



National Institute for Public Health
and the Environment
Ministry of Health, Welfare and Sport

Update on activities in ISO and CEN

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Relevant groups in ISO and CEN

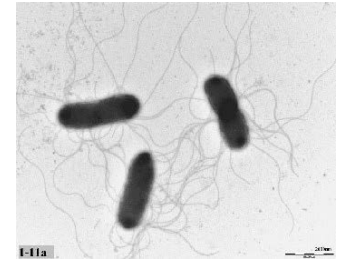
- ISO/TC34/SC9: International Standardisation Organisation / Technical Committee 34 on Food products / Subcommittee 9 - Microbiology of the food chain
- CEN/TC463: European Committee for Standardisation / Technical Committee 463: Microbiology of the food chain

Next annual (hybrid) meeting: 10-14 June 2024, St. Louis, USA

Salmonella activities in:

ISO/TC34/SC9 – WG9 'Detection of *Salmonella*'

ISO/TC34/SC9 – WG10 'Typing of *Salmonella*'



WG9 Detection of *Salmonella*

EN ISO 6579-1:2017/Amd.1:2020 'Microbiology of the food chain - Horizontal method for the detection, enumeration and serotyping of *Salmonella* - Part 1: Detection of *Salmonella* spp. – Amendment 1: Broader range of incubation temperatures, amendment to the status of Annex D, and correction of the composition of MSRV and SC'

Aims reactivated WG9:

1. To complete the performance characteristics of ISO 6579-1 ('Detection of *Salmonella*) for all relevant product categories (broad range of food, animal feed, environmental samples and samples from the primary production stage).
2. To consider the comments to ISO 6579-1:2017 from the systematic review of 2022.



Summary activities WG9 2023-2024

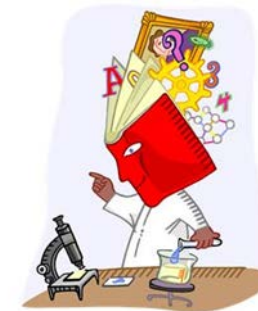
- › 28 March 2023: 1st meeting WG 9 (online): agreed to start with literature review of validation studies (especially Afnor and MicroVal validations) .
- › 26-30 June 2023: plans WG9 presented at annual meeting ISO/TC34/SC9.
- › Fall 2023: review validation studies of Afnor, MicroVal and Nordval.
- › 15 January 2024: 2nd meeting WG 9 (online):
 - Presentation results literature review;
 - Discussion next steps for completion of the performance characteristics of ISO 6579-1.
 - Presentation external WG about a study on use of BPW instead of milk for pre-enrichment cocoa samples.
- › March-April 2024: Discussions with ISO-WG3 (Validation) and joint subgroup WG2 ('Statistics') and WG3 ('Validation') on next steps.



Missing performance characteristics in EN ISO 6579-1:2017

- › 2 Additional food categories (to make sure that the standard is validated for a broad range of food);
- › Animal feed (like cereals, flours, bone meal, soybean meal, fish, meat);
- › Environmental samples from the food or feed production (like swabs, dusts, process water);
- › Larger test portion sizes (>25 g);
- › LOD₅₀ values for use of MSRV agar as (second) selective enrichment medium for analysing food/feed/environmental samples.





Results literature review

- › In total 10 validation studies (interlaboratory studies – ILS) with data of possible use for generation performance characteristics.
- › These 10 studies include 6 additional categories: 5 different food categories, plus category pet food and animal feed.
- › Performance characteristics still lacking for:
 - Environmental samples from the food or feed production.
 - LOD₅₀ values for use MSRV testing food/feed/environment.
 - Larger test portion sizes (>25 g).



Combine PT and ILS environmental samples? - I

- › EURL-*Salmonella* organises a PT on environmental samples from food/feed production in Sept 2024, including (often) use of MSRV.
- › Can data of this PT also be used to determine performance characteristics?
- › Aims PT and ILS are different:
 - In an PT the performance of laboratories is tested.
 - In an ILS the performance of methods is tested.
- › Protocol ILS shall be based on ISO 17468 and ISO 16140-2:
 - At least 10 valid datasets from at least 10 participants;
 - Participants from at least 5 different organisations;
 - Participants from at least 2 different countries;
 - 24 samples (3 different concentrations) tested by each participant;
 - At least 240 results needed (80 results per level).





Combine PT and ILS environmental samples? - II

- › In EURL-*Salmonella* PT: approx. 34 NRLs-*Salmonella* participate from approx. 34 different countries.
- › In EURL-*Salmonella* PT: also 3 different concentrations are used, but less samples than prescribed for an ILS.
- › In ILS: low concentrated samples should result in 'fractional recovery' (approx. 50% of samples tested pos.) – this may be different for a PT.
- › Agreement of ISO-WG2/3 with proposed set-up combi PT-ILS:
 - Adapted number of samples and concentrations in samples;
 - Less samples (16 instead of 24) but more participants (34 instead of 10) than prescribed for an ILS.





ISO-WG9 next steps



- › 3rd WG 9-meeting (online) planned on 4 June 2024:
 - Present outcome discussions ISO-WG3 and ISO-WG2/3.
 - Discuss options for validation of larger test portion sizes.
 - Next steps.
- › Present progress WG9 at annual meeting of ISO/TC34/SC9 (11-14 June).
- › Organisation PT-ILS for 'environmental samples from the food or feed production' in Sept/Oct 2024 and analysis & reporting results. Results expected beginning 2025
- › Analysis of available data from literature for remaining categories. Results also expected beginning 2025.
- › WG 9 will explore options for organisation of an ILS for the validation of larger test portion sizes.



WG10 Typing of *Salmonella*

Development of **ISO(/TS) 6579-4**: 'Microbiology of the food chain - Horizontal method for the detection, enumeration and serotyping of *Salmonella* - Part 4: Identification of monophasic *Salmonella* Typhimurium (1,4,[5],12:i:-) by polymerase chain reaction (PCR)'.

Describes 3 different PCR methods, applicable for:

- > differentiation of the isolate under analysis between monophasic *Salmonella* Typhimurium and the monophasic variant of another *Salmonella* non-Typhimurium serovar;
- > identification of the isolate under analysis being either monophasic *Salmonella* Typhimurium or (biphasic) *Salmonella* Typhimurium.



Summary activities WG10 2023-2024

- › 1 June - 12 July 2023: 6th draft ISO/DTS 6579-4 sent to members of ISO/TC34/SC9 and CEN/TC463 and to NRLs-*Salmonella* for comments.
- › 26-30 June 2023: Progress WG10 presented at annual meeting SC9: agreed to change status of document in full ISO instead of TS.
- › August – October 2023: Preparation of draft ISO/DIS 6579-4.
- › 22 Dec 2023 – 15 March 2024: CEN enquiry and ISO/DIS 6579-4 ballot.
- › 16 March 2024: Results CEN & ISO ballot 100% approval; 19 pages comments (mainly editorial).
- › March-April 2024: (draft) observations given to comments of ISO/DIS 6579-4 and preparation draft FDIS 6579-4.
- › 23 April 2024: 5th meeting (online) ISO-WG10: discussion draft observations to comments of ISO/DIS 6579-4 and draft FDIS 6579-4.



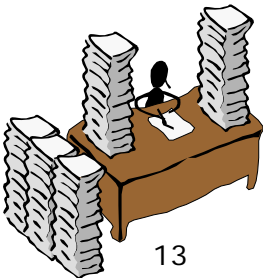
ISO-WG10 next steps

- › Submission of final draft ISO/FDIS 6579-4 to ISO/TC34/SC9 for launching the FDIS-ballot (before 5 July 2024).
- › Present progress WG9 at annual meeting of ISO/TC34/SC9 (11-14 June).
- › Publication of ISO 6579-4 expected by the end of 2024.
- › In meantime the report on validation (method evaluation and ILS) of ISO 6579-4 will be finalised (currently ready in draft) and will become available through EURL-*Salmonella* website.



ISO-AHG1 Guidance doc for drafting ISO/CEN standards

- › ‘Internal’ Guidance document to help convenors and project leaders ISO/TC34/SC9 and CEN/TC463 with the drafting of ISO/CEN documents.
- › To harmonise content and layout of standards for microbiology of the food chain.
- › Will need regular updating to any new agreements made in ISO and CEN.
- › Edition 1 was published in 2018; ED2 in 2020; ED3 in 2022.
- › April-May 2024: Start preparation draft ED4.
- › June 2024: If needed, incorporate new info from ISO/CEN annual meeting.
- › July/August 2024: Draft ED4 send to AHG 1-members for comments.
- › October 2024: 3rd (web)meeting AHG1.
- › Approx. early 2025: Submission of updated draft ED4 to ISO/CEN-members.





ISO-WG3 Method validation - I

- › **ISO 16140-1:2016** (*'Method validation – Vocabulary'*): First steps revision started April 2023.
- › **ISO 16140-2:2016** (*'Protocol for the validation of alternative (proprietary) methods against a reference method'*): First steps revision started April 2023; official revision after publication of ISO 16140-2/Amd1.
- › **ISO 16140-2/Amd.1** (*'Revision of qualitative method ...'*): FDIS ballot: 29/4 – 24/6 2024.
- › **ISO 16140-3:2021/Amd.1** (*'Protocol for the verification of reference methods and validated alternative methods in a single laboratory'*): to include info of ISO 16140-6 and -7; CD ballot: 1/5 – 13/6 2024.



ISO-WG3 Method validation - II

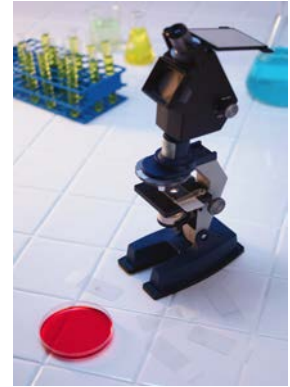
- › **ISO 16140-4:2020/Amd.1** (*'Protocol for method validation in a single laboratory/ Validation of a larger test portion size for qualitative methods'*): FDIS ballot: 29/4 – 24/6 2024.
- › **ISO 16140-4/Amd.2**: to include info of ISO 16140-6 and -7; CD ballot: 1/5 – 13/6 2024.
- › **ISO 16140-7** (*'Protocol for the validation of identification methods of microorganisms'*): FDIS voting: summer 2024.
- › **ISO 16140-8** (*'Protocol for the validation of alternative methods against a reference method for viruses or parasites'*): development started fall 2023.
- › **ISO 16140-9** (*'Protocol for the validation of alternative methods for preformed bacterial toxins and biogenic amines in food intended for human consumption'*): development started fall 2023.



ISO-WG3 Method validation - III

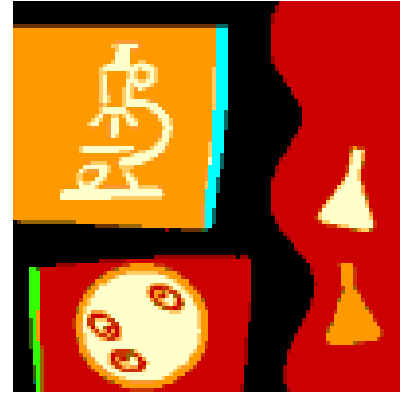


- › **ISO 17468** ('Technical requirements and guidance on the establishment or revision of a standardized reference method'): revised version published December 2023.
- › **Subgroup WG2/WG3**: Joint sub-group of WG 2 (Statistics) and WG 3 (Method validation) to: 'Review evaluation/validation protocols for ISO standards'
- › **WG 3/Project Group** 'Drafting templates for (interlaboratory) study protocols': templates for comments by SC9 16/4-22/5.



ISO-JWG5 revision ISO 11133

- › Title: *'Microbiology of food, animal feed and water - Preparation, production, storage and performance testing of culture media'*
- › ISO 11133 was published in 2014.
- › Amd.1 'Corrections and explanations' published in 2018.
- › Amd.2 'Performance testing of confirmation media and reagents' published in 2020.
- › Table with control strains for performance testing of culture media and reagents from published standards from food, feed and water microbiology published at website ISO/TC34/SC9: <https://committee.iso.org/home/tc34sc9>
- › ISO/CD 11133 ballot 10/1 – 6/3 2024: 50 pages comments.



ISO-WG7 Revision of ISO 7218

- › Revision of ISO 7218:2007/A.1:2014 started in 2019.
- › Title: 'Microbiology of the food chain — General requirements and guidance for microbiological examinations'
- › FDIS ballot: 31/1 – 27/3 2024: 97% positive, 23 pages comments.



ISO-WG8 ISO 6887 series

- › General title: 'Preparation of test samples, initial suspension and decimal dilutions'.
- › **ISO 6887-1:2017/Amd.1** (*'General rules for the preparation of the initial suspension and decimal dilutions'*): Amd.1 to update info on validation of larger test portion sizes (parallel to ISO 16140-4/Amd.1): FDIS ballot 29/4-24/6 2024.
- › **Revision ISO 6887-4:2017** (*'Specific rules for the preparation of miscellaneous products'*): Call on needs of modifications in SC9 18/1 – 29/2 2024.



Any questions?

