

## **BUSINESS PLAN**

### **CEN/TC 275**

#### **Food analysis – Horizontal methods**

#### **EXECUTIVE SUMMARY**

##### **Business Environment**

- Internal trade of food, drinks, tobacco in Euro-Zone in thousand millions of Euro in 2017:
  - Export: approximately 190,5
  - Import: approximately 187,3
- EU legislation in the field of foodstuffs (as later on in detail)
- Interested parties:
  - Consumers;
  - Farmers, Food distributors, Food industry;
  - Official and private food control laboratories; and food inspection;
  - National Agencies for Food Safety and ECDC/EFSA
  - European Commission, DG Santé & DG GROW.

CEN/TC 275 works in close collaboration with ISO/TC 34, with a number of common standards developed under the Vienna agreement, with either an ISO or a CEN lead, thus seeking to ensure common international requirements or guidelines, both within and outside Europe to facilitate trade exchange and international protection of consumers and travelers.

##### **Benefits**

The user of the standards, i.e. the analysts in the laboratories, have the possibility to use methods of analysis which

- have already been successfully validated;
- are described in an understandable and clear manner;
- give clear instructions in which cases they are applicable;
- have high levels of recognition compared to non-standardized methods;
- are referenced in a national or European regulation or in *Codex Alimentarius*.
- work.

Risk managers have the possibility to use methods of analysis which are fully validated with defined performance characteristics and scope, recognized and confirmed to fit-for-purpose for assessing compliance of samples or goods to defined official criteria of regulation.

The consumers of foods will be protected from low quality foodstuffs which may not be assessed as not safe but which do not fulfil the European legislation concerning the allowed contents of additives, residues or contaminants.

By applying harmonized methods of food analysis standardized by CEN/TC 275, food industry and food control can avoid generating conflicting results when using different methods. One aim of CEN/TC 275 is to develop, if possible, full EN ISO standards in the area of food microbiology that are more recognized than Technical Specifications in CEN member states.

Since 1991, 137 European Standards, 67 EN ISO standards, 28 Amendments of (EN and EN ISO standards, 20 CEN/Technical Specifications, 8 CEN/ISO TS), 9 CEN/Technical Reports, 1 CEN/ISO TR) and 6 Prestandards were adopted. Since the beginning of CEN/TC 275, 26 of the now existing 104 European Standards and 12 of the now existing 55 EN ISO standards were updated and re-published, 9 of the Technical Specifications and 5 of the European Prestandards (ENVs) were transformed into ENs, and 13 once available Amendments were taken up in the now revised versions. CEN/TC 275 is currently having 44 active work items and 3 preliminary work items.

## **Priorities**

CEN/TC 275 sets priorities for methods to be standardized according to the current EU-legislation and actual needs (e.g. pesticides, mycotoxins, microbiology, allergens, process contaminants and algal toxins).

# **1 BUSINESS ENVIRONMENT OF THE CEN/TC**

## **1.1 Description of the Business Environment**

The work of CEN/TC 275 concerns the trade of all kinds of foodstuffs, as defined in European regulation EC 178/2002. The interested parties in the standardization process are all institutions which deal with the trade of foods and with quality of foodstuffs, e.g. food producers (large and small companies), food trade institutions, official and private food inspection services, consumer's protection institutions.

Moreover, in some specific area such as Microbiology (WG 6), the scope of CEN TC 275 covers the food chain and began from primary production samples (samples of animal faeces, or from the environment of animals or non-faecal samples from breeding flocks) and irrigation water until consumed food and bottled water but also covers environmental samples in the area of food/feed production and food/feed handling.

CEN/TC 275 does not work on animal health but the international mirror committee for microbiology, i.e. ISO/TC 34/SC 9 is in liaison with World Organisation for animal health (OIE) when their standardized methods cover samples of primary production. CEN/TC 275 standards for Microbiology were reported in the OIE terrestrial manual.

The scope of CEN/TC 275 is as follows:

*Standardization of methods of analysis for the detection and/or determination of*

- additives, residues and contaminants in food,*
- nutrients in food and food supplements,*
- irradiated foodstuffs,*
- food allergens,*
- genetically modified foodstuffs,*
- species (excluding methods which are dealt by vertical CEN-Technical Committees).*

*In addition, standardization of horizontal microbiological methods for all food and animal feeding stuffs and for any other sample that can be the source of microbial contamination of food products (no human samples).*

*In general, CEN/TC 275 does not elaborate standards on terminology.*

### **1.1.1 Legislation on the official control and ownchecks control of foodstuffs**

The European standards shall be available as quotable reference documents for existing and future European and Swiss directives and regulations. In brief, it can be stated that the European legislation lays down that consumers shall be protected, i.e. foods as traded in the European market shall be analysed for acceptability concerning the content of additives, residues and contaminants. Maximum levels of additives, residues and contaminants are fixed within several European directives and regulations. The overall aim of CEN/TC 275 is to support for the European consumer's health protection. This is why CEN/TC 275 already received four Mandates i.e. Standardization Requests for the following areas irradiated foodstuffs, microbiology (M381), mycotoxins (M383), heavy metals (M422), process contaminants (M463) and again mycotoxins (M520).

All the following listed legislations are meant including amendments.

#### **1.1.1.1 General (horizontal) legislation on the official control of foodstuffs**

At present, the following regulations exist:

**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

Excerpt: (3) The free movement of food and feed within the Community can be achieved only if food and feed safety requirements do not differ significantly from Member State to Member State.

(4) There are important differences in relation to concepts, principles and procedures between the food laws of the Member States. When Member States adopt measures governing food, these differences may impede the free movement of food, create unequal conditions of competition, and may thereby directly affect the functioning of the internal market.

**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 (including Corrigendum to 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 (OJL 165, 30.4.2004))

Excerpt: Article 11: Methods of sampling and analysis

1. Sampling and analysis methods used in the context of official controls shall comply with relevant Community rules or,

(a) if no such rules exist, with internationally recognised rules or protocols, for example those that the European Committee for standardisation (CEN) has accepted or those agreed in national legislation; or, ..."

And its successor:

**Regulation (EU) 2017/625** of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law ...

Excerpt CHAPTER IV Sampling, analyses, tests and diagnoses

Article 34 Methods used for sampling, analyses, tests and diagnoses

1. Methods used for sampling and for laboratory analyses, tests and diagnoses during official controls and other official activities shall comply with Union rules establishing those methods or the performance criteria for those methods.

2. In the absence of the Union rules as referred to in paragraph 1, and in the context of official controls and other official activities, official laboratories shall use one of the following methods according to the suitability for their specific analytical, testing and diagnostic needs:

(a) available methods complying with relevant internationally recognised rules or protocols including those that the European Committee for Standardisation (CEN) has accepted; or

relevant methods developed or recommended by the European Union reference laboratories and validated in accordance with internationally accepted scientific protocols; (...)

**Commission Regulation (EC) No 669/2009** of 24 July 2009 implementing Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin and amending Decision 2006/504/EC

**Regulation (EC) No 852/2004** of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs

**Regulation (EC) No 853/2004** of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin

**Regulation (EC) No 854/2004** of the European Parliament and of 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

#### **1.1.1.2 Specific legislation on food additives**

**Commission Directive 91/321/EEC** of 14 May 1991 on infant formulae and follow-on formulae.

**Commission Directive 1999/21/EC** of 25 March 1999 Dietary foods for special medical purposes

**Commission Directive 2006/141/EC** of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC.

**Commission Directive 96/5/EC** of 16 February 1996 on processed cereal-based foods and baby foods for infants and young children

**Commission Directive 96/8/EC** of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction

**Directive 2002/46/EC** of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements

**Regulation (EC) No 1924/2006** of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods

**Regulation (EC) No 1925/2006** of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods, amended by

**Commission Regulation (EC) No 1170/2009** of 30 November 2009, which amends also Directive 2002/46/EC of the European Parliament and of Council, see above

**Regulation (EC) No 1331/2008** of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings

**Regulation (EU) No 231/2012** of the European Parliament and of the Council of on specification on food additives

**Regulation (EC) No 1333/2008** of the European Parliament and of the Council of 16 December 2008 on food additives.

**Regulation (EU) 497/2014 of 18 May 2014**, fixing the use conditions, dosage and food applications

### **1.1.1.3 Specific legislation on pesticide residues**

**Council Regulation (EC) No 396/2005** of 23 February 2005, on maximum residue levels of pesticides in or on food and feed of plant and animal origin.

### **1.1.1.4 Specific legislation for contaminants**

**Council Regulation (EC) No 396/2005/EEC** of 23 February 2005, on maximum residue levels of pesticides in or on food and feed of plant and animal origin, which is also relevant for copper and mercury.

**Council Regulation (EC) No 315/93** of 8 February 1993 laying down Community procedures for contaminants in food

Excerpt: It is essential, in the interest of public health protection, to keep contaminants at levels which are toxicologically acceptable. Food, containing a contaminant in an amount which is unacceptable from the public health viewpoint, - and in particular at a toxicological level, shall not be placed on the market.

**Commission Regulation (EC) No 401/2006** of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs

**Commission Regulation (EC) No 1881/2006** of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs

**Commission Regulation (EC) No 1882/2006** of 19 December 2006 laying down methods of sampling and analysis for the official control of the levels of nitrate in certain foodstuffs

**Commission Regulation (EC) No 333/2007** of 28 March 2007 laying down the methods of sampling and analysis for the control of the levels of trace elements and processing contaminants in foodstuffs

**Commission Implementing Regulation (EU) No 884/2014** of 13 August 2014 imposing special conditions governing the import of certain feed and food from certain third countries due to contamination risk by aflatoxins and repealing Regulation (EC) No 1152/2009.

**Commission Recommendation** of 15 March 2012 on the monitoring of the presence of ergot alkaloids in feed and food **(2012/154/EU)**

**Commission Recommendation** of 27 March 2013 on the presence of T-2 and HT-2 toxin in cereals and cereal products **(2013/165/EU)**

**Commission Regulation (EC) No 2074/2005** of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 and (EC) No 854/2004 (amongst others for marine Biotoxins)

**Commission Regulation (EC) No 589/2014** laying down methods of sampling and analysis for the control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs.

**Commission Recommendation (EC) 2014/661** on the monitoring of the presence of 2- and 3-Monochloropropane-1,2-diol (2- and 3-MCPD), 2- and 3-MCPD fatty acid esters and glycidyl fatty acid esters in food

**Commission Regulation** of 20 November 2017 establishing mitigation measures and benchmark levels for the reduction of the presence of acrylamide in food **(EU) 2017/2158**

**Commission Recommendation** of 10 September 2014 on good practices to prevent and to reduce the presence of opium alkaloids in poppy seeds and poppy seed products **(2014/662/EU)**

**Commission Recommendation** of 1 December 2016 on the monitoring of the presence of  $\Delta^9$ -tetrahydrocannabinol, its precursors and other cannabinoids in food **((EU) 2016/2115)**

**Commission Recommendation** of 4 April 2014 on the reduction of the presence of cadmium in foodstuffs **(2014/193/EU)**

**Commission Recommendation** of 29 April 2015 on the monitoring of the presence of perchlorate in food **(EU) 2015/682**

**Commission Regulation (EU) 2017/1980** amending Annex III to Regulation (EC) No 2074/2005 as regards paralytic shellfish poison (PSP) detection method

#### **1.1.1.5 Specific legislation for irradiated foodstuffs**

**Directive 1999/2/EC** of the European Parliament and of the Council of 22 February 1999 on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionizing radiation

**Directive 1999/3/EC** of the European Parliament and Council of 22 February 1999 on the establishment of a Community list of food and food ingredients treated with ionising radiation

**2009/C 283/02** List of Member States' authorisations of food and food ingredients which may be treated with ionising radiation (According to Article 4(6) of Directive 1999/2/EC of the European Parliament and of the Council on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionising radiation)

#### **1.1.1.6 Specific legislation for genetically modified foods and feeds**

**Regulation (EC) No 1829/2003** of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (replacing the requirements for GMO of Regulation (EC) No 258/97 and labelling requirements of Regulation (EC) No 1139/98, Regulation (EC) No 49/2000, Regulation (EC) No 50/2000) (effective as of 18 April 2004)

**Regulation (EC) No 1830/2003** of the European Parliament and of the Council of 22 September 2003 on traceability and labelling of genetically modified organisms and traceability of genetically modified food and feed and amending Directive 2001/18/EC (effective as of 18 April 2004)

**Commission Regulation (EC) No 65/2004** of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (effective as of 16 January 2004)

**Commission Regulation (EC) No 641/2004** of 6 April 2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the application for the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation (effective as of 18 April 2004)

**Commission Recommendation 2004/787/EC** of 4 October 2004 on technical guidance for sampling and detection of genetically modified organisms and material produced from genetically modified organisms as or in products in the context of Regulation (EC) No 1830/2003

**Commission Regulation (EU) No 619/2011** of 24 June 2011 laying down the methods of sampling and analysis for the official control of feed as regards presence of genetically modified material for which an authorisation procedure is pending or the authorisation of which has expired.

#### **1.1.1.7 Specific legislation for allergens**

**Regulation (EU) N° 1169/2011** of the European Parliament and of the Council of 25 October 2011, on the provision of food information to consumers (ANNEX II).

**Commission Implementing Regulation (EU) No 828/2014** of 30 July 2014 on the requirements for the provision of information to consumers on the absence or reduced presence of gluten in food.

#### **1.1.1.8 Specific legislation for microbial contaminants**

##### **Foodstuffs:**

**Commission Regulation (EC) 2073/2005** of 15 November 2005 on microbiological criteria for foodstuffs

**Commission Regulation (EC) No 1441/2007** of 5 December 2007 amending Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs.

**Commission Regulation (EC) No 365/2010** of 28 April 2010 amending Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs as regards Enterobacteriaceae in pasteurised milk and other pasteurised liquid dairy products and *Listeria monocytogenes* in food grade salt.

**Commission Regulation (EU) No 1086/2011** of 27 October 2011 amending Annex II to Regulation (EC) No 2160/2003 of the European Parliament and of the Council and Annex I to Commission Regulation (EC) No 2073/2005 as regards salmonella in fresh poultry meat.

**Commission Regulation (EU) No 1019/2013** of 23 October 2013 amending Annex I to Regulation (EC) No 2073/2005 as regards histamine in fishery products.

**Commission Regulation (EU) No 209/2013** of 11 March 2013 amending Regulation (EC) No 2073/2005 as regards microbiological criteria for sprouts and the sampling rules for poultry carcasses and fresh poultry meat.

**Commission Regulation (EU) No 217/2014** of 7 March 2014 amending Regulation (EC) No 2073/2005 as regards Salmonella in pig carcasses.

**Commission Regulation (EU) 2015/2285** amending Annex II to Regulation (EC) No. 854/2004 of the European Parliament and of the Council laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption as regards certain requirements for live bivalve molluscs, echinoderms, tunicates and marine gastropods and Annex I to Regulation (EC) No. 2073/2005 on microbiological criteria for foodstuffs.

**Commission Delegated Regulation (EU) 2016/127** of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding.

**Commission Implementing Regulation (EU) 2016/443** of 23 March 2016 amending Annex I to Regulation (EC) No 669/2009 as regards the list of feed and food of non-animal origin subject to an increased level of official controls on imports.

**Commission Regulation (EU) No 669/2009** of 24 July 2009 implementing Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin and amending Decision 2006/504/EC.

**Commission Regulation (EU) No 1019/2013** of 23 October 2013 amending Annex I to Regulation (EC) No 2073/2005 as regards histamine in fishery products.

**Commission Implementing Regulation (EU) 2015/1607** of 24 September 2015 amending Annex I to Regulation (EC) No 669/2009 implementing Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin.



### Zoonosis surveillance:

**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 90/424/EEC and repealing Council Directive 92/117/EEC

**Regulation (EU) No 2160/2003** of the European Parliament and of the Council of 17 November 2003 on the control of *Salmonella* and other specified food-borne zoonotic agents.

**Commission Regulation (EU) No 200/2010** of 10 March 2010 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards a Union target for the reduction of the prevalence of *Salmonella* serotypes in adult breeding flocks of *Gallus gallus*.

**Commission Regulation (EU) No 517/2011** of 25 May 2011 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards a Union target for the reduction of the prevalence of certain *Salmonella* serotypes in laying hens of *Gallus gallus* and amending Regulation (EC) No 2160/2003 and Commission Regulation (EU) No 200/2010.

**Commission Regulation (EU) No 200/2012** of 8 March 2012 concerning a Union target for the reduction of *Salmonella enteritidis* and *Salmonella typhimurium* in flocks of broilers, as provided for in Regulation (EC) No 2160/2003 of the European Parliament and of the Council.

**Commission Regulation (EU) No 1190/2012** of 12 December 2012 concerning a Union target for the reduction of *Salmonella Enteritidis* and *Salmonella Typhimurium* in flocks of turkeys, as provided for in Regulation (EC) No 2160/2003 of the European Parliament and of the Council.

**Commission Implementing Regulation (EU) 2015/1375** of 10 August 2015 laying down specific rules on official controls for *Trichinella* in meat

#### 1.1.1.9 Specific legislation for food fraud and species analysis

**Regulation (EU) No 1169/2011** of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, which stipulates stipulates the mandatory declaration of the origin and the requirements/constitution of meat and fishery products (species).

**Commission Implementing Decision (EU) 2015/1918** of 22 October 2015 establishing the Administrative Assistance and Cooperation system ('AAC system') pursuant to Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules, which particularly concerns a possible non-compliance perpetrated through deceptive fraudulent practices, e.g. cases of food fraud (horse meat).

### **1.2 Quantitative Indicators of the Business Environment**

In 2016, the one-way-trade (export) between European countries and other countries with foodstuffs and agricultural products was about 116 Billions € whereas one-way-trade (import) between European countries and other countries with foodstuffs and agricultural products was about 109 Billions € (Source: Eurostat).

Innovations for quality improvements in the food, beverages and tobacco industry is about 1,2 % of the turnover (Source: ZEW (2017): Branchenreport Innovationen 2016 – Nahrungsmittel-Getränke- und Tabakindustrie).

However, the availability of European Standards means that official or private food testing laboratories (including food industry laboratories) in all European countries can use the comprehensible list of methods which give repeatable and reproducible results. Time consuming double research, which method could be the appropriate one for a given problem, will become more and more superfluous. The money such laboratories save due to the availability of this list of methods can not be calculated accurately, however, it can reasonably assumed to be enormous.

European regulation in some specific fields allows to use alternative analytical methods to reference EN standards if they are validated against them according to an EN ISO standard for their validation (e.g. EN ISO 16140 series in microbiology of the food chain). This facility is a main advantage for the market of European manufacturers of proprietary methods based on the presence of two main certification bodies of validated alternative methods in Europe: AFNOR certification (France) and MICROVAL (The Netherlands), and to facilitate the use of updated methods and highthroughput methods in food testing laboratories and their network.

## **2 BENEFITS EXPECTED FROM THE WORK OF THE CEN/TC**

The availability of standardized horizontal methods is of utmost importance to fulfil the requirements of a free movement of goods in the common market and international trade. The basis for a uniform judgment of food in the common market is set up by standardized methods of analysis.

Official or private food testing laboratories (including food industry laboratories), certification/accreditation bodies in all CEN-member countries can make use of the work of CEN/TC 275, i.e. of the comprehensible list of methods that give reliable (repeatable and reproducible) results with defined performance characteristics obtained from validation. In those cases, where already horizontal standards have been elaborated and thus, where in-house methods for a specific use or products are not necessary, it is no longer necessary for analysts in the laboratory to carry out time consuming duplicate research, which method could be the most appropriate one for a given problem. It has to be repeated: The money such laboratories save due to the availability of this list of methods can not be calculated accurately, however, it can reasonably assumed to be enormous. Furthermore, it saves time and money to apply one horizontal method for diverse foods instead of different vertical methods for each kind of food.

The fact that all European laboratories will be familiar with the same methods enables the laboratories to exchange their experience and to easily develop and improve the methods. This is also a prerequisite to the accreditation of these methods according EN ISO 17025 and to evaluate by Proficiency testing scheme performance of food testing laboratories. This helps to protect consumer's health in all European Member Countries.

## **3 PARTICIPATION IN THE CEN/TC**

All the CEN national members are entitled to nominate delegates to CEN Technical Committees and experts to Working Groups, ensuring a balance of all interested parties. Participation as observers of recognized European or international organizations is also possible under certain conditions.

At present, liaisons with the following "internal" institutions exist:

## **CEN/TC 275 Business Plan**

**Date: 2018-10-11**

**Version: Draft 8**

**Page: 11**

CEN/TC 307 "Oilseeds, vegetable and animal fats and oils and their by-products - Methods of sampling and analysis"

CEN/TC 327 "Animal feeding stuffs - Methods of sampling and analysis"

CEN/TC 338 "Cereal and cereal products"

ISO/TC 34 "Food products"

At present, liaisons with the following "external" institutions exist:

EC, European Commission,

ECOS, European Environmental Citizens Organisation for Standardisation

JISC, Japanese Industrial Standards Committee

OIV, International Organization of Vine and Wine

Spirits Europe,

UECBV, l'Union Européenne du Commerce du Bétail et des Métiers de la Viande (The European Livestock and Meat Trades Union)

To participate in the activities of this CEN/TC, please contact the national standards organization in your country.

## **4 OBJECTIVES OF THE CEN/TC AND STRATEGIES FOR THEIR ACHIEVEMENT**

### **4.1 Defined objectives of the CEN/TC**

The objective of CEN/TC 275 is the elaboration of standardized horizontal test methods for the analysis of additives, residues and contaminants in foodstuffs (for all WGs) and samples of primary production (for WG 6), priority was set to aspects of consumer's health.

The scope reads as follows:

"Food analysis - Horizontal methods: Standardization of methods of analysis for the detection and/or determination of - additives, residues and contaminants in food, - nutrients in food and food supplements, - irradiated foodstuffs, - food allergens, - genetically modified foodstuffs, - species (excluding methods which are dealt by vertical CEN-Technical Committees). In addition, standardization of horizontal microbiological methods for all food and animal feeding stuffs and for any other sample that can be the source of microbial contamination of food products (no human samples). In general, CEN/TC 275 does not elaborate standards on terminology."

CEN/TC 275 is active in 12 specific areas and has therefore established 14 working groups and within these 14 working groups several task groups were formed.

**CEN/TC 275 Business Plan**

**Date: 2018-10-11**

**Version: Draft 8**

**Page: 12**

The following table shows in detail the expert groups of CEN/TC 275 and the conveners and secretaries as per October 2018.

<b>Working groups of CEN/TC 275</b>	<b>Name</b>	<b>Secretariat</b>	<b>Convener</b>	<b>Secretary</b>
WG 1	Sulfites	DIN, Germany	NN	Carola Seiler
WG 2	Sweeteners	DIN, Germany	Dierk Martin	Kristin Marquardt
WG 3	Pesticides	DIN, Germany	Magnus Jezussek	Tom Resler
WG 4	disbanded in 2018			
WG 5	Biotoxins	NEN, Netherlands	Martien Spanjer	Hieke Reijnhoudt
WG 6	Microbiology of the food chain	AFNOR, France	Alexandre Leclercq	Gwénola Hardouin
WG 6/TAG 3	General requirements relating to molecular methods	Germany	Kornelia Berghof-Jäger	
WG 6/TAG 4	Viruses in food	UK	James Lowther	
WG 6/TAG 9	Pre-enrichment	Switzerland	David Thomas	
WG 6/TAG 18	E. coli	EU-RL E. coli, IT	Stefano Morabito	
WG 6/TAG 19	Campylobacter	Netherlands	Els Biesta Peters/Wilma Jacobs Reitsma	
WG 7	Nitrate/nitrite	DIN, Germany	NN	Tom Resler
WG 8	Irradiated foodstuffs	DIN, Germany	Irene Straub	Carola Seiler
WG 9	Vitamins and carotenoids	NEN, Netherlands	Erik Konings	Marcel de Vreeze
WG 10	Elements and their chemical species	DIN, Germany	Peter Fecher	Matthias Müller
WG 11	Genetically modified foods and species identification	DIN, Germany	Lutz Grohmann	Carola Seiler
WG 12	Food allergens	DIN, Germany	Manuela Schulze	Marius Löffler
WG 13	Process contaminants	NEN, Netherlands	Jacqueline van der Wielen	Marcel de Vreeze
WG 14	Marine Biotoxins	DIN, Germany	Angelika Preiß-Weigert	Carola Seiler

#### **4.2 Identified strategies to achieve the CEN/TC's defined objectives.**

The task of the WGs is to identify

- which successfully collaboratively tested methods are available;
- which of these give comparable results;
- which of the available methods, if possible one of the comparable ones, is the most appropriate for adoption.

Already from the beginning, the TC has given the responsibility to WGs to elaborate the drafts in a form which complies with the PNE Rules. Checking the PNE-Rules has usually to be done by the WG secretariat but WG experts are also supported by the TC secretariat if the WG secretariat has not enough personnel or financial resources. All meetings are held in English language (no translation). Technical discussions are only held during the meetings of WGs (physical meetings with the possibility of some experts to participate also via web and since 2015 also pure web-meetings), not in the TC, which mainly deals with superior and administrative topics and also takes special care of new needs of methods for European Commission. However, to comply with the Internal Rules of CEN, the TC adopted each draft to be launched for Formal Vote by July 2016. Since then, the secretary and chair decide on the versions to be submitted to Formal Vote – if necessary after consultation with the convener, project leader or secretary of the WG from where the proposal for final draft was elaborated.

The TC and WGs are supported by members/experts from Austria, Belgium, Bulgaria, Czech Republic, Denmark, Finland, France, Germany, Hungary, Ireland, Italy, Lithuania, Netherlands, Norway, Poland, Portugal, Slovenia, Spain, Sweden, Switzerland and the United Kingdom. Not all countries are represented in each WG and at each TC meeting. The technical resources currently available to the working groups include expertise from the interested parties, i.e. food industry, governmental agencies such as food inspection laboratories, private food laboratories and research institutes, e.g. universities. These highly qualified experts do not only attend the European meetings but are (ideally) also involved in National preparatory meetings in which the expertise of all interested National parties is concentrated.

All WGs have secretarial support by professional staff of the National Standardization Institutes with experience in CEN and/or ISO operational procedures.

The editing committee did its work in the beginning mainly by correspondence. There has only been one meeting, up to now, but did not meet again in the last 20 years.

In the areas of microbiological contaminants (WG 6) and genetically modified foodstuffs (WG 11), some of the documents (standards or technical specifications, etc) were and are elaborated under the Vienna agreement, both under ISO-lead as well as under CEN-lead. All projects of WG 11 which were elaborated and finalized under CEN-lead were during the revision being handled under ISO-lead by the corresponding ISO body, ISO/TC 34/SC 16.

As the working groups are active at different levels of intensity, the active projects are not described here in detail. Details are provided in the work programme.

Up to 2018, CEN/TC 275 has received six mandates from the EU commission in the area of irradiated foodstuffs, microbial contaminants, biotoxins, heavy metals, and process contaminants.

CEN/TC 275 has internal liaisons with other Technical Committees within CEN who deal with the standardization of methods of analysis, e.g. with CEN/TC 307 " Oilseeds, vegetable and animal fats and oils and their by-products - Methods of sampling and analysis", CEN/TC 327 on "Animal feeding stuffs - Methods of sampling and analysis", with CEN/TC 338 on "Cereal and cereal products" and with ISO/TC 34 "Food products".

According to the outcome of the validation studies, CEN/TC 275 has mainly elaborated European Standards, but also Technical Specifications and, in some exceptional cases, Technical Reports. However, the main task is to elaborate methods for analysis, but in some cases (e.g. with mycotoxins or heavy metals), also criteria for methods have been elaborated.

The criteria for the selection of methods have already been laid down according to directive 85/591/EEC at its first and again at its third meeting (superseded by regulation (EC) 882/2004 Annex III and are as follows:

- 1 Collaborative trial according to ISO 5725:1994 (for chemical analyses) or equivalent<sup>1</sup>
  - a specificity
  - b accuracy
  - c precision, repeatability, intra-laboratory (within laboratory) and reproducibility interlaboratory (within and between laboratories) variabilities.
- 2 Limit of detection
- 3 Sensitivity
- 4 Practicability
- 5 Applicability as broad as possible
- 6 Speed; personnel requirements
- 7 Hazardous materials
- 8 State of the art
- 9 Other criteria which may be selected as required

For microbiology and for also the ownchecks of food operators in this field,

- ISO 17648 *Technical requirements and guidance on the establishment or revision of standardized reference methods for the analysis (detection or quantification) of microorganisms or*
- ISO 16140-6 *Method Validation: Protocol for the validation of alternative methods for microbiological confirmation and typing*

are followed.

#### **4.3 Environmental aspects**

CEN/TC 275 does not elaborate standards which are definitely addressed to environmental issues. However, already at its 3<sup>rd</sup> meeting in 1993, CEN/TC 275 has set up the just mentioned list of criteria for selection of methods for food analysis. In this list, amongst others, the aspect of hazardous materials appeared. Furthermore, it has been stated at several meetings that the attendees and experts within Working Groups of CEN/TC 275 are very much aware of environmental aspects.

The secretariat informs its members on all environmental topics of CEN regularly, e.g. information on training courses (N 639), the environmental checklist (N 674) and the CEN-Environmental approach (N 804) as well as the fact that CEN-Guide 4 was revised taking into account the environmental aspects for analytical and testing standards (N 1328) and the new version of CEN-Guide 4 (N 1522) as well as CEN-Guide 33 (N 1572) were forwarded to members of CEN/TC 275 for information.

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<sup>1</sup> or equivalent means that also the statistical requirements for collaborative trials as outlined in the ISO/IUPAC/AOAC harmonized protocol are acceptable for methods considered by CEN/TC 275 (according to clause 6 para 2 of the report of the third meeting of CEN/TC 275 = doc CEN/TC 275 N 82)

If new work items are proposed who would encounter the use of hazardous material or reagents, the providers would need a good justification to let their projects be adopted. In the last years, it appeared that the one method which made use of an (meanwhile unnecessarily) hazardous reagent has been withdrawn and replaced by a more modern alternative.

## **5 FACTORS AFFECTING COMPLETION AND IMPLEMENTATION OF THE CEN/TC 275 WORK PROGRAMME**

Since financial resources for the validation of methods run towards exhaustion and may be not in the terms of reference of nominated European Reference Laboratories, it will become difficult in the future to choose already validated methods for standardization. It will be necessary to initiate validation of new methods for new interests. Consequently, working groups will have to be established without projects in their work programme as the new 3-years-time-frame leaves no time for generation of validation data. Moreover, in case of Vienna agreement, ISO has no financial resources to support validation of its methods.

Mandated projects, where the validation is funded by the EU Commission could be a way out combined with research and developments and results of scientific European project funded by the EU Commission for improvement of existing or not yet existing EN standards.