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Independent Validation and Certification of Analytical Methods

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Introduction

- Uniform determination of milk characteristics is required by globalizing dairy production and market
- Reference method / material (‘golden standard’)
- Alternative methods
  - Advantages: e.g. high-throughput, faster
  - Requirements: e.g. precision, accuracy

- Alternative methods to be compared with reference methods

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Validation and certification of an alternative method

Validation: establishment of the performance characteristics of a method and provision of objective evidence that the performance requirements for a specified intended use are fulfilled *(ISO 16140-1:2016)*.

Certification as proof of successful validation

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Independent Validation

- Assurance of independency by using expert laboratory
  - Conducting the validation activities by a separate organization which did not contribute to the development of the analytical method

- Advantages
  - Evaluation performed by unbiased, emotionally or economically not involved third party
  - Identification of issues that might have escaped the attention of the developer

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Certification

- Evaluation of validation procedure and results
- Issuing certificate upon compliance with stated acceptability limits for performance and equivalence with internationally standardized methods
- Examples of certification organizations

MICROVAL

ICAR THE GLOBAL STANDARD FOR LIVESTOCK DATA

afnor CERTIFICATION

AOAC INTERNATIONAL

NordVal International

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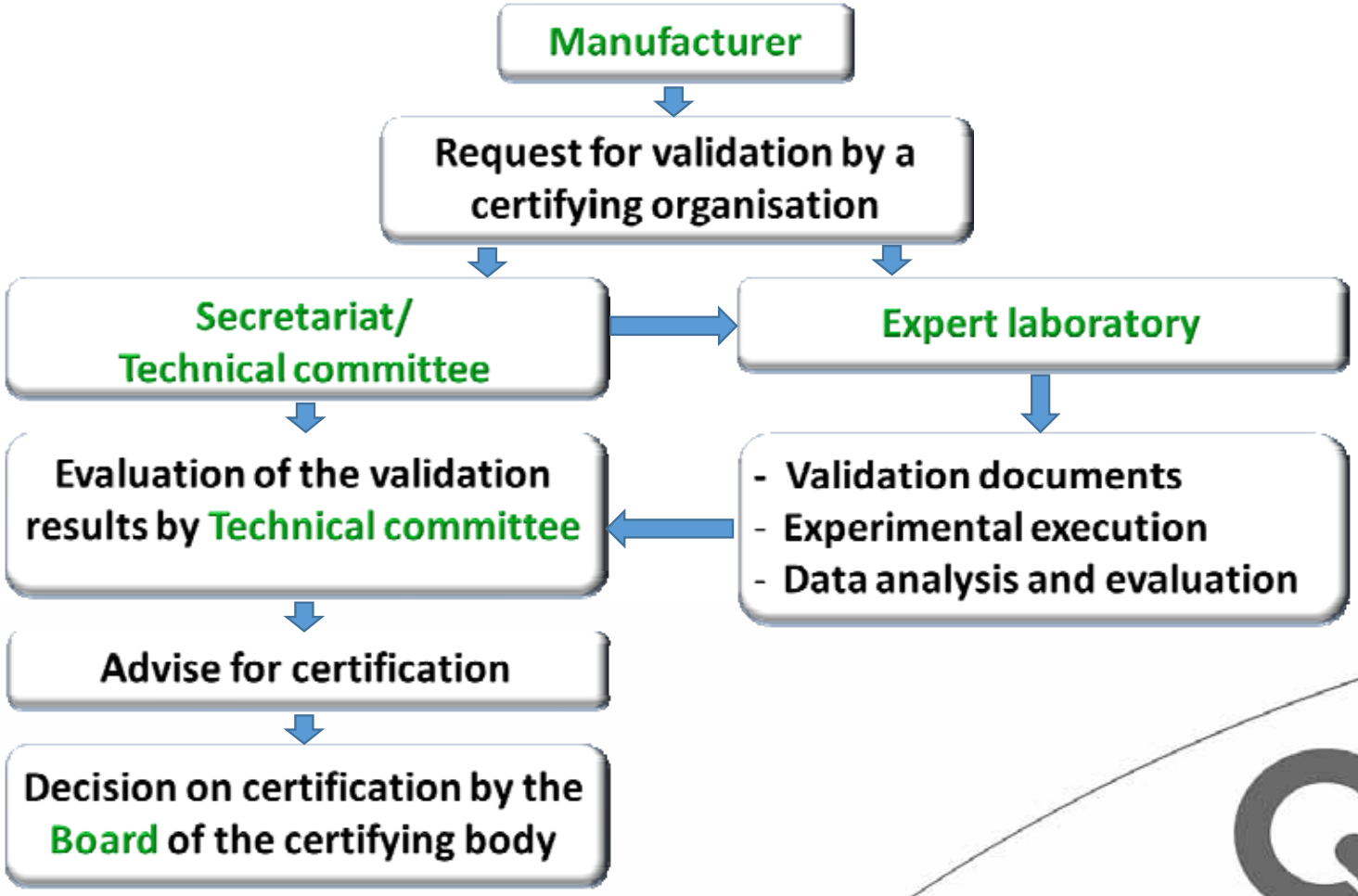
Process



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Validation of an alternative method

Step 1

- Within laboratory:

  Method comparison study

- Demonstration of the performance of the method
- Checking compliance with acceptability limits
- Examination of potential influence of factors affecting the relationship between alternative and reference method
- Estimating the accuracy of the alternative method

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Validation of an alternative method

Step 2

- Between laboratory:

  Method confirmation or interlaboratory study

  - Measuring routine and pilot samples during a period of time
  - Precision characteristics of the method: repeatability and reproducibility (within-lab, between-lab)

➔ Evaluation and comparison of the method performance under routine conditions

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Validation in case of a new but similar model

- Establishing degree of equivalence

- Decision by certification body on need for
  - Full validation

  or

  - Limited validation

- Differ in the estimation of the accuracy of the alternative method
  - Full validation – accuracy of the alternative against the reference method
  - Limited validation - accuracy of the alternative the already validated alternative method

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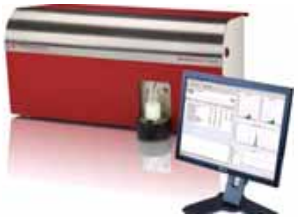
Examples of certified methods

For regulatory purposes

- Validation required by EU Regulations 2074/2005 and 1664/2006
- Validation procedure described in EURL MMP documents

- Instruments for total bacterial count
  - ISO 16140-2
  - ISO 16297|IDF 161

- Instruments for somatic cell count
  - ISO 8196-3|IDF 128-3
  - ISO 13366-2|IDF 148-2



More information at www.microval.org

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Examples of certified methods

For milk recording purposes

- Required by ICAR
- Instruments for measurement of milk compositional parameters and somatic cell count
- ICAR certification process follows ISO protocols for validation
  - ISO 8196-3|IDF 128-3
  - ISO 9622|IDF 141
  - ISO 13366-2|IDF 148-2

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Conclusions

- The globalizing market needs a uniform, reliable and traceable way of milk testing
- Independent validation demonstrates and assures that alternative analytical method is fit for purpose
- Subsequent certification provides tangible proof of adequate performance
- Independent validation and certification helps the acceptance of the results by public authorities, food industry, laboratories and end users

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Thank you for the attention

Questions?

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