Reference System
Principle and Practice

Meeting of ICAR Reference Laboratory Network

35th ICAR Session
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Contents briefly...

• What does „reference“ mean?
• „reference“ in a linear calibration model
• draw-backs ⇒ „reference system“
• an ideal reference system for SCC as an example
• some conclusions

Reference?

• Definition 1 ⇒ testimonial
  Synonyms = certificate, certification, character, credentials, endorsement, good word, recommendation, tribute

• Definition 2 ⇒ information
  Synonyms = dictionary, encyclopedia, evidence, source, thesaurus, writing

Reference – the traditional way of life

Why do we need different methods?

• reference methods for definition
• routine methods for “daily life”
• routine methods are often automated methods because of
  - high throughput
  - high performance (precision characteristics)
  - data availability and handling
  - low labour, low costs
Routine raw milk testing

<table>
<thead>
<tr>
<th></th>
<th>Germany</th>
<th>World*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Labs</td>
<td>18</td>
<td>700 (1,700)</td>
</tr>
<tr>
<td>Samples/year</td>
<td>40 Mio.</td>
<td>300 - 500 Mio.</td>
</tr>
<tr>
<td>Analyses</td>
<td>140 Mio.</td>
<td>1,000 - 1,300 Mio.</td>
</tr>
</tbody>
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Analytical results should be comparable and “equivalent” ...and they are not!!!

- worldwide
- over time on the long run
- between different methods

⇒ anywhere - anytime - anyhow

Main limitations of traditional calibration schemes

⇒ there is an insufficient definition of the parameter to measure ("definition of the truth")
⇒ the uncertainty of analysis linked to the reference method is high
⇒ there is no CRM which could be used as a "golden standard"
⇒ the use of available SRMs is limited by shelf life and poor homogeneity of batches during the labeled shelf life

Steps to improve

Reference lab
Routine analyzer
SRM

⇒ Control all sources of variation!

Ideal system for somatic cell counting

⇒ a clear definition, what SCC is (which cell populations to be counted, ...) ⇒ what do we want to know?
⇒ a precise (highly repeatable/reproducible) standard or "reference" method, based on clear precision data from method evaluation AND practical use
⇒ a well defined certified reference material (CRM) and several secondary reference materials (SRMs) based on different types of (milk) cell populations for calibration purpose with high stability over a very long shelf life to be used in routine raw milk analysis
⇒ high-yielding SCC analyzers for routine applications

⇒ a reporting system for calibration data of all routine SCC analyzers
⇒ a data base to collect all data and to provide information for routine AND reference labs
⇒ a network of labs performing the reference method as anchors to fix an internationally accepted SCC level
⇒ a network of "safeguards" to provide all necessary input to the system from all parties involved (competent authorities, reference labs, routine labs, scientists and "users" as breeding and DHI organizations, dairy companies etc.) and to develop the system to its best function.
Implementation - status report

- Step 1: reference method – definition of “the truth”
- Step 2: CRM (????) and SRMs (officially adopted)
- Step 3: proficiency testing schemes
- Step 4: reference lab network
- Step 5: training courses
- Step 6: data collection and extracting
- Step 7: developing procedures for “interference” - how should elements of the system influence each other
- Step 8: safeguarding network (competent authorities, reference labs, routine labs, scientists and “users” as breeding and DHI organizations, dairy companies etc.)

Conclusions

- Instead of single linear models „reference systems” are needed, using feedback and redundancy effects.
- All systems should be interlinked, to utilize all information available!
- International structures for implementation are missing so far. What is the role of ICAR?
- We could do much better as we are doing now!