

Update ISO and CEN activities

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EURL-*Campylobacter*
workshop 2022

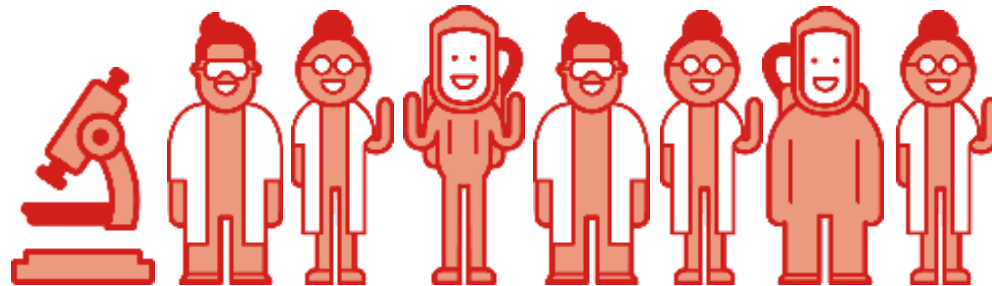


Current relevant ISO work

- ISO/TC 34/SC 9 Food products – Microbiology
 - **WG 2:** Statistics, no new projects
 - **WG 3:** Method validation, see next slides
 - **WG 7:** General requirements and guidance for microbiological examinations
 - Revision of ISO 7218 (current version from 2007, Amd 2013), DIS Enquiry ended in August
 - **WG8:** Preparation of test samples, initial suspensions and decimal dilutions
 - Looking for project leader for revision of ISO 6887-6 (preparation of samples from the primary production stage)
 - **WG 25:** Whole-genome sequencing for typing and genomic characterization
 - ISO 23418: Microbiology of the food chain — Whole genome sequencing for typing and genomic characterization of foodborne bacteria — General requirements and guidance. Published in June 2022.

ISO/TC 34/SC 9/WG 3: Method validation

- ISO 16140 series, part 1-6 published
- Ongoing work on standards
 - Revision **EN ISO 16140-1 and 2** and **Amd1** to **16140-4** (annex H, Validation of larger test portion size for qualitative methods)
 - New: **ISO 16140-7** ‘Protocol for the validation of methods for the identification of microorganisms’: ISO/DIS enquiry is expected in 2023.





ISO/TC 34/SC 9/WG 3: Method validation

- To be able to use the ISO 16140-series in full, the objective is that all EN ISO standards should be validated, especially the ones listed in legislation.
- The scope of standardized reference methods:
 - Intended to be broad
 - To cover, where relevant, the whole food chain
- Validation studies should cover the whole scope of the standardized method:
 - In particular, for a “broad range of food” (ISO 16140-2 = all food), matrices from ≤ 5 food categories to be used in ILS
 - + matrices from other categories, depending on the scope of the method

ISO/TC 34/SC 9/WG 3: Method validation



- In the EU, the validation requirements for the use of alternative methods (ISO 16140-2) are included in the European Regulation 2073/2005 (Regulation on Microbial Criteria). A text is also being drafted for implementation of EN ISO 16140-3 (verification) and EN ISO 16140-6 (confirmation methods). The proposal will be sent to CEN/TC 463 members for consultation.
- Since not all EN ISO standards are (fully) validated, there is a transition period until 2027-12-31, when user laboratories may perform method verification of non-validated reference methods. After this transition period:
 - a validation study will be required to introduce non-validated methods into a laboratory (ISO 16140-4)
 - Same requirement applies for (food) categories outside the scope of validation of the method

ISO/TC 34/SC 9/WG 3: Method validation

- ISO/SC9 Ad'hoc group 'Validation status of ISO standards':
 - Produced a list of EN ISO standard that needs (additional) validation. E.g., it is listed that ISO 10272 needs validation of a fifth food category to validated for “broad scope”.
 - According to 'Microbiology of the food chain — Template and guidance for drafting ISO/CEN standard', validation data is valid for smaller test portion sizes, but when larger size test portions are used, the performance characteristics may be different. The largest test portion size routinely used should be applied for validation.
 - Collected information from members on test portion size used for detection methods. For ISO 10272-1; 10, 25 and also 325 g mentioned (but limited responses).



ISO/TC 34/SC 9 ballot on test portion sizes

			CATEGORY: Raw milk and dairy products TYPE: Raw milks and/or fermented/acidified milks (not heat treated)	CATEGORY: Raw meat and ready-to-cook meat products (except poultry) TYPE: Fresh meats (unprocessed)	CATEGORY: Raw meat and ready-to-cook meat products (except poultry) TYPE: Ready-to-cook (processed)	CATEGORY: Ready-to-eat, ready-to-reheat meat products TYPE: Cooked meat products	CATEGORY: Raw poultry and ready-to-cook poultry products TYPE: Fresh meats (unprocessed)	CATEGORY: Raw poultry and ready-to-cook poultry products TYPE: Ready-to-cook products (processed)	CATEGORY: Ready-to-eat, ready-to-reheat meat poultry products TYPE: Cooked meat products	CATEGORY: Fresh produce and fruits TYPE: Vegetables and fruits (unprocessed) not described above	CATEGORY: Multi-component foods or meal components TYPE: Composite processed foods (cooked)	CATEGORY: Environmental samples (food or feed production) TYPE: Equipment or production environment	CATEGORY: Environmental samples (food or feed production) TYPE: Waters used in the manufacturing process	CATEGORY: Primary production samples (PPS) TYPE: Animal faeces
ISO 10272-1:2017	10						FR UK SE			NL				
	25		DE	FR KR	FR	NL	FR UK DE NL	FR UK NL	AU		NL	FR	FR	
	375													
	Other: 0,01 ml													SE
	Other: 325						US							

ISO/TC 34/SC9 website

<https://committee.iso.org/home/tc34sc9>



What do we do?

SC 9 'Microbiology' of ISO/TC 34 'Food products' covers the development of methods in the field of microbiological analysis of the food chain from primary production stage to food and feed products including food production and handling.

SC 9 focuses its work on spoilage, pathogenic micro-organisms (including their toxins), viruses and parasites. Horizontal topics such as development of standard for genomic analysis as well as general standard for method validation are included in the scope of the SC 9.

This webpage contains various sections to cover news (hot topic), on-going projects, guidelines and relevant information to contact committee manager as well as chairperson.

- Guides for ISO 16140-series
- Links to calculation tools, recorded webinars etc
- Table with control strains for performance testing of culture media and reagents from published standards from food, feed and water microbiology

CEN/TC 463/WG 3 '*Campylobacter*'

- **Amendment 1** to ISO 10272:2017 (one for each part)
- The amendments include;
 - The addition of 3 informative annexes:
 - Annex D: A PCR method for confirmation of thermotolerant *Campylobacter* spp.
 - Annex E: Two PCR methods for confirmation and identification of thermotolerant *Campylobacter* spp.
 - Annex F: The results of an interlaboratory study (ILS) for validation of the PCR methods
 - Updates of table B1 “Performance testing of culture media for *Campylobacter*”.
 - Update of description of indoxyl acetate test
 - For part 1: Update of composition of Preston broth

Stage process Amd 1 to ISO 10272:2017

- Enquiry stage (DIS): 2021-11-25 to 2022-02-24

100% approval ISO DIS and CEN Enquiry for both parts
National Members; Approval: 17, Abstention: 15
Comments: by 7 Members (14/13 pages)

- ISO FDIS started 2021-09-02 and close on **2022-10-28**.



Future work for CEN/TC 463/WG 3 '*Campylobacter*'

- Every 5 years, SC9 and CEN members are asked if they think a full review is needed for a standard
- Ballot on revision of ISO 10272:2017 was closed 2022-09-02
- One member voted for revision of both parts.
- Comments raised on next slide:

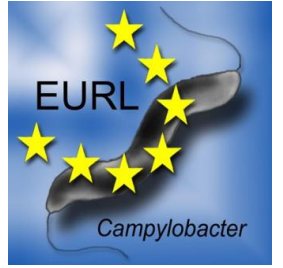


Future work for CEN/TC 463/WG 3 '*Campylobacter*'

- **Comments raised in ballot for revision of ISO 10272-1**
 - The performance of Preston broth should be improved.
 - Changes/additions in the Amd (inclusion of molecular methods, corrections for performance testing) to be included in a full standard
 - The standard is not fully validated (fifth food category missing for "broad scope")
- **Comments raised in ballot for revision of ISO 10272-2**
 - Changes/additions in the Amd (inclusion of molecular methods, corrections for performance testing) to be included in a full standard
 - The standard is not fully validated (fifth food category missing for "broad scope")



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Thank you for your attention!

Questions?