



BUSINESS PLAN

CEN/TC 159 Hearing protectors

EXECUTIVE SUMMARY

Business Environment

CEN/TC 159 is preparing standards on:

- Hearing protectors – Safety requirements and testing
- Hearing protectors – Physical and acoustical test methods
- Hearing protectors – Guidance document

The total European market potential of products covered by CEN/TC 159 standards amounts to several hundred million Euro/year.

The following qualitative indicators may be of interest:

- The integration of electronics in hearing protectors and the use of new communication technologies and protocols in them. This brings hearing protection at the cross roads of different fields.
- The growing market of custom moulded earplugs.
- The awareness that noise is not only a risk in the work environment, but also in other aspects of our lives, e.g. music concerts, hobbies, etc.
- The awareness that noise does not only lead to hearing damage but can also cause other unwanted effects (psychological and social problems, fatigue, cardiovascular problems...), even at levels where no direct hearing damage can be expected.
- The upgrade of hearing protectors to Category III in the PPE Regulation (EU) 2016/425.
- The awareness of the individual sound attenuation and resulting therefrom a growing importance of individual fit check.

Benefits

European Standards developed by CEN/TC 159:

- remove barriers to trade in Europe,
- provide a high level of safety for hearing protectors throughout Europe,
- support European legislation and, if possible, international legislation,
- make available conformity assessment methods for hearing protectors with integrated electronic communication facilities as far as requirements of the PPE Regulation are concerned.

Priorities

To make European standards available related to:
Confidence of consumers and professional users.

CEN/TC 159 Business Plan**Date: 2023-10-12****Last review date: 2021-11-18****Version of revision: Draft #5****Page: 2****1 BUSINESS ENVIRONMENT OF THE CEN/TC****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 how the relevant standards development processes are conducted and the content of the resulting standards:

Noise is a big environmental problem, in fact one of the biggest world-wide. The European Foundation for the Improvement of Living and Working Condition (an EU organ) has studied the work environment for the almost 150 million of employees in EU-countries. At that examination, 28 percent have said that loud noise was a problem at work.

The market for hearing protectors is a high volume, multi-million € market. There are hearing protectors for both professional and private use. The use varies from different industrial uses to hunters and marksmen and also users who just need a comfortable night at places with noisy surrounding. Export and import of hearing protectors can differ per type of product, but are generally not confined to the European territory. However, most hearing protectors, for example earmuffs, are produced in Europe for the world-wide market. The field in question is extremely vast and of major economic importance for The Community and for Europe as a whole. It can be said, in a very general sense, that a large proportion of products is manufactured in small and medium-sized companies.

Due to the severe damages caused by noise, the use of hearing protectors at the workplace is in many countries subject to legislation. In the European Union, the basic requirements for the design and manufacture of personal protective equipment (PPE) in general and for hearing protectors in particular are laid down in Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC. Under the terms of the "New Approach", the requirements in relation to noise hazards are elaborated by CEN/TC 159, on request of the European Commission, in a number of harmonized standards showing how to comply technically. Manufacturers may refer to harmonized European Standards, which give presumption of conformity with the essential health and safety requirements as laid down in the Regulation. Also, the harmonized European Standards may give the user some assurance as to the usability for the intended purpose.

A second EC Directive is also relevant to hearing protectors: Council Directive 2003/10/EC that included also the use of PPE by workers at noisy workplaces. This directive contains employers' obligations including the need to carry out a risk analysis, which is the basis for the subsequent selection of the correct PPE. European legislation requires that PPE designed to prevent the harmful effects of noise at the workplace must be capable of attenuating the noise to such an extent that the equivalent sound levels the user is exposed to do not under any circumstances exceed the daily exposure limit values specified in the directive 2003/10/EC.

The harmonized European Standards prepared by CEN/TC 159 are mandated by the European Commission under a Standardization Request.

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:

In 2012 the market volume of hearing protection was about 158,9 million € in the core European countries (GER, GBR, FRA, ESP, ITA, SUI, AUT, Benelux, Scandinavia, IRL, POR; source: A+A 2013, International Trade Conference, "Distribution of PPE today and tomorrow", Michael Jansen: Market Development PPE and Distribution Structure in Germany 6 th November 2013).

The trend of the integration of electronics in hearing protectors and the use of new communication technologies and protocols in them as well as the growing market for custom moulded earplugs will lead to a growing market volume, because such hearing protectors are much more expensive than conventional products.

As hearing protectors are category III products according to Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC, for all such products on the European market an EU type-examination certificate had to be carried (Annex V of the PPE Regulation), which is typically based on the European standards developed by CEN/TC 159. Moreover, an annual production control by a notified body according to Module C2 (Annex VII) or Module D (Annex VIII) is necessary.

In countries like Germany, Austria and Switzerland the percentage of workers in industry exposed to noise with noise exposure levels reaching or exceeding 85 dB(A), which requires the use of hearing protectors (DIRECTIVE 2003/10/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 February 2003 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (noise)), is about 10 % (personal communication within the experience exchange meetings of Austrian, Swiss and German experts). This leads to an estimate for the EU of about 25 million exposed workers, who have to use hearing protectors.

In 2008 in Germany the total costs payed for e.g. treatment, pensions and compensation of occupational hearing impairment added up to about 141 million € ("Dokumentation des Berufskrankheiten-Geschehens – BK DOK 2008", Deutsche Gesetzliche Unfallversicherung (DGUV), Berlin). In Germany as well as in other European countries such expense could be avoided or at least decreased by efficient noise control, which includes inter alia efficient use of hearing protection.

2 BENEFITS EXPECTED FROM THE WORK OF THE CEN/TC

EN 352 parts 1 to 10 are harmonised standards, i.e. they are listed in the "Commission communication in the framework of the implementation of Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC - OJ C 209 of 15/06/2018". The series of EN 352 is supported by the testing standards EN 13819 parts 1 to 3.

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That results in ten available standards in the series of EN 352, which have already been cited in the Official Journal of the European Union under Regulation (EU) 2016/425 and confer presumption of conformity with Essential Requirements of that Regulation.

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. 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 objectives of CEN/TC 159 are:

- to draft suitable standards in every area of the sector (terminology, performance, requirements, test methods);
- to be aware of the market needs and according to that continuously adjust the work programme;
- follow the increased use of electronics in hearing protectors and revise standards in relation to this;
- to be aware of the individual sound attenuation;
- requirements and appropriate use of fit check systems;
- to work in co-ordination with ISO standardisation of acoustic test methods;
- to give guidance to all persons who have to supply, purchase or wear hearing protectors, and to encourage the use of effective criteria in their selection, use, care and maintenance.

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

The high quality of the standards will be achieved by active participation of all interested parties in the preparation of standards. Industries at national and international level and public authorities, institutes, laboratories, users representatives and other non-governmental organisations as for example trade unions are interested and active parties in the standardisation process, thus ensuring good consensus when drafting the standards.

CEN/TC 159 keeps a close contact with the Notified Bodies regarding hearing protectors and takes care of comments regarding ambiguous texts found in standards.

CEN/TC 159 is normally having plenary meetings yearly. In between, working groups have their own meetings and all other matters are solved by correspondence.

Liaisons with relevant committees have been established. At present with the following bodies:

- CEN/TC 122
- CEN/TC 211 Acoustics.

Social factors

CEN/TC 159 regards a high level of safety of PPE as a fundamental social factor. This level of safety will be ensured by specifications contained in European Standards. The definition of improved ergonomic design in the standards can increase the acceptance of hearing protectors. The number of hearing related injuries and related costs can be reduced considerably.

Technical factors

The technical factors influencing the elaboration of standards for hearing protectors is based in particular on the following technological developments:

- advances in the materials and manufacturing processes used;
- increased use of electronics in hearing protectors;
- the further development of legislation in the field of occupational safety;
- the awareness of the professional as well as the non-professional user, that the use of hearing protectors can help to ensure his/her quality of life;
- scientific knowledge of human physiology and ergonomic factors;
- further development / improvement of test methods;
- knowledge of fit check systems and methods for selection and use of hearing protectors.

Standardization in line with these views is seen as a key component of the European market.

4.3 Environmental aspects

The need to reduce the potential impacts on the environment of a product that can occur during all stages of its life is recognized around the world. The potential environmental impacts of products can be reduced by taking into account environmental issues in product standards. CEN/TC 159 attends to consider environmental issues when drafting product standards in support of sustainable international trade.

CEN/TC 159 Business Plan**Date: 2023-10-12****Last review date: 2021-11-18****Version of revision: Draft #5****Page: 6****5 FACTORS AFFECTING COMPLETION AND IMPLEMENTATION OF THE CEN/TC WORK PROGRAMME**

CEN/TC 159 is not allowed to develop acoustic test methods that are normally needed in all standards dealing with hearing protectors. The acoustic test methods CEN/TC 159 needs are provided by ISO/TC 43 "Acoustics" and then be implemented by CEN/TC 211 "Acoustics". This procedure constitutes a big risk as CEN/TC 159 is dependent on other TC's to keep its own target dates. The same problem arises when there is a need of R&D regarding acoustic test methods. In order to try to solve this problem an overlap of delegates in the CEN and ISO work has been established. The convenors and some experts of CEN/TC 159/WG 2, CEN/TC 159/WG 5 and CEN/TC 159/WG 6 take part in ISO/TC 43/SC 1/WG 17.

Almost the whole work programme of CEN/TC 159, including already published items, is clearly one package. In fact it even is one standard in many parts. It is a challenge to keep this whole package consistent and up to date.

The objectives of the CEN/TC can only be met with the voluntary support from all parties concerned. This support will only be forthcoming if these groups see that the necessary external support is provided to ensure that action is taken to effectively use the standards in the market place.

In addition CEN and the European Commission require an assessment by a HAS Consultant (Harmonized Standards Consultant) before publication of a harmonized standard. A delay of publication is inevitable in case of a negative assessment.

In order to improve the situation CEN/TC 159 will try to engage the HAS Consultant as early as possible in case the CEN/TC fears problems with the assessment by the HAS Consultant.

Currently many contributors doubt that enforcement agencies have the capability or willingness to ensure that the PPE Regulation is enforced. This might bring down the contributors' efforts to aim at standards ensuring users' optimum level of protection and comfort because otherwise the competitive deformation could grow too much.