CEN Personal Protective Equipment Sector Forum

Standardization Strategy 2020¹

Background

Even if for some types of professional PPE European standardization work started earlier, the boost for European standards on PPE came with the publication of the PPE Directive 89/686/EEC. A general mandate (M/031) has been issued by the European Commission (EC) for the development of harmonized European standards. Several Technical Committees (TCs) have been set up to develop the PPE standards, a TC for each type of product (head protection, footwear, fall protection, protective clothing).

Over the years, more than 300 harmonized European standards were developed and revised, addressing test methods and requirements on products for professional and non-professional use.

In the last few years more and more standards in the PPE sector are developed under the Vienna (or Dresden) Agreement.

The CEN Personal Protective Equipment Sector Forum (PPE Sector Forum) was created as a platform for exchange of information between the different TCs on PPE. In accordance with the CEN policy (<u>BOSS</u>) the PPE Sector Forum cannot produce their own standardization deliverables. It can provide guidance to the relevant TC, but without direct power to enforce application of this guidance.

Legislation

The new PPE Regulation (EU) 2016/425 has been published on the 31st of March 2016 and will be applicable as of the 21st of April 2018.

Moreover, on the basis of the Framework Directive on Occupational Health and Safety (OHS), Directive 89/391/EEC, a specific Directive 89/656/EEC on the use of PPE by workers at the workplace was developed and published. Even if there is no mandate linked to this Directive, some standardization deliverables have been developed to assist employers in their responsibilities.

Mission Statement of the PPE Sector Forum

The PPE Sector Forum supports the work of the concerned standardization bodies (TCs and working groups) by:

- 1. providing relevant information on legislation, standardization and other relevant horizontal issues, including information on emerging risks and market developments;
- 2. enhancing networking amongst and between concerned standardization bodies, and between the concerned standardization bodies and relevant stakeholders;
- 3. discussing and offering solutions for horizontal issues.

¹ This strategy was approved by the CEN/BT in August 2016 through Decision BT C115/2016

Implementation of the mission statement

- 1. Information to be provided by the PPE Sector Forum concern the following aspects:
 - legislation;
 - standardization;
 - emerging risks.
- 2. Enhancing of a networking:
 - amongst concerned standardization bodies and
 - between concerned standardization bodies and other stakeholders:
 - either at meetings or through establishing contacts;
 - the European Commission, mostly Directorate General (DG) GROW and DG EMPL, other DGs on a case-by-case basis;
 - Notified Bodies;
 - European associations:
 - e.g. Federation of the European Sporting Goods Industry (FESI), European Textile Services Association (ETSA), European Safety Federation (ESF), Association for the Co-ordination of Consumer Representation in Standardisation (ANEC), Small Business Standards (SBS), European Trade Union Institute (ETUI), Business Europe, Federation of European Ergonomics Societies (FEES) etc.
 - other CEN bodies:
 e.g. CEN Strategic Advisory Board for Occupational Health and Safety (SAB OH&S), other sector fora
 - standardization bodies in CENELEC and ETSI and joint working groups with these organisations:
 e.g. CENELEC/TCs 78 'Equipment and tools for live working' and

e.g. CENELEC/TCs 78 'Equipment and tools for live working' and CEN/CLC/JWG 07 'PPE against electrostatic risks',

- 3. Horizontal issues to be discussed concern the following issues:
 - uncertainty of measurement,
 - innocuousness,
 - consequences of other legislation on PPE standards, e.g. the Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) REACH
 - Chemical, biological, radiological and nuclear (CBRN)
 - SUCAM (selection, use, care and maintenance) including (cross)contamination leading to health problems
 - interfaces between different kinds of PPE, compatibility, ensembles and systems
 - ergonomics,
 - gaps in the existing set of PPE standards,
 - funding opportunities for round robin testing and/or pre-normative research.

Interaction with the European regulatory and policy framework

The participation of representatives of the EC, from both DG GROW and DG EMPL is highly appreciated and essential for the work of the PPE Sector Forum.

The aim is to keep up with the legislative evolution and assess its impact on standardization for PPE. When relevant, the PPE Sector Forum provides guidance and assistance to the

concerned standardization bodies on how to deal with the specific changes in the most effective way.

With the new PPE Regulation, there is certainly a need among the concerned standardization bodies for information and guidance on necessary actions to be carried out regarding the existing harmonized European standards as well as the ongoing work (comprising both revisions and brand new draft standards). This includes updating the existing check list for the preparation of Annex ZA and revising the existing guidance documents issued by the PPE Sector Forum.

The participation of the Horizontal Committee of Notified Bodies is beneficial to encourage a good working relation between the concerned standardization bodies and the Vertical Groups.

The PPE Sector Forum recognizes that market surveillance on PPE is essential for the correct working of the EU market and encourages member states to be active in this field. However, standardization has no direct influence on the market surveillance activities. On the other hand, experience from market surveillance authorities on the use of standards is valuable information for the concerned standardization bodies.

Quality of standards

In the PPE sector, like in many other sectors, harmonised European standards are an important element in the conformity assessment in Europe. Standards are developed to translate the essential health and safety requirements from the legislation into practical technical requirements used by manufacturers, notified bodies, market surveillance authorities, users and other stakeholders to check conformity of products.

As in other sectors, PPE harmonised standards are being revised regularly. In practice, with every revision, additional requirements are introduced. Comparison of the first versions of European standards, most of which were published in the early 90ies, with those of today shows a clear increase in number and complexity of tests, leading to increased costs for testing and certification.

An important concern is the high quality of standards. While health and safety of the wearers of PPE is to be the first priority, attention must also be given to the economic impact for the stakeholders, to the health and safety for the personnel in the testing laboratories, to the environmental impact of the testing and product etc.. Therefore, only those requirements that have a clear and direct impact on the health and safety of the wearer should be included in PPE standards and the impact on the other concerns should be checked during the development of the standardisation deliverables.

Continuous attention should also be given to the translation of real life conditions into testing conditions in a laboratory. Test methods must be validated and robust, meaning that the same result must be obtained at any time in any laboratory when following the test procedure as described in the relevant European standard. Therefore, round robin testing and inclusion of the information on uncertainty of measurements in the European standards are essential.

The PPE Sector Forum should develop a common methodology for the concerned standardisation bodies in the PPE sector to assess in a simple and efficient way the impact on elements as described above. Fulfilling the essential health and safety requirements of the legislation, is obligatory. However, if different test methods are available in order to show

compliance with the EHSR, other considerations need also to be taken into account when deciding on which test to include in the standard.

The PPE Sector Forum should gather information on funding possibilities for round robin testing and distribute this information to the relevant TCs. In addition, horizontal guidance on how to deal with uncertainty of measurement, environmental aspects, etc. should be developed.

Key recommendations from the report on the programming mandate M/509

Early 2014 CENCLC BT WG 8 'Protective textiles and personal protective clothing and equipment' issued the final report on the programming mandate M/509.

In addition to providing a number of well-founded proposals for standardization projects themselves other proposals are included looking towards improving the organization of the standardization work itself, improving uniformity of testing and quality of test methods, as well as on the conformity assessment protocols necessary for PPE having to comply with different sets of European legislation.

Attention is also given in the report on how to improve the participation of end users as well as the R&D community into the standardization work. Similarly, the cooperation of experts from different but related fields, e.g. textiles, PPE, electronics, ICT and machinery requires some attention in the short term to improve the current situation.

Other important topics identified in the report are the need to improve handling Intellectual property rights (IPR) and the need to ensure that test methods remain robust, sound and repeatable the latter requiring sufficient resource for development and validation purposes.

Stakeholder involvement

While in the concerned standardization bodies, manufacturers, notified bodies and test laboratories are well represented, there is very poor involvement of users (employers, employees, consumers etc.) and authorities (market surveillance, labour inspection etc.). Taking into account that it might be nearly impossible for a user to be active in all concerned standardization bodies, organizations representing users are invited to participate at the meetings PPE Sector Forum which can serve as an intermediary between technical bodies and users. However, due to lack of resources and/or interest, these organizations are rarely participating in the work of the PPE Sector Forum. Further efforts are necessary to increase their involvement.

In order to improve the input of users in the actual standardization work, a proposal has been initiated to create working groups for specific sectors or type of work. Experience with the Joint Working Groups: JWG for Fire Fighters PPE (resorting under CEN/TC 162 'Protective clothing including hand and arm protection and life-jackets' and later shifted to the PPE Sector Forum) as well as with the CEN/CLC/JWG 07 'PPE against electrostatic risks' shows that this approach leads to good results and improvement of standards on product requirement. The focus of those groups should be limited to describing the actual risks encountered in their sector or type of work. With this structured and complete information, the specific product groups can make sure that the requirements in the product standards are linked to the actual risks encountered. Also all concerned standardization bodies start from the same information rather than use their own experience and knowledge on the risk levels encountered in practice.

Support to innovation and R&D

Standardization is a key factor in the success for R&D and innovation projects. Unfortunately, these are often two completely separated communities with very little interest in the other. The PPE Sector Forum organized at the end of 2011 a workshop bringing these two communities together. This initiative was well received by the participants.

In the period 2012-2014, the SustaSmart project worked on this issue. A liaison between the Sector Forum and this project was established.

A mechanism to ensure information exchange between the R&D/innovation community and the PPE standardization should be developed and promoted.

To avoid repeated work, knowledge of test methods developed in other TCs is desirable for TCs developing product standards. This is not always the case within the group of PPE TCs and therefore a system to coordinate such knowledge should be set up.

For PPE with integrated electronics/ICT, CEN TC 248 'Textiles and textile products' WG 31 'Smart textiles' is developing interesting documents. Information on the progress in this WG is certainly useful for the further development of PPE standards and will therefore be included in the PPE Sector Forum on a regular basis.

Parts of the developments are related to new materials. To allow easy market access it is essential to encourage standards to contain functional requirements as opposed to product/material related requirements. The PPE Sector Forum should give some general guidance to the concerned standardisation bodies on how to include functional requirements.

Organization of PPE standardization

Trends from innovation and R&D include clearly a system approach (starting from the person wearing PPE from head to toe and from skin to outer layer, but also incorporation of ICT in PPE is part of this approach), rather than an approach based on individual, separate products. As standardization has to reflect the state-of-the-art in the sector, the system approach needs to be included in the PPE standardization. This type of standardisation will require clarity in the definition of roles between users, certifiers and manufacturers with respect to compatibility. Mostly this is not part of the certification by the manufacturer but rather the responsibility of the user (in case of professional use, the employer – see Directive 89/656). Standardisation deliverables are a way to assist in this important step to correct and efficient protection of the wearer of PPE. It has to be remarked that in the new PPE Regulation the categorisation is expressed in terms of risks while in the Directive 89/686/EEC this was mainly expressed in terms of products.

The standardization bodies involved in the PPE standardization are mainly based on type of product. This does not always contribute to a common (system) approach or clarity for stakeholders. Even if the current product legislation and standards do not foresee certification of systems, the employers need guidance in their selection process.

It also needs to be remarked that the work at ISO level is organized in a different way than at CEN level. There is only one ISO TC dedicated to PPE, ISO/TC 94 'Personal safety - Protective clothing and equipment'). It is divided in several subcommittees (some of which have a similar scope to the CEN TCs). There are also some differences in the voting process and some other

procedures and the non-existing role of the New Approach Consultants in ISO and the necessary inclusion of Annex ZA on European level have also to be taken into account.

A clear overview and proposals to simplify should be developed (e.g. some standards for PPE for sports are developed in TC 162 while others in TC 136 for sports equipment). At the same time, a European standardisation body to develop standardisation deliverables based on a system approach is needed to keep up with the state-of-the-art in this sector.

In some (exceptional) cases, national initiatives are started in the PPE field. It would be beneficial if the PPE Sector Forum was informed on such new projects so that, when possible, the initiative can be taken on a larger scale. This would ensure that the same standards are applicable all over the EU (including standards related to selection, use, care and maintenance and services, so-called SUCAM-documents).

Suggested short term actions to be carried out by PPE Sector Forum:

- encouraging all related standardisation bodies (CEN and CENELEC) to be involved in the work of the PPE SF;
- encouraging and organising exchange of relevant information with ETSI;
- analysis of consistency of the PPE standardization work with the aim of increasing efficiency of work;
- involvement in the preparation of a proposal for the creation of a joint TC which would follow the system approach and may cover those elements that are not in the scope of the current TCs (compatibility, interfaces, inclusion electronics/ICT etc.);
- assistance to R&D / innovation projects in order to develop a systematic mechanism for information exchange;
- informing and guiding TCs on necessary actions for the existing harmonized European standards following the publication of Regulation (EU) 2016/425. This includes updating the existing check list for the preparation of Annex ZA;
- developing a methodology that could be used by the TC to assess in a simple and efficient way the impact of new or revised standards on costs, environment, health and safety of laboratory personnel versus the protection of wearers of the PPE.

Annexes:

- A. List of all CEN, CENELEC, ISO, IEC groups involved
- B. Current organizations on mailing list + participation
- C. List of mandates in the PPE field
- D. Overview of the scope of the concerned TCs

Bibliography:

- Final report programming mandate M/509
- SustaSmart documents see <u>www.susta-smart.eu</u>

List of CEN, CENELEC, ISO and IEC technical bodies relevant for PPE

THE MOST IMPORTANT RELEVANT for PPE				
CEN				
CEN/TC 79	Respiratory protective devices			
CEN/TC 85	N/TC 85 Eye protective equipment			
CEN/TC 136	Sports, playground and other recreational facilities and equipment			
CEN/TC 158	Head protection			
CEN/TC 159	Hearing protectors			
CEN/TC 160	Protection against falls from height including working belts			
CEN/TC 161	Foot and leg protectors			
CEN/TC 162	Protective clothing including hand and arm protection and lifejackets			
JWG within the PPE Sector Forum	'Fire-Fighters'			
	CENELEC			
CLC/TC 78	Equipment and tools for live working			
	CEN and CENELEC JOINT WORKING GROUPS			
CEN/CLC/JWG 07	PPE against electrostatic risks			
	ISO			
ISO/TC 94	ISO/TC 94 Personal safety Protective clothing and equipment			
ISO/TC 94/TG 1	Compatibility of PPE items			
ISO/TC 94/SC 1	Head protection			
ISO/TC 94/SC 3	Foot protection			
ISO/TC 94/SC 4	Personal equipment for protection against falls			
ISO/TC 94/SC 6	Eye and face protection			
ISO/TC 94/SC 12	Hearing protection			
ISO/TC 94/SC 13	Protective clothing			
ISO/TC 94/SC 14	Fire-fighters' personal equipment			
ISO/TC 94/SC 15	Respiratory protective devices			
	IEC			
IEC/TC 78	Live working			

RELATED CEN, CENELEC AND IEC BODIES		
CEN/TC 122	Ergonomics	
CEN/TC 211	Acoustics	
CEN/TC 231	Mechanical vibration and shock	
CEN/TC 248	Textiles and textile products	
CLC/SR 101	Electrostatics	
IEC/TC 101	Electrostatics	
CLC/TC 62	Electrical equipment in medical practice	
IEC SC 62B	Diagnostic imaging equipment	

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List of mandates for PPE

Mandate number	Short mandate title	Complete mandate title	Mandate BT approval date	Related directive reference	Comment
		Current PPE standar	dization request	S	
M/031	Personal Protective Equipment	Standardization mandate to CEN/CENELEC concerning standards for Personal Protective Equipment	1993-11-19	89/686/EEC	The main mandate for PPE, ongoing work. According to the information received from the EC it is the only valid PPE mandate which is not completed
	•	Some previous standa	rdization reque	sts	· · · · ·
M/307	Protection against falls	Mandate to CEN concerning the execution of standardization work, within the context of directive 89/686/CEE relating to personal protective equipment, for the purpose of revising standard EN 795 "Protection against falls from a height - anchor devices - requirements and testings"	2002-07-03	89/686/CEE	
M/472	Personal Protective Equipment	Standardisation mandate given to the European Committee for Standardisation (CEN) under directive 1989/686/EEC on Personal Protective Equipment with a view to amendment of standard EN 353- 1:2002 - Personal protective equipment against falls from a height - Part 1: Guided type fall arresters including a rigid anchor line	2010-10-20	89/686/EEC	

Annex C

	Protective textiles	Programming mandate to CEN, CENELEC and ETSI on protective textiles and personal protective clothing and equipment	2012-11-07	89/686/EEC	completed
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Overview of the scope of the concerned TCs

CEN				
CEN/TC 79	Respiratory protective devices	To prepare European Standards for respiratory protective devices for use in the work place and for fire fighting and for rescue purposes, where there exists a risk to health from inhaling dusts, fumes, gases, vapours or from oxygen deficiency, as well as European Standards for underwater breathing apparatus.		
CEN/TC 85	Eye protective equipment	Establishment of specifications and test methods relevant to eye and face protectors.		
CEN/TC 136	Sports, playground and other recreational facilities and equipment	Standardization of specific items of sports, playground and other recreational facilities and equipment with a special regard to: terminology, safety requirements, operational requirements, service requirements, performance requirements, test methods, marking, consumer/user information, installation and maintenance		
CEN/TC 158	Head protection	To prepare European standards for all types of protective helmets.		
CEN/TC 159	Hearing protectors	To prepare European standards related to personal hearing protective equipment to be used when sound exposure is expected to be hazardous to the ear.		
CEN/TC 160	Protection against falls from height including working belts	Standardization of requirements for personal protective equipment against falls (systems, subsystems and components), working belts and accessories including definitions of terms and establishment of test methods.		
CEN/TC 161	Foot and leg protectors	To prepare European standards in the field of protective footwear and leg protectors. Note: leg protectors are defined as an extension of protective footwear.		
CEN/TC 162	Protective clothing including hand and arm protection and lifejackets	To prepare European Standards (requirements and testing) in the field of clothing to protect against physical and chemical hazards. Hand and arm protectors are included as well as high visibility clothing and clothing against drowning (e.g. lifejackets).		
JWG within the PPE Sector Forum	'Fire-Fighters'	n/a		
CENELEC				
CLC/TC 78	Equipment and tools for live working	To prepare CENELEC standards for work equipment, devices and tools, including personal protective equipment used for work on or near live electrical systems or installations.		
CEN and CENELEC JOINT WORKING GROUPS				
CEN/CLC/JWG 07	PPE against electrostatic risks	n/a		

ISO				
ISO/TC 94	ISO/TC 94 Personal safety Protective clothing and equipment	Standardization of the quality and performance of clothing and personal equipment designed to safeguard persons against hazards other than those concerned with nuclear radiation.		
	RELAT	TED CEN, CENELEC AND IEC BODIES		
CEN/TC 122	Ergonomics	Standardisation in the field of ergonomics principles and requirements for the design of work systems and work environments, including machinery and personal protective equipment, to promote the health, safety and well-being of the human operator and the effectiveness of the work systems.		
CEN/TC 211	Acoustics	Standardization in the field of acoustics, including methods of measuring acoustical phenomena, the generation, transmission and reception of sound, all aspects of the effects of sound on man and his environment, and methods of noise reduction. Excluded: acoustical performance requirements and measurement methods for building components and buildings; acoustical performance requirements for hearing protectors.		
CEN/TC 231	Mechanical vibration and shock	Standardization in the field of mechanical vibration and shock, including: - methods for measuring and evaluating mechanical vibration and shock; - methods for assessing human exposure to mechanical vibration and shock in any kind of environment; - description of the effects caused by human exposure to mechanical vibration and shock and guidelines for the reduction of these effects; - methods for evaluating the effects of mechanical vibration and shock on structures; - methods for reducing by machine design, risks resulting from exposure to mechanical vibration and shock; - methods for measuring and assessing the vibration and shock reduction characteristics of personal protective equipment (e.g. antivibration gloves), vibration isolators (e.g. resilient materials) and suspension systems (e.g. seats).		
CEN/TC 248	Textiles and textile products	Standardization of the following aspects of textiles, textile products and textile components of products: 1) test methods; 2) terms and definitions; 3) specifications, and if necessary classifications, in terms of their expected behaviour, in particular where required by other CEN Technical Committees or the CEC or EFTA. Equipment relevant for the testing and use of textiles.		
IEC/TC 78	Live working	To prepare International standards for tools, equipment and devices for utilization in Live Working, including their performance requirements, care and maintenance. Excluded: Work practices and methods for Live Working. To prepare technical publications related to the utilization of tools, equipment and devices on, and in the vicinity of, live parts of electrical installations and systems.		
CLC/SR 101	Electrostatics	n/a		
IEC/TC 101	Electrostatics	Standardization in the field of electrostatics to provide general guidance on - test methods to evaluate the generation, retention and dissipation of electrostatic charges;		

		 ascertaining the effect of electrostatic discharges; methods of simulation of electrostatic phenomena for testing purposes; requirements for design and implementation of handling areas or procedures, equipment, and materials used to reduce or eliminate electrostatic hazards or undesirable effects. Limitations and exclusions: The simulation of electrostatic discharges applied to powered electric and electronic equipment, systems and installations which is covered by TC 77. Horizontal safety function: To specify methods of test and relevant equipment to evaluate generation, retention and dissipation of electrostatic charges on materials.
CLC/TC 62	Electrical equipment in medical practice	To establish harmonized standards and other publications concerning electrical equipment, electrical systems and software used in healthcare and their effects on patients, operators, other persons and the environment. NOTE: This scope includes items that are also within the scopes of other committees and will be addressed through cooperation. Attention will focus on safety and performance (e.g. radiation protection, data security, data integrity, data privacy and environmental aspects) and will contribute to regulatory frameworks. Healthcare includes medical practice as well as emergency medical services, homecare, and support of persons with disabilities in their daily lives (i.e. Ambient Assisted Living).
IEC SC 62B	Diagnostic imaging equipment	To prepare international publications for safety and performance for all kind of medical diagnostic imaging equipment (e.g. X-ray imaging equipment, computed tomography, magnetic resonance imaging equipment) including related associated equipment and accessories as well as quality procedures (e.g. acceptance tests and constancy tests) to be applied during the life-time of imaging equipment. Included is also the development of related terminology, concepts, terms and definitions.