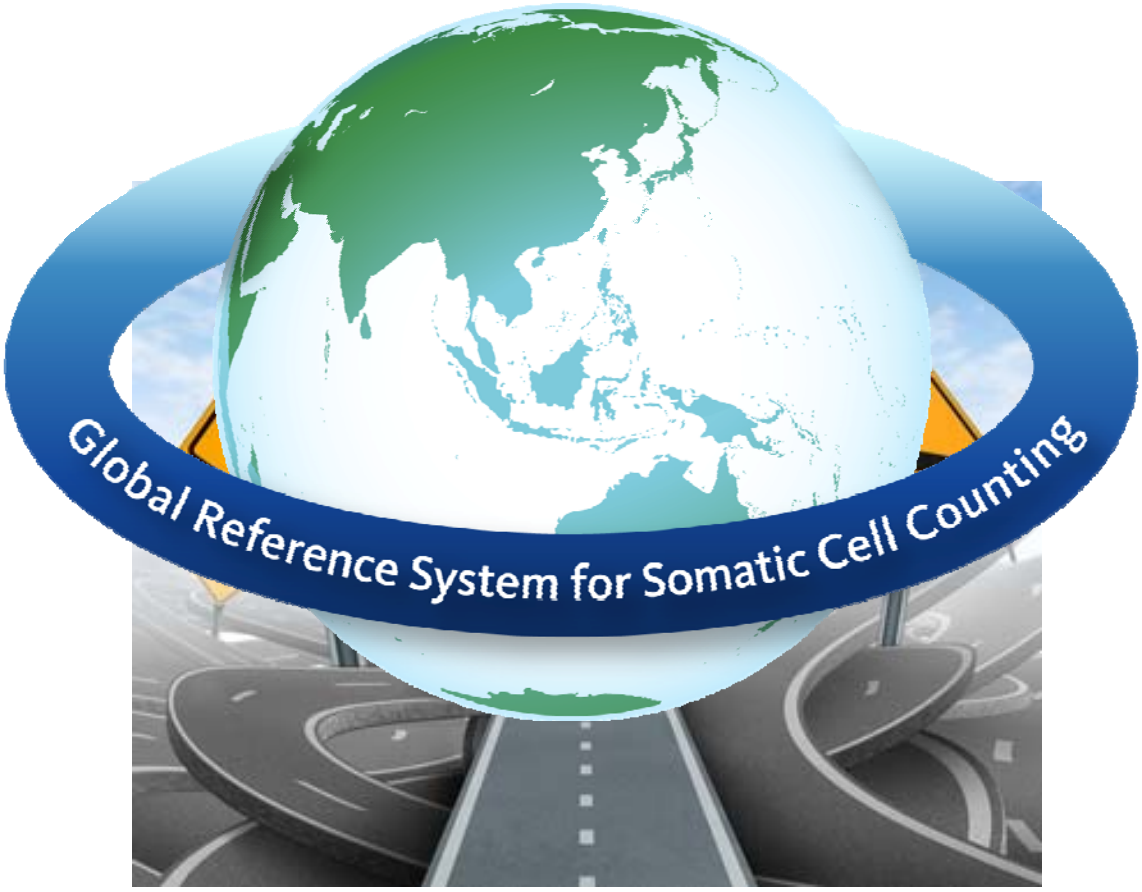
RESUMÉ

The launch of the EC JRC CRM is a major step towards better global equivalence in somatic cell counting in milk

It can be applied in method performance verification, in calibration in assigning values to SRM's and in proficiency testing

Re-anchoring to the EC JRC CRM may in some geographies com with a significant shift in counting levels. This should be prudently dealt with between involved local stakeholders to secure a proper landing. IDF and ICAR can assist with guidance in this.

THANK YOU TO ALL WHO CONTRIBUTED!



THANK YOU FOR YOUR ATTENTION!