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A Focus for Analytical Chemistry in Europe

Workshop
Method Validation in Analytical Sciences
Current practices and future challenges

Gent, 9-10 May 2016

Report from WG 3

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Validation in microbiology

- Moderator:
  - Olivier Molinier, AGLAE Association, France

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Validation in microbiology

- Participants
- Turkan ABBASOVA : State Committee on Standardization, Metrology and Patent
- Florence FERBER: ASBL REQUASUD
- Elke PEETERS : Eurofins Food Testing Belgium
- Guy LAMON : SGS Belgium NV
- Leen DESMYTER: Inagro
- Evelyne DEWULF: APB-DGO
- Els KESTENS: BELAC
- André MATHIEU : BELAC
- Olivier MOLINIER : AGLAE
- Bahar HOSSEINZADEH: Pasargad Quality Pioneers
- Jörn PILON: AQUALAB Zuid
- Dag GRøNNINGEN : NMKL
- Ozge OZGEN ARUN: Istanbul University Veterinary Faculty

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Validation in microbiology

- Different microbiology fields represented
- Food / water / medical…
- Accreditation bodies
- Food institute
- Consumer product safety
- Consultancy
- PT provider

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Questions

- What are the different approaches applied in different fields?
- How do you decide about the extent of validation needed?
- Where does microbiology laboratories have to deviate from the “normal” approaches (e.g. like those recommended in the Eurachem “Fitness for Purpose” Guide)?
- What are the documents available for guidance?
- What are the challenges experienced in different areas?

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Questions

- What are the different approaches applied in different fields?

Microbiological field	food / feed/water /Medical	Cosmetology	Validation	Verification	
Categorical perf. Characteristics : Sensitivity / specificity / false (+) / false (-)		Matrix effect / addition of inhibitors	X		
selectivity			X		
Lower limit / upper limit (working range)			X		
Relative recovery			X	X	
Precision			X	X	
Measurement uncertainty			X	X	
robustness			X		

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Questions

- How do you decide about the extent of validation needed?
  - Distinction between validation (characterization) and verification:
  - Colony counts methods (quantitative) were discussed
  - Semi-quantitative (MPN methods) / qualitative method were only mentionned but not completely covered
  - qPCR / impedancemetry

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Questions

- Where does microbiology laboratories have to deviate from the “normal” approaches (e.g. like those recommended in the Eurachem “Fitness for Purpose” Guide)?
  - In terms of :
    - Performance characteristics:
      - Lower limits (detection level / limit of determination) well defined based on statistical approach
    - Specific random variability (Poisson distribution)
    - Discussion about the log10 transformation of data

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Questions

- What are the documents available for guidance?
  - International or national standards
    - ISO standards were used during the discussion :
    - ISO 13843 – ISO 16140-1 and 16140-2
  - Other documents available
    - Eurachem MV Guide (second edition 2014) – Microbiology not sufficiently covered
    - Nordval / NMKL - Protocol for the validation of alternative microbiological methods

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Questions

- What are the challenges experienced in different areas?
  - Samples used : Naturally contaminated samples/ spiked samples
    - Representativeness / cultivability
  - Determination of relative recovery
    - Use of PT samples / assigned value as a reference

- Criteria definitions
- Commercial aspects (cost / time consuming)