International Reference System for Somatic Cell Counting in Milk

A World Wide Challenge

Christian Baumgartner

on behalf of the

IDF/ICAR Project Group on
Reference System for Somatic Cell Counting in Milk

IDF/ICAR Project Group (April.2010)

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3 continents
14 countries
10 male – 10 female

IDF and ICAR

……you know!

IDF and ICAR

www.fil-idf.org

International Dairy Federation

IDF is the pre-eminent source of scientific and technical expertise for all stakeholders of the dairy chain. Membership covers 56 countries and is growing. IDF accounts for about **86%** of current total milk production worldwide.

The mission of IDF is *to represent the dairy sector worldwide by providing the best global source of scientific expertise and knowledge in support of the development and promotion of quality milk and dairy products to deliver consumers with nutrition, health and well-being.*

IDF members (May.2010)

ESADA (Kenya, Malawi, Mauritius, Rwanda, Tanzania, Uganda and Zambia)
ARMENIA (AM) AUSTRIA (AT) AUSTRALIA (AU) BELGIUM (BE) BRAZIL (BR)
CANADA (CA) SWITZERLAND (CH) CHINA (CN) CYPRUS (CY)
CZECH REPUBLIC (CZ) GERMANY (DE) DENMARK (DK) EGYPT (EG)
SPAIN (ES) FINLAND (FI) FRANCE (FR) UNITED KINGDOM (GB)
GREECE (GR) CROATIA (CR) HUNGARY (HU) INDONESIA (ID)
ISRAEL (IL) IRAN (IR) ICELAND (IS) ITALY (IT) JAPAN (JP) KOREA (KR)
KUWAIT (KW) KAZAKHSTAN (KZ) LITHUANIA (LT) LUXEMBOURG (LU)
LATVIA (LV) MONGOLIA (MN) MEXICO (MX) NETHERLANDS (NL)
NORWAY (NO) NEW ZEALAND (NZ) PHILIPPINES (PH) POLAND (PL)
PORTUGAL (PT) RUSSIAN FEDERATION (RU) SWEDEN (SE) SLOVENIA (SI)
SLOVAKIA (SK) TURKEY (TR) UKRAINE (UA) UNITED STATES (US)
SOUTH AFRICA (ZA) ZIMBABWE (ZW)

Goal of IDF/ICAR cooperation?

international

Standardization

➔ Equivalence

Not only setting standards, but trying to ensure that standards are kept!!!

Why Analytical Standardization?

When goods are moving, analytical results should (must) be comparable and “equivalent”

- worldwide
- on the long run
- between different methods

➔ Equivalence… anywhere – anytime – anyhow

But what „Normal“ / Reference to relate to?

equivalent
and
correct / “true”

Reference Methods

- Reference methods serve as **anchor** (examples):
  - defining methods like Codex Type I methods
    - Milk – Protein: ISO 8968-1|IDF 20-1 (Kjeldahl titrimetry)
    - Cheese – Moisture: ISO 5534|IDF 4 (gravimetry)
  - designated methods like Codex Type II methods
    - Butter – Salt: ISO 1738|IDF 12 (titrimetry)
    - Whey powder – Lactose: IDF 79B (enzymatic)

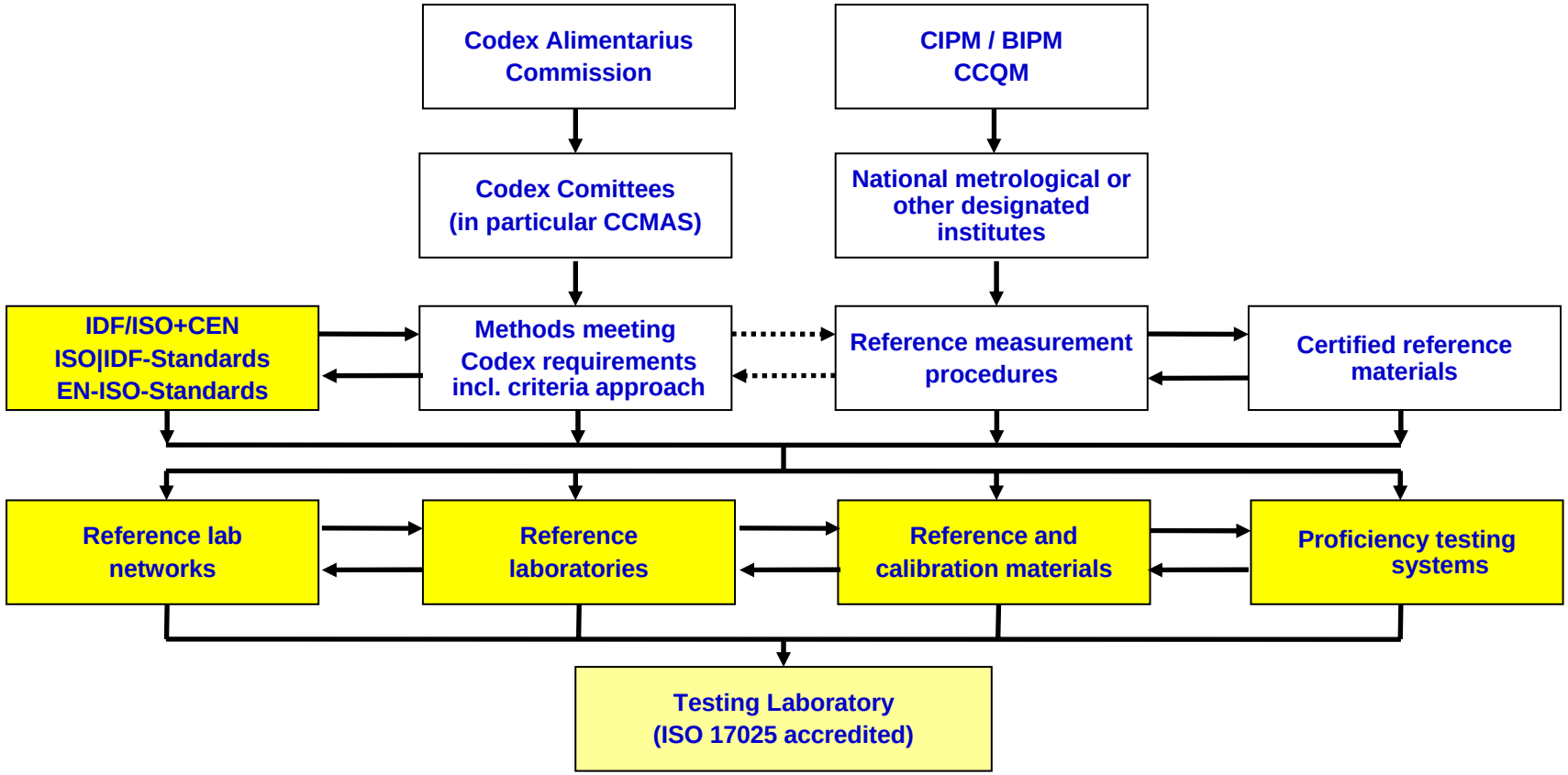
But Reference Methods are too costly and time consuming for daily work…

Routine Methods

- High throughput, often automated
- High precision
- User friendly
- Immediate availability of data
- Low labour, low cost per analysis
- Crucial for the functioning of “daily dairying life”

Traceability to **defined units** is key for a coherent expression and use of results!

Metrologically Traceable Measurement System for Food Analysis (CIPM/BIPM)

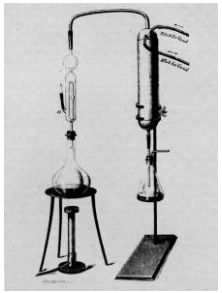


Overall goal ➔ Comparable, traceable measurement results with stated uncertainty, providing reliable data for decisions in trade, regulation and risk assessment.

The ´Traditional´ Approach

Uncertainty of the reference method

Stability and homogeneity of RM



Reference value

Calibration

Adjustment

Reference method

Reference material

Routine method

Protein
Fat
Lactose

→ **Kjeldahl**
Röse-Gottlieb
HPLC

→ **calibration set**

→ **Fourier Transform Infrared Spectroscopy (FTIR)**

…and the ´Real Life´ Situation

- Reference methods are indispensable, but…
  - often not suitable for large scale routine application
  - with some important practical applications the precision is not satisfactory
  - no guarantee for a reliable reference when applied in only one laboratory
- Solutions cannot always be achieved by straightforward analytical means or reference materials
- Implementing a **reference system** is a complementary option to safeguard “equivalence”

What is a Reference System?

- Well-structured anchoring **system** fed by different types of information
  - reference method
  - routine method results
  - proficiency testing results

from many different sources

- Traceable competence as prerequisite
- Recognition/adoption by regulatory bodies, competent authorities

For further information...

Bulletin of the International Dairy Federation 427/2008

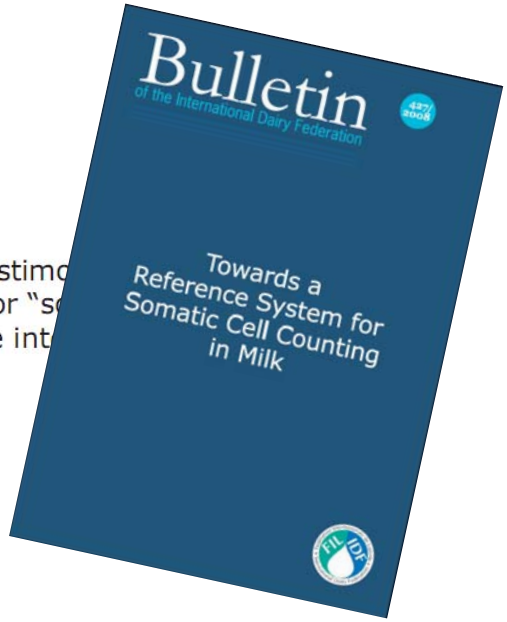
Towards a Reference System for Somatic Cell Counting in Milk

2. Architecture of reference systems, status quo of Somatic Cell Counting and concept for the implementation of a reference system for Somatic Cell Counting

C. Baumgartner[1]

Summary

The definition of "reference" relates to two meanings. One relates to "testimo
or "certification", the other to the aspect of "information", "evidence" or "s
are a good description of the purpose of reference systems, which are int
and improve the traditional way of calibration of routine methods.



Why SCC as a First Example?

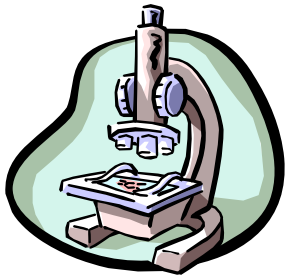
- SCC is one of the most frequently performed tests worldwide (~ 500.000.000 tests/year)
- SCC – as an indicator for udder health status – is relevant in food legislation, payment of raw milk and also has a major impact on farm management and breeding programs
- Farm management, breeding programs
  ➔ economics!

SCC as a Typical Problem

- No clear definition what to analyze; i.e. the analyte is defined by the traditional microscopic reference method;
- The reference method derives from “historic” ages;
- The reference method is tedious, cumbersome and has poor performance;
- “Target analyte” of nowadays´ routine methods is not commonly accepted as new “reference” basis;
- No CRM/“golden standard” available;
- SRMs have problems with shelf life and batch homogeneity during storage;

Somatic Cell Counting in Milk

Reference method



Direct microscopic somatic cell count

Routine methods

Somascope™

Somacount™

Nucleocounter™

DCC Counter™

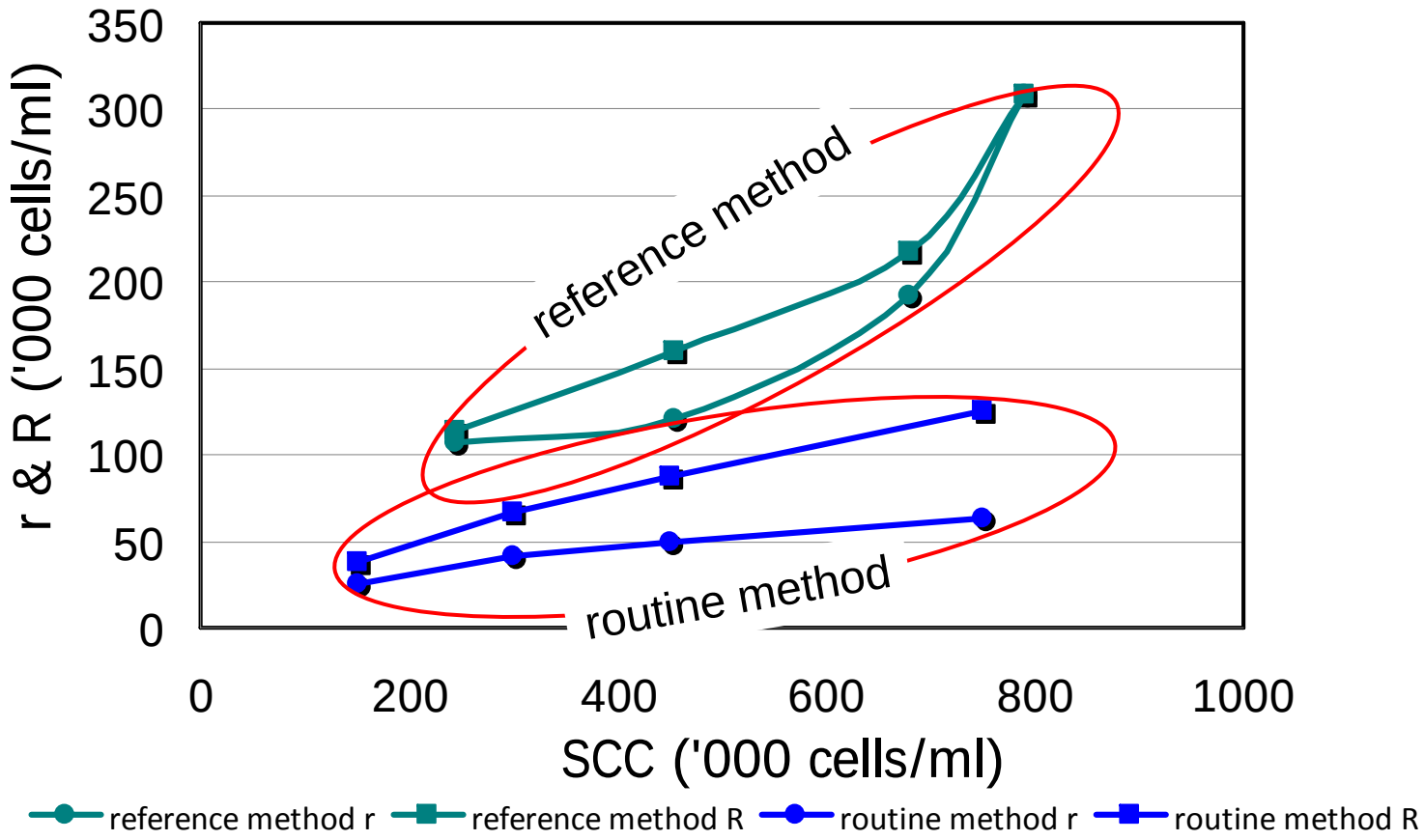
Fossomatic™

Precision Reference vs. Routine

- ISO 13366|IDF 148, part 1 vs. part 2
- All SCC values in '000/ml:

	Mean	s_r	sR	r	R
Reference	245	38	41	107	114
	679	69	79	192	218
Routine	245	13	20	36	57
	679	21	40	59	112

Precision Reference vs. Routine

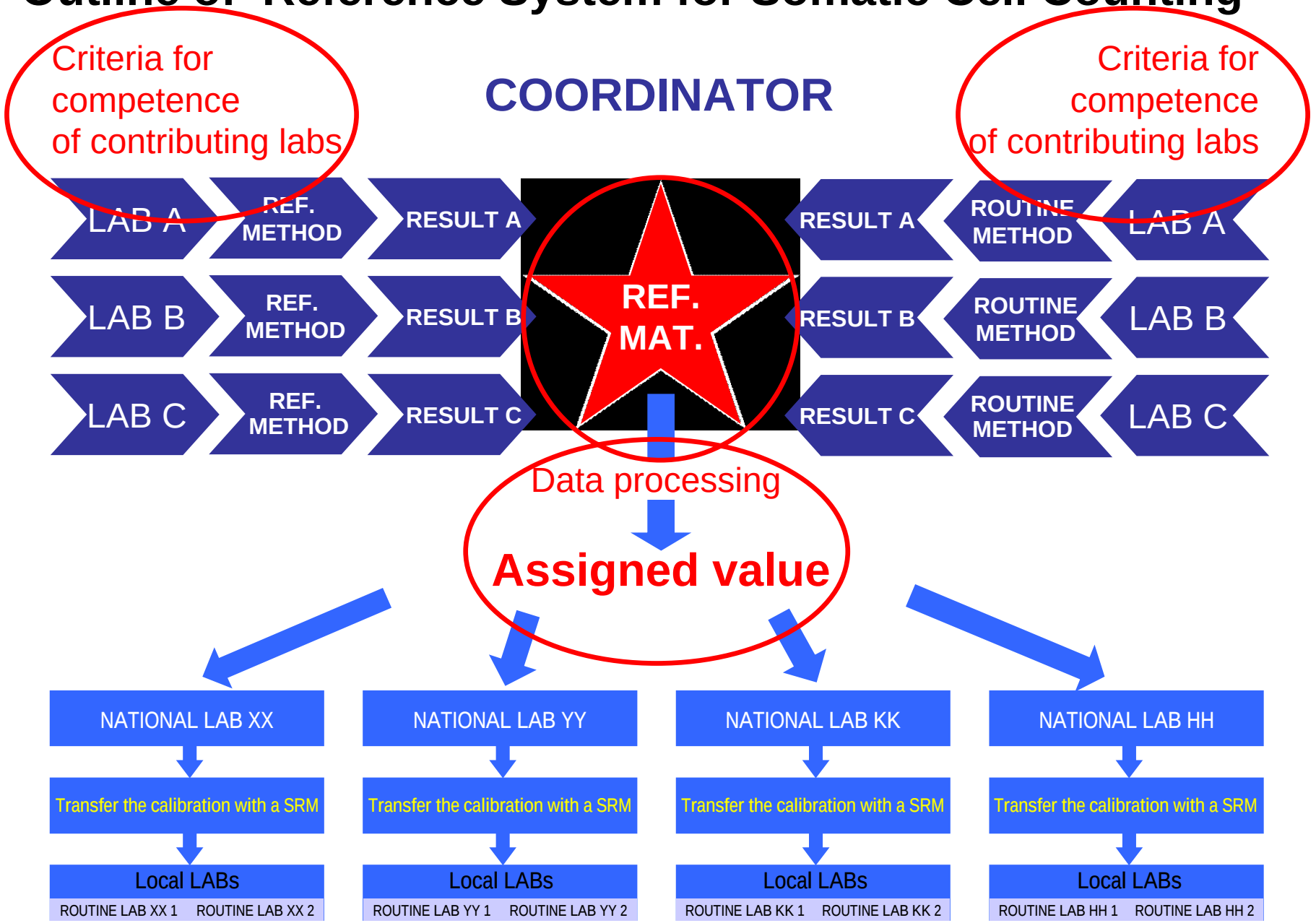


How to begin?

Building Blocks for a Reference System

- Standards: ISO 13366|IDF 148 parts 1-2 (2008)
- Willingness to cooperate in a laboratory network
- Reference materials
- Proficiency testing schemes
- Training course system
- Gathering all data and create a data base

Outline of ‘Reference System for Somatic Cell Counting’



Criteria for Reference Materials

- Range (cow, goat, sheep)
- Representativeness (matrix, cell material, preservation)
- Adequately assigned values
- Homogeneity
- Stability during shipment, storage and pretreatment
- Validated as being ‘fit for purpose’

➔ RM to be selected and optimized

Traceable Competence of Labs

- Level of analytical quality assurance
- Participation and performance in proficiency testing
- Recording and scoring of performance in laboratory database

➔ scoring system to be developed

Calculation Model

Arriving at assigned values based on:

- reference method results
- routine method results
- data processing model with applying weighing factors based on traceable competence of contributing labs

➔ calculational model to be developed

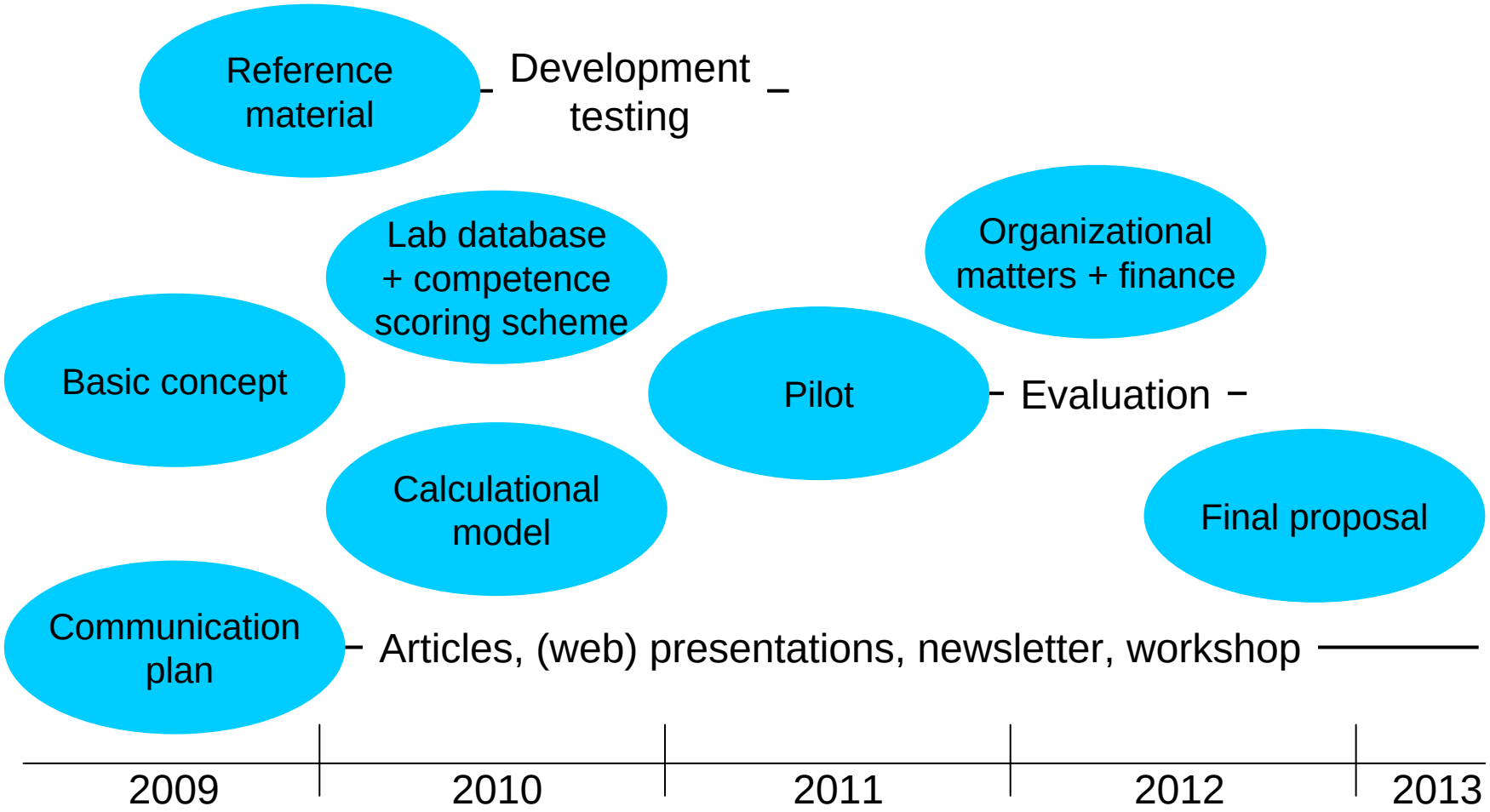
Next Actions (1)

- Arriving at suitable reference material
  - Contact with reference material suppliers
  - Questionnaire on applied reference materials
  - Selection/optimization
- Laboratory database
  (incl. system for scoring competence)
- Outline of calculation model

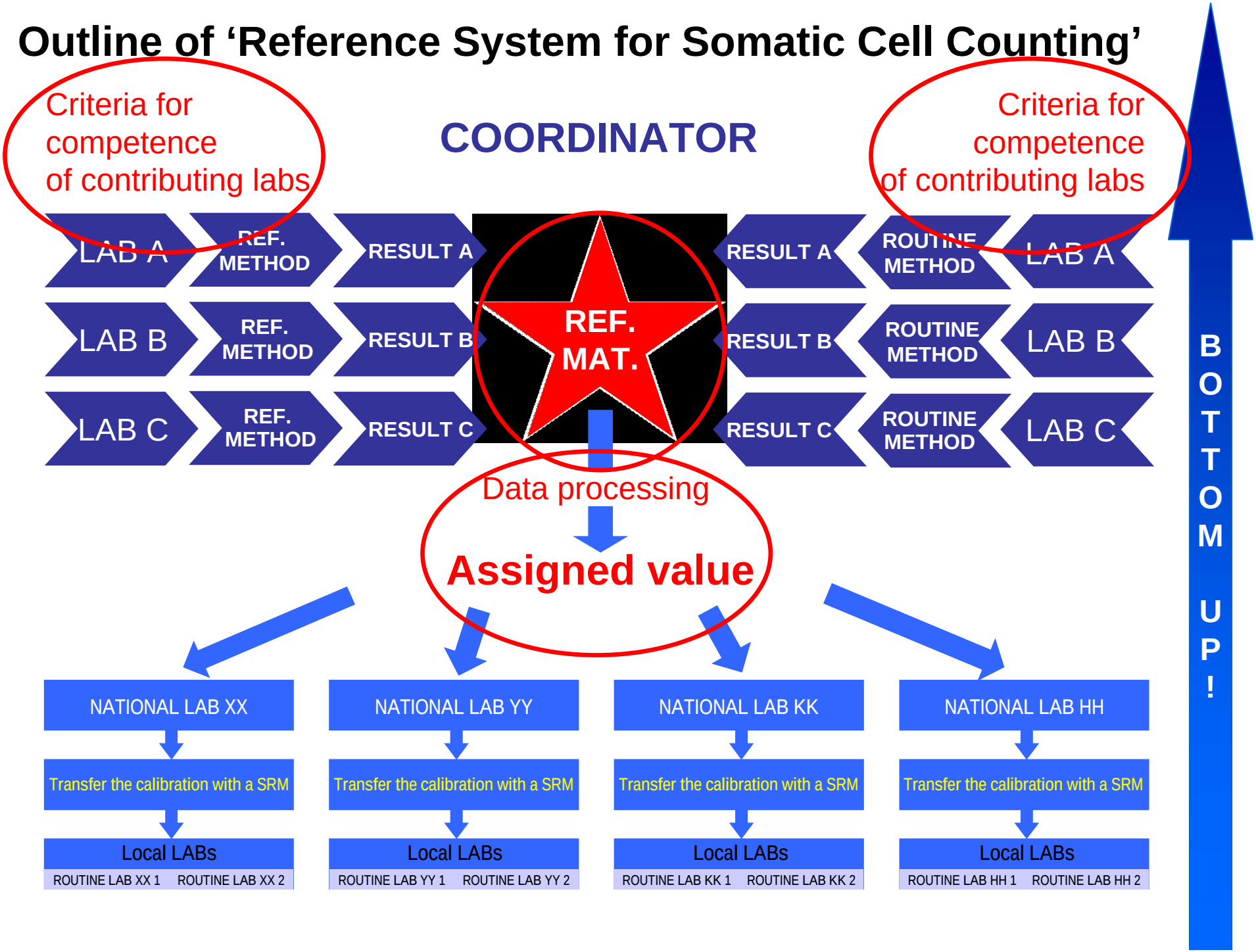
Next Actions (2)

- Communication plan about the project
  - Analytical-oriented stakeholders (labs, RM providers)
  - Other stakeholders (animal health bodies, authorities)
- Ordering thoughts about
  - Training course system
  - Coordinator (position, competence, tasks)
  - Finance

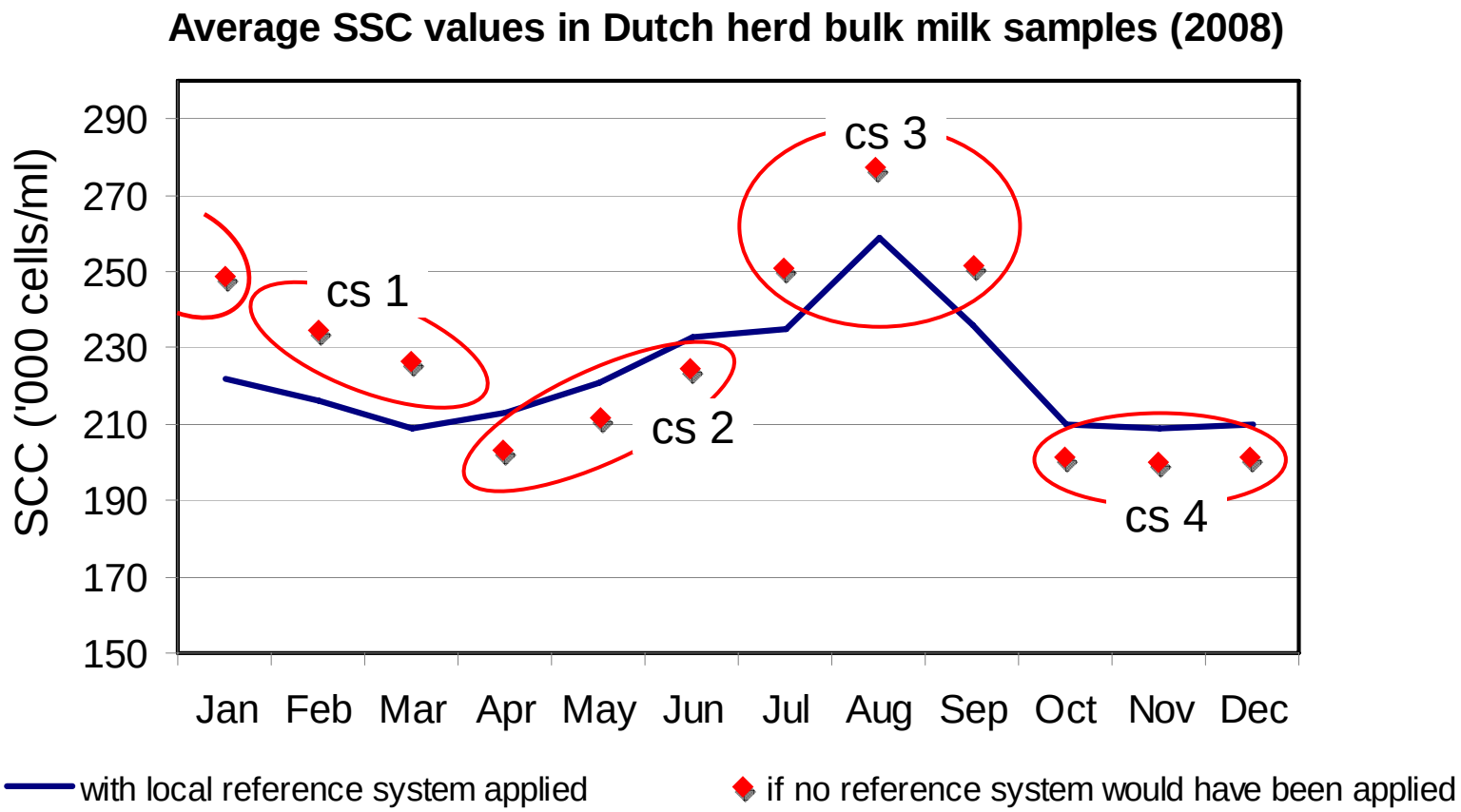
Time Plan


Reference material
Development testing
Lab database + competence scoring scheme
Organizational matters + finance
Basic concept
Pilot
Evaluation
Calculational model
Final proposal
Communication plan
Articles, (web) presentations, newsletter, workshop
2009
2010
2011
2012
2013

Outline of ‘Reference System for Somatic Cell Counting’



Local Example from NL



cs = calibration set

Conclusions

- Reference systems serve to complement the ‘traditional’ way of calibration of routine methods for safeguarding the validity of analytical results.
- A wider implementation of recognized reference systems will improve the acceptance and mutual confidence in analytical results.
- Somatic cell counting is an excellent parameter to explore the feasibility of a world-wide functioning reference system, thereby demonstrating the potential benefit of an implementation for other parameters.

A Sisyphus job… maybe…

...but with a little help from our friends?!