



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL
Directorate D - Food Safety: production and distribution chain
D2 - Biological risks

Brussels, 19th January 2006

M / 381 EN

MANDATE FOR STANDARDISATION
ADDRESSED TO CEN
in the field of
METHODS OF ANALYSIS OF FOODSTUFFS
CONCERNING FOOD HYGIENE

1. MOTIVATION.

1.1 This mandate falls within the framework of food hygiene legislation setting down rules to ensure food safety in relation to biological hazards, in particular

- Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
- Regulation (EC) No 852/2004 of the European Parliament and the Council of 29 April 2004 on the hygiene of foodstuffs
- Regulation (EC) No 853/2004 of the European Parliament and the Council of 29 April 2004 laying down specific rules for food and animal origin
- Regulation (EC) No 854/2004 of the European Parliament and the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption.
- Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90424/EEC and repealing Council Directive 92/117/EEC

This legislation covers the whole food chain from the primary production up to the consumer.

Regulation 882/2004 provides that sampling and analysis methods used in the context of official controls shall comply with relevant Community rules or, if no such rules exist, with internationally recognised rules or protocols, for example those that the European Committee for Standardisation (CEN) has accepted.

In particular, the Commission Regulation (EC) No¹ on microbiological criteria for foodstuffs contains provisions requiring the use of analytical methods in the field of

¹ Pending adoption and publication

food hygiene including production environment. It is addressed to food business operators, so that their products must comply with microbiological criteria set down in this Regulation. The Regulation will apply from 1 January 2006.

- In this Regulation a reference method has been fixed for each microbiological criterion. Horizontal EN or EN ISO methods, when available, have received the status of reference methods in the Regulation. However, food business operators may use other testing methods, if they can demonstrate to the satisfaction of the competent authority that these procedures provide at least equivalent guarantees. (EN ISO standard 16140, Protocol for the validation of alternative methods.)

1.2 In the field of food hygiene including production environment there is a lack of standardised and validated methods. Those methods having a status of a reference method in Community legislation should preferably be standardised and validated. In Commission Regulation on microbiological criteria for foodstuffs intended for food business operators' in-house control checks, reference methods are fixed for each microbiological criterion. As regards official controls the reference methods play an important role particularly in the event of a dispute (Regulation (EC) 882/2004). Regulation 882/2004 includes provisions for the Community reference laboratories (CRL). They have a significant coordinating role in relation to national reference laboratories. They are e.g. responsible in their area of competence for providing national reference laboratories with details of analytical methods, including reference methods, and coordinating practical arrangements needed to apply new analytical methods and informing national reference laboratories of advantages in this field. The expertise and experience of the CRLs could be utilised when new methods in the field of food hygiene are developed, standardised and validated.

- 1.3 The establishment of standardised reference methods is of utmost importance to guarantee a uniform application and control of Community legislation in all Member States. Standardised and validated reference methods are an indispensable element in guaranteeing a high level of food safety, and are the references against which other methods can be validated.

2. DESCRIPTION OF THE MANDATED WORK.

The Commission mandates the CEN to produce standards of methods requested and to ensure that those methods have been validated as presented in point 2. in Annex III of Regulation (EC) No 882/2004. This is important in order to be able to verify in a harmonised way compliance with the provisions of Community legislation in the field of food hygiene including production environment.

The methods of analysis are listed in tables 1, 2 and 3 in the Annex I

- Table 1: Elaboration of validated CEN standards
- Table 2: Elaboration of validated CEN standards from existing ISO standards
- Table 3: Validation of the existing EN ISO standards and revision of the standards

3. BODIES TO BE ASSOCIATED

The elaboration of the standards and their validation should be undertaken in co-operation with the International Organisation for Standardization (ISO), the Nordic Committee on Food Analysis (NMKL), the Community Reference Laboratories as relevant (no single contact point, but a contact point for single issues), the World Organisation for Animal Health (OIE).

ANEC (European Association for the co-ordination of consumer representation in standardisation), ECOS (European Environmental Citizens Organisation for Standardisation) and NORMAPNE (European Office of Craft/Trades and Small and Medium-sized Enterprises for Standardisation) will be invited to take part in the mandated work.

The CEN will also invite the Commission to participate in the standardisation work covered by this mandate.

4. EXECUTION OF THE REQUEST.

- 4.1 CEN will have to present the draft standards mentioned above by the date specified in the tables in Annex I. The European standards will have to be adopted by the agreed dates. On these dates, the three linguistic versions (DE, EN, FR) must be available as well as the correct titles in the other official Community languages.
- 4.2 The acceptance of this standardisation mandate by CEN will provide a more complete set of standardised as well as validated standardised methods of analysis, thereby contributing to a high level of food safety and to a proper functioning of the internal market.
- 4.3 To improve transparency, the CEN will inform the Commission of any new programme of activities, not covered by this mandate, planned on methods of analysis and their validation in the field of food hygiene concerning biological hazards.
- 4.4 The CEN will keep the Commission informed of the measures taken to execute this mandate and of any difficulties, which arise in the process. By 30 November each year, the CEN will submit a progress report on the activities of the various working parties concerned by this mandate.
- 4.5 Collaborative studies performed in connection with validation are considered an integrated part of the mandate.
- 4.6 The standstill period referred to in Article 7 of Directive 98/34/EC of 22 June 1998 shall commence when the CEN accepts this mandate².

Annex: I Programme

² OJ L 204, 21.7.1998, p. 37. Regulation as amended by Directive 98/48/EC (OJ L 217, 5.8.1998, p. 18)

CEN/TC 275

Food Analysis

ANNEX I

PROGRAMME

Table 1. ELABORATION OF VALIDATED CEN STANDARDS

N	Title	Deadlines for EN	Reference to the legislation
1	Detection of food-borne viruses in food based on PCR technique	2009	Regulation (EC) No 178/2002 ¹
2	Histamine	2009	Commission Regulation on microbiological criteria for foodstuffs ²
3	Staphylococcal enterotoxin detection for dairy products and other matrixes	2010	Commission Regulation on microbiological criteria for foodstuffs ²
4	<i>Bacillus cereus</i> enterotoxin detection in food (emetic and diarrheal toxins)	2010	Regulation (EC) No 178/2002 ¹

¹Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

²Commission Regulation on microbiological criteria for foodstuffs, pending adoption and publication

Table 2. ELABORATION OF VALIDATED CEN STANDARDS FROM EXISTING ISO STANDARDS

N	Title	Deadlines for EN	Reference to the legislation
1	Detection of <i>Enterobacter sakazakii</i> (Reference document: ISO/DTS 22964, not existing yet)	2008	Commission Regulation on microbiological criteria for foodstuffs ¹
2	Detection of pathogenic <i>Vibrio</i> Reference document: ISO/TS 21872 -1, -2	2009	Regulation (EC) No 178/2002 ²
3	Enterobacteriaceae Reference document: ISO 21528-1	2008	Commission Regulation on microbiological criteria for foodstuffs ¹

¹ Commission Regulation on microbiological criteria for foodstuffs, pending adoption and publication

² Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

Table 3. VALIDATION OF THE EXISTING CEN STANDARDS AND REVISION OF THE STANDARDS

N	Title	Deadlines for EN	Reference to legislation
1	<i>Listeria monocytogenes</i> standard (Validation and revision of EN/ISO 11290 -1, -2/Amd. 1)	2008	Commission Regulation on microbiological criteria for foodstuffs ¹
2	<i>E. coli</i> O157 standard (Validation and revision of EN/ISO 16654)	2009	Regulation (EC) No 178/2002 ²
3	<i>Campylobacter</i> growing at 41,5 degrees, detection (Validation and revision of EN/ISO 10272 -1, method not finished yet)	2009	Regulation (EC) No 178/2002 ²
4	<i>Campylobacter</i> growing at 41,5 degrees, enumeration (Validation and revision of EN/ISO 10272 -2, method shall become ISO/TS)	2009	Regulation (EC) No 178/2002 ²
5	Detection of <i>Salmonella</i> in faeces (Validation and revision of EN/ISO 6579/Amd. 1)	2008	Regulation (EC) No 2160/2003 ³
6	Presumptive <i>Yersinia enterocolitica</i> (Validation and revision of EN/ISO 10273)	2010	Regulation (EC) No 178/2002 ²

¹Commission Regulation on microbiological criteria for foodstuffs, pending adoption and publication

²Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

³Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other zoonotic agents