ISO/CEN ACTIVITIES

EURL-*Campylobacter* workshop 2018

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RELEVANT GROUPS IN ISO AND CEN

- **ISO/TC34/SC9**:

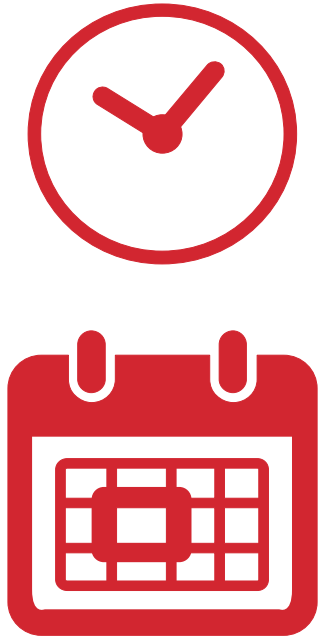
- ISO: International Standardisation Organisation
- TC34: Technical Committee 34 on Food products
- SC9: Subcommittee 9: Microbiology

- **CEN/TC275/WG6**:

- CEN: European Committee for Standardisation
- TC275: Technical Committee 275 for Food analysis – Horizontal methods
- WG6: Working Group 6 for Microbiology of the food chain

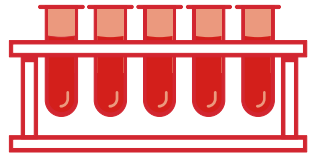
ISO/TC34/SC9 AND CEN/TC275/WG6
37TH ANNUAL MEETING

18-22 June 2018,
Lausanne, Switzerland



Activities going on in ISO/TC34/SC9 and CEN/TC275/WG6 of interest to the EURL-*Campylobacter* network

ISO 16140 METHOD VALIDATION



- The standardized methods developed by ISO/TC 34/SC 9 and CEN/TC 275/WG 6 are mainly based on culturing techniques.

- ISO 16140:2003 Protocol for the validation of alternative methods
- Revision- produce several parts 1-6

- ISO 16140-1:2016 Method validation -- Part 1: Vocabulary
- ISO 16140-2:2016 Method validation -- Part 2: Protocol for the validation of alternative (proprietary) methods against a reference method

ISO 16140 METHOD VALIDATION PARTS 3-6

DIS voting 15/12/2017 – 09/03/2018 of:

- Part 3: Protocol for the verification of reference and validated alternative methods implemented in a single laboratory
- Part 4: Protocol for single-laboratory (in-house) method validation
- Part 5: Protocol for factorial interlaboratory validation of nonproprietary methods
- Part 6: Protocol for the validation of alternative (proprietary) methods for microbiological confirmation and typing procedures

OTHER PROCESSES OF POSSIBLE INTEREST

- **Revision of ISO/TS 22117 -** Specific requirements and guidance for proficiency testing by interlaboratory comparison:
- DIS voting 2018-02-07 –2018-05-02: Approved by ISO and CEN
- FDIS autumn 2018

- **Revision of ISO/TS 19036 -** Estimation of measurement uncertainty for quantitative determinations:
- DIS voting 2018-05-17 to 2018-08-09: Approved by ISO and CEN
- FDIS in 2019

- **Revision of ISO 6887-5 -** Preparation of test samples, initial suspension and decimal dilutions for microbiological examination – Part 5: Specific rules for the preparation of milk and milk products:
  - DIS voting start October 2018

OTHER PROCESSES OF POSSIBLE INTEREST

- **ISO/WG25** ’Whole-genome sequencing for typing and genomic characterization’
  - NWIP vote in spring 2018 – positively received
  - provide a framework for generating and processing NGS/WGS data to address global problems in food/feed microbiology
  - The ISO standard will merely be a guidance document than giving requirements

ISO 10272:2017 ’MICROBIOLOGY OF THE FOOD CHAIN -- HORIZONTAL METHOD FOR DETECTION AND ENUMERATION OF CAMPYLOBACTER SPP.’

AMENDMENTS:

- One reference to ISO 6887 is not correct in part 2 (now ISO 6788).
- As it is already planned to publish an amendment to this ISO (to include species identification by PCR), the correction will be included in this amendment.
- Therefore two amendments will be performed, one for each part.

CEN/WG6/TAG3 MOLECULAR METHODS

- Group leader: Kornelia Berghof-Jäger
- Project leader ‘Identification of *Campylobacter* by PCR methods’ : Ute Messelhaeusser

- **Wang et al. 2002**
- Gel based (targeting *C. jejuni, C. coli, C. lari, C. upsaliensis, C. fetus)*
- Inclusitivity (72 *C. jejuni,* 22 *C. coli*, 8 *C. lari*, 7 *C. upsaliensis*, 7 *C. fetus*)
- Exclusitivity (67 strains of which 14 *Campylobacter*)
- Note: It is known, that some *C. lari, C. upsaliens*is and *C. fetus* can give negative results using the PCR system described.

- **Mayr et al. 2010**
- Real-time PCR (targeting *C. jejuni. C.coli and C. lari*)
- Inclusitivity (21 *C. jejuni*, 13 *C. coli*, 17 *C. lari*)
- Exclusitivity (63 strains of which 27 *Campylobacter*)

CEN/WG6/TAG3 MOLECULAR METHODS

- A draft has been produced and the work will be moved to CEN-TAG19
- WG6 members will be invited to nominate experts within TAG19

Further things to decide/do:

- An interlaboratory study will be carried out according to ISO 16140-6

- Method comparison study according to ISO 16140-6:
- Inclusitivity: 100 target strains per species
- Exclusitivity: 100 non-target strains (50 campy, 50 other spp.)

- Should TAG19 perform a full validation of the methods according to ISO 16140-6 (method comparison study + interlaboratory study)?

QUESTIONS OR COMMENTS?