

**CEN/TC 137 Business Plan** 

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#### **BUSINESS PLAN**

# CEN/TC 137 Assessment of workplace exposure to chemical and biological agents

# **EXECUTIVE SUMMARY**

#### **Business Environment**

The main activity of CEN/TC 137 is standardisation in the field of assessment of exposure to chemical and biological agents at the workplace also taking into account the dermal exposure. This includes the planning and performing of measurements but excludes the establishment of limit values.

#### Parties involved:

- industry as employer;
- trade unions as representative of the employees;
- national authorities for the protection of workers (e.g. INRS (F), HSE (UK), BG's (DE))
- representatives of the national governments:
- producers of protection devices;
- European Commission.

#### **Benefits**

Workers can be exposed to hazardous substances during their work by inhalation or dermal exposure. These hazardous substances, present as chemicals and biological agents, can be very toxic, toxic, harmful, corrosive, irritant, sensitising, carcinogenic, mutagenic, teratogenic and pathogenic. National lists can contain for more than 500 different substances occupational exposure limit values (OELVs) for the workplace atmosphere. So it is necessary to avoid the presence of these substances at the workplace or to limit their concentrations to values at which an acceptable risk to health exists. To support this it is necessary to have technical rules for the measurement strategy and the methods for the determination of theses substances.

CEN/TC 137 prepares European Standards, CEN Technical Specifications and CEN Technical Reports, for the assessment of the workplace exposure to chemical and biological agents and the dermal exposure as a fundamental basis for the risk assessment of workplaces.

For such documents, finally made to protect the life and health of workers, occupational health and safety aspects shall have priority over market needs.

#### **Priorities**

To make European Standards or other CEN deliverables available related to:

- General requirements of measuring procedures:
- Basic performance requirements on procedures for the determination of the concentration of chemical agents in workplace environment;
- Strategy to perform representative measurements of exposure by inhalation to chemical agents in order to demonstrate the compliance with occupational exposure limit values;
- Measurement of dustiness of bulk materials;
- Measurement of airborne microorganisms and microbial compounds in workplace environment;
- Certain common used types of measuring devices, e.g. samplers, pumps, direct-reading instruments:
- Guide for the selection, installation, application, use and maintenance of measuring devices and procedures;
- Principles and c methods on dermal exposure measurement.

#### 1 BUSINESS ENVIRONMENT OF THE CEN/TC 137

#### 1.1 Description of the Business Environment

The following political, economic, technical, regulatory, legal, societal and/or international dynamics describe the business environment of the industry sector, products, materials, disciplines or practices related to the scope of this CEN/TC, and they may significantly influence the relevant standards development processes and the content of the resulting standards:

The policy of the European Commission on Article 153 of the Lisbon Treaty on the functioning of the EU through amendment and renumbering of the EU Treaty of Nice in 2009 is developed in communication from the Commission on the role of standardization in relation to Article 118a of the (former EC) Treaty (DGV-1995) which is published at the Official Journal of the European Communities. The policy of CEN on standardization policy in the area of the former Article 118a (BT N 4777) was approved by BT Resolution 22/1997.

In 1988 the

"Council Directive 88/642/EEC of 16 December 1988 amending Directive 80/1107/EEC on the protection of workers from the risks related to exposure to chemical, physical and biological agents at work"

was published.

This Directive made references at several points to CEN standards which should be prepared, especially related to the measurement methods and the particle size distribution of inhalable dust. For the support of this Directive CEN/TC 137 was established and the standards were prepared. The Directive 88/642/EEC is a Directive according Article 118a which has later become Article 153 of the EU Treaty of Lisbon. This means that more stringent requirements may by established by the national governments.

So all work of CEN/TC 137 refers to this European Directive and the Memorandum

"The role of standardization in relation to article 118a of the EC Treaty"

which was prepared by the European Commission, Directorate General V "Employment, Industrial Relations and Social Affairs".

Therefore, the establishment of occupational exposure limit values is excluded from the scope of the TC.

In 1998 the Council Directive 88/642/EEC was replaced by

"Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)".

The deliverables (EN's, CEN/TS's, CEN/TR's etc.) prepared by CEN/TC 137 shall support the existing Directive, give advice on the use/application of the Directive and specify test methods which are suitable to be used in the sense of the Directive.

The Directive is a basic European instrument for regulation and consequently European Standardization is, therefore, the primary tool. However, some aspects have been introduced in ISO and are dealt with in the corresponding International committee, i.e. ISO/TC 146/SC 2 "Workplace atmospheres".

#### 1.2 Quantitative Indicators of the Business Environment

The following list of quantitative indicators describes the business environment in order to provide adequate information to support actions of the CEN/TC 137:

- Increasing number of implemented European OELVs linked to the increasing need for establishing validated measuring procedures
- Increasing number of certified measuring devices and procedures according to European Standards prepared by CEN/TC 137
- Indication of cases where European Standards prepared by CEN/TC 137 are cited as normative references in European Standards of its own and by other CEN committees
- Indication of cases of governmental adoption of the CEN committee's European Standards into legislation, regulations or procurement requirements

### 2 BENEFITS EXPECTED FROM THE WORK OF THE CEN/TC 137

- Improvement of health and safety on the workplace due to a reliable assessment of the workplace exposure to chemicals and biological agents
- Implementation of new and control of existing OELVs as a result of the availability of standardised measuring procedures and devices
- Support to the European chemical and biological agents policy
- Fulfilling the needs and the requirements of the Chemical Agents Directive by the preparation of harmonised European standards for the measurement of chemical and biological agents
- Provision of tools for the validation of measuring procedures according to general requirements for the uncertainty of measurements
- Increase of the quality level of measuring procedures and their implementation
- Increase the quality level of the use of devices with respect to selection, installation, handling and maintenance
- Improvement of comparability of measuring results by using harmonised measuring procedures
- Removement of technical barriers to trade and open markets throughout Europe by providing requirements and test methods for type testing and certification of measuring devices and procedures

#### 3 PARTICIPATION IN THE CEN/TC 137

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 recognised European or international organisations is also possible under certain conditions. To participate in the activities of this CEN/TC, please contact the National Standard Body (NSB) in your country.

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

#### 4.1 Defined objectives of the CEN/TC 137

Elaboration of CEN deliverables in the field of assessment of exposure to chemical and biological agents at the workplace also taking into account the dermal exposure.

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

Most of the European Standards (or other CEN deliverables) prepared by CEN/TC 137 are in a field for which standards never existed. This concerns especially the European Standard on basic performance requirements on procedures for the determination of the concentration of chemical agents which shall be fulfilled by the measurement methods for the determination of hazardous substances in workplace atmosphere; but also the European Standard which gives a strategy to perform representative measurements of exposure by inhalation to chemical agents in order to demonstrate the compliance with OELVs.

In these cases basic considerations were necessary in the structure and content of these European Standards. This was done by physical meetings only. For the distribution of documents and to provide general information to its members CEN/TC 137 uses the internet platform "Livelink". Livelink provides an electronical committee structure consisting of different folders, e.g. for general committee documents, meetings and resolutions and projects, which allows registered members of CEN/TC 137 a world-wide access on any TC documents at any time. Due to face-to-face meeting restrictions getting in force as appropriate health protection measure in conjunction with the COVID-19 pandemic spread in early 2020, virtual meetings conducted via internet have become more relevant as alternative means to physical meetings.

In a very early stage the TC decided to work in English only. There were no translations during the meetings and also the reports and decisions were prepared in English only. The translations of elaborated documents into French and German were done prior to the Enquiry stage (e.g. publication as Draft European Standard) and/or Formal Vote (respectively TC Approval) stage (e.g. CEN Technical Specifications or CEN Technical Reports, if required).

The basic structure, i.e. establishment of different WGs, was decided according to the first tasks measurement strategy (WG 1), general requirements (WG 2) and particulate matter (WG 3). Later on it was decided to prepare CEN deliverables on definitions (WG 4), biological agents (WG 5) and dermal exposure (WG 6). For the preparation of European Standards for electrical apparatus used for direct detection and direct concentration measurement of toxic gases and vapours a joint working group with CENELEC/TC 31-9 was established.

During past years WG 1, WG 4, WG 5 and WG 6 were disbanded and set "dormant" due to finalization of the standardisation work assigned to these Working Groups. However, in May 2013 WG 6 became re-activated in conjunction with the EU Mandate M/461 on nanotechnologies and nanomaterials. From December 2014 to May 2019 also WG 1 was re-activated to revise EN 689:1995. Finally, WG 5 has been re-activated in September 2017 to revise the EN's on biological agents already published between 2000 and 2004.

## The work of CEN/TC 137 is based on:

- the International Labour Organization
   (e.g. ILO Convention 170 concerning the safety and the use of chemicals at work);
- the Organization for Economic Co-operation and Development (e.g. OECD 's documents on risk reduction for chemicals e.g. Risk reduction Monograph N° 2: Methylene chloride, 1993);
- the United Nations Conference on Environment and Development (UNCED e.g. Safe use of toxic chemicals);
- the co-operation of the European Commission with the World Health Organization (e.g. evaluation of hazardous chemicals);
- the International Programme on Chemical Safety (IPCS).

The work of CEN/TC 137 does not depend on the work of other CEN/TC's, but care shall be taken that the work does not overlap with the work of other CEN/TC's.

Therefore CEN/TC 137 observes the work of

- CEN/TC 264 "Air quality" and
- CEN/TC 352 "Nanotechnology".

For the same reason also the work of ISO/TC 146/SC 2 "Workplace atmospheres", ISO/TC 229 "Nanotechnology" and ASTM D 22.04 "Workplace air" is monitored.

Since 2008 the cooperation between CEN/TC 137 and ISO/TC 146/SC 2 has been intensified by common revision of already existing ENs of CEN/TC 137 (in particular, on measuring devices, general performance requirements and terminology) under Vienna Agreement, ISO lead. Additionally, both TCs have begun at the same time to elaborate completely new deliverables in common (e.g. EN ISO 28439, EN ISO 13138).

Liaisons are formally established with

IOHA – International Occupational Hygiene Association (currently not active)

WHO - Office of Occupational Health, World Health Organisation (currently not active)

ETUI - European Trade Union Institute

IMA Europe – European Industrial Minerals Association

Cerame-Unie – European Ceramic Industry Association

CEMBUREAU – European Cement Association

"NanoReg2"-Project – EU Project Development and implementation of Grouping and Safe-by-Design approaches within regulatory frameworks'

#### 4.3 Environmental aspects

Since the technical committee is focussed on occupational health at workplaces environmental aspects are of minor importance. If environmental aspects become a matter, for example disposal of materials or toxic substances, they will be considered in the respective standards.

# 5 FACTORS AFFECTING COMPLETION AND IMPLEMENTATION OF THE CEN/TC 137 WORK PROGRAMME

Many of the TC work items are projects for which no national standards or other regulations are available. Under these conditions unforeseeable problems can occur. The capacity of the working groups as well as of the TC secretariat is sufficient to handle such problems but a delay in the preparation of the corresponding CEN deliverables is then unavoidable. At present the CEN/TC 137 has not such problems.