

# Scientific and regulatory outcomes of the CEN Mandate in the microbiology of the food chain

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## Abstract

Reference methods in the field of microbiology of the food chain are standardised at the European level by the European Committee for Standardization (CEN) and at international level by the International Organization for Standardization (ISO). Historically, these methods were not fully validated. In 2010, the European Commission gave a mandate to CEN to fully validate a set of 15 methods covering the main bacteria, viruses, as well as bacterial toxins and metabolites, through inter-laboratory studies, and to standardise these methods or to revise the existing standards. The programme ended in July 2017 with the publication of the corresponding 15 CEN/ISO validated Standards. In addition, the *International Journal of Food Microbiology* recently published a special issue with the results of the validation studies that were conducted, and the European Regulation (EC) 2073/2005 on microbiological criteria was amended to include references to the new standards resulting from the CEN Mandate.



## Keywords

- ★ Food Microbiology
- ★ Methods
- ★ Validation studies

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Reliable microbiological methods in microbiology of the food chain represent an important tool for risk managers (public control authorities) and food business operators to ensure that safe food is provided to consumers. Reference methods applicable to the whole food chain, from primary production, food processing to the provision of food products to consumers, are standardised at the European level by CEN/TC 275/WG 6 and at the international level by ISO/TC 34/SC 9. Both standardisation bodies work closely together as part of a CEN/ISO cooperation agreement to establish common CEN/ISO Standards in most cases. In the past, these standardised reference methods were based on experts' opinions and, sometimes, experimental data, but were not fully validated through inter-laboratory studies (ILS). A European project, SMT4-CT96-2098, conducted from 1997 to 2000 and financed by the European Commission (EC), made it possible to validate six standardised methods on the enumeration of *Bacillus cereus*, coagulase-positive staphylococci, *Clostridium perfringens*, *Listeria monocytogenes*, as well as on the detection of *L. monocytogenes* and *Salmonella* (Lahellec, 1998).

In 2010, EC gave a mandate to CEN, with € 3.1m of funding, (i) to validate a set of 15 reference methods in the field of food chain microbiology using ILS, and (ii) to standardise these methods, or to revise the existing standards, including the performance characteristics resulting from the validation studies. These methods were selected as reference methods in European Regulation (EC) 2073/2005 on microbiological criteria for food (Anonymous, 2005) for the microorganisms covered by existing criteria, or may be included at a later stage, because this regulation is regularly amended. This regulation is directly applicable to own-checks conducted by food business operators, but also indirectly to official controls defined in Regulation (EU) 2017/625 (Anonymous, 2017). These methods mostly deal with bacteria (*Campylobacter* spp., *Cronobacter* spp., *Enterobacteriaceae*, *Escherichia coli* O157, *L. monocytogenes*, *Salmonella* spp., *Vibrio cholerae*-*Vibrio parahaemolyticus*, *Vibrio vulnificus*, pathogenic *Yersinia enterocolitica*) but also viruses (norovirus, hepatitis A virus), bacterial toxins (*B. cereus* cereulide toxin, staphylococcal enterotoxins) and a bacterial metabolite (histamine). Each method has been validated and standardised in a CEN/TC 275/WG 6 task group led by a project leader, most of whom belonged to a EU Reference Laboratory for the microorganism in question, if relevant. The 15 validation trials were carried out by 150 laboratories in 35 countries, mainly in Europe but also in the USA. This CEN mandate ended in July 2017 with the publication of the 15 new or revised CEN/ISO Standards. In addition, this programme gave a sound basis for the development of the EN ISO 17468 Standard on the establishment or revision of a standardised reference method, with, in particular, the validation studies required (Anonymous, 2016).

This is the largest international programme to validate standardised methods in the microbiology of the food chain. Its scientific outcome led to the publication in January 2019 of a special issue of the *International Journal of Food Microbiology*, coordinated by Alexandre Lelercq. This issue compiles papers describing each validation study, written by their respective project leaders (*European and international validation of 15 main reference methods in the microbiology of the food chain*, 2019). The validation study on the detection of staphylococcal enterotoxins is expected to be published separately.

From a regulatory point of view, the significant outcome of this mandate was the recent publication of Regulation (EU) 2019/228 amending Regulation (EC) 2073/2005 (Anonymous, 2019). In particular, the reference to two new standards has been introduced: EN ISO 19020 for the detection of staphylococcal enterotoxins and EN ISO 19343 for the quantification of histamine. Other standards were already included in the regulation as undated references; their reference has been updated when necessary and their new version is automatically applicable. In addition, the expression of the qualitative limit in criteria has been modified from "absence in x g" to "not detected in x g", in accordance with the new versions of standardised qualitative methods.

Finally, the performance characteristics derived from the ILS conducted as part of this CEN Mandate provide essential information for (i) public authorities on the performance of the me-



thods used for official controls to check compliance with regulatory criteria; (ii) food business operators on the methods to use for their own checks; (iii) food microbiological laboratories on validated methods for their EN ISO 17025 accreditation (Anonymous, 2017) and (iv) validation/certification bodies to validate alternative commercial methods in comparison with fully characterised reference methods.

## References

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