INTRODUCTION TO
THE STANDARD EN ISO 19036 AND THE EURLs GUIDE

EURLs *Campylobacter*, CPS & *Lm* webinar on MU
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INVESTIGATE, EVALUATE, PROTECT

Introduction

# Why to estimate measurement uncertainty? (1)

- Significance of microbiological analysis of food
  = direct hazard for the consumers' health

- Quantitative methods in food microbiology

  = highly variable results (0,1-1 $\log_{10}$)

  ➔ need to quantify this variability

Why to estimate measurement uncertainty? (2)

- Needed for accredited laboratories
- What are the main requirements of ISO 17025 (2017)?

  - See clause 7.6:

    - ➢ To identify contributions to measurement uncertainty (MU)
    - ➢ To evaluate MU of test results
    - ➢ To take into account the main contributions to MU
    - ➢ If the test method precludes "rigorous" MU evaluation

    ↳ MU estimation can be based on understanding of theoretical principles or practical experience of method performance (= case for food microbiology)

Why to estimate measurement uncertainty? (3)

- MU values may be used to interpret analytical results in terms of conformity to a legal limit in Reg. 2073/2005

- Different cases are shown below (adapted from EURACHEM / CITAC Guide CG 4)
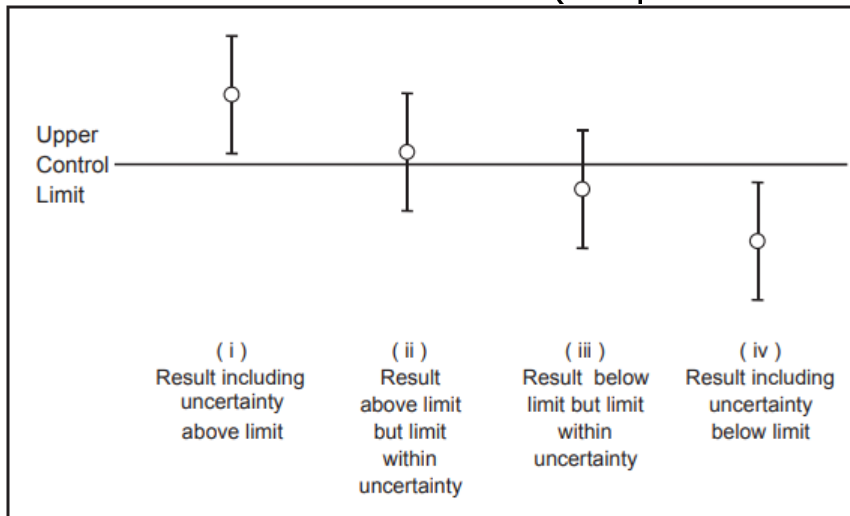
- In particular where the result, including MU, approaches the limit (iii) or just exceeds to the limit (ii), such results are questionable

Introduction to the Standard EN ISO 19036

INTERNATIONAL STANDARD

ISO 19036

First edition
2019-10

Microbiology of the food chain —
Estimation of measurement
uncertainty for quantitative
determinations

- Published by ISO in October 2019 and adopted by CEN as European Standard
- Prepared by WG 2 « Statistics »
  of Sub-Committee 9 « Microbiology »
  of ISO Technical Committee 34 « Food products » (ISO/TC 34/SC 9)
- Co-Project Leaders: Basil JARVIS, Keith JEWEL, Paul IN'T VELD
- Revision of ISO Technical Specification 19036 (2006, amended in 2009)

    ✓ Took into account feedback from the users of the first version

    ✓ Converted into a full ISO Standard

    ✓ Partly harmonised with water microbiology (ISO 29201)

  - Presentation support available on
    ISO/TC 34/SC 9 website:
    https://committee.iso.org/sites/tc34sc9/home/general-standards/content-left-area/culture-media/iso-19036-estimation-of-measurem.html

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Approach adopted in food microbiology

« Half-global » approach, 3 main MU components:

1. Technical uncertainty

- Major component ← global approach

- Experimental reproducibility standard-deviation on the final measurement result

- Advantages/GUM decomposition
  - ✓ Less risk to under-estimate MU
    - ✓ ↳ type of matrix, sub-sampling of test portion taken into account
  - ✓ No need to estimate each MU component
  - ✓ *A priori* less heavy to implement

2. Matrix uncertainty
↳ Distribution of bacteria in the sample matrix

3. Distribution uncertainties
↳ Depending on the principle of the method used

Sampling uncertainty

Error associated with the drawing of the laboratory sample from a lot under investigation

- can contribute significantly to the overall error, but
- is not considered as part of the uncertainty linked to the laboratory test results
- ➢ Sampling uncertainty not included in ISO 19036

Bias

- Estimate of a systematic measurement error
- For quantitative methods in food chain microbiology, no "true" value exists which is independent of the method used

  - o assigned values or reference material values are not available for all routine test results

  - o so cannot reliably estimate bias for a routine test result

➢ Bias not included in MU estimation according to ISO 19036

Calculations

- Excel tool implementing the calculations of ISO 19036 (2019)

  - Developed by Campden BRI (UK)

  - Verified by WG 2 of ISO/TC 34/SC 9

  - Freely available on line at https://committee.iso.org/sites/tc34sc9/home/general-standards/content-left-area/culture-media/iso-19036-estimation-of-measurem.html

- Refer to the 1st worksheet "Read me" for the instructions

Introduction to the EURLs MU guide

Presentation of the guide (1)

- *Guide on the implementation of the Standard EN ISO 19036:2019 for the estimation of measurement uncertainty associated with the enumeration of* Campylobacter*, coagulase positive staphylococci and* Listeria monocytogenes *in the food chain*

- Version 1, 23/06/2022, available on the web-site of the 3 EURLs
  - *Campylobacter*: https://www.sva.se/en/about-us/eurl-campylobacter/laboratory-procedures/measurement-uncertainty-for-the-enumeration-of-microorganisms/
  - *Lm*: https://sitesv2.anses.fr/en/minisite/listeria-monocytogenes/measurement-uncertainty
  - CPS*: https://sitesv2.anses.fr/en/minisite/staphylococci/measurement-uncertainty

- Drafted by Working group of
  - EURL *Campylobacter*: Helena Höök, Elina Lahti and Hanna Skarin
  - EURL Coagulase Positive Staphylococci: Abakabir-Mahamat Abdelrahim
  - EURL *Listeria monocytogenes*: Adrien Asséré, Léna Barre and Ludivine Bonanno
  - Expert: Bertrand Lombard

Presentation of the guide (2)

- Draft submitted for comments to the 3 NRLs networks, October-November 2021

- Comments taken into account to prepare the final draft endorsed by the Standing Committee on Plants, Animals, Food and Feed (PAFF), 3 June 2022

Content of the guide (1)

- Introduction & scope
  - Guidance to NRLs and official labs for *Campylobacter*, *Lm* and CPS on
  1. How to implement EN ISO 19036 (2019) for MU estimation associated with
     - ✓ The enumeration of these 3 bacteria
       - + may also apply to the enumeration of any target bacteria
     - ✓ In samples from the food chain, except water (ISO 29201)
     - ✓ No rephrasing of the standard but clarifications and details on certain aspects, choice of certain options
       - ➢ Harmonised implementation of the standard by the 3 EURLs, NRLs networks and official labs
  2. How to assess that acceptable MU values are obtained
  - Based and replaced EURL *Lm* guide (2009)

Content of the guide (2)

- MU definition (clause 1)

- MU estimation (clause 2)
  - General aspects: to use EN ISO 19036 (2019) with some recommended choices, see later
    - ✓ To be noted: clause 8.2.2 of the EC Guidance Document *on official controls, under Regulation (EC) No 882/2004, concerning microbiological sampling and testing of foodstuffs* (2006) refers to ISO/TS 19036 (2006)
      → reference needs to be updated to EN ISO 19036 (2019)
  - Technical, matrix and distributional uncertainties

- Acceptable MU values (clause 3)

Content of the guide (3)

- MU interpretation (clause 4)
  - How to take MU into account when interpreting an enumeration result/conformity to a limit of a microbiological criterion?
  - Not dealt in this guide but in clause 8.2 of the EC *Guidance Document on official controls, under Regulation (EC) No 882/2004, concerning microbiological sampling and testing of foodstuffs*, 2006
  - Clause 8.2 expected to be modified in the frame of the on-going revision of this EC guidance document
    - Replacement of ISO/TS 19036 by the Standard EN ISO 19036:2019
    - Change in practices