July 2013

The European Union's System of Conformity Assessment for Personal Protective Equipment

Final Report

Prepared for

National Institute for Occupational Safety and Health
National Personal Protective Technology Laboratory
Pittsburgh, PA 15236

Prepared by

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RTI International is a trade name of Research Triangle Institute.

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EXECUTIVE SUMMARY

As a benchmarking target, the EU offers a rich and evolving model of conformity assessment and market surveillance. The challenges EU officials have faced in building an effective system to remove internal barriers to trade across 28 Member States and the approach they have used to resolve those challenges are highly instructive. The EU system suggests the kinds of resources, procedures, and systems that may be needed in any effective conformity assessment system. Through recent and ongoing improvements, many "best practices" appear to be in place or are emerging. The evolution of the EU system underscores the value, in a conformity assessment system, of shared responsibilities and a collaborative public-private network of organizations and online information systems to foster communication, problem identification, informal technical assistance, and capacity building.

The European Union's system of conformity assessment is a comprehensive approach that features principle-based rather than rule-based product requirements, pre-market assessments as well as post-market controls, and both proactive and reactive market surveillance. Manufacturers must prove products conform to "Basic Health & Safety Requirements" covering horizontal risks before products can be placed on the EU market. There are no technical product requirements. "Harmonized standards" (which legally convey an assumption of conformity) and other European standards are developed by independent European standards organizations, in collaboration with the Member States.

The EU's pre-market conformity assessment requirements are risk-based. EU law divides all PPE into three categories, by level of risk, and establishes a set of conformity assessment procedures for each category.

The procedures for market surveillance of products that have been placed on the market is also governed by EU law. They are designed to be effective, proportionate to the economic scope of the PPE product, and dissuasive. Even when third party involvement is required, manufacturers are given a choice between quality assurance and product certification modules.

A key feature of the EU system is shared responsibility. Manufacturers are responsible for pre-market conformity assessment and are ultimately liable for product safety; other economic operators (importers, distributors) also have responsibilities. Conformity to basic requirements is documented with the Supplier's Declaration of Conformity, technical documentation, and a CE mark affixed to the product. For low-risk products, independent testing is not required. For medium to high-risk products, manufacturers must obtain certificates of conformity from independent, third party conformity assessment bodies. High-risk products also require a quality control system with third party involvement.

Market surveillance is the responsibility of the Member States of the EU. Market Surveillance Authorities conduct proactive surveillance activities on high-risk products and respond to consumer complaints about products posing a danger to the user.

The EU's role is to set policy, coordinate conformity assessment and market surveillance authorities, provide technical assistance, and control the borders in collaboration with the market surveillance authorities.

Conformity assessment and market surveillance are also supported by a network of private, independent coordinating bodies and an array of databases, online tools, rapid information systems and other features that encourage compliance with the procedures, provide technical assistance, and share best practices.

1. INTRODUCTION

The purpose of this report is to describe the European Union's (EU's) system of conformity assessment for personal protective equipment (PPE). This report is part of a larger effort being led by the National Institute for Occupational Safety and Health (NIOSH) in response to a recent Institute of Medicine recommendation that NIOSH develop and implement a risk-based conformity assessment process for non-respiratory PPE (Cohen et.al., 2010).

This report is based on a review of the literature. The documents reviewed include legislative and administrative documents, professional conference papers and proceedings, and information from the websites of stakeholder groups such as the standards organizations and independent safety organizations that form an integral part of the EU conformity assessment system.

The EU defines conformity assessment as the process of demonstrating that a PPE product, before it is placed on the market, meets specific requirements such as standards, regulations and other specifications. It typically includes inspection, testing, certification, accreditation, and related procedures, and covers both the design and production phases of production. The essential objective of a conformity assessment procedure is to demonstrate to public authorities that products placed on the market conform to the requirements as expressed in the relevant legislation, particularly with regard to the health and safety of users.

Market surveillance is a separate process that consists of controls after the product has been placed on the market. The two systems are complementary and equally necessary to ensure the smooth functioning of the EU's internal market. (See ***Appendix A*** for a glossary of terms related to conformity assessment systems.)

Key Features of the European PPE Market

- The EU has approximately 30% of the global PPE market.
- Three product groups make up 71% of the total PPE market (protective clothing, protective gloves, and safety footwear).
- The industry sectors with the highest demand for PPE are manufacturing, construction, mining, and health care.
- Approximately 4,000 companies in the EU are involved in manufacturing PPE.
- A large percentage of enterprises involved in the manufacturing of PPE (56%) are SMEs.
- There are few key players in the European PPE industry; some product market sectors (eye, hearing, and respiratory protection equipment) are highly concentrated.
- Price competition is intense; the margins at production are also low.

The EU is an economic and political union of 28 Member States.[1] Together with the Member States of the European Free Trade Association (EFTA), the EU's system of conformity assessment covers a population of over 490 million.[2] The European PPE market is large, diverse, international and—in some sectors—highly concentrated (European Commission, 2010). The European PPE industry benefits from European employers' and employees' high awareness of workplace safety, which creates a steady demand, and from the EU regulatory framework, which reduces the cyclicality of demand and, through the introduction of high standards, shields European producers against competition from abroad (European Commission: 2010).

The European conformity assessment and market surveillance systems are based on the following principles:

- **Principle-based rather than rule-based requirements.** EU legislation specifies what must be achieved rather than how it should be achieved. Manufacturers must only demonstrate that products fulfill these legislative design and performance requirements. The application of technical standards is voluntary.

- **Balance between pre-market assessment and post-market control**. The EU system goes beyond product certification to include procedures for both enforcement and accountability, through market surveillance.

- **Proactive as well as reactive market surveillance.** Consumer complaints are to be investigated and action taken where appropriate. Market surveillance also includes proactive inspection and testing of products that have been placed on the market.

- **Risk-based conformity assessment, surveillance and corrective actions.** Requirements are designed to be proportional to risks, from the point of view of both the likelihood and the consequences of the product failing to conform to the requirements.

- **Good regulatory practice.** In selecting conformity assessment procedures, the European Commission conducts impact assessments, solicits stakeholder inputs, and conducts Competitiveness Proofing assessments to ensure procedures are appropriate to the scale of production (Sacchetti, 2009).

- **Transparency**. Information is shared about market surveillance activities including test results, risk assessments, accident information, corrective measures taken, and other information. The purpose of this transparency is to help make the system efficient and to encourage accountability.

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[1] The members are: Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom. There are also five candidate countries: Iceland, Macedonia, Montenegro, Serbia and Turkey.

[2] The four countries forming EFTA (that are not also EU members) are Iceland, Liechtenstein and Norway, and Switzerland.

- **Collaboration.** The EU supports a wide range of efforts through communication, technical assistance, and joint action to help all stakeholders comply with the system.

- **Shared responsibility.** Manufacturers have primary responsibility for the safety of products and are held liable for product failures. Independent organizations develop standards, provide conformity assessment and market surveillance services, (authorized and coordinated by EU Member States), and coordinate various aspects of the system. The EU establishes the legal obligations of the various parties, provides financial support to the independent coordinating organizations, and oversees and monitors the system.

This shared responsibility is illustrated in ***Exhibit 1***. In contrast to the U.S. approach, which focuses on pre-market surveillance, the EU seeks a balance between pre-market assessment and post-market control (OECD, 2009; Sacchetti, 2009). Prior to placing a product on the market, the manufacturer

- determines which requirements apply to the product;

- designs, manufactures, and tests the product in accordance with requirements, including the required procedures for the assessment of the conformity (enlisting, when required, the assessment services of third parties);

- drafts the technical documentation of the product;

- takes all measures necessary so that the manufacturing process ensures compliance of the products; and

- upon positive assessment of the products, draws up a declaration of conformity and affixes the required conformity marking on the products (European Commission, 2000).

Importers and distributors also must know product regulations in detail to fulfill their new obligations and responsibilities and are obligated to import or distribute only compliant products. The following are the general obligations of importers and distributors (which are expected to be applicable to PPE in the near future):

- verify the presence of conformity markings, technical documents, user instructions, and information about suppliers and clients (economic operators);

- take corrective measures for non-compliant products, including notifying authorities when a product on the market is non-compliant and poses a risk to consumer or end user; and

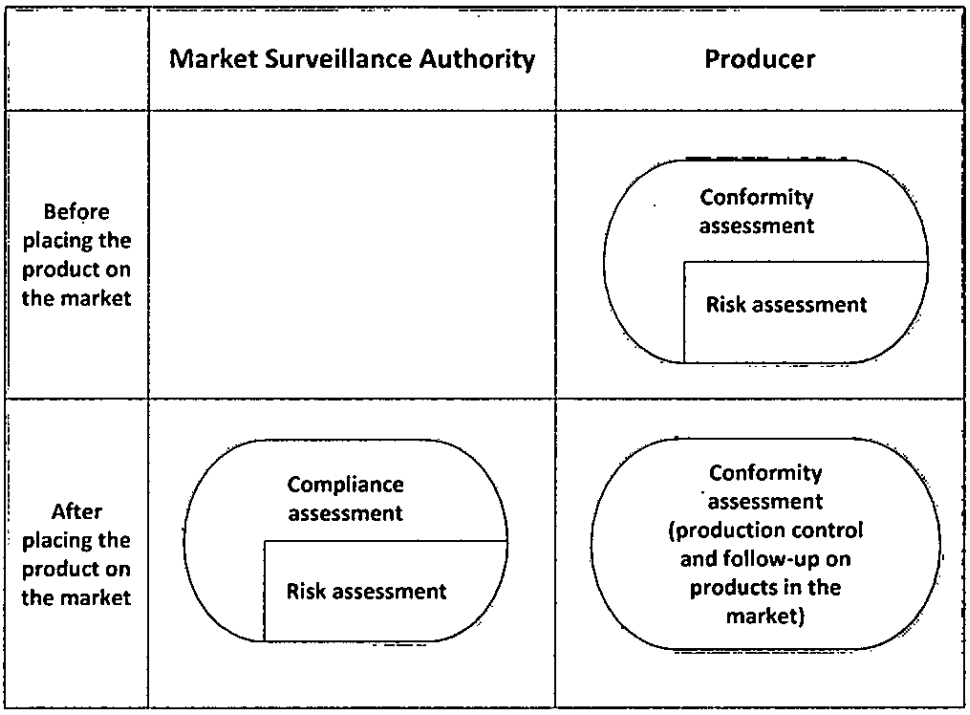
- cooperate with market surveillance authorities.

Independent conformity assessment bodies provide conformity assessment services and perform market surveillance activities. They must be authorized to perform these functions by national government authorities.

Member States are responsible for post-market control to ensure, through market surveillance, that products that have been placed on the market comply with basic requirements. Market surveillance activities are performed by independent organizations, often the same ones responsible for third-party conformity assessments.

This report describes the organizations and requirements for each of these conformity assessment and market surveillance systems, beginning with the legislative context in the following chapter.

Exhibit 1. Responsibilities of Economic Operators and Market Surveillance Authorities Before and After Placing a Product on the EU Market



Source: Reproduced from PROSAFE (2009), Best Practice Techniques in Market Surveillance.

2. LEGISLATIVE AND REGULATORY FRAMEWORK

The EU operates in part through supranational institutions much like those of a federal system or confederation. The legislative institutions of the EU include the following:

- **The European Parliament:** Elected every 5 years by EU citizens, the European Parliament can amend or reject proposed legislation, but cannot initiate legislation. Like the U.S. Congress, the European Parliament does not select or control the top EU executive. PPE conformity assessment issues are typically addressed by the European Parliament's Internal Market and Consumer Protection (IMCO) Standing Committee.

- **The Council of the European Union:** A Council (also known as a "Council of Ministers") is composed of one national minister from each Member State. The national minister chosen to represent a Member State depends on the topic. There are currently 10 Council "configurations" (collectively known as the Council). Those involved most with conformity assessment issues are the Competitiveness Council (COCOM) and the Employment, Social Policy, Health and Consumer Affairs Council (EPSCO).

The vast majority of European laws are adopted jointly by the European Parliament and the Council. The following are the executive institutions of the EU:

- **The European Commission:** This administrative body of about 23,000 civil servants is split into departments called Directorates-General (DGs) and Services. The European Commission is responsible for proposing legislation, implementing decisions and treaties, and conducting the day-to-day work of the EU. The DGs most involved with conformity assessment are the Directorate-General for Enterprise and Industry (DG ENTR) and the Directorate-General for Health and Consumers (DG-SANCO). The European Commission is led by a Cabinet of Commissioners, one from each DG.

- **The European Council**: Composed of the heads of the governments of the Member States, the European Council serves as the collective presidency of the EU.

A key feature of EU legislation is that it tends to be principle-based rather than rule-based. The former specifies what must be achieved (the principle), while the latter specifies how it must be done (the rules). Rule-based legislation is more common in the United States. Principle-based legislation in the EU takes the form of Directives.

The legislative framework for assuring the safety of PPE in the EU is based on two broad policy goals of the EU:

- removing technical barriers to trade caused by differing requirements across markets; and

- protecting the health and safety of consumers, including the workforce.

The EU takes into account the impact of conformance assessment measures on cost competitiveness, capacity to innovate, and international competitiveness, especially with respect to small- and medium-sized enterprises (SMEs). The EU approach to standard setting, testing, and certification requirements for PPE is based primarily on the harmonization of technical standards in each member country.

The EU's legislative framework for harmonizing conformity assessment has evolved significantly since the EU's formation in 1993 and is still evolving. The rest of this chapter provides an overview of the key elements of the legislative framework for PPE conformity assessment in the EU. Details about specific procedures are provided in later sections of this report.

2.1 New Approach and Global Approach Directives

In 1985, the European Council adopted a new approach to technical harmonization and standards aimed at simplifying the removal of technical barriers to trade. The original policy on technical harmonization for PPE (and other products) involved detailed technical requirements, which frequently covered only one product or one element of a product. The adoption of such directives proved to be cumbersome and slow, and today these "old approach" directives no longer apply to PPE.[3]

The Global Approach introduced by the Council Resolution of December 21, 1989 establishes a new policy for how manufacturers can demonstrate that their products meet the legally binding technical requirements in New Approach directives. Before the adoption of the Global Approach, it was common for countries to require mandatory testing and approval by government authorities before a product could be placed on the market (Australian Department of Industry, Science and Resources, 2001). The following are key features of the New and Global Approaches:

- **Principle-based requirements:** EU law (the directives) is limited to establishing "basic requirements" or performance levels to which a product must conform. Basic requirements refer to large families of products (e.g., PPE) and cover horizontal risks (e.g., ergonomics, protection against mechanical impact).
- **Standards are not mandatory:** Alternate paths are permitted for guaranteeing product quality. However, the producer has an obligation to prove that the products conform to the basic requirements.
- A **clear separation between EU legislation and European standardization:** The technical specifications required of products to comply with the directive are established by independent European standards agencies.

[3] Old Approach directives still apply to products for which the nature of the risk requires extensive product-by-product or component-by-component legislation (e.g., chemicals, motor vehicles, pharmaceuticals and foodstuffs).

- **Harmonized standards:** Products manufactured in conformity with harmonized standards are presumed to be conformant to the basic requirements.
- **Requirements for CE Marking:** Common rules are established for affixing the CE Marking on products.
- **A common set of conformity assessment procedures ("modules"):** Procedures are based on the level of risk.

The method of determining conformity is intended to provide adequate assurance of conformity with essential requirements at the lowest possible cost. The conformity assessment modules include self-assessment by the manufacturer, type assessment by an independent body ("Notified Body"), quality assurance assessment by a Notified Body, and inspection of production items by a Notified Body. For the low risks, a supplier's declaration of conformity (SDoC) is sufficient; for the highest risks, third party assessment of products and quality management systems will be specified. Various combinations of modules can be included to give suppliers some choice while still maintaining the required level of assurance of conformity.

2.2 New Legislative Framework

The New Legislative Framework (NLF)[4] was adopted in 2008 as a complement to the New Approach model of legislation and represents a major step forward for market surveillance. The NLF contains two legal instruments that strengthen the conformity assessment system.

Regulation (EC) 765/2008 on Accreditation and Market Surveillance of the NLF sets out the minimum requirements for accreditation and market surveillance relating to the marketing of products. The Regulation took effect in 2010.[5]

Types of EU Legislation

Directives: Set out general rules to achieve a particular result but do not specify the means of achieving that result. Requires Member States to implement by making changes to their laws (through "transposition"). Aims at harmonizing EU law (removing contradictions and conflicts) across Member States.

Regulations: Self-executing. Do not have to be transposed into national law but confer rights or impose obligations on the Union citizen in the same way as national law. Aims at unifying EU law across Member States.

Decisions: Like a regulation, it is binding legislation with direct effect, but is focused more narrowly on a specific person or entity.
http://ec.europa.eu/legislation/

Decision 768/2008/EC of the NLF establishes a common framework for the marketing of products by establishing more clear, transparent and coherent conformity assessment procedures. The Decision sets the policy blueprint for future Community legislation relating

[4] Formally called the New Internal Market Goods Package.

[5] There is some confusion about which of the provisions applies in which situations, and efforts are underway to resolve the confusion with a single market surveillance regulation. The Regulation stipulates that its provisions shall apply if there are no specific provisions with the same objective in EU harmonization legislation (such as the PPE Directive). The Commission is drafting a report on the implementation of Regulation (EC) 765/2008 to provide needed clarifications (Brown, 2011).

to products. Its provisions are expected to become effective for PPE once the PPE Directive is revised.

2.3 Personal Protective Equipment (PPE) Directive

PPE Directive 89/686/EEC has been in effect since 1995. The Directive applies to safety defects arising from the design, manufacture, or marketing of PPE. It is "Union harmonization legislation" designed to implement the New Approach Directive. It applies to protective equipment that is worn or held by the individual in order to protect him or herself against one or more health and safety hazards. It covers equipment for professional use at the workplace as well as for leisure or sports activities.[6]

The PPE Directive

- lays down basic requirements regarding safety;
- divides PPE into three categories depending on the degree of risk;
- lays down risk-based requirements regarding conformance assessment procedures for the three categories of PPE; and
- sets out minimum safety requirements for the use of the PPE.

Fulfilling the Directive's requirements is the responsibility of the manufacturer. PPE can only be placed on the market if it has met all the Directive's requirements.[7] Foreign producers are also obliged to comply with quality standards, sizing, and packaging requirements set down by the Directive.

A recent study for the European Commission concludes that, although "it is difficult to isolate the impact of the Directive on the PPE market and EU economy as a whole," the Directive appears to have had positive effects. The Directive has led to the harmonization of standards and regulations on protective equipment, which removed barriers to trade related to the need to comply with the standards and regulations of different jurisdictions. The harmonization of standards, in turn, has meant that suppliers have had to face more direct competition from other producers within the EU, which put downward pressure on prices while shielding European producers against competition from low-cost, low-quality producers in other parts of the world. The study also noted there had been reduction in the number injuries and of working days lost as a result of these injuries since the PPE Directive came into force. However, available data are not disaggregated enough to be able to

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[6] It excludes equipment designed for use by the armed forces, police, self-defense or rescue operations on aircraft or ships; helmets and visors for users of 2 or 3-wheeled motor vehicles, and those designed for private use against adverse atmospheric conditions, damp, water, and heat (e.g., umbrellas or dishwashing gloves).

[7] Annex 1 of the PPE Directive provides a list of PPE that are not covered, which it labels as Category 0.

attribute trends in injuries directly to the PPE (European Commission DG Enterprise and Industry, 2010a).

The PPE Directive is currently being revised to bring its rules into alignment with Decision 768/2008/EC of the New Legislative Framework. The main elements to be addressed are accreditation, Notified Bodies, CE marking and conformity assessment, definitions and obligations, and market surveillance. The proposed amendments to the PPE Directive are designed to increase consistency between the products covered by the Directive and the health and safety risks associated with the use of these products. They are also designed to eliminate legal uncertainties and increase compliance with the Directive's provisions. In the revised PPE Directive,

- some products will be included and others will be excluded from the scope of the Directive;
- the risk categories under which some products are classified will likely change;
- some of the Basic Health and Safety Requirements that have proven impractical and difficult to enforce will be modified;
- alignments will be made with Regulation (EC) 765/2008 and Decision 768/2008/EC of the New Legislative Framework; and
- some conformity assessment requirements will likely be redefined (European Commission DG Enterprise and Industry, 2010a).

The expected amendments are described in more detail in this report. The expected changes to the conformity assessment requirements include the following:

- **Validity of EC type-examination certificates for Category 2 and 3 products:** Currently the CE marking for PPE products has no time limit. This means that if the standards of the Directive change, products that do not meet the new standards can nonetheless still be sold under the CE marking. The proposed changes would introduce time limits for examination certificates (5 years is proposed) and are intended to improve clarity and facilitate market surveillance.
- **Content of EC type-examination certificates:** The proposed change would codify the content of the EC type examination certificates either by including the standard content into the Directive or by asking the Notified Bodies to agree on minimum content. The purpose is to make it easier for market surveillance authorities to identify products.
- **Quality control requirements:** The proposed changes would clarify the quality control requirements. The proposed amendments would also introduce the duty to send declarations of conformity to the market surveillance authorities.
- **EC declaration of conformity:** The proposed amendment is to create a requirement to provide a copy of the EC declaration of conformity (DoC) with the PPE. It is intended to facilitate market surveillance.

- **Introduction of a technical file requirement for Category 1:** The purpose is to provide better clarity about stakeholders' responsibilities and to facilitate market surveillance.

- **Introduction of definition/responsibility of economic operators:** The proposed amendments would extend the requirements of the Directive to importers and distributors. It is intended to avoid legal uncertainties (European Commission DG Enterprise and Industry, 2010a).

One expected effect of the revised Directive will be to require conformity assessment by a Notified Body for most types of PPE (Thierbach, 2012). The European Commission may also change the nature of this legal act from a Directive to a Regulation. By eliminating the need to transpose the rules into national law (which is required for directives), this would speed up the application of the revised act.

As part of the revision process, the European Commission conducted an Impact Assessment of the proposed changes. In general, Impact Assessments are required for the most important Commission initiatives and those which will have the most far-reaching impacts (European Commission, 2009). This is the first time that an Impact Assessment Study has been carried out in the field of PPE (European Commission, 2013). The Impact Assessment Report recommends each of the proposed changes listed above (European Commission, 2010a).

Impact Assessments

The European Commission's guidelines specify 6 key analytical steps that must be completed in any Impact Assessment:

1. identification of the problem,
2. definition of objectives,
3. development of policy options,
4. analysis of the impact of the options,
5. comparison of the options and identification of the preferred options, and
6. outlining policy monitoring and evaluation.

Part of the Impact Assessment involved a Competitiveness Proofing, which focused on three dimensions of enterprise competitiveness:

- **Cost competitiveness:** the cost of doing business, which includes cost of intermediate inputs (including energy) and of factors of production (labor and capital);

- **Capacity to innovate:** the capacity of the business to produce more and/or higher quality products and services that meet better customers' preferences; and

Competitiveness Proofing

The aims of Competitiveness Proofing are to (1) further improve the analytical quality of impact assessment reports, and (2) facilitate the design of policies that take full account of competitiveness impacts, given their overall set of objectives (European Commission, 2012).

- **International competitiveness:** the likely impact of the policy proposal on the European industries' market shares and comparative advantages (European Commission, 2012).[8]

Specific attention is paid in Competitiveness Proofing to the impact of proposed amendments on small and medium-sized enterprises. Once Impact Assessments and Competitiveness Proofing reports are approved by the Impact Assessment Board, the European Commission formulates the text of the revised Directive/Regulation and submits the proposal to Council and Parliament (Thierbach, 2012).

2.4 European Standardization Regulation

A recent reform of the European Standardization system, Regulation (EC) No 1025/2012, is designed to enhance the transparency of the standardization process by facilitating representation and participation of SMEs in the process (European Commission, 2012c). The Regulation, which went into effect in January 2013, promotes greater involvement of consumer and societal organizations, including public authorities, in standardization activities, by establishing rules regarding

- the cooperation between European standardization organizations, national standardization bodies, Member States and the European Commission;
- the establishment of European standards and European standardization deliverables for products and for services in support of Union legislation and policies; and
- the financing of European standardization organizations by the Union (European Commission, 2012b).

2.5 Product Safety and Market Surveillance Package

A proposed new regulation, submitted to the European Parliament and Council by the European Commission in February 2013, would further amend the PPE and other harmonized sector Directives by establishing a single regulation on market surveillance. The EU's Single Market Act II of 2012 (COM, 2012) identified the Product Safety and Market Surveillance Package as priority initiative that would contribute to boosting growth and creating jobs. If passed, it is expected to go into effect in 2015 (European Commission, 2013a).

Currently, market surveillance rules for PPE and other products are covered by three sets of legislation (Regulation [EC] 765/2008, the General Product Safety Directive and various pieces of product harmonized legislation such as the PPE Directive) (European Commission, 2013b: 60 and 2013c: 61). The proposed regulation would do the following:

[8] Competitiveness Proofing has been required since 2010 for all important new policy proposals with significant effects on industry as part of the impact assessment process (European Commission, 2010b). In January 2012 a "Competitiveness Proofing Toolkit" was presented for use in the Impact Assessment procedures (European Commission, 2012a).

- Ensure consistency in EU market surveillance activities by not distinguishing between consumer and non-consumer products or between harmonized and non-harmonized products.

- Streamline procedures for the notification by Member States of information about products presenting a risk and corrective measures taken. The same system of notifications would be used for all products.

- Strengthen controls at external borders.

- Promote the exchange of information relating to market surveillance in an easily accessible database. Market surveillance authorizes would not need to repeat tests and assessments already carried out in relation to a product by authorities in another Member State.

- Give market surveillance authorities the power to charge economic operators fees when they require corrective action to be taken in relation to a product or must monitor corrective action proposed by an operator.

- Improve the RAPEX system, simplifying notification criteria, providing more detailed information to increase the relevance and follow-up, and making time limits for sending notifications more realistic and workable.

- Establish a European Market Surveillance Forum to develop best practices for harmonized implementation across the EU.

- Develop a multi-annual plan for market surveillance to identify and pursue areas in which coordination by the European Commission would add value and bring real improvements.

3. PRODUCT STANDARDS

3.1 Basic Health and Safety Requirements

The design and manufacture of PPE for the EU market is subject to Basic Health and Safety Requirements (BHSRs) established by the PPE Directive.[9] Manufacturers must meet the relevant BHSRs before placing products on the EU market. The BHSRs "define the results to be attained, or the hazards to be dealt with, but do not specify or predict the technical solutions for doing so" (European Commission, 2010c). Some BHSRs are general requirements that apply to all PPE; others are specific to classes or types of PPE or to particular risks. The list of BHSRs is provided in ***Appendix B***. The categories of requirements are provided in ***Exhibit 2***.

In line with the principles of the New Approach, the BHSRs are formulated to "enable the assessment of conformity with those requirements, in the absence of European harmonized standards or in case the manufacturer chooses not to apply [the harmonized standards]" (European Commission, 2010c, 42). By giving manufacturers the flexibility to choose the most suitable way to meet the requirements, the aim of the PPE Directive is to allow technical progress in materials and product design "since assessment of whether requirements have been met or not are based on the state of technical know-how at a given moment" (European Commission, 2010c, 42).

3.2 Standards

The primary objective of European standardization is to define voluntary technical or quality criteria with which manufacturers, production processes or services may comply (European Commission, 2013c). The European standardization process is a voluntary activity of building consensus through an independent, recognized standardization body. Compliance with technical standards is not legally compulsory. Manufacturers are only required to demonstrate that the product fulfills the BHSRs. In practice, however, European retailers and buyers often demand that products are in compliance with standards (European Commission, 2013d).

Manufacturers may choose to comply with various standards to demonstrate the fulfillment of the BHSRs, including

- international standards adopted by an international standards organization;
- European standards adopted by one of the three independent European Standards Organizations (ESOs);
- Harmonized standards adopted by one of the three independent European Standards Organizations at the request of the European Commission; or

[9] In PPE Directive 89/686/EEC the term Basic Health and Safety Requirement is used. In other directives, the term is Essential Health and Safety Requirement (EHSR or ER).

- national standards adopted by a national standardization body.

European and harmonized standards (collectively referred to as EN) describe in detail how a particular type of product should be tested and what performance is required. The tests are designed to assess the products against the BHSRs for the risks of the particular activity for which the product is intended to be used (Doughty, 2012). The standards are posted on the European Commission's website.[10]

Exhibit 2. Types of Basic Health and Safety Requirements for PPE

General requirements for all PPE	1. Design principles 2. Innocuousness of PPE 3. Comfort and efficiency 4. User information
Classes or types of PPE	1. PPE incorporating adjustment systems 2. PPE "enclosing" the parts of the body to be protected 3. PPE for the face, eyes and respiratory tracts 4. PPE subject to ageing 5. PPE which may be caught up during use 6. PPE for use in explosive atmospheres 7. PPE intended for emergency use or rapid installation and/or removal 8. PPE for use in very dangerous situations 9. PPE incorporating components which can be adjusted or removed by the user 10. PPE for connection to another, external complementary device 11. PPE incorporating a fluid circulation system 12. PPE bearing one or more identification or recognition marks directly or indirectly relating to health and safety 13. PPE in the form of clothing capable of signaling the user's presence visually 14. "Multi-risk" PPE
Particular risks	1. Protection against mechanical impact 2. Protection against (static) compression of part of the body 3. Protection against physical injury (abrasion, perforation, cuts, bites) 4. Prevention of drowning (lifejackets, armbands and lifesaving suits) 5. Protection against the harmful effects of noise 6. Protection against heat and/or fire 7. Protection against cold 8. Protection against electric shock 9. Radiation protection 10. Protection against dangerous substances and infective agents 11. Safety devices for diving equipment

[10] http://www.newapproach.org/Directives/ProductFamilies.asp?89/686/EEC

European and harmonized standards are developed through a consensus-based approach that is open to all stakeholders, including public authorities and economic operators, and European organizations and associations representing SMEs and societal stakeholder interests.[11] The European Commission encourages standards to be based on relevant international standards. Standards must take into account environmental impacts throughout the life cycle of products. The European Commission's Joint Research Centre (JRC) plays an active role in the European standardization system.

3.3 European Standards Organizations (ESOs) for PPE

The European Standards Organizations involved with developing standards for PPE are the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC). There are currently about 350 CEN, CEN ISO, or amendment standards and 7 CENELEC standards covering PPE. Standards are still missing for some types of PPE (European Commission, 2013e). The work of the European Standards Organizations is financed in part by grants from the EU.[12]

3.4 CEN/CENELEC Standards Development Process

European and harmonized standards for PPE are developed by CEN and CENELEC according to principles of national delegation whereby their members develop a European consensus. For example, CEN's National Members are the National Standards Bodies (NSBs) of the 28 European Union countries, the Former Yugoslav Republic of Macedonia, and Turkey plus three countries of the European Free Trade Association (Iceland, Norway, and Switzerland). There is one member per country.

CEN Technical Committees for PPE

CEN 79	Respiratory protective devices
CEN 85	Eye protective equipment
CEN 158	Head protection
CEN 159	Hearing protectors
CEN 160	Protection against falls from height including working belts
CEN 161	Foot and leg protectors
CEN 162	Protective clothing including hand and arm protection and lifejackets
CEN 122	Ergonomics

The process of developing a new European standard can be initiated by public agencies, non-governmental organizations or private persons, including the Vertical and Horizontal coordinating bodies of Notified Bodies (described in Chapter 7). Most European Standards have been drawn up in Technical Committees. A CEN Technical Committee is a technical decision making body that manages the preparation of the CEN standardization process for a particular category of PPE.

[11] These include the European Office of Crafts, Trades and SMEs for Standardization (NORMAPME), European Association for the Co-ordination of Consumer Representation in Standardization (ANEC), European Environmental Citizens Organization for Standardization (ECOS), and European Trade Union Institute (ETUI).

[12] CEN standardization system costs approx. 800 million Euro per year. 80% of the costs are carried by industry.

Committee members are national delegations designated by the CEN members. The process takes an average of 36 months (but is possible in 16 months) (European Committee for Standardization, 2013). Once adopted, ENs are transposed into national standards.[13] The steps in the process are described in ***Exhibit 3.***

3.5 Harmonized Standards

Of the four types of standards, harmonized standards are the only ones that provide a presumption of conformity with the corresponding BHSRs. A harmonized standard is a European standard developed based on a request (or "mandate") from the European Commission to a recognized European Standards Organization (e.g., CEN or CENELEC). The request provides guidelines, which the standards must respect to meet the basic requirements or other provisions of relevant European Union harmonization legislation. CEN has developed guidelines, including a checklist, for drafting and verifying mandated European standards for PPE (European Committee for Standardization, 2007). About 26% of European standards have been developed following specific mandates from the European Commission (European Commission, 2011).

Content of EC Mandates

- Justification and indication of the framework of the European and regulatory policy (e.g., legislation such as a New Approach directive).
- Reference to and clarification of the requirements, providing a clear and precise indication of the relationship between its content and the Basic requirements covered.
- Involvement of the parties concerned, that specifies the collaboration and involvement of certain interested parties, such as environmental bodies or consumer associations.
- Completion dates, establish a timeline for adoption of a standard by the ESO
- "Standard" clauses such as the standstill for national activities and the close cooperation among ESOs.

The use of these standards remains voluntary, but compliance with harmonized standards provides a presumption of conformity with the corresponding requirements of harmonization legislation. Manufacturers, other economic operators (importers, authorized representatives, distributors) and conformity assessment bodies can use harmonized standards to demonstrate that products, services, or processes comply with relevant EU legislation. Most harmonized product standards are based on international standards (Rajamäki, 2002).

The standardization requests that have been issued by the European Commission and accepted by the ESOs are available in the EC's database of mandates.[14] The content of the mandates is covered in EC law (European Commission, 2009a).

[13] CEN also facilitates CEN Workshop Agreements (CWAs), which are less formal documents. A CWA can satisfy market demands for a more flexible and timelier alternative to the traditional European Standard.

[14] http://ec.europa.eu/enterprise/standards_policy/mandates/database/index.cfm?fuseaction=titSearch.main&CFID=5843496&CFTOKEN=2de220420c55c3a4-1C7563A5-B074-45CC-3A961DA00862A3B7&jsessionid=f5122f601404b59cd02d593938641e505556TR

Exhibit 3. Steps in the Development of an EN

Step	Description
1. Proposal to develop an EN	Any interested party can introduce a proposal for new work in CEN. Most standardization work is proposed through the National Standards Bodies of one or more of the EU Member States.
2. Acceptance of the proposal	Once a project to develop an EN is accepted by the relevant CEN Technical Committee (TC), the member countries put all national activity within the scope of the project on hold. This means that they do not initiate new projects, nor revise existing standards at national level. This obligation is called "standstill" and allows efforts to be focused on the development of the EN.
3. Drafting	The EN is developed by experts within a Technical Body. The Technical Body prepares a technical report with recommendations about issues to be covered in the standards
4. CEN Enquiry: Public comment	Once the draft of an EN is prepared, it is released for public comment, a process known in CEN as the "CEN Enquiry." During this public commenting stage, everyone who has an interest (e.g., manufacturers, public authorities, consumers, etc.) may comment on the draft. These views are collated by the CEN national members and analyzed by the CEN Technical Body.
5. Adoption by weighted vote	Taking into account the comments resulting from the CEN Enquiry, a final version is drafted, which is then submitted to the CEN national members for a formal vote, weighted by population size.
6. Publication of the EN	After its publication, a European Standard must be given the status of national standard in all CEN member countries, which also have the obligation to withdraw any national standards that would conflict with it. This guarantees that a manufacturer has easier access to the market of all these European countries when applying European Standards and applies whether the manufacturer is based in the CEN territory or not.
7. Review of the EN	To ensure that a European Standard is still current, it is reviewed at least within five years from its publication. This review results in the confirmation, modification, revision or withdrawal of the EN.

Source: European Committee for Standardization (2013)

The European Commission drafts mandates through a process of consultation with stakeholders (social partners, consumers, SMEs, relevant industry associations, etc.). Draft mandates are submitted to a Committee on Standards (European Commission, 2012d). They are then submitted to the Member States in the Standing Committees of the standards organization.

To create the capacity to confer this presumption of conformity, the references of harmonized standards must be published in the *Official Journal of the European Union*. Once approved and published in the journal, all diverging national standards must be withdrawn, according to internal rules of the European Standards Organizations. The official list of

harmonized standards for PPE are posted on the European Commission's website[15] and are listed in ***Appendix C*** of this report.

3.6 Role of International Standards

CEN and the International Organization for Standardization (ISO) coordinate standards development on the basis of the "Vienna Agreement" of 1991.[16] About 30% of the ENs in the CEN collection are identical to ISO standards (European Committee for Standardization, 2013). The European Standards Organizations are also involved in a regular and ongoing dialogue and exchange of information with the American National Standards Institute (ANSI). At their meeting in Dublin in February 2013, they agreed they will "intensify their collaboration with a view to aligning their standards related issues arising from the implementation of the proposed Trade Agreement between the European Union and the United States...The Transatlantic Trade and Investment Partnership (TTIP) will aim to remove barriers to trade between the EU/EEA and the USA, and therefore it will be important to reduce any remaining differences between American and European standards in a number of sectors, and also to encourage a common approach, preferably at global level" (CEN-CENELEC, 2013).

[15] http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/personal-protective-equipment/index_en.htm

[16] Officially, the *Agreement on Technical Cooperation Between ISO and CEN*.

4. PRE-MARKET CERTIFYING OF CONFORMITY

Manufacturers and other economic operators must verify and declare compliance with BHSRs for PPE before placing goods on the market. This is done with a combination of several risk-based tools. The assessment of conformity is carried out either by the manufacturer or by a third-party conformity assessment body, depending on risk level.

4.1 Notified Bodies

Where the PPE Directive requires third-party conformity assessment activities, these are undertaken in the EU by a "Notified Body." A Notified Body is a European-based organization that has been appointed by a Member State's national notifying authority to perform certification, inspection, or testing for the DoC of products. National notifying authorities "notify" the European Commission of the organizations designated to perform conformity assessment services.

Member States are responsible for ensuring that the Notified Bodies are competent and fulfill the requirements for Notified Body as defined in the PPE Directive. To be eligible as a Notified Body, an organization must be a legal entity established in the territory of the Member State concerned and under its jurisdiction. Notified Bodies must be technically qualified, fully independent, impartial, and have a high level of professional indemnity insurance (European Commission, 2010c). In addition, some non-EU Conformity Assessment Bodies (CABs) may also conduct investigations, certifications, and laboratory tests under Mutual Recognition Agreements. All Notified Bodies are subject to routine surveillance at regular intervals by the competent authorities of the Member States to verify their qualifications.

A Notified Body may not be the manufacturer, designer, or supplier of the PPE under assessment. The Notified Body may accept measurement results from a manufacturer's laboratory and can have part of their work carried out by another body/laboratory (through subcontracting) on the basis of established and regularly monitored competence. However, the Notified Body remains responsible for all of its activities and issued documents.

Notified Bodies are designated for a defined range of conformity assessment procedures and types of products and risks. A manufacturer can choose any Notified Body in Europe that is designated for the type of product and required conformity assessment procedures. There are currently 112 European-based Notified Bodies in the field of PPE. The European Commission publishes a list of all Notified Bodies in the *Official Journal of the European Union* and on their website (NANDO Net).[17]

[17] http://ec.europa.eu/enterprise/newapproach/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=6

Prior to the development of the EU, public institutions typically provided product certification services that Notified Bodies now perform. Today, those public organizations have largely been privatized and consolidated under international ownership. Some now exist as non-profit organizations; others are owned by a multinational body such as the Underwriters Laboratory.

4.2 Accreditation and Auditing of Notified Bodies

National notifying authorities must demonstrate the technical competence of their Notified Bodies. Decision 768/2008/EC encourages demonstration through accreditation and promotes a high, uniform level of performance of Notified Bodies through strengthened supervision by Member States. Accreditation is a third-party attestation of the Notified Body's competence to carry out specific conformity assessment tasks. It serves as an impartial means of assessing and conveying the technical competence, impartiality, and professional integrity of conformity assessment bodies (European Commission, 2008).

The use of accreditation differs across Member States and across sectors, but is expected to become required under the revised PPE Directive/Requirement. Some Member States have made accreditation for notification purposes compulsory, and there is evidence of an increasing use of this method.[18] Under the current PPE Directive, accreditation operates in all Member States, but lacks a common set of rules.

Accreditation institutions in the EU are national public bodies with a defined monopoly. Regulation (EC) 765/2008 of the New Legislative Framework, which is in effect for the PPE sector, sets out requirements for accreditation (including ISO/IEC 17011 requirements) and creates a legal framework for operating accreditation in Europe. Specific provisions of the regulation include the following:

- Accreditation is carried out by one single national accreditation body (NAB) appointed by its Member State.
- Accreditation is performed as a public authority activity, completely separated from commercial assessment activities.
- National accreditation bodies operate free from commercial motivations and on a not-for-profit basis.
- Competition between accreditors and between accreditors and accredited conformity assessment bodies within the EU internal market is prevented.
- A set of requirements for NABs is established.

[18] At the end of 2009, before the Regulation came into force, 1,118 of 2,249 Notified Bodies (49.7%) were accredited; as of June 2012, 2,196 of 3,106 Notified Bodies (70.7%) were accredited (European Commission, 2013f).

- The European Cooperation for Accreditation (EA) is established to oversee the European accreditation infrastructure for PPE, including peer evaluation of national accreditation bodies, and cross-border accreditation issues.
- Member States have an obligation to share information about their accreditation activities.

The National Accreditation Bodies have been established in all the Member States (they are listed on the European Commission's website[19]), although not all national accreditation bodies perform the full scope of activities (European Commission, 2013f).

To avoid the need for multiple accreditations, the European Commission has also adopted a policy document that explains how accreditation bodies should proceed for multi-site international conformity assessment bodies and subcontracting. The EA developed guidelines on how to put into practice these policy principles (European Commission, 2013f).

Peer Evaluation of National Accreditation Bodies

The EU also encourages peer evaluation to ensure continuous quality control of the European accreditation system. The EA is an association of national accreditation bodies in Europe that have been officially recognized by their national governments to assess and verify conformity assessment organizations (http://www.european-accreditation.org/home). The EA's 35 full members are accreditation bodies located in an EU or EFTA Member State, or in an EU candidate country. The EA also has 13 associate members. The EA is financed by the European Commission to manage the official European accreditation infrastructure, including the operation and management of the peer evaluation system.

Through the EA, members can apply for peer-group evaluation. Members who pass evaluation may sign the multilateral agreement (MLA) for accreditation as a certification body, laboratory, or inspection body. The MLA establishes a uniform level of competence of the accredited body. Signers of the MLA recognize and promote the equivalence of each other's systems, certificates and reports.

A similar system of peer review and auditing of testing laboratories is in place at the international level through the International Laboratory Accreditation Cooperation (https://www.ilac.org/) for laboratories and inspection accreditation. Peer review and auditing of accreditation bodies is also conducted through national membership in the International Accreditation Forum (IAF, http://www.iaf.nu/). The IAF focuses on management systems, products, services, personnel and other similar programs of conformity assessment. The EA coordinates with each of these institutions.

[19] http://ec.europa.eu/enterprise/newapproach/nando/index.cfm?fuseaction=ab.main

4.3 Risk-based Product Categories and Conformity Assessment Modules

The PPE Directive establishes the conformity assessment procedure to be followed by manufacturers before the PPE product is placed on the market. Manufacturers determine the risk category for pre-market assessment. The procedure depends on the severity of the risk concerned and covers the design and/or the production of the product. The Directive makes a distinction between three, risk-based (rather than product-based) categories of PPE.

Category I PPE

Category I PPE are simple design products designed to protect the user against gradual or unexceptional risks. It assumes the user can assess the level of protection provided against the minimal risks concerned, the effects of which, when they are gradual, can be safely identified by the user in good time (European Commission, 1989). Category I PPE is intended to protect the wearer against

- mechanical action whose effects are superficial (e.g., gardening gloves, thimbles);
- cleaning materials of weak action and easily reversible effects (e.g., gloves affording protection against diluted detergent solutions);
- risks encountered in the handling of hot components which do not expose the user to a temperature exceeding 50 °C or to dangerous impacts (gloves, aprons for professional use);
- atmospheric agents of a neither exceptional nor extreme nature (e.g., headgear, seasonal clothing, footwear);
- minor impacts and vibrations which do not affect vital areas of the body and whose effects cannot cause irreversible lesions (e.g., light anti-scalping helmets, gloves, light footwear); and
- sunlight (sunglasses).

Category II PPE

Category II PPE are intermediate design products designed to protect against medium risk, i.e., those risks not enumerated under Category I or Category III such as protectors for motorcyclists, high-visibility vests.

Category III PPE

Category III PPE are complex design products designed to protect against mortal danger or against dangers that may seriously and irreversibly harm health "the immediate effects of which the designer assumes the user cannot identify in sufficient time." Category III PPE is intended to protect the wearer against

- filtering respiratory devices for protection against solid and liquid aerosols or irritant, dangerous, toxic or radiotoxic gases;

- respiratory protection devices providing full insulation from the atmosphere, including those for use in diving;
- PPE providing only limited protection against chemical attack or against ionizing radiation;
- emergency equipment for use in high-temperature environments the effects of which are comparable to those of an air temperature of 100°C or more and which may or may not be characterized by the presence of infra-red radiation, flames or the projection of large amounts of molten material;
- emergency equipment for use in low-temperature environments the effects of which are comparable to those of an air temperature of −50 °C or less;
- PPE to protect against falls from a height; and
- PPE against electrical risks and dangerous voltages or that used as insulation in high-tension work.

The specific types of PPE that fall into these three categories is listed in ***Appendix D***. Some products fall into more than one category.

Pre-market conformity assessment procedures are designed to avoid unnecessary burdens for economic operators (especially SMEs) by providing a choice of appropriate conformity assessment procedure (Sacchetti, 2009). Even when third party involvement is mandatory, manufacturers are given a choice between quality assurance and product certification modules. The goal is to be proportionate and effective, taking into account the economic infrastructure of the PPE sector, including the complexity of the product, size of companies, and the scope of production (European Commission, 2013f). The EU selects conformity assessment procedures for categories of PPE based on appropriateness to the type of product and the nature and level of risk involved.

Conformity Assessment Modules

The three-category system for PPE conformity assessment derives from a menu of eight conformity assessment modules.[20] The modules enable the conformance assessment procedure to be tailored from the least to the most stringent, in proportion to the level of risk involved and the level of safety required.

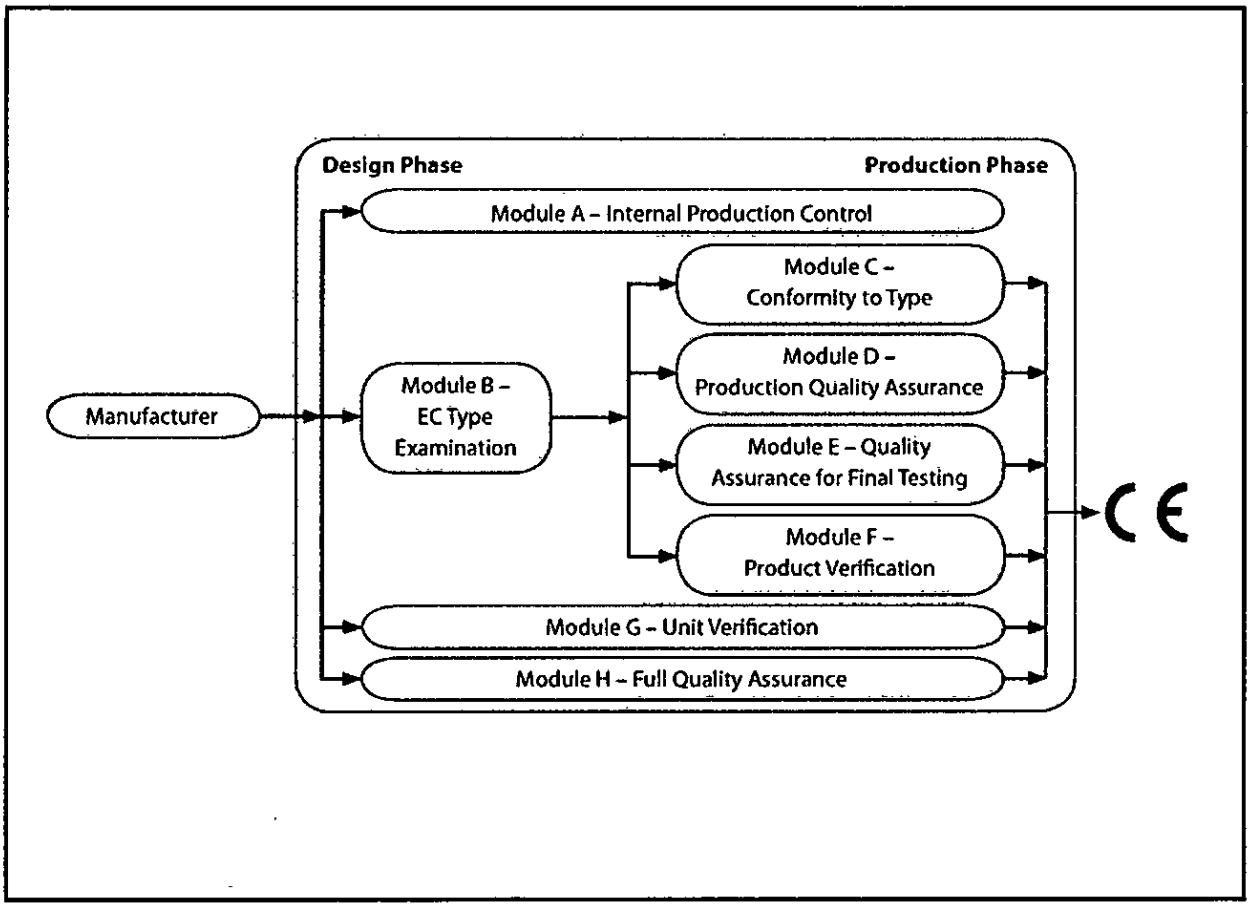
Modules range from manufacturer's declaration of conformity to full quality assurance certification (see ***Exhibit 4***). All procedures give equivalent results, i.e., the presumption of conformity. A full description of the modules is provided in ***Appendix E.*** A summary of the

[20] Originally established in 1993 as part of the Global Approach to conformity assessment, the use of the modules as the basis for PPE and other harmonized products is reinforced by Decision 768/2008/EC of the NLF.

procedures is presented in ***Exhibit 5***. They are similar (though not identical) to the seven-type product certification system described in the ISO/IEC Guide 67.[21]

The correspondence between the modules and the three risk-based PPE Categories is defined in the PPE Directive. Category I products correspond with Module A; Category II products require Modules B and C; and Category III products require Modules B, C, and D (European Commission, 2000).

Exhibit 4. Overview of Pre-Market Conformity Assessment Procedures



Source: European Commission (2000).

[21] The modules based on ISO EN standards. The quality assurance techniques (modules D, E, H and their variants) describe the elements a manufacturer must implement in order to demonstrate that the product fulfills the essential requirements of the applicable directive, and are derived from EN ISO 9000 and EN ISO 9001. Module A1 corresponds somewhat with ISO/IEC System 1b; Modules A2 plus B with System 1a; Module C with System 2; and so forth. Both systems call for increasing involvement of third parties in testing, oversight, verification, and surveillance across the modules.

Exhibit 5. Conformity Assessment Requirements, by Module

Requirement	Module							
	A	B	C	D	E	F	G	H
Manufacturer establishes technical documentation	X	X		X	X	X	X	X
Internal production control. Manufacturer ensures compliance of the manufactured products with the technical documentation and/or the applicable requirements of the legislative instrument.	X		X	X	X	X	X	X
Internal production control. Manufacturer ensures compliance of the manufactured products with the EC type-examination certificate			X	X[3]	X	X		
Conformity marking (CE marking)	X		X	X	X	X	X	X
Supplier's Declaration of Conformity (attestation)	X		X	X	X	X	X	X
Product testing (Supervised or conducted by a Notified Body)	X[1]		X[2]		X			
EC type-examination by a Notified Body		X				X		X[6]
Quality system, assessed by a Notified Body				X	X[4]			X
Surveillance by a Notified Body				X	X			X
Verification by a Notified Body						X[5]	X	
Design examination by a Notified Body								X

[1] Applies to two optional additions to Module A: A1, Supervised product testing of specific aspects of the product or A2, Supervised product checks at random intervals

[2] Applies to two optional additions to Module C: C1, Supervised product testing of specific aspects of the product or C2, Supervised product checks at random intervals. Follows Modules B.

[3] Module D includes optional D1, Quality assurance of the production process.

[4] Module E includes optional E1, Quality assurance of final product inspection and testing

[5] Module F includes optional F1, Conformity based on product verification

[6] Module H includes optional H1, Conformity based on full quality assurance plus design examination

Conformity Assessment Procedures for Category I PPE

All procedures for demonstrating compliance with regulatory requirements produce the same level of conformity (see ***Exhibit 6***). The required procedures for Category I PPE products are

- a Supplier's Declaration of Conformity (SDoC
- technical documentation, and
- CE mark.

Independent testing is not required for Category I products.

Conformity Assessment Procedures for Category II PPE

The required procedures for Category III PPE products are

- EC type-examination and EC certificate of conformity by a Notified Body (an authorized, independent inspection organization),
- SDoC attesting the PPE is identical to the product for which the EC declaration has been issued,
- technical documentation, and
- CE mark.

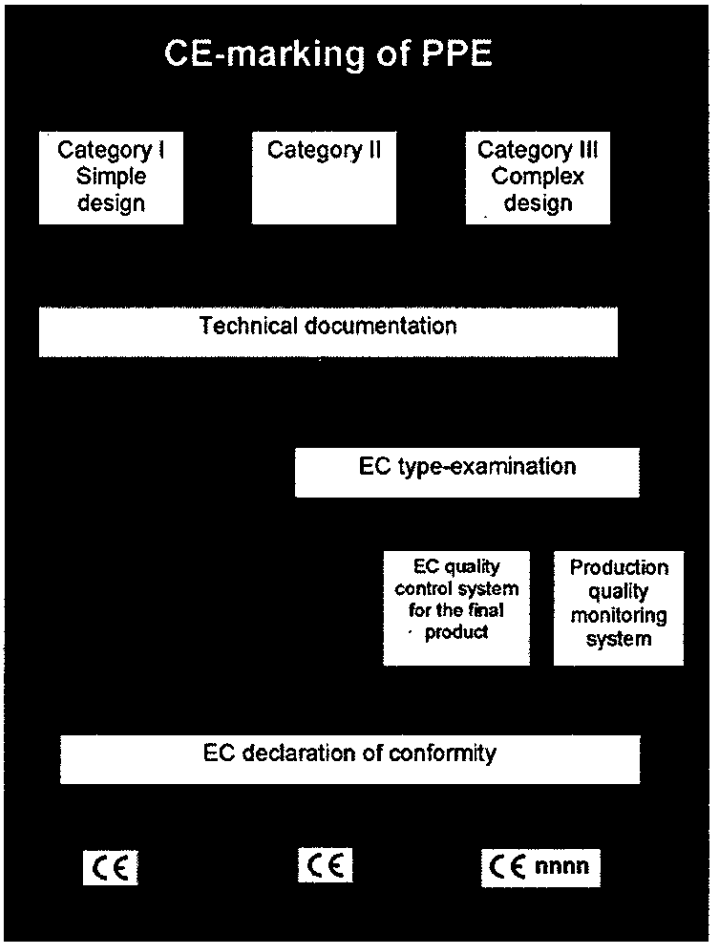
The production process is not independently assessed, but regular product samples are submitted for testing.

Conformity Assessment Procedures for Category III PPE

The required procedures for Category III PPE products are

- EC type-examination and EC certificate of conformity by a Notified Body;
- Quality Assurance procedures, either (a) an internal EC quality control for the final product supervised or conducted by Notified Body, which would conduct random checks at least annually, or (b) a system for ensuring EC quality of production by means of monitoring (e.g., ISO 9001);
- technical documentation; and
- CE mark that includes the Notified Body's 4-digit identification number.

Exhibit 6. Pre-Market Conformity Assessment



Source: European Commission (2010c).

4.4 Technical Documentation to be Supplied by the Manufacturer

Technical documentation is the technical file that provides information on the design, manufacture and operation of the product. A main purpose of drafting the technical documentation is to provide supporting evidence of the conformity of the product in

question. The content of the technical documentation is determined by the PPE Directive and is based on EN ISO 17050-2:2004.

All manufacturers must establish a technical file documenting the methods used by the manufacturer to ensure that the PPE complies with the basic requirements relating to it. For Category II and III PPE, technical documentation should also cover at least the following elements:

- general description of the product;
- design sketches, working blueprints, charts including assemblage blueprints and arrangement of parts, etc.;
- descriptions and explanations of blueprints;
- reference to the EU Directive(s), harmonized standards and other normative documents taken into account in the production of this type of goods;
- instruction for the use of the product, including safety instructions;
- copy of the SDoC;
- certificate or technical report of the Notified Body; and
- name and address of the manufacturer (representative) and the Notified Body.

Any changes made to the product must be documented in the technical file. Technical files must be stored for no less than 10 years after the last product is placed on the market and is recommended for the entire period of product service. Technical files must be presented on request to market surveillance authorities of the EU.

4.5 Supplier's Declaration of Conformity (SDoC)

If a product complies with all the requirements of the Directives, the manufacturer must complete the Supplier's Declaration of Conformity (SDoC). The SDoC indicates that the product meets all the necessary requirements of the Directive(s) applicable to the specific product. The model SDoC provided in the PPE Directive is reproduced in ***Appendix F***.

4.6 EC Type-examination Certificates

The PPE Directive requires that an EC type-examination be performed for Category II and III products. EC type-examination is a check on the design and documentation of a prototype or initial example of an item of PPE to ensure it satisfies the basic requirements. The process is based on claims made about the product in the user information and is achieved by

- examining the design documentation (technical file) to ensure it satisfies all the relevant BHSRs and that the product is adequately described through the use of diagrams and lists giving the source of all materials; and

- carrying out a series of tests and examinations on the products to ensure they meet the claimed performance levels and have been produced in accordance with the manufacturer's technical file (this testing is from an agreed technical specification, usually a European standard) (Doughty, 2012).

An EC type-examination is carried out once, and test reports of the EC type-examination are added to the technical file (European Commission, 2012).

If the model passes the examination, the Notified Body grants an EC type-examination certificate called a Certificate of Compliance CE (or, CE Certificate of Conformity). For Category II products, this is effectively the end of the Notified Body's pre-market involvement and the certificate holder becomes responsible for ensuring that subsequent production remains the same as the model examined by the Notified Body.

4.7 Quality Assurance

Category III products are also subject to checks by a Notified Body to ensure the production versions of the PPE continue to comply with the initial sample previously approved by the EC type-examination. The Notified Body carrying out the production checks need not be the same as the one that carried out the original type approval.

Once the product has been placed on the market, manufacturers or their authorized representatives[22] may choose one of two methods for checking the conformity of ongoing production:

1. **EC quality control for the final product:** This involves the Notified Body obtaining a random sample of recently manufactured items of PPE which are then tested by methods used in the original EC type-examination to ensure continued compliance. These are referred to as Article 11A assessments.

2. **Quality monitoring system:** The Notified Body makes checks at the manufacturing site to ensure that the quality systems being used are capable of enabling consistent production of the certified product. These are referred to as Article 11B assessments. (Doughty, 2012). The minimum requirements can be satisfied following EN ISO 9001:2000.

In both cases, a Notified Body carries out the check on the final product or monitors the production process. Checks have to be carried out periodically while that item of PPE remains in production, at least once a year.

[22] An authorized representative is any natural or legal person established within the EU who has received a written mandate from a manufacturer to act on his behalf in relation to specific tasks. This can be an importer or distributor.

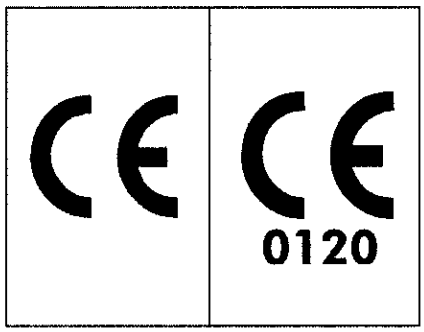
The Certificate of Compliance CE remains the property of the Notified Body. The Notified Body performing these pre-market quality checks can withdraw the certificate if there are sufficient grounds.

4.8 CE Marking

All products must be affixed with a CE marking[23] before being placed on the EU market. The CE marking indicates the product conforms with requirements and that the manufacturer has carried out all required conformity procedures established by the EU and related to the product. The CE mark must be applied by the manufacturer, authorized representative, or person responsible for placing the product on the market. It may be affixed in a third country if the PPE is manufactured there.

For Category I and II products, the "short CE mark" is affixed on the product. For Category III products, a Notified Body was involved in the production control phase, and the "Long CE mark" is affixed on the product (by the manufacturer) with the Notified Body's unique 4-digit identification number (***Exhibit 7***).

Exhibit 7. CE Marking, with and without Notified Body's Identification Number



[23] The term is from the French "Conformité Européenne."

5. ENFORCEMENT: POST-MARKET MONITORING OF COMPLIANCE

Market surveillance in the EU is the responsibility of the Member States. Member States are free to organize market surveillance to fit their own cultural, political, and legal system, so there is no single organizational model. Some organize market surveillance centrally while others follow a decentralized model organized by region or locality. As a result, several Member States use a single Market Surveillance Authority (MSA) for the PPE market while others have multiple MSAs (e.g., Germany has 16 and the United Kingdom has 14) (European Commission, 2013i).

5.1 Market Surveillance Resources

In a European Commission study of general EU market surveillance (MS) programs conducted in 2010, the authors identified key features of the MS programs in the EU. The study found that Member States varied widely in their market surveillance resources and procedures. The MSAs of three Member States had over 2,000 inspectors each while the MSAs of four other Member States had fewer than 10 each. Only four Member States had a unique qualification for their Market Surveillance Inspectors. There was also a large variation in the process MSAs used to obtain their samples for testing (purchased, seized or both) as well as differences in inspector productivity.[24]

Key points made in the report regarding market surveillance resources were as follows:

- **Resources:** Well-defined and assured budgets are necessary for good enforcement. Dedicated sampling and testing budgets allow for better long term planning and involvement in co-operation programs. Test purchasing of products is an important inspectional tool and is important in assessing the safety of equipment that is available for hire or rent. Carry-over of funding allows for strategic reserves to be created to enable appropriate reactive responses to emergency situations.

- **Inspectors:** The professionalism and competences of the inspectorate coupled with its ability to successfully recruit, train and retain Inspectors with the necessary knowledge and relevant skills will determine to a great extent the effectiveness of the MSA. A distinct or unique qualification for MS Inspectors is a proven way to ensure that the required knowledge and skills are developed. Close links with educational establishments are important to ensure the identified training needs can be met (BSI Development Solutions, 2011).

Regulation (EC) 765/2008, which went into effect in 2010, establishes common minimum requirements for the national market surveillance authorities. Among these are requirements regarding Member States' capacity to perform market surveillance, including the following:

[24] The average number of inspections per inspector per year ranges from 15 to 117.

- Member States have an obligation to give their national Market Surveillance Authorities (MSAs) the powers, resources, and knowledge needed to perform enforcement activities.

- Member States submit their list of national MSAs, along with contact and other identifying information, to the European Commission, which publishes the lists on its website.[25]

- Member States have an obligation to organize cooperation between authorities within their national territory.

- Member States must have a national market surveillance program (NMSP):

  - NMSPs must be updated annually and shared with the European Commission and other Member States and must be posted on national websites.
  - NMSPs will also be posted on the European Commission's CIRCA website (an internal web portal for European institutions).
  - NMSPs can be general or sector specific (the majority of the Member States have chosen to develop sector-specific NMSPs).
  - Elements of a general NMSP are enumerated.[26]
  - The European Commission is responsible for ensuring that the NMSPs are comprehensive and comparable across Member States.

- Member States must regularly evaluate their national market surveillance programs:

  - They must send the results of the review to the European Commission and make them publicly available.
  - Evaluations must be conducted every 4 years (the first reports are due in 2014).
  - The purpose of the evaluations is to detect problems early, facilitate improvements, detect good practices, and share lessons learned (both good and bad).

5.2 Market Surveillance Procedures

The European Commission 2010 study also addressed operational issues and reached the following conclusions:

- **Performance measures**: An effective and efficient MSA needs to set clear and measurable overall performance targets; accurately monitor its performance and record and publicize its results. It also needs to monitor the performance of its staff both as individuals and teams.
- **Inspection Planning:** MSAs need detailed and accurate information regarding the status of the economic operators that deal in the product sectors for which it is legally responsible. The required information includes a) location and contact details; b) category of products supplied; c) position in supply chain; d) type and

[25] A combined list of market surveillance authorities for PPE is posted on PROSAFE's website at http://www.prosafe.org/default.asp?itemid=27 http://www.prosafe.org/default.asp?itemID=27&itemTitle=undefined#PPE

[26] The revised PPE Directive is likely to include a PPE-specific template (Sacchetti, 2011).

effectiveness of management and quality systems; and e) previous inspection and compliant history.

- **Inspection Methodology:** Economic operators are very concerned from a competitive viewpoint that they are all treated equally and that there is consistency of decisions and enforcement actions between individual Inspectors and between inspections in different regions of the country. Consumers are concerned that inspections are vigorous, free from outside influences, well targeted and effective in identifying dangerous products. MSA management needs to be able to manage the consistent delivery of effective market surveillance activities in a range of product sectors over time and geographical location.

  The methodology should include a) inspection rules; b) documented inspection procedures; c) quality management systems; d) inspection handbooks; e) checks on products from third countries (at ports/airports/borders); f) supply chain inspections (at importer and distributor levels as well as main stream retail outlets); g) a documented procedure to underpin their sample planning and sampling procedures (BSI Development Solutions, 2011).

These issues are captured in Regulation (EC) 765/2008 by the following requirement:[27]

- Authorities must perform appropriate checks on an adequate scale, based on the risk assessment and on information from other Member States through their market surveillance actions and results (e.g., RAPEX notifications).

5.3 Border Controls

The EU market surveillance system is based on the principle that the earlier in the supply chain a non-conforming product is stopped, the easier and more efficient will be the remedies. Member States are obligated to have appropriate control mechanisms in place to verify that all products covered by EU legislation originating from third countries and entering the EU market comply with the requirements set out in EU legislation.[28] They must provide border control authorities with sufficient funding and policy guidance and must ensure that border controls are properly targeted and that trade facilitation is not adversely affected.

To promote cooperation between market surveillance and customs authorities, the EU requires Member States to

- establish a single point of border control contact;
- establish written agreements between customs and market surveillance authorities to strengthen cooperation in the area of border controls; and
- provide cooperation between customs and market surveillance authorities (e.g., through information sharing and cooperation with market surveillance authorities of third countries).

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[27] A number of additional changes are being considered as part of the Product Safety and Market Surveillance Package, discussed in Chapter 2.

[28] Regulation (EC) No 765/2008 provides the regulatory framework.

Controls of products at external borders are facilitated under the EU's Customs Program, which aims to "achieve good administrative cooperation and proper communication between Customs and Market Surveillance Authorities" (European Commission, 2012g). The European Commission drafted guidelines to promote collaboration between customs and market surveillance authorities. The guidelines include practical tools for customs officers, i.e., information sheets and checklists for individual product groups (European Commission, 2012f). The European Commission also distributes relevant RAPEX notifications to customs officials and sponsors RAPEX training seminars for national market surveillance and customs authorities to strengthen knowledge of the RAPEX system and to improve enforcement capacity (Finnish Institute of Occupational Health, 2012, 19).

In addition, Decision 768/2008/EC requires border control authorities to ensure that technical documentation has been provided for products. In addition to the CE markings, SDoC, and user instructions, this documentation must include the manufacturer's and importer's name and address. The latter, which economic operators are required to provide, helps with traceability by ensuring products are identified and linked to both the manufacturer and importer (this requirement is expected to be reflected in the revised PPE Directive/Requirement).

6. ENFORCEMENT: CORRECTIVE ACTIONS AND SANCTIONS

EU Member States are free to choose the sanctions to be used when infringements take place. Regulation (EC) 765/2008 requires the following:

- Authorities must perform appropriate checks on an adequate scale, based on the risk assessment and on information from other Member States through their market surveillance actions and results (e.g., RAPEX notifications).
- Authorities must establish adequate procedures to follow up complaints, monitor accidents, order corrective action, and verify its implementation.
- MSAs must provide for effective, proportionate, and dissuasive penalties for economic operators in case of infringements. Appropriate measures include corrective action, withdrawal, recall, or destruction.
- MSAs must exchange information with the European Commission and other Member States on serious risk cases via the Community Rapid Information System (RAPEX). Member States must have a single RAPEX Contact Point.
- Economic operators that do not cooperate with MSAs can be forced to cooperate via their "home authority."

The most common corrective measures reported through the RAPEX system are the bans of sales, withdrawal of a dangerous product from the market (or its recall from consumers); and import rejection by the customs authorities. Supplies can also be restricted, or destroyed (RAPEX, 2012). The EU New Approach Directive requires that the actions selected be based on an appropriate risk assessment.

New Approach directives also require that action be taken against

- persons who affix the CE marking to non-compliant products;
- the manufacturer (or other person) responsible for placing a non-compliant product on the market; and
- the Notified Body, if it was involved in the conformity assessment procedure that had, as a result, non-compliant products.

The sanctions must be effective, proportionate and dissuasive, and can consist of warnings or legal proceedings (European Commission, 2000). Available sanctions for non-compliance include forfeiture or destruction of the dangerous goods, court fines, administrative fines, and prison sentences (sought through the courts).

EU law recommends that market surveillance authorities seek voluntary withdrawals and recalls by economic operators before similar enforcement action is ordered. If no result can be achieved, the MSA must restrict or prohibit the placing on the market of the product and, if necessary, ensure that it is also withdrawn from the market. The MSA must document the

grounds for the corrective action and notify the manufacturer. Unless the product presents a serious and immediate danger, the manufacturer should have an opportunity to be consulted in advance of the corrective action.

6.1 RAPEX

When products are considered to present a serious risk, Member States must immediately inform the European Commission of the measures taken by using the RAPEX rapid information system (GRAS-RAPEX). RAPEX (formally, the Community Rapid Information System) is a European rapid alert system for dangerous non-food products. It allows market surveillance authorities and the European Commission to share information about dangerous products found on the European market quickly and efficiently, so that appropriate action can be taken everywhere in the EU. Thirty countries currently participate in the system (including all the EU countries and three EFTA/EEA countries: Iceland, Liechtenstein and Norway).

Each participating member designates a RAPEX Contact Point for communications and notifications. When the national authorities (or a producer/distributor) take measures which prevent or restrict the marketing or use of a product posing serious risks to the public interest, the RAPEX Contact Point submits details about the product to the European Commission by means of a standard notification form, including

- product identification (name, brand, model, description, picture);
- risks posed by the product (type of risk, results of laboratory tests and risk assessment);
- measures adopted to prevent risks (type of measure, scope, duration, date of entry into force); and
- distribution channels of the notified product (manufacturer, exporter, importer, distributors and countries of destination).

This process is called notification. The European Commission examines the information with regard to its compliance with EU law and the RAPEX guidelines, and checks its completeness. The result of this process is called "validation" (e.g., a notification is not validated if another country has already notified measures against the same product and same risk).

Once validated, the European Commission circulates the notification to the RAPEX Contact Points in all countries participating in the system. RAPEX Contact Points then forward this information to their competent national authorities, who check whether the notified product is present within their market and, if necessary, take appropriate action. The results of these market surveillance activities, including additional information relevant for other national authorities, are then reported back to the European Commission through the RAPEX

system. These feedback messages are called "reactions". A reaction normally contains information about the presence of the notified product in other Member States and the measures taken.

Producers and distributors, if they become aware that a product is dangerous, are required under EU law to immediately inform the competent authorities in their country, clearly identifying the product in question, the risk(s) it poses, and the information necessary to trace it. They must also inform the authorities of any measures taken to prevent further risk to consumers. The information is then submitted to RAPEX via the RAPEX Contact Point (RAPEX, 2012).

RAPEX statistics from 2011 (the most recent annual data available) show a very uneven distribution of notifications among Member States, suggesting varied levels of adherence to the RAPEX requirements. The Market Surveillance Package, when it is adopted by the European Parliament, will require Member States' participation.

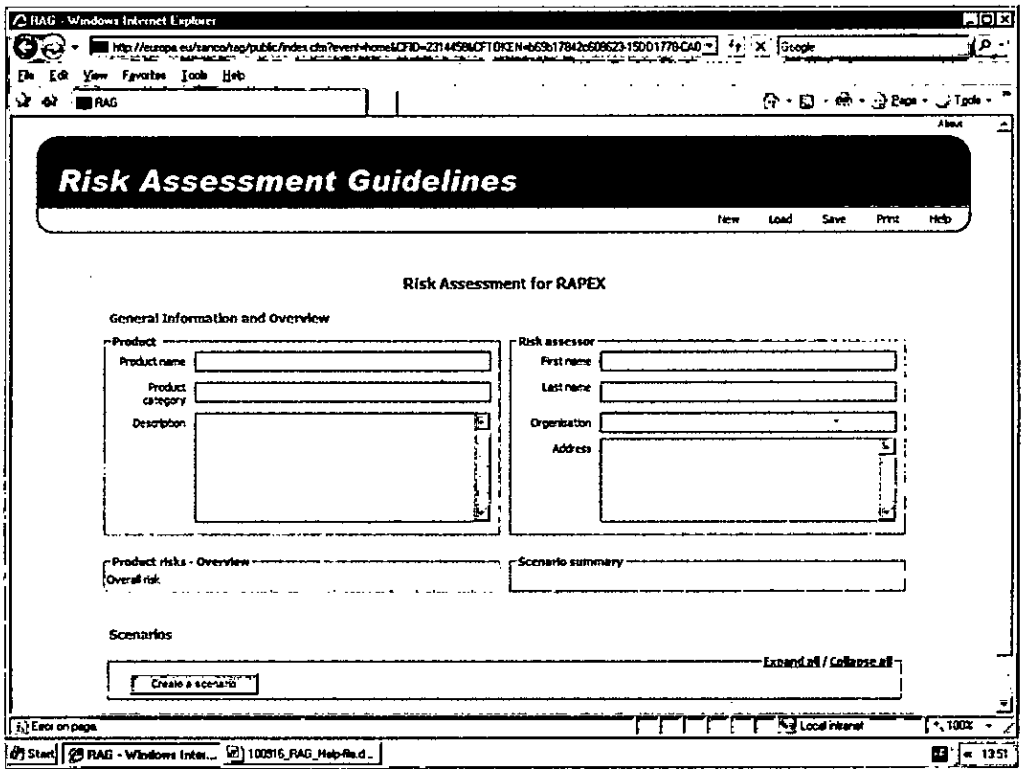
6.2 Risk Assessment

The European Commission has developed RAPEX risk assessment guidelines to help Member States identify the correct level of risk posed by specific products and to focus their notifications on those products posing the most serious risks. An online tool facilitates the preparation of risk assessments (see ***Exhibit 8***).[29] Details about the tool are provided in ***Appendix G***. The European Commission has also prepared guidelines for using the tool (European Commission, 2010d).

The RAPEX risk assessment method is increasingly being applied by market surveillance authorities in the EU. A recent Risk Assessment Task Force concluded that the RAPEX risk assessment methodology should be used for all non-food products, and recommended adding explicit references to the product's essential requirements and to the relevant harmonized standards. The revised PPE Directive/Regulation is likely to incorporate RAPEX notification requirements (European Commission, 2012e).

[29] The tool is at http://europa.eu/sanco/rag.

Exhibit 8. Risk Assessment Guidelines



6.3 Safeguard Clause

The decision by a market surveillance authority to restrict or forbid the placing on the market of a CE marked product or to have a product withdrawn from the market usually invokes the safeguard clause procedure. The safeguard clause obliges all Member States to restrict or forbid the placing on the market of dangerous products, or to have them withdrawn from the market. The procedure is restricted to products that have been ascertained by the Member State to present a substantial risk. It is considered a last resort to prevent or remedy particular problems or threats.

Safeguard measures may be initiated either by the European Commission independently or at the request of any Member State. The European Commission decides whether action is justified, and the measures to be taken, on a case-by-case basis following investigation and consultations with the market surveillance authorities and Member States (European Commission, 2013g).

6.4 Enforcement Indicators

Data on market surveillance activities at the EU level is somewhat limited. The mechanisms for sharing national level data with the European Commission consist of RAPEX notifications and "reactions," survey data, and Enforcement Indicators (BSI Development Solutions, 2011).

RAPEX publishes monthly and annual reports with statistics on the number and type of notifications received and the number of Member State "reactions" to the notifications. In its most recent annual report, for 2011, a total of 1,803 notifications had been submitted through the RAPEX system.[30] The RAPEX statistics do not reflect all market surveillance corrective activities carried out in Member States (e.g., they do not cover products not sold outside of the Member State concerned).

Survey of Administrative Decisions Taken by Member States

This EC-sponsored survey collects information on market surveillance including:

- Resources that assess Member States' enforcement capabilities such as:
  - the budget
  - the number of inspectors on enforcement activities
- Preventive and investigative activities such as:
  - the number of inspections
  - the number of laboratory tests
- Results of compliance checking such as:
  - the number of detected infringements and irregularities
  - the number of products identified as posing a serious risk
- Corrective measures taken such as:
  - product withdrawals from the market
  - product recalls from consumers
  - suspensions of products at the border

(European Commission, 2013g)

In 2008 the European Commission established the annual Survey of Administrative Decisions Taken by Member States to collect more comprehensive information on enforcement and market surveillance activities (see text box). Member States provide data on market surveillance resources and results through an online questionnaire.

The European Commission also collects Enforcement Indicators from Member States. These include information on the number and type of measures national authorities in the EU take against products presenting a risk to health and safety of consumers. The accuracy and comparability of the information collected is limited because (a) not all measures taken by national authorities are required to be reported to the European Commission, (b) there is no reporting on the results of border controls, and (c) one measure can cover more than one product or one type of a product, so the number of products taken off the EU market is higher than the number of measures reported to the European Commission (European Commission, 2013g).

[30] Of those, 31 (2%) concerned PPE covered under general product safety legislation; the PPE Directive does not require RAPEX notifications.

7. MEASURES TO ENCOURAGE CONFORMITY

Cooperation and exchange of information between authorities are key to the EU system of conformity assessment and market surveillance. A strong infrastructure is in place to foster these efforts, consisting primarily of independent organizations established to coordinate specific activities across Member States. The European Commission supports many of these organizations with funding for specific coordinating activities. In addition, the European Commission has invested significant resources to provide online coordinating and reporting mechanisms, enhance accountability through transparency, and promote high-quality and consistent conformity assessment and market surveillance systems through information campaigns, training, and practical guidelines.

7.1 Coordination Activities

CEN's Personal Protective Equipment (PPE) Sector Forum

The PPE Sector Forum coordinates European standardization in the PPE field. The forum is used to discuss horizontal issues for the benefit of all PPE standards. Members of the PPE Sector Forum include the European Commission and EFTA, social partners,[31] PPE manufacturers associations,[32] and Notified Bodies for PPE.

European Coordination of Notified Bodies in the Field of PPE

European Coordination of Notified Bodies in the Field of PPE, established in 1992, is an independent network of representatives from the Notified Bodies that meet on a regular basis to ensure that the standards and legislation are being applied uniformly across Europe (Brinks, 2012).[33] The organization provides a platform for discussing horizontal (general) as well as vertical (PPE-specific) topics, and for obtaining advice from other members, e.g., on the interpretation of type-examination procedures or quality control measures. It consists of a Horizontal Committee, an Ad Hoc Group, and several Vertical Groups. The organization receives funding from the European Commission and is supported by Decision 768/2008/EC of the NLF, which encourages consistency in the application of the conformity assessment modules through coordination and cooperation mechanisms between Notified Bodies (Noetel, undated).

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[31] These include the European Association for the Coordination of Consumer Representation in Standardization (ANEC), the European Office of Craft, Trade and Small and Medium-sized Enterprises for Standardization (NORMAPME), the European Occupational Safety and Health Network (EUROSHNET), the Trade Union Technical Bureau (TUTB), and the Union of Industrial and Employers' Confederations of Europe (UNICE).

[32] European Safety Federation (ESF) and Federation of the European Sporting Goods Industry (FESI)

[33] Council Decision 93/465/EEC contains a general obligation for Notified Bodies to participate, or ensure proper representation, in the co-ordination and co-operation activities of Notified Bodies at a European level.

The organization's Technical Secretariat is responsible for coordinating the activities of the Committees and acts as the contact point for Notified Bodies for PPE in Europe. The Chairman of the Technical Secretariat represents the organization in relevant Working Groups of the Standing Committee at the EU Commission (e.g., the PPE Working Group, which functioned between 1995 and 2011, the PPE Administrative Cooperation (AdCo) group (a European group of experts for PPE market surveillance), and the PPE Sector Forum at the CEN) (Finnish Institute of Occupational Health, 2010:14).

The Horizontal Committee of the organization is the forum in which representatives from the Notified Bodies, the Vertical Groups, and national coordination groups discuss general issues concerning the implementation of the PPE Directive's conformity assessment procedures and requirements. The Horizontal Committee has an Ad Hoc Group that deals specifically with issues concerning Article 11 of the PPE Directive (regarding product monitoring and quality system monitoring). To ensure transparency and allow for a full exchange of ideas among stakeholders, representatives from the EU Commission (DG Enterprise and DG Social Affairs), PPE AdCo, CEN/CENELEC, the EFTA secretariat, and European manufacturers' federations are invited to participate in the annual Horizontal Committee meetings as observers.

The organization's Vertical Groups discuss technical issues such as the testing and certification of individual types of PPE, the interpretation of standards, testing regulations used for certifying non-standardized products, etc. The Vertical Groups also organize round robin testing to ensure test results obtained by Notified Bodies are comparable (Finnish Institute of Occupational Health, 2010:16). The Vertical Groups meet at least once a year, depending on the priority of current issues. The Vertical Groups are listed in ***Exhibit 9***. In addition to Notified Bodies, members of the Vertical Groups can include test houses which do not perform certification themselves and observers from different fields such as standardization or manufacturers' associations.

Recommendation for Use sheets (RfUs) summarize the discussion results of the committees and the recommended solutions to questions. RfUs can be issued by both Vertical and Horizontal Committees. Horizontal RfUs are submitted to the relevant Standing Committee of the EU Commission for confirmation or approval. Vertical RfUs are confirmed by the Vertical Group and approved by the Horizontal Committee, then published on the European Commission's website.[34]

Some, but not all, Member States require their Notified Bodies to be involved in these coordination activities and to participate in inter-laboratory testing to keep up their

[34] Vertical RfUs are posted at http://ec.europa.eu/enterprise/sectors/mechanical/files/ppe/ppe-vertical-rfu_en.pdf. Horizontal RfUs are posted at http://ec.europa.eu/enterprise/sectors/mechanical/files/ppe/ppe_horizontal_rfu_en.pdf

competence. As of 2010, only 50%–60% of the approximately 112 Notified Bodies in the PPE area attended the meetings or participated in the round robin testing.

Exhibit 9. Vertical Groups in the European Coordination of Notified Bodies

Vertical Group	PPE Type
1	Head Protection
2	Respiratory Protection
3	Eye and Face Protection
4	Hearing Protection
5	Protective Clothing, Hand and Arm Protection
7	Protective Clothing against Hand-held Chain Saws
8	Lifejackets
9	Protective Clothing for Motorcycle Riders
10	Foot and Leg Protection
11	Protection against Falls from a Height

Source: http://www.nbcoordinationppe.eu/home/

Administrative Cooperation Group for PPE (PPE AdCo)

PPE AdCo is an informal group of the national market surveillance authorities for the PPE sector.[35] It provides a forum for collaboration and exchange of information to encourage a consistent approach to surveillance activities, reduce the overlapping of national surveillance operations, diffuse good market surveillance practices, exchange views and solve practical problems. The European Commission is also represented in the group.

European Cooperation for Accreditation (EA) Committees

The EA's horizontal harmonization committee as well as its laboratory, certification and inspection committees work on furthering a common understanding of accreditation procedures and on supporting accreditation in the relevant regulated sectors (European Commission, 2013f).

Senior Officials Group—Market Surveillance Group (SOGS-MSG)

SOGS-MSG is an ad hoc group of Commission and Member States experts that discusses market surveillance, accreditation and conformity assessment issues. It is a subgroup of the Senior Officials Group for Standardization and Conformity Assessment Policy (SOGS).

[35] PPE AdCo is one of 20 AdCo groups in the EU. Each New Approach directive has an AdCo.

RAPEX Contact Points Groups

RAPEX Contact Points Groups include (a) at the EU level, the RAPEX Contact Points Network, a meeting forum involving the European Commission and persons responsible for managing RAPEX Contact Points in Member States, which discusses and solves problems relating to notifications to RAPEX, (b) RAPEX Networks within Member States, (c) RAPEX Contact Points Working Groups, and (d) the European Commission's RAPEX Team.

European Commission's Expert Group on the Internal Market for Products

The European Commission's Expert Group on the Internal Market for Products is a forum for cooperation between the Member States' customs and market surveillance authorities.[36] The role of the group is to provide advice and expertise to the European Commission and its departments in relation to the preparation of legislative proposals and policy initiatives and the implementation of existing EU legislation, programs and policies, including coordination and cooperation with member countries and stakeholders in that regard. The first meeting took place on November 30, 2012 (http://ec.europa.eu/transparency/regexpert/index.cfm?do=faq.faq&aide=2).

7.2 Measures to Promote Transparency

EC regulations include obligations for transparency of conformity assessment and market surveillance activities. Transparency puts pressure on less active Member States, and encourages them to think of the larger internal market rather than only their national market. The primary tools to encourage transparency are databases. In addition to RAPEX (described above), these include the following.

The NANDO Information System

Information about third party conformity assessment bodies is shared through the New Approach Notified and Designated Organizations (NANDO) Information System. The NANDO Information System is an online access point for regulatory information about all Notified Bodies that Member States have designated as responsible for carrying out conformity certification and assessment procedures for products marketed in the EU, and their respective competence areas.[37] The system includes information about certification bodies, inspection bodies, and test laboratories. It also includes conformity assessment bodies (CABs) from third countries authorized through Mutual Recognition Agreements to assess products for the EU market as well as "EU CABs," which are European bodies designated to conduct assessments on products to be placed on the market in specific third countries. In

[36] The application of the PPE Directive was until 2011 managed at a European level by a PPE Experts Working Group, chaired by the European Commission, and involving representatives of all stakeholders. Its purpose was to advise the Commission on any issue related to the transposition of Directive 89/686/EEC (PPE) and serve as a forum for collaboration and exchange of information. The PPE Experts Working Group no longer exists.

[37] Available at http://ec.europa.eu/enterprise/newapproach/nando/index.cfm?fuseaction=search.main

addition, the NANDO Information System provides a list of all national Accreditation Bodies, including contact information.

Information and Communication System for Pan-European Market Surveillance (ICSMS)

The European Commission maintains an online EU-wide database called the Internet-Supported Information and Communication System for Pan-European Market Surveillance (ICSMS).[38] The ICSMS includes information on general issues relating to market surveillance activities and information on products presenting a risk, test results, provisional measures, and contacts with economic operators. All Member States are required to use the ICSMS.[39]

The ICSMS allows quick and efficient sharing of test results, product identification data, photographs, economic operator information, risk assessments including hazard data, accident information, and measures taken by surveillance authorities. It consists of an internal and a public area. The internal area is for the use of market surveillance authorities, customs authorities and EU officials.

ICSMS gathers test results on more than 47,500 products and lists more than 650 authorities in all EU and EFTA countries, and covers more than 45 EU directives (including the PPE Directive). The number of user accounts is 3,600. The database is searchable by, for example, individual products, test results, entire product groups (e.g., PPE), manufacturers, importers, dealers, and results for products from specific countries. Information can be obtained for products coming under specific directives, safeguard clause notifications, or RAPEX notifications. Data confidentiality is protected by a system of access authorizations. Market surveillance authorities can add data about products not yet in the database or add comments to an already existing product information file, i.e., feedback about the activities of market surveillance authorities with regard to investigated products.

A recent European Commission study found that the exchange of information on test results and investigations help market surveillance authorities in the following ways:

- **Prompt intervention:** Information on unsafe products can be announced immediately and immediate measures may be taken.
- **Deterrence:** "Black sheep" among manufacturers can be detected earlier and punished more effectively.

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[38] The ICSMS web portal is at: https://www.icsms.org/icsms/App/blankPublic.jsp?threadId=7418&callId=4&winId=1

[39] This obligation was set forth in Regulation (EC) 765/2008. Originally an independent database with only a subset of European states participating, the ICSMS was acquired by the European Commission's Directorate General for Enterprise and Industry in 2011 and has expanded to include all EU Member States.

- **Avoiding duplication of work:** Test results by one surveillance authority are immediately made available to all other Member States.
- **Surveillance data:** Statistics can easily be generated by sector, product, etc.

In addition, the ICSMS provides a platform for implementing the European market surveillance policy by creating the basis for coordinating wide-scale market interventions against suspicious products, identifying best practices, exchanging general knowledge and experience, and creating a common approach to market surveillance (European Commission, 2013f). Discussions are currently underway regarding the exchange of information between the RAPEX and ICSMS systems (European Commission, 2012h).

7.3 Information/Training, Capacity Building

CE Marking information Campaign

To support conformity assessment and market surveillance, the European Commission conducted an information campaign during 2010-2012 about the CE marking and its requirements. The target audience included manufacturers, importers, distributors, professional associations, specialized press, and consumers. The campaign involved the creation a dedicated website on CE marking, with step by-step instructions for manufacturers, by product type; a series of educational seminars and informational booths at trade shows; and leaflets, brochures, factsheets, videos, and articles in specialized publications (European Commission, 2013j). The European Commission also developed a set of guidelines for legislators and Notified Bodies on selecting conformity assessment modules and performing conformity assessment.

Product Safety Enforcement Forum of Europe (PROSAFE)

PROSAFE is an independent organization of European market surveillance officials that supports a wide range of initiatives (http://www.prosafe.org/). Through PROSAFE, for example, market surveillance authorities participate the EMARS ("Enhancing market surveillance through best practice") project, which is financed by the European Commission. PROSAFE manages the project on behalf of the participating Member States. EMARS aims to ensure a basic level of expertise and practical experience among the market surveillance organizations. Through collaborative work groups of Member State organizations, EMARs disseminates best practices, plans and manages joint surveillance actions and other activities, provides training in risk assessment and market surveillance, and develops guidelines.

Between 2007 and 2012, Joint Market Surveillance (or Enforcement) Activities targeting 17 different product groups had taken place (none, however, have focused on PPE to date). All EU Member States and 2 EFTA Member States have participated in at least one of these Joint Actions. They involve administrative and surveillance cooperation between the

authorities of several Member States and EFTA/EEA countries and typically focus on product testing, risk assessment, market monitoring, and the exchange of expertise and best practices related to market surveillance. The European Commission has supported a number such actions.

Through PROSAFE, market surveillance authorities also participate in the Rapid Advice Forum. The goal of the forum is to provide a rapid and informal first assessment and feedback from fellow surveillance officers (from other Member States). The Rapid Advice Forum has been operational since the spring of 2007. Through the forum, Member States and the European Commission representatives receive informal advice on a range of market surveillance issues including procedures, risk assessment, applicable legislation and interpretation, and practical experience. The advice is given on an individual basis by fellow market surveillance officers. It is not intended to represent a national position and the recipient of the advice is in no way bound to follow it. PROSAFE says the exchange of experience helps promote a harmonized approach across different member states to the same issues.

RAPEX

The European Commission has facilitated the participation of Member States in RAPEX by publishing RAPEX guidelines, developing the risk assessment application and online tool, and organizing several RAPEX seminars. Participation in RAPEX varies across Member States. Barriers to participation involve the way in which the national market surveillance networks are organized, the size (and resources) of the countries, and production and market structures.

8. CONCLUSION

The European Union's model of conformity assessment has a number of distinct features. The model has evolved from a system of detailed technical product standards to one that allows manufacturers to select the methods used to fulfill the basic health and safety requirements established in the PPE Directive. Economic operators tend to use standards developed by independent, European standard-setting organizations for this purpose. Those organizations work closely with the EU Member States to develop standards that fulfill the requirements while also attending to international requirements (they do this through, for example, their development of standards in parallel with the ISO).

Conformity assessment procedures are defined in the PPE Directive and are based on risk. They are likely to be further clarified in the forthcoming revised PPE Directive.

Conformity assessment is also based on the principle of shared responsibility. Roles and responsibilities have been established for economic operators, third-party assessment bodies, Member States, the EU (including customs authorities), and non-governmental organizations. A key to the operation of pre-market compliance assessment in the EU appears to be the existence of a strong network of organizations, both public and private, to foster exchange of information, collaboration, and transparency. This builds organizational capacity, especially of those Member States with less experience of robust compliance assessment systems, while also providing mechanisms for organizational peer pressure.

Market surveillance programs in the EU are the responsibility of the Member States and until recently, there was very little structure at the EU level to encourage consistent practices. This issue has been a major focus of the European Commission in recent years, and provides valuable insights into the elements needed for effective market surveillance. These appear to include[40]

- adequate resources, including dedicated sampling and testing budgets and the ability to carry over funds to provide for strategic reserves in the event of emergency situations
- defined qualifications and educational resources for market surveillance inspectors
- a set of clear and measurable overall performance targets and an ability to accurately monitor both individual inspectors' and the MSA's performance
- access to detailed and accurate information regarding the status of the economic operators that deal in the product sectors for which it is legal responsible. The required information includes a) location and contact details; b) category of products supplied; c) position in supply chain; d) type and effectiveness of management & quality systems; and e) previous inspection and compliant history.
- documented inspection rules, inspection procedures, quality management systems. These should include collaboration with customs authorities at ports/airports/borders

[40] These elements were identified in BSI Development Solutions, 2011.

and inspections of importers, distributors, and mainstream retail outlets. Close working relationships with Customs Authorities is also an integral part of market surveillance.

- documented sampling methodology to structure sample planning and documented sampling procedures for inspectors to follow
- enforcement actions that are proportionate to the risk presented by the unsafe product. A full range of enforcement powers should be made available in order to be able to select an appropriate and proportionate response to each instance of non-compliant or dangerous product.
- In addition, the overall performance of conformity assessment and market surveillance systems need to be regularly monitored to determine if they are effective and to identify improvements. This allows MSAs to better target scarce results to produce better results.

  Regarding market surveillance, for example, high quality data should be collected on the MSA's resources (budget, number of inspectors), territory (geographic size, number of high/medium/low risk premises) and activities (numbers of inspection visits, samples taken, products tested, and enforcement actions). Interactions with consumers and manufacturers should also be tracked (e.g., number of enquiries & complaints, level of advice and information services provided).

As a benchmarking target, the EU offers a rich and evolving prototype of conformity assessment and market surveillance. The challenges EU officials have faced in building an effective system that removes internal barriers to trade are particularly instructive. Through the recent and ongoing changes of the EU's system, many of the prerequisites of an effective system are in place or are emerging. They highlight the kinds of resources, procedures, and systems that may be needed in any effective conformity assessment system. The evolution of the EU system highlights, for example, the value of shared responsibilities and a collaborative public-private network of organizations and online information systems that foster communication, problem identification, opportunities to build from lessons learned, informal technical assistance, and capacity building.

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APPENDIX A: GLOSSARY

Accreditation. In conformity assessment systems, accreditation provides independent attestation of the competence of an individual or an organization to offer specified conformity assessment services (e.g. testing, inspection or certification), through third party assessment.

ADCO. Each New approach directive has an "ADCO", i.e. the informal group of the national administrations in charge of the market surveillance for this directive. The ADCO group supports and complements the work of the formal committee or the working party of the directive. ADCO group provides administrative cooperation and consistent application of surveillance. At European level, joint market surveillance campaigns are carried out and information exchanged on irregularities found.

Basic health and safety requirements (BHSRs). Basic health and safety requirements lay down the necessary health and safety elements for protecting public interest. Essential safety requirements for design, manufacture, testing, marking, labeling, instructions and materials, usually written in general terms, are mandatory and must be met before products may be placed on the market in the European Community.

Benchmarking. A management tool for comparing performance against an organization that is widely regarded as outstanding in one or more areas, in order to improve performance.

CAB. Conformity Assessment Body

CAP. Conformity assessment procedure: methods used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled.

CE Marking declares the completion of conformity assessment and that the equipment or assembly complies with the provisions of the Directive and meets the essential safety requirements.

CEN. (from the French "Conformité Européenne") The European Committee for Standardization (CEN) is one of the three European Standardization Organizations (ESOs). A business facilitator in Europe, removing trade barriers for European industry and consumers. Its mission is to foster the European economy in global trading, supporting regulation where it has technical aspects, the welfare of European citizens and the environment. Through its services it provides a platform for the development of European Standards and other technical specifications. More than 60 000 technical experts and 30 member countries are involved in the CEN.

CENELEC, the European Committee for Electrotechnical Standardization, is one of the three European Standardization Organizations (ESOs). CENELEC provides the electrotechnical standards requested by the market and harmonized standards in support of European legislation (15 000 technical experts from 30 European countries).

Certification. In conformity assessment systems, certification by a certification body formally establishes, after evaluation, testing, inspection or assessment, that a product, service, organization or individual meets the requirements of a standard.

Conformity Assessment (CA) Conformity assessment are the methods used to determine that a process, product, or service meets relevant technical standards and fulfills

relevant requirements. They must be undertaken by the manufacturer or notified body, depending on the category of the equipment, in order to demonstrate that the essential safety requirements are met.

Conformity Assessment Procedure Any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled.

Declaration of conformity (DoC) The declaration of conformity is a document that must always accompany the recreational craft, the components and the propulsion engines, and must always be attached to the owner's manual. It contains data on the manufacturer, the product and the administrative and legal procedures and information that have been taken into consideration when developing and manufacturing the product. The legal requirements regarding the content of the Declaration of Conformity can be found in Annex XV of the Recreational Craft Directive.

Distributor Means any professional in the supply chain whose activity does not affect the safety properties of a product, other than the manufacturer or the importer (who makes a product available on the market.)

Economic operators. Means manufacturers, importers and distributors.

EC European Commission

EFTA European Free Trade Association

EN European Standard. Means a standard adopted by a *European Standardization Organization* and made available to the public.

ETA. European Technical Approval: a favorable technical assessment of an individual product or technology based upon its fitness for an intended use, which is issued when it is judged a European standard is not possible.

ETUC. European Trade Union Confederation

Harmonized products. Mean products for which there is EU legislation harmonizing the conditions for marketing. (see also *Sector specific legislation on harmonized products)*.

Harmonized standard. A standard adopted by one of the European Standardization bodies listed in Annex I to Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on information society services on the basis of a request made by the Commission in accordance with Article 6 of that Directive.

hEN Harmonized European standard

Harmonized Standard (HS). One "Harmonized standard" is a standard used for implementing a given Directive. It translates in precise technical terms the Directive essential requirements. A European standard, adopted by CEN, CENELEC or ETSI, following a mandate issued by the European Commission after consultation of Member States enters into force as a "Harmonized standard" when it is referenced as

such in the OJEU. They are developed through an open and transparent process, built on consensus between all interested parties. Compliance with Harmonized standards provides presumption of conformity to the corresponding essential requirements of the EU new approach Directives. Compliance with Harmonized standards remains voluntary, and manufacturers are free to choose any other technical solution that provides compliance with the essential requirements.

IFU. Instructions For Use

Inspection. In conformity assessment systems, it is the examination of a product design, product, process or installation and the determination of its conformity with requirements.

International Organization for Standardization (ISO) International Organization for Standardization is the world's largest developer and publisher of International Standards other than electrotechnical or telecommunication ones. ISO is a network of the national standards institutes of 162 countries, based in Geneva. Therefore, ISO enables a consensus to be reached on solutions that meet both the requirements of business and the broader needs of society.

Market surveillance. Means the activities carried out and measures taken by public authorities to ensure that products comply with the requirements set out in the relevant Union harmonization legislation and do not endanger health, safety or any other aspect of public interest protection.

Market Surveillance Authority. Means an authority of a Member State responsible for carrying out market surveillance on its territory.

Mutual Recognition Agreements (MRAs). MRAs have the objective of promoting trade in goods between the European Union and third countries by facilitating market access. They are bilateral agreements, and aim to benefit industry by providing easier access to conformity assessment procedures. MRAs lay down the conditions under which the EU and the third country concerned will mutually accept test reports, certificates and marks of conformity issued by the conformity assessment bodies (CABs) of the other party to the agreement, in conformity with the legislation of the other party.

Nando (New Approach Notified and Designated Organizations) Information System. Notification is an act whereby a Member State informs the Commission and the other Member States that a body, which fulfills the relevant requirements, has been designated to carry out conformity assessment for goods according to a given directive. Notification of Notified Bodies and their withdrawal are the responsibility of the notifying Member State. Lists of Notified Bodies can be searched on the NANDO web site. The lists include the identification number of each notified body as well as the tasks for which it has been notified, and are subject to regular update.

NCB. Notified Certification Body

New Legislative Framework (NLF). Adopted in July 2008, the New Legislative Framework (NLF) is in fact an update of the New Approach by three texts:

- Regulation (EC) 764/2008 on the free circulation of products in the non Harmonized area

- Regulation (EC) 765/2008 on the accreditation of conformity assessment bodies and on the organization of market surveillance

- Decision 2008/768/EC on general principles that the Parliament & Council should follow in the future for legislation covering the free circulation of products (definitions, rights and obligations of the various players, and conformity assessment modules)

NIB. Notified Inspection Body

Notified Body. Notified Body is a semi-official or private technical organization appointed by Member States, either for approval and monitoring of the manufacturers' quality assurance system or for direct product inspection. A Notified Body may be specialized for certain products/product categories or for certain modules.

Notification for Information. Means a notification which cannot be sent through the system as a RAPEX notification due to various reasons (such as the non-availability of some of the information required to be present in the *RAPEX notification*, absence of the *cross-border effect*, impossibility to determine whether one or more *RAPEX notification criteria* were met, yet the notification involves information on product safety likely to be of interest for other Member States etc.), but the Contact Point has nevertheless decided to circulate such notification for information purpose.

NSB. National Standardization Body

NTL. Notified Testing Laboratory

OJEU. Means the Official Journal of the European Union.

PECAs. Protocol to the Europe agreements on Conformity Assessment and acceptance of industrial products. The Europe Agreements are the basic accords governing bilateral relations between the European Communities and their Member States and each candidate country in central and eastern Europe. Under the terms of the Europe Agreements, candidate countries for EU membership should approximate their legislation to that of the Community. In the field of industrial standards and conformity assessment, the Europe Agreements aim to achieve the candidate countries' full conformity with Community technical regulations and European Standardization and conformity assessment procedures. They also envisage the conclusion of agreements on mutual recognition in these fields.

Presumption of Conformity. Means that products which are in conformity with harmonized standards or parts thereof the references of which have been published in the Official Journal of the European Union are presumed to be in conformity with the requirements covered by those standards or parts thereof, set out in the harmonization legislation.

Professional Use. The application and use of products by persons in the exercise of their professional activity.

PROSAFE (the Product Safety Enforcement Forum of Europe) is a non-profit organization established by market surveillance officers from various countries throughout Europe. The primary focus of PROSAFE is to promote informal discussions between

the various market surveillance officers in order to share and learn from each others' experiences and to further develop best practices and enhance market surveillance activities as operated within the European Economic Area (EEA).

Published Harmonized (European) Standards. Published Harmonized (European) Standards list are a specific subset of European Standards (EN, produced by CEN and available from the national Standards Institutes) with particular consideration of the Essential Safety Requirements the reference number of which is published in the Official Journal of the European Commission. The use of a Published Harmonized Standard in the design and manufacture of a product will give the presumption of conformity (Article 5.1) to those ESRs listed in Annex ZA of the particular Harmonized Standard.

RAPEX. Means *the Union Rapid Information System for non-food Consumer Products* which Member States use to notify to the Commission measures taken to prevent or restrict the marketing or use of products posing a serious risk.

RAPEX Notification Criteria. Under Article 12 of the *General Product Safety Directive*, Member States have a legal obligation to notify the Commission when the following four notification criteria are met: (a) the product is a consumer product, (b) the product is subject to measures that prevent, restrict or impose specific conditions on its possible marketing or use ('preventive and restrictive measures'), (c) the product poses a serious risk to the health and safety of consumers, (d) the serious risk has a cross-border effect.

RfUs. Recommendation for Use sheets. These "Technical sheets for coordination" report the common position of the Notified Bodies - sector PPE - approved by the Expert Group "PPE". The topics range from the interpretation of provisions of the Directive to practical problems as encountered by NB. It is expected that all NBs stick to the common positions as published.

Risk assessment guidelines. Mean procedures for identifying and assessing levels of risks posed by consumer products as set out under point 5 of Part IV of *RAPEX Guidelines*

Small and Medium-sized Enterprises (SMEs). According to Article 2 of the Annex to Recommendation 2003/361/EC, the category of micro, small and medium-sized enterprises (SMEs) is made up of enterprises which employ fewer than 250 persons and which have an annual turnover not exceeding €50 million, and/or an annual balance sheet total not exceeding €43 million (see: SME definition). SMEs are the backbone of the EU economy - they represent 99% of all enterprises in the EU. Some 23 million SMEs provide around 75 million jobs.

Standard. A technical specification approved by a recognized Standardization body for repeated or continuous application with which compliance is not compulsory and which is one of the following:

- international standard : a standard adopted by an international Standardization organization and made available to the public;

- European standard : a standard adopted by a European Standardization body and made available to the public;

- national standard : a standard adopted by a national Standardization body and made available to the public.

Standardization. Standardization is the process through which the EU aims to establish high quality criteria throughout its member countries. It is based on consensus among the various partners involved - industry, consumers and public authorities. Interoperability, i.e. the technical compatibility of complementary products, services and processes is the desired outcome. The process also involves setting up test methods and requirements for safety, health, organizational and environmental performance. Standardization allows SMEs to stay up to date with technology and business practices. It is a symbol of quality, recognized by customers. It is also a means of capitalizing on European leadership in new markets.

Serious undesirable effect. An undesirable effect which results in temporary or permanent functional incapacity, disability, hospitalization, congenital anomalies or an immediate vital risk or death.

Technical Documentation. Means documentation which makes it possible to assess the conformity of a product to the relevant requirements, includes an adequate analysis and assessment of the risk(s), specifies the applicable requirements and covers, as far as relevant for the assessment, the design, manufacture and operation of the product.

Testing. In conformity assessment systems, it is the determination of a product's characteristics against the requirements of the standard, typically performed by a test laboratory.

Traceability. Means an obligation to ensure that the origin of the product can be determined, for example, by indicating on the product, its packaging or in the accompanying documents, the identity of the manufacturer and/or the importer, i.e. an indication of the firm, trade name or a trademark and the address where they can be contacted, product reference or the reference to the batch of products to which the product belongs, by keeping and providing for documentation necessary for tracing the origin of the product etc.

User Inspectorates. User Inspectorates are appointed by Member States to carry out the tasks of notified bodies within their own companies under Modules A1, C1, F and G only. (The CE marking should not be affixed to pressure equipment and assemblies assessed by user inspectorates).

Withdrawal. Any measure aimed at preventing the making available on the market of a cosmetic product in the supply chain.

APPENDIX B: BASIC HEALTH AND SAFETY REQUIREMENTS FOR PPE

1.6 ANNEX II

ESSENTIAL REQUIREMENTS OF HEALTH AND SAFETY

Basic Health and Safety Requirements (BHSRs) at Annex II are drafted to ensure the highest possible level of protection. In practice this means the best compromise between efficiency of protection, usability and comfort ***according to the generally acknowledged state of the art****. These requirements are to be applied in accordance with the foreseeable conditions of use. They either lay down the possible protection objectives and/ or refer to the performance of the product itself.*

Although no detailed manufacturing specifications are included in the BHSRs, their wording is aimed at being precise enough to create legally enforceable obligations, and at facilitating the drafting of mandates by the Commission to the European Standardisation Organisations in order to produce European harmonised standards.

BHSRs define the results to be attained, or the hazards to be dealt with, but do not specify or predict the technical solutions for doing so. They are also formulated so as to enable the assessment of conformity with those requirements, in the absence of European harmonised standards or in case the manufacturer chooses not to apply them.

This flexibility allows manufacturers to choose the most suitable way to meet the requirements. It also allows, for example, the materials and product design to be adapted to technological progress. Accordingly, so-called "New Approach" directives such as the PPE directive do not need regular adaptation to technical progress, since assessment of whether requirements have been met or not are based on the state of technical know-how at a given moment.

Annex II is divided into three sections:

- General requirements applicable to all PPE;

- Additional requirements common to several classes or types of PPE;

- Additional requirements specific to particular risks.

Therefore, in addition to the application of the general requirements, manufacturers need to clearly identify:

- the hazards the PPE is intended to protect against in order to determine the additional BHSRs to be applied to the PPE;

- the foreseeable conditions of use and possible foreseeable misuse of their product.

If the manufacturer chooses to use European harmonised standards to assess the conformity of the PPE directive, he shall make sure that these standards cover all BHSRs applicable to his products under the foreseeable conditions of use. If the existing European harmonised standards do not cover all applicable BHSRs he has, in addition to the application of these standards, to assess the conformity to the BHSRs not covered by using other relevant technical specifications and test methods .

BHSRs set out in Annex II include all that is necessary to achieve the objective of the directive. PPE may be placed on the market and put into service only if they are in compliance with all applicable BHSRs. The guidance provided on this part of the directive has been carefully drafted to give the best possible advice to stakeholders. However, it should

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always be kept in mind that as a "New Approach" Directive all technical solutions are available to the manufacturer in order to meet the relevant BHSRs to be applied to his product.

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1. GENERAL REQUIREMENTS APPLICABLE TO ALL PPE

PPE must provide adequate protection against all risks encountered.

• To make sure that the protection offered by PPE is adequate against the risks encountered, the manufacturer needs to carry out a risk assessment[23] of the PPE in order to identify the intended level of protection and on the basis on the above analysis:
- identify all applicable BHSRs;
- design the characteristics of the components and constituent materials of PPE corresponding to these risks and additional factors such as environmental conditions, usability, tasks to be performed corresponding the foreseeable conditions of use.

1.1 Principles of design

1.1.1 Ergonomics

The PPE must be so designed and manufactured that in the foreseeable conditions of use for which it is intended the user can perform the riskrelated activity normally whilst enjoying appropriate protection of the highest possible level.

At the design stage of the PPE ergonomic principles need to be applied to make PPE suited to its protection function under the foreseeable conditions of use.
The operating requirements of PPE have to be evaluated simultaneously on the basis of the level of:
- protection which must be highest possible according to the current state of the art;
- maximum reasonably "usability" to fit to the characteristics and to the environmental factors of the tasks to be performed by possible different users groups taking into account the tasks to be undertaken.

1.1.2 Levels and classes of protection

1.1.2.1. Highest level of protection possible

The optimum level of protection to be taken into account in the design is that beyond which the constraints imposed by the wearing of the PPE would prevent its effective use during the period of exposure to the risk or normal performance of the activity.

This requirement introduces the principle of the best possible compromise between as high a level of protection as possible and the lowest possible level of constraint. (see 1.1.1). Nevertheless, for very specific applications, the safety of the wearer takes precedence. This is particularly the case, where according to the general recognised state of the art it is not possible to simultaneously ensure comfort and protection against high hazard levels (e.g. self rescue during an emergency situation, protection against ionising radiations, land mines removal…).

[23] This "risk assessment" should not be confused with the obligation of the employer to undertake a risk assessment with respect to ensuring that all potential hazards are either removed, reduced to a non-harmful degree or, where this is not possible, to provide the PPE to protect the employee.

Practical performance tests using test subjects can be performed to evaluate the acceptability of PPE and the feasibility of carrying out the intended activity.

1.1.2.2. Classes of protection appropriate to different levels of risk

Where differing foreseeable conditions of use are such that several levels of the same risk can be distinguished, appropriate classes of protection must be taken into account in the design of the PPE.

It is easier to indicate the nature of a risk than to quantify its level. Therefore it is difficult to

define classes of protection appropriate to the levels of risks against which the PPE is intended to protect. This is why, in practice, classes of protection are generally defined by the levels of performance of one or several characteristics. These levels of performance are determined by conventional testing methods simulating the situations of risks as close as possible to the reality.
The number of classes should be kept to a minimum in order to avoid difficulties and errors during the selection phase of the appropriate PPE by users and purchasers. In fact, the creation of several classes of protection can only be justified by the corresponding existence of a number of various fields of application, in terms of both risk levels and ergonomic factors, which can not be covered by a single class of PPE.
On the other hand, different classes of protection can be useful, to offer where appropriate the possibility to use more comfortable PPE instead of PPE having an unnecessarily high level of protection.
In any case, if several classes of protection and or performance levels are used, the corresponding levels of risks and/or fields of application are to be clearly identified and given in the information to be supplied by manufacturer.
Furthermore, when defining classes of protection the uncertainty of measurements attached to the test results need to be taken into account to avoid difficulties of interpretation. It is recommended that the width (the difference between the lower and upper limit value) of a protection class is clearly bigger than two times the estimated uncertainty.

1.2 Innocuousness of PPE

1.2.1 Absence of risks and other "inherent" factors of nuisance effect

PPE must be so designed and manufactured as to preclude risks and other nuisance factors under foreseeable conditions of use.

The use of PPE causes always some nuisance to the wearer. Those additional risks are not related to the risks against which they protect.
The following examples illustrate the inherent risks which can be generated by PPE:
□ tight PPE preventing the evaporation of sweat and causing risk of hyperthermia, skin irritations, discomfort…;
□ the slip of a harness or a safety helmet, resulting from bad design of the adjustment system;

□ pockets of protective clothing allowing hot or cold products to be caught;
□ PPE leading to difficulties in identifying optical or acoustical warning signals.
□ the psycho-physiological constraints such as the increase of metabolic rate or fatigue.

1.2.1.1. Suitable constituent materials

PPE materials and parts, including any of their decomposition products, must not adversely affect user hygiene or health. The materials constitutive of PPE and their possible products breakdown should not have harmful effects on hygiene or health of the user.

The constituent materials cannot (in the foreseeable conditions of normal use), release or degrade to release substances generally known to be toxic, carcinogenic, mutagenic, allergenic, teratogenic or otherwise harmful.
The following list is examples of possible documents to demonstrate conformity to this requirement:
a) Information supplied by the manufacturer might include a declaration confirming that the

product does not contain any substances at levels that are known or suspected to adversely effect user hygiene or health;
b) Materials specifications;
c) Safety data sheets relating to the materials;
d) Information relating to the suitability of materials for use with food, in medical devices, or other relevant applications;
e) Test reports or other information relating to toxicological, allergenic, carcinogenic, toxic to reproduction or mutagenic investigations and measurements on the materials;
f) Information relating to eco-toxicological and other environmental investigations on the materials.
Particular attention should be paid to the presence of plasticizers, unreacted components, heavy metals, impurities and the chemical identity of pigments and dyes.
The exposure limit values of harmful substances, such as Cr(VI), Ni, Azo colorants etc. are often laid down in European or national regulations. In particular, the manufacturer may need to consider:
□ Individual directives on the protection of workers from risks related to exposure to chemical, biological agents at work within the meaning of Article 16 of Directive 89/391/EEC;
□ Council Directive 92/32/EEC of 30 April 1992 amending for the seventh time Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, annex I of this directive is an index of 8000 dangerous substances for which harmonised classification and labelling have been agreed at Community level There are currently fifteen classes of danger such as: toxic, harmful, corrosive, irritant, sensitising, carcinogenic, mutagenic, toxic for reproduction, etc considered in this directive;
□ European Parliament and Council Directive 94/27/EC of 30 June 1994 relating to restrictions on the marketing and use of certain dangerous substances and

preparations. This directive is also applicable to PPE, and is related to the nickel release from those parts of PPE containing Nickel that come into direct and prolonged contact with the skin. (E.g. metallic spectacle frames).

1.2.1.2. Satisfactory surface condition of all PPE parts in contact with the user

Any PPE part in contact or in potential contact with the user when such equipment is worn must be free of roughness, sharp edges, projections and the like which could cause excessive irritation or injuries.

The assessment of the characteristics of roughness, sharp edges etc. likely to cause injury can be based on objective tests and/or practical experience. Injuries may originate not only from the characteristics of the PPE but also from the activity of the user.

1.2.1.3. Maximum permissible user impediment

Any impediment caused by PPE to movements to be made, postures to be adopted and sensory perception must be minimized; nor must PPE cause movements which endanger the user or other persons.

Impediment to movement depends in particular on the PPE weight and design sizes have to take into account not only the morphology of intended users but also the dynamic movement

required by their activity, the adjustment possibilities and on the characteristics of constituent materials. For example, the more the constituent materials are thick and rigid, the more likely they are to be impediment movements.
Impediment to sensory perception by the intended user can take many different forms. E.g. hearing protectors are intended to ensure the attenuation of noise which arrives at the intended user's ear but this requirement needs also to be considered alongside the need of the intended user to communicate with other operators and/or to hear warning signals.
Another example is fire-fighter clothing that needs to ensure protection against heat and flame. The protection may be of a lower level for minor part of the body in order for the intended user to be more quickly become aware of the danger and to escape more quickly.
With respect to sensory perception, it is necessary to seek the best possible compromise between safety and usability. For example, a glove needs to preserve the dexterity and tactile sensitivity of the intended wearer yet nevertheless ensure protection against risks which can be mechanical, chemical and/or thermal.
In order to assess the conformity of the PPE to this BHSR, objective test methods can be used to measure physical characteristics of the PPE having an effect on user impediment such as: sizes, rigidity, weight, field of vision ... When no objective method for the measurement of the level of impediment to movement exists, subjective trials can be performed, consisting in practical tests on a panel of test persons carrying out tasks simulating the possible foreseeable conditions of use.

1.3. Comfort and efficiency

1.3.1. Adaptation of PPE to the user morphology

PPE must be so designed and manufactured as to facilitate correct positioning on the user and to remain in place for the foreseeable period
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of use, bearing in mind ambient factors, movements to be made and postures to be adopted. For this purpose, it must be possible to optimize PPE adaptation to user morphology by all appropriate means, such as adequate adjustment and attachment systems or the provision of an adequate size range.

PPE must be designed and manufactured in order to provide the highest possible comfort for each wearer, thus for different morphology types and for both sexes.
Many variables are necessary to describe morphology i.e. to define the shapes of the human body. Moreover, sizes of people and ethnical composition of the European population are likely to evolve (rapidly) in time. This should be carefully considered by referring to updated anthropometric databases while designing PPE. Where possible systems of adjustment are useful to adapt the PPE to each wearer to avoid custom-made products, which are not economically viable.
PPE needs to be equipped with elements capable of ensuring its remaining in place, taken into account all possible foreseeable factors, such as forces affecting the PPEs stability, movements to be made and postures to be adopted during the tasks, etc.
For example:
□ Protective helmets need to be stable on the head of the wearer: a balanced weight distribution, an appropriate location of the centre of gravity and a nape strap are a few ways to do this. When necessary, and acceptable from a safety point of view, the helmet could also be equipped with a chin strap.

□ Lifejackets need to remain in place when the user falls into water.
PPE must be so designed and manufactured as to facilitate correct positioning on the user. This could be evaluated by subjective tests, e.g. considering the opinion of wearers executing a conventional task. In certain cases, this facility of correct positioning can be evaluated by measuring technical properties specific to the risk to prevent, for example, the degree of tightness of the face piece of a respiratory protective device test subjects performing dynamic tasks.
Trials with test subjects or laboratory measurements could also be used to assess:
□ Adjustability, the stability of adjustments;
□ Consequences of displacement of the PPE, and the maximum tolerable displacement;
□ Static and dynamic forces that might be exerted on the PPE in normal use, and during circumstances in which it is intended to provide protection.
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1.3.2 Lightness and design strength

PPE must be as light as possible without prejudicing design strength and efficiency.

Apart from the specific additional requirements which they must satisfy in order to provide adequate protection against the risks in question (see 3), PPE must be capable of withstanding the effects of ambient phenomena inherent under the foreseeable conditions of use.

The manufacturer should design the PPE so that the best compromise between the weight and protection efficiency is realised. PPE can have adverse effects on the body by increasing muscle strain or energy consumption through increased or altered passive or dynamic loading. The weight (and its distribution) of PPE has to be considered in relation to the specific body part or parts likely to be affected. For example, additional mass on the head produces forces in the neck that have to be countered by the neck muscles and thus might have a negative influence on the wearer's health and safety. Heavy weights on the body or body parts increase energy consumption, especially when walking or running.
The efficiency of PPE can be affected by any number of environmental factors. These factors can lower the protection efficiency in time. The manufacturer should give enough information how environmental factors affect the protection level so that the user can assess the service life of the PPE. The manufacturer needs to include in the instructions for use the foreseeable environment and working conditions he has taken into account when designing the PPE in order to allow correct use and selection in any given situation.
For example, PPE integrating electronic components the behaviour in an EMC "disturbed" environment must be thoroughly checked. The PPE needs to remain safe and not lead to dangerous situations in cases of failure of or damage to the circuit or errors in the circuit logic.

1.3.3 Compatibility of different classes or types of PPE designed for simultaneous use

If the same manufacturer markets several PPE models of different classes or types in order to ensure the simultaneous protection of adjacent parts of the body against combined risks, these must be compatible.

When different types of PPE from a manufacturer are intended to be worn simultaneously, the manufacturer will need to ensure that the safety function and comfort of each PPE are not compromised by the wearing of another PPE. For example an ear muff or a face shield is

considered as compatible with a safety helmet, if the protective characteristics and the comfort of the hearing protector and of the face shield are not impaired by the simultaneous wearing of these PPE.
In all cases, the manufacturer will also need to draw the attention of intended users on any limitation of use or possible incompatibility.
See also requirement 2.14
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1.4. Information supplied by the manufacturer

In addition to the name and address of the manufacturer and/or his authorized representative established in the Community, the notes that must be drawn up by the former and supplied when PPE is placed on the market must contain all relevant information on:

The information supplied by the manufacturer constitutes a fundamental element in order to judge the conformity of a PPE. **It is considered an integral part of the** PPE it refers to and shall be checked, in terms of content and understandability, by the Notified Body when undertaking an EC-type examination. The Notified Body shall verify that the equipment can be used in complete safety for its intended purpose. In order to do this, the Notified Body shall check that the claims of the manufacturer on the area and limits of protection of the product are in line with the technical specification used and with the relevant essential safety requirements
This document shall be established in conformity with this BHSR, but also, where relevant, with other applicable requirements, such as:
1.3.3 Compatibility of different classes or types of PPE designed for simultaneous use
2.4 PPE subject to ageing
2.8 PPE for use in very dangerous situations
2.12 PPE bearing one or more identification or recognition marks directly or indirectly relating to health and safety
3.1.2.2 Prevention of falls from a height
3.5 Protection against the harmful effects of noise
3.6.2 Complete PPE ready for use
3.7.2 Protection against heat and/or fire
3.8 Protection against electric shock
3.9.1 Non-ionizing radiation
3.9.2.2 Limited protection against external irradiation
3.10. Protection against dangerous substances and infective agents :
3,10.1 Respiratory protection
3.10.2 Protection against cutaneous and ocular contact
The manufacturer has the obligation to deliver the information in paper form to users with each unit of PPE put on the market.
For some types of PPE, such as ear-plugs or specific protective gloves which are sometimes sold in dispenser boxes, the instructions for use can be affixed to the boxes or be provided with each unit.
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1.4 (a)
(a) storage, use, cleaning, maintenance, servicing and disinfection. Cleaning, maintenance or disinfectant products recommended by manufacturers must have no

adverse effect on PPE or users when applied in accordance with the relevant instructions;
The storage instructions must specify the conditions, for example: to store only in its original packaging, in a dry atmosphere, at a maximum temperature of 60°C, away from light, etc.
The instructions for use have to give necessary information for putting on or taking off the PPE as well as how to make the necessary adjustments to the wearer's morphology.
The manufacturer cannot deviate from the obligation to define cleaning, maintenance and (if applicable) disinfection processes, since these are necessary to ensure the hygiene of the intended user of the PPE.
The instructions for cleaning, maintenance and disinfection must not only specify the products (or at least the criteria necessary to select them) but if relevant also the procedures to be applied. These procedures will specify the preliminary operations such as the disassembling of certain sensitive components, and the actual operations including the concentrations of cleaning product, the temperature, etc). The procedures will also mention any operation necessary to apply after cleaning or maintenance, to ensure that the PPE retain the optimum level of effectiveness. For example, the cleaning procedures include the conditions of drying for a PPE intended for heat and flame protection or the precautions to be taken with respect to the electrical risk if the PPE has electric or electronic components.
The conditions of disinfection depend on the type of PPE and the way in which it is carried/worn by the user. They can be less constraining if there is no direct contact of the PPE with the skin of the wearer, for example, the harnesses of fall arresting systems. On the other hand, they should be very prescriptive if there is direct and prolonged contact with the skin, for example, as is the case with respiratory protective devices or safety gloves.
The maintenance instructions must specify which are the operations the wearer can carry out himself, and how to do so (in particular giving precise information on spare parts), as well as when this requires the intervention of the manufacturer or a specialised person.
Any product specified by the manufacturer for the cleaning, maintenance or disinfection of the PPE will not be harmful for the PPE or its user. For instance, products that are recommended will be tested on carcinogenic or allergic reactions or they will not destroy the integrity of the material used in the PPE. The harmful effects on a potential user can be verified using safety data sheets of the products while the effects on the integrity of PPE can be checked applying the cleaning procedure before carrying out the test to determine the performance of the PPE.
1.4 (b) performance as recorded during technical tests to check the levels or classes of protection provided by the PPE in question;
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The information shall mention the levels or classes of protection, determined by the manufacturer according to European harmonised standards or other relevant specifications and shall not duplicate the content of the test report.
1.4 (c) suitable PPE accessories and the characteristics of appropriate spare parts;
The manufacturer needs to indicate the accessories and spare parts compatible with the PPE in the instructions. The manufacturer is responsible for the design of these accessories and of their compatibility with the PPE. As a consequence he cannot assume any responsibility if a person uses those accessories other than those envisaged by him.
The characteristics of the spare parts mentioned in this requirement relate to the necessary information to their replacement and the limits for their use.

1.4 d) the classes of protection appropriate to different levels of risk and the corresponding limits of use;
For a class of protection claimed by the manufacturer, the instructions must specify the level of the risk covered and the corresponding limits of use. These are generally expressed by:
- the nature of the covered risk;
- the limitation of the parameters defining the risk (temperature, pressure, acoustic level, list of chemicals…);
- the limitation of the exposure duration to the risk.
These levels of the risks covered are sometimes difficult to know beforehand. In such cases they can be indicated by reference to the test conditions in which the examination of the type was undertaken.
1.4 (e) the obsolescence deadline or period of obsolescence of PPE or certain of its components;
Date of obsolescence is the date from which, the PPE becomes useless for its intended use or is no longer fit for its purpose, due, either to changes in its protective properties or to loss in functionality and it must be discarded or repaired. This date of obsolescence or period of obsolescence refers either to the self life, or to the useful life span, or to the time of use or to the ageing or to any other circumstance that may affect the PPE performances.
The manufacturer must provide all information necessary so that the user can determine a reasonable period of obsolescence. However the manufacturer is not obliged to affix the date of manufacture on the product or on the instructions for use.
This can be expressed by relevant information on how to identify the "end of life", a limiting date of use or a maximum service time.
The service life of PPE depends on many factors such as the conditions of storage, use, cleaning, revision, maintenance where a manufacturer does not have control. The manufacturer has to provide any useful information so that the intended user can determine a reasonable time limitation. It can be a question of the evolution of a characteristic of use (for

example, an increase in respiratory resistance making the use painful) or of a characteristic of aspect and/or integrity (for example, striped or split eyepiece). It could also refer to the ageing of materials. For example, the appearance of cracks or discolouration on the surface of a thermoplastic safety helmet is an objective sign of ageing.
1.4 (f) the type of packaging suitable for transport;
This is related to the description of packing to be used for transport, for example, original packaging, tight packing etc., to keep the safety and usability characteristics of the PPE. The term "transport" is related not only to the transportation from the manufacturing place to other places but also to the protection of the PPE when not in use and moved.
1.4 (g) the significance of any markings (see 2.12).
Requirement 2.12 is related to the markings affixed on PPE concerning directly or indirectly the health or the safety of the intended user. There are other provisions of the directive which mention the affixing of markings with particular significance, thus for example requirements 2.4 (relating to the PPE subject to ageing), 3.5 (relating to hearing protectors), 3.9 (relating to eye protectors against the ionizing radiations), 3.10 (relating to respiratory protective devices).
In addition to these markings whose affixation is mandatory, other markings or pictograms can exist e.g. as defined in standards, providing useful information on field of use of the PPE

and its level of performance. This shall be clearly explained in the instructions for use and can not lead to confusion with respect to the mandatory marking requirements (CE marking).
1.4 (h) where appropriate, the references of the directives applied in accordance with article 5 (6) (b);
This requirement refers to an Article concerning the application of Directives for which the CE marking is foreseen, the references detailed here are only so-called "New Approach" Directives that have been applied to the PPE.
In the information supplied by the manufacturer details have to be provided as to which directives the manufacturer has decided to apply.
1.4 (i) the name, address and identification number of the notified body involved in the design stage of the PPE.
The design stage includes all the operations of design and manufacture of the PPE which was subjected to EC-type examination. This requirement relates only to PPE of category II and III. Using a Notified Body during the phase of design of PPE (the Body which makes the EC-type examination) does not discharge the manufacturer from his responsibilities, such as defined in the Articles of the directive.
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These notes, which must be precise and comprehensible, must be provided at least in the official language(s) of the Member State of destination.
The manufacturer has the responsibility for the establishment of the original version of the instructions for use and of the validated versions in the languages of the Member States of the EU where he intends to place the PPE on the market.
This document has to be written in the language(s) of the Member States where the product is intended to be sold, the translation is made by the manufacturer and/or his authorized representative established in the Community under his responsibility, and must include his address.
Product information is one of the fundamental elements of any product and as such it has to be clear, concise, understandable and giving the appropriate information for the end users. It should be taken into account that the information supplied by the manufacturer may only be considered as effective, when it is perceived, understood, retained and appropriately used. Since the information supplied by the manufacturer provides the basis on which consumers can make a reasoned selection, it is also one of the means to increase the health and safety of the intended end user. High quality information minimises the risk of an incorrect selection and/or wrong use. The better the quality of information, the easier the selection and correct use of the PPE.
Further, CEN has elaborated a guide on information supplied by the manufacturer, which can be found at:
http://www.cenorm.be/cenorm/workarea/sectorfora/personal+protective+equipment/index.asp

2. ADDITIONAL REQUIREMENTS COMMON TO SEVERAL CLASSES OR TYPES OF PPE

2.1. PPE incorporating adjustment systems

If PPE incorporates adjustment systems, the latter must be so designed and manufactured as not to become incorrectly adjusted without the user's knowledge under the foreseeable conditions of use.

The manufacturer shall ensure by proper design that no unintentional changes of adjustment can influence the protection afforded by the PPE.

In the case of attachment units, this condition is met if, for example, they are inaccessible during conducting the task or, if they would be accessible, the system needs to be unlocked e.g. the simultaneous voluntary execution of two distinct movements.

2.2. PPE 'enclosing' the parts of the body to be protected

As far as possible, PPE 'enclosing' the parts of the body to be protected must be

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sufficiently ventilated to limit perspiration resulting from use; if this is not the case, it must if possible be equipped with devices which absorb perspiration.

The main method that the body uses to keep a suitable temperature is sweat evaporation. Evidently, PPE has an influence on the conditions applying to the wearer affecting this physiological phenomenon.

As a result, the PPE has to be designed so as to allow a sufficient level of ventilation according to the task and foreseeable use conditions or the manufacture has to use breathable materials. In order to increase comfort, for example where protection against a toxic environment is required and hence the PPE has to be impermeable, sweat absorbing materials can evidently be chosen.

Where this BHSR is to be applied, the information supplied by the manufacturer needs to specify the necessary ventilation rate if the PPE is to be supplied with air ventilation. Useful information in respect of maintenance also has to be given, by specifying the cleaning and drying operations to be carried out after use.

This information has to be sufficient to make it possible for the employer to determine the maximum physiologically acceptable duration use of the PPE in accordance with directive 89/656/EEC.

2.3. PPE for the face, eyes and respiratory tracts

Any restriction of the user's field of vision or sight by PPE for the face, eyes or respiratory tract must be minimized.

The degree of optical neutrality of the vision systems of these PPE classes must be compatible with the type of relatively meticulous and/or prolonged activities of the user.

If necessary, they must be treated or provided with facilities to prevent moisture formation.

PPE models intended for users requiring sight correction must be compatible with the wearing of spectacles or contact lenses.

Any restriction to the natural field of vision of the intended user must be minimised in order to minimise risks or discomfort associated with either the intended tasks or environment.

In order to ensure the comfort of a user not requiring vision correction, safety oculars should not impair his vision. In other terms to be optically neutral by having refractive power as low as possible. Safety oculars with very low refractive powers are recommended for a permanent use or a meticulous work and the others only for intermittent or even for very short duration use.

Lenses provided with "anti-fogging" coating need to be designed to be so that this characteristic remains preventing moisture formation in all foreseeable conditions of use. If this is the case, information is to be given in the instruction for use, on how to clean the antifogging

lenses to avoid degradation of the coating.

Devices integrated into PPE to reduce moisture have to be designed to prevent fogging whilst

not downgrading the PPE protection level (e.g. ventilation holes in goggles).
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Regarding integrated air ventilation, the air flow cannot create adverse health effects or nuisance (noise, comfort disturbing draught…).
If the PPE is intended to be put over corrective spectacles, the manufacturer needs take into account the normal dimensions of the spectacles to determine those for the PPE.
The manufacturer will want to be aware that, wherever possible, it is advisable to integrate the optical correction to PPE oculars or to provide a suitable mounting supporting the corrective spectacles.

2.4. PPE subject to ageing

If it is known that the design performances of new PPE may be significantly affected by ageing, the date of manufacture and/or, if possible, the date of obsolescence, must be indelibly inscribed on every PPE item or interchangeable component placed on the market in such a way as to preclude any misinterpretation; this information must also be indelibly inscribed on the packaging.

If a manufacturèr is unable to give an undertaking with regard to the useful life of PPE, his notes must provide all the information necessary to enable the purchaser or user to establish a reasonable obsolescence date, bearing in mind the quality level of the model and the effective conditions of storage, use, cleaning, servicing and maintenance.

Where appreciable and rapid deterioration in PPE performance is likely to be caused by ageing resulting from the periodic use of a cleaning process recommended by the manufacturer, the latter must, if possible, affix a mark to each item of PPE placed on the market indicating the maximum number of cleaning operations that may be carried out before the equipment needs to be inspected or discarded; failing that, the manufacturer must give this information in his notes.

The ageing factors influencing the performance of the PPE that need to be taken into account are the effects of time, environment and use. The manufacturer will define in his technical file the ambient conditions as well as the foreseen use conditions taken into account when evaluating the effect of ageing on the PPE. It is understood that the date of expiry of the PPE corresponds with the decrease, by ageing effects, of the protective performance to the level that is not adequate against the risk.
The manufacturer needs to ensure that the storage will not change the PPE characteristics significantly.
The lifetime of the PPE, corresponding with the expiry date, is influenced by the use conditions of the PPE or the interchangeable components. The lifetime can be expressed in terms of time or of number of exposures. It is understood that the manufacturer cannot have full control over these conditions. Therefore the manufacturer will assist the user in determining the moment to dispose of the PPE with all relevant information on the foreseen use conditions as well as on all other factors influencing the lifetime (storage, cleaning, maintenance, etc. see also paragraph 1.4).
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In the case that the prescribed cleaning process leads to a rapid and important deterioration of

the PPE performance, the maximum number of cleaning cycles that can be performed without overhaul or disposal needs to be indicated.
For example:
□ Certain protective clothing has a finish that will resist only a few wash cycles, but can be restored following the instruction of the manufacturer – in that case the maximum number indicated means the number of cleaning cycles between restoring the finishing or the maximum amount of re-treatments.
Certain materials used in protective clothing or gloves do not resist cleaning. In that case an indication that the product is only intended for a single use needs to be fixed to the PPE.

2.5. PPE which may be caught up during use

Where the foreseeable conditions of use include in particular the risk of the PPE being caught up by a moving object thereby creating a danger for the user, the PPE must possess an appropriate resistance threshold above which a constituent part will break and eliminate the danger.

The design of PPE shall be such that no risk of being caught can exist. If a residual risk of the PPE being caught remains, the product shall be so designed that that component has a suitable breaking resistance to avoid injuries due to PPE catching. This threshold depends on the characteristics of the components of PPE and their assembly. It must be designed by taking account the characteristics of part of the body to be injured and the severity of the possible health damage. The breaking force of the cord connecting ear plugs (for example) shall be much lower than the breaking force of a protective clothing.
In some cases it is difficult to confirm this requirement. In those cases the information supplied by the manufacturer shall clearly give warning to use these PPE in situations where this risk exists.

2.6. PPE for use in explosive atmospheres

PPE intended for use in explosive atmospheres must be so designed and manufactured that it cannot be the source of an electric, electrostatic or impact-induced arc or spark likely to cause an explosive mixture to ignite.

PPE intended to be used in an explosive environment, needs to:
□ have anti-static properties which remain effective during all its service life when used and maintained correctly in accordance with the manufacturer instructions;
□ be made of material which are known not to cause sparks e.g. by impact;
□ strictly avoid PPE components likely to create sparks by shock or friction initiated by a PPE intended to be used in explosive atmosphere;
□ not include unprotected electric components or parts which do not comply (where relevant) to directive 94/9/EC of 23 March 1994 on the approximation of the laws of the Member States concerning equipment and protective systems intended for used in potential explosive atmospheres.

2.7. PPE intended for emergency use or rapid installation and/or removal

These PPE classes must be so designed and manufactured as to minimize the time required for attachment and (or) removal.

Any integral systems permitting correct positioning on, or removal from, the user must be susceptible of rapid and easy operation.

The ease of donning and doffing of PPE intended for emergency use shall be as good as

possible, taking into account the foreseeable emergency situations and the duration of the tasks. The verification of the required time can only be made by using test subjects in realistic simulated conditions.
In some cases it is important to be able to remove the PPE quickly to avoid or limit severe injuries: e.g. when hot or cold particles or liquids accidentally enter the PPE.
Instructions for use shall contain the information on quick donning and doffing of the PPE and advice for proper training of the users.

2.8. PPE for use in very dangerous situations

The information notes supplied by the manufacturer together with PPE for use in the very dangerous situations referred to in Article 8 (4) (a) must include, in particular, data intended for the exclusive use of competent trained individuals who are qualified to interpret them and ensure their application by the user.

They must also describe the procedure to be adopted in order to verify that PPE is correctly adjusted and functional when worn by the user.

If PPE incorporates an alarm which is activated in the absence of the level of protection normally provided, this must be so designed and accommodated as to be perceived by the user in the conditions of use for which the PPE is marketed.

PPE intended for this type of task is category III.
Where the manufacturer considers that the PPE can only be used by trained persons, further information needs to be provided, as follows:
□ the details of the training of the "trainers" themselves so that the intended users;
□ the correct donning and adjustment of the PPE to maximise its effectiveness;
□ the correct procedure to verify the functionality of the PPE (e.g. content and periodicity of controls).
The warning device integrated in PPE needs to be designed so that it remains effective (e.g. visible and/or audible) in all foreseeable conditions of use and irrespective of the intended environmental variations (e.g. heat, cold, moisture, electromagnetic radiation, shocks...). This alarm device may, amongst other relevant factors, need to take into account the following:
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□ the sound environment;
□ the wearing of hearing protectors (see requirement 3.5);
□ the ambient illumination;
□ the use of coloured optical filters against radiation.
Where, even with a warning device the manufacturer considers that the required level of protection cannot be assured, he will need to include a suitable warning in the instructions for use.

2.9. PPE incorporating components which can be adjusted or removed by the user

Any PPE components which can be adjusted or removed by the user for the purpose of replacement must be so designed and manufactured as to facilitate adjustment, attachment and removal without tools.

The instructions given by the manufacturer need to specify the adjustments and replacements that can be made by the user himself without tools and those which are to be done only by competent trained persons. In the first case the procedures to be followed to make them safely and easily without tools are to be included in the instructions for use.

2.10. PPE for connection to another, external complementary device

If PPE incorporates a system permitting connection to another, complementary,

device, the attachment mechanism must be so designed and manufactured as to enable it to be mounted only on appropriate equipment.

As far as possible the design of PPE needs to prevent the incorrect connection. The information given by the manufacturer therefore has to describe how to ensure safe connection and where appropriate give adequate warnings to ensure that this is the case.

If PPE is designed so that several devices can be connected, for example to adapt it to different conditions of use, the information given by the manufacturer has to provide an exhaustive list of these devices and guidance on how to use them correctly.

For example, if the PPE is to be connected with breathable gas mixtures supply, the connector should be conceived so that it is impossible to connect it to non breathable gas supply, such as a nitrogen circuit.

2.11. PPE incorporating a fluid circulation system

If PPE incorporates a fluid circulation system, the latter must be so chosen, or designed, and incorporated as to permit adequate fluid renewal in the vicinity of the entire part of the body to be protected, irrespective of user gestures, posture or movement under the foreseeable conditions of use.

The most frequent use of these systems is in hot or cold environments or in situations when the user must be totally insulated from polluted atmospheres and it is necessary to maintain the body temperature within acceptable limits.

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2.12. PPE bearing one or more identification or recognition marks directly or indirectly relating to health and safety

The identification or recognition marks directly or indirectly relating to health and safety affixed to these types or classes of PPE must preferably take the form of harmonized pictograms or ideograms and must remain perfectly legible throughout the foreseeable useful life of the PPE. In addition, these marks must be complete, precise and comprehensible so as to prevent any misinterpretation; in particular, when such marks incorporate words or sentences, the latter must appear in the official language(s) of the Member State where the equipment is to be used.

If PPE (or a PPE component) is too small to allow all or part of the necessary marking to be affixed, the relevant information must be mentioned on the packing and in the manufacturer's notes.

These marks cannot create confusion in respect of e.g. the risk covered or the category of PPE. Information given by the manufacturer has to specify the correct meaning of any pictogram (see requirement 1.4 g). They need be so designed to remain legible during the service life of the product, that means e.g. that the marking affixed on the PPE shall not be easily removable and/or damaged by e.g. scratching, cleaning or sun exposure.

These marks can only be considered as effective, when complete, precise and comprehensible, in other terms when it is properly perceived, understood, retained by the intended end user.

For the use of harmonised pictograms or ideograms the manufacturer may refer in particular to ISO 7000 "Graphical symbols for use on equipment-Index and synopsis."

2.13. PPE in the form of clothing capable of signalling the user's presence visually

PPE in the form of clothing intended for foreseeable conditions of use in which the user's presence must be visibly and individually signalled must have one (or more) judiciously positioned means of or devices for emitting direct or reflected visible radiation of appropriate luminous intensity and photometric and colorimetric

properties.

The intention of this requirement is to make the intended user of PPE visible especially when moving in an area where motor vehicles or other mobile machines are moving, in particular when the illumination is poor. Respect of this requirement allows for a better identification of the users of these PPE by the drivers but does not protect these users of PPE against the collision risks. The form of direct signalling or reflective material affixed to PPE needs to make it possible for the driver to recognize that it is a pedestrian and not a fixed obstacle. Signalling devices or materials have to be so positioned on the clothing so that in the foreseeable conditions of use the signalling surfaces are not obstructed.

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2.14. Multi-risk' PPE

All PPE designed to protect the user against several potentially simultaneous risks must be so designed and manufactured as to satisfy, in particular, the basic requirements specific to each of those risks (see 3).

3. ADDITIONAL REQUIREMENTS SPECIFIC TO PARTICULAR RISKS

3.1. Protection against mechanical impact

3.1.1. Impact caused by falling or projecting objects and collision of parts of the body with an obstacle

Suitable PPE for this type of risk must be sufficiently shock-absorbent to prevent injury resulting, in particular, from the crushing or penetration of the protected part, at least up to an impact-energy level above which the excessive dimensions or mass of the absorbing device would preclude effective use of the PPE for the foreseeable period of wear.

Impact tolerance criteria have been developed for different body regions usually derived from a combination of accident and casualty data.

The influence of impact is not only related to its energy level but also to other parameters such as the direction of the impact. The principle to find optimum level of protection is then to be applied at design stage.

3.1.2. Falls

3.1.2.1. Prevention of falls due to slipping

The outsoles for footwear designed to prevent slipping must be so designed, manufactured or equipped with added elements as to ensure satisfactory adhesion by grip and friction having regard to the nature or state of the surface.

There are several factors affecting the risk of slipping. One of most important influencing factors is the friction of the outsole of the footwear. The friction of the sole on the walking surface shall be in a suitable range of friction values. The properties of the walking surfaces corresponding to the foreseeable conditions of use shall be taken into account. The outsoles made from certain materials can also vary with the temperature or during the lifetime by wear and tear of the sole. For some use situations it is very difficult to design footwear having proper friction.

For footwear intended to be permanently used on very slippery ice surfaces, the manufacturer may equip the footwear with spikes or similar integrated additional elements. The manufacturer can also design specific removable PPE which shall be able to be attached easily, firmly and securely onto the footwear.

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3.1.2.2. Prevention of falls from a height

unconscious. Hence, the inflatation time of inflatable devices needs to be as short as possible to be able to save (in particular) an injured or unconscious person.
The luminous or sound signal device referred to must be able to perceived by the rescuers in all foreseeable conditions of use. Evidently, the reflective materials have to be effective when wet.
For prolonged use/ immersion, this PPE has to consider ergonomics requirements to be comfortable and usable during activities where the risk of a fall into water might exist.

3.4.1. Buoyancy aids

Clothing which will ensure an effective degree of buoyancy, depending on its foreseeable use, which is safe when worn and which affords positive support in water. In foreseeable conditions of use, this PPE must not restrict the user's freedom of movement but must enable him, in particular, to swim or take action to escape from danger or rescue other persons.

There has been a good deal of discussion over recent years over the borderline between different types of buoyancy aides. The general understanding is as follows:
• Arm rings are category II PPE which provide an aid to buoyancy;
• Floating seats are covered by the GPSD;
• Inflatable buoys are toys in terms the Toys Directive when they are to be used in shallow waters by children less than 14 years of age - In other cases, they are covered by the GPSD.
Buoyancy aids allow an unconscious user to be afloat but do not necessarily keep the head out of water, whereas the PPE intended for the prevention of drowning maintains the head out of water but may offer only very reduced mobility.
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3.5. Protection against the harmful effects of noise

PPE designed to prevent the harmful effects of noise must be capable of attenuating the latter to such an extent that the equivalent sound levels perceived by the user do not under any circumstances exceed the daily limit values laid down by Council Directive 86/188/EEC of 12 May 1986 on the protection of workers from the risks related to exposure to noise at work (;).

All PPE must bear labelling indicating the noise attenuation level and the value of the comfort index provided by the PPE; should this not be possible, the labelling must be fixed to the packaging.

Directive 86/188/EEC has been replaced by directive 2003/10/EC on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (noise). Member states were required to transpose this new directive into national legislation before 15 February 2006.
The necessary attenuation foreseen here can be obtained by using earmuffs, earplugs or a combination of both.
Communication systems included in some hearing protectors are to be designed in order not to exceed the harmful noise "dose".
The ability to understand speech or to hear warning signals may be taken into account in the design of hearing protectors for certain applications.
For some users (such as musicians) it is essential to hear the sound of different frequencies correctly and therefore ear protectors need to have even sound attenuation characteristics throughout the whole frequency area.

If the earplugs are custom made, tests on prototypes and the instructions (for competent persons) on how to mould these plugs correctly need to be drawn up by the manufacturer and evaluated by the Notified Body.
The comfort index includes the effects of aspects related to the comfort for the user. These aspects can include pressure against the head, weight, type of materials, and so on. In the instructions for the user, the manufacturer includes clear information on how to use the hearing protector correctly so that the discomfort is minimised. For the time being it is not possible to determine comfort index, but the factors mentioned above should be taken into account in the design.

3.6. Protection against heat and/or fire

PPE designed to protect all or part of the body against the effects of heat and/or fire must possess thermal insulation capacity and mechanical strength appropriate to foreseeable conditions of use.

In most cases this type of PPE consists of several protective material layers, with the thermal insulation capacity which gives necessary protection.. The protection efficiency will depend not only on the insulation capacity but also on the proper coverage of the insulation of PPE. The size and model of the PPE has to be such that heat or flame is not able to harm the user through possible openings in the PPE and that the protection against heat and flame is not

lowered during the exposure. Therefore, PPE needs sufficient mechanical strength against abrasion, cuts and tearing.

3.6.1. PPE constituent materials and other components

Constituent materials and other components suitable for protection against radiant and convective heat must possess an appropriate coefficient of transmission of incident heat flux and be sufficiently incombustible to preclude any risk of spontaneous ignition under the foreseeable conditions of use.

Where the outside of these materials and components must be reflective, its reflective power must be appropriate to the intensity of the heat flux due to radiation in the infra-red range .

Materials and other components of equipment intended for brief use in hightemperature environments and of PPE which may be splashed by hot products such as large quantities of molten material must also possess sufficient thermal capacity to retain most of the stored heat until after the user has left the danger area and removed his PPE.

PPE materials and other components which may be splashed by large amounts of hot products must also possess sufficient mechanical-impact absorbency (see 3.1).

PPE materials and other components which may accidentally come into contact with flame and those used in the manufacture of fire-fighting equipment must also possess a degree of non-flammability corresponding to the risk class associated with the foreseeable conditions of use. They must not melt when exposed to flames nor contribute to flame propagation.

This requirement applies to constituent materials and components and not to complete PPE. The manufacturer needs to select materials, components or combinations of them so that in the foreseeable conditions of use:
- the heat flux transmitted to the wearer is under the tolerable exposure limit values;
- their flammability and/or melting do not create an additional burning risk for the PPE

PPE designed to prevent falls from a height or their effects must incorporate a body harness and an attachment system which can be connected to a reliable anchorage point. It must be designed so that under the foreseeable conditions of use the vertical drop of the user is minimized to prevent collision with obstacles and the braking force does not, however, attain the threshold value at which physical injury or the tearing or rupture of any PPE component which might cause the user to fall can be expected to occur.
It must also ensure that after braking the user is maintained in a correct position in which he may await help if necessary.
The manufacturer's notes must specify in particular all relevant information relating to:
- the characteristics required for the reliable anchorage point and the necessary minimum clearance below the user,
- the proper way of putting on the body harness and of connecting the attachment system to the reliable anchorage point.
PPE for the prevention against falls from a height shall be designed so that:
□ the user is prevented from reaching any dangerous area where the risk of free fall exists (restraint equipment);
□ or in case where the risk of free fall cannot be prevented, the PPE prevents the collision with obstacles or with the floor and minimise the risk of injury by dissipating the kinetic energy to the level which is not harmful to the user e.g. by leading-in the forces into the strong parts of the body or by the use of energy absorbing devices.
The manufacturer needs to list the components which can be used together in the fall arresting system and how to assemble them properly.
All of the components of all fall arrest systems and the assemblies need to be in conformity with the directive. The manufacturer has the responsibility to indicate the components which can be used together in the system and how to assemble them properly.
The design has to be so that in case of an accident, the victim can wait for rescue in a good position without excessive harmful effects.

3.1.3 Mechanical vibration

PPE designed to prevent the effects of mechanical vibrations must be capable of ensuring adequate attenuation of harmful vibration components for the part of the body at risk.
Under no circumstances must the effective value of the accelerations transmitted to the user by those vibrations exceed the limit values recommended in the light of the maximum foreseeable daily exposure of the part of the body at risk.
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The directive regarding to the exposure of workers, 2002/44/EC, contains provisions aimed at avoiding or reducing risks arising from vibration. PPE can be part of the prevention programme. PPE against vibration can be difficult to use and therefore the directive recommends other prevention means. One recommendation of this directive is to provide suitable clothing to minimise the effect of mechanical vibration to those workers who are working in cold and damp conditions.
The efficiency of PPE against vibration needs to be evaluated by reference of the exposure action and limit values given in this directive.

3.2. Protection against (static) compression of part of the body

PPE designed to protect part of the body against (static) compressive stress must be sufficiently capable of attenuating its effects to prevent serious injury or chronic complaints.

3.3. Protection against physical injury (abrasion, perforation, cuts, bites)

PPE constituent materials and other components designed to protect all or part of the body against superficial injury caused by machinery, such as abrasion, perforation, cuts or bites, must be so chosen or designed and incorporated as to ensure that these PPE classes provide sufficient resistance to abrasion, perforation and gashing (see also 3.1) under the foreseeable conditions of use.

For "machinery" one should consider "mechanical actions". Therefore this requirement is applicable to all injuries independently from their origin.

This requirement is related to the real risks corresponding to the foreseeable conditions of use and to the physical safety of the user, and not to the quality of the product.

Resistance to abrasion, perforation and cut are important properties for many PPE as consequence that these risks are present in most of the tasks. In most cases they are caused by

- Abrasion: contact with abrasive surfaces or abrasive products, sandblasting.
- Perforation: contact with sharp pointed objects
- Cut: contact with sharp or toothed edges.

3.4. Prevention of drowning (lifejackets, armbands and lifesaving suits)

PPE designed to prevent drowning must be capable of returning to the surface as quickly as possible, without danger to his health, a user who may be exhausted or unconscious after falling into a liquid medium, and of keeping him afloat in a position which permits breathing while awaiting help.

PPE may be wholly or partially inherently buoyant or may be inflated either by gas which can be manually or automatically released or orally.

Under the foreseeable conditions of use:

- PPE must, without prejudice to its satisfactory operation, be capable of withstanding the effects of impact with the liquid medium and the environmental factors inherent in that medium,

- inflatable PPE must be capable of inflating rapidly and fully.

Where particular foreseeable conditions of use so require, certain types of PPE must also satisfy one or more of the following additional requirements:

- it must have all the inflation devices referred to in the second subparagraph, and/or a light or sound-signalling device,

- it must have a device for hitching and attaching the body so that the user may be lifted out of the liquid medium,

- it must be suitable for prolonged use throughout the period of activity exposing the user, possibly dressed, to the risk of falling into the liquid medium or requiring his immersion in it.

The PPE which meets this requirement protects the user against a risk of drowning. In general, it is considered that "liquid medium" refers to water.

Buoys and life jackets not carried permanently by people on board of aircrafts and ships are not subject to the PPE Directive (see Annex I) but to other specific directives (e.g. marine equipment directive 96/98/EC).

It should be noted that this type of PPE needs to protect against drowning even of the user is

wearer.
In addition to the insulation properties, the reflective capacity of materials used is important in that it ought to be as high as possible without increasing other harmful factors like heat stress resulting from clothing materials impermeability.
The thermal capacity of materials, material combinations or components to be used in high temperature environments must be designed such that the PPE user will have, after exposure, enough time to leave the danger area and remove the PPE before the accumulated heat in the materials causes him any harm.
The mechanical resistance of PPE materials and other components, must, when necessary be adequate to meet the impact energy, nature and temperature of the splashes of hot products in order to provide sufficient protection to the user.
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3.6.2. Complete PPE ready for use
Under the foreseeable conditions of use:
1. The quantity of heat transmitted by PPE to the user must be sufficiently low to prevent the heat accumulated during wear in the part of the body at risk from attaining, under any circumstances, the pain or health impairment threshold;
2. PPE must if necessary prevent liquid or steam penetration and must not cause burns resulting from contact between its protective integument and the user.
If PPE incorporates refrigeration devices for the absorption of incident heat by means of liquid evaporation or solid sublimation, their design must be such that any volatile substances released are discharged beyond the outer protective integument and not towards the user.
If PPE incorporates a breathing device, the latter must adequately fulfil the protective function assigned to it under the foreseeable conditions of use.
The manufacturer's notes accompanying each PPE model intended for brief use in high-temperature environments must in particular provide all relevant data for the determination of the maximum permissible user exposure to the heat transmitted by the equipment when used in accordance with its intended purpose.
The manufacturer has to design the PPE such that in the foreseeable conditions of use:
- the accumulation of heat by the PPE while in use does not cause thermal stress, pain or harmful effects to the user;
- it prevents any penetration of liquid or steam liable to cause burns (e.g. by proper coverage of body parts to be protected);
- any part of the PPE which may be heated up to harmful temperature will not be in direct contact with the user.

PPE incorporating refrigeration devices for the absorption of incident heat must, where relevant, be designed such that in the foreseeable conditions of use, volatile substances released are discharged away from the user in order not to cause any additional harmful effect.
PPE against heat incorporating a breathing device, must be designed such that, in the foreseeable conditions of use, it fulfils the requirements applicable to respiratory protective devices: e.g. the air flow in ventilated suits must be high enough to protect against excessive heat load and contaminant inhalation.
With regards to PPE for brief use in high temperatures, the manufacturer must provide

enough information so that the user can determine for each of his intended actions, the maximum effective protection time and/or the maximum acceptable use time from the physiological point of view.
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3.7 Protection against cold
PPE designed to protect all or part of the body against the effects of cold must possess thermal insulating capacity and mechanical strength appropriate to the foreseeable conditions of use for which it is marketed.
PPE against cold is designed according to the foreseen risks and usually consists of several protective material layers. The protection efficiency of this type of PPE depends on the insulation capacity as well as proper coverage. The size and model of the PPE needs to, be such that cold does not directly harm the user through possible openings in the PPE.
PPE of this type also needs to have adequate mechanical strength against abrasion, cuts and tearing.
3.7.1. PPE constituent materials and other components
Constituent materials and other components suitable for protection against cold must possess a coefficient of transmission of incident thermal flux as low as required under the foreseeable conditions of use. Flexible materials and other components of PPE intended for use in a low-temperature environment must retain the degree of flexibility required for the necessary gestures and postures.
PPE materials and other components which may be splashed by large amounts of cold products must also possess sufficient mechanical-impact absorbency (see 3.1).
This requirement applies to constituent materials and components and not to complete PPE. The manufacturer needs to select materials, components or a combination of them so that in the foreseeable conditions of use:
- the thermal flux transmitted through the PPE shall be as low as possible;
- the flexibility remains acceptable to insure comfort, usability and integrity of the products.
The mechanical resistance of materials of components, needs to be, where necessary, appropriate to the impact energy, nature and temperature of the splashes of cold products.
3.7.2. Complete PPE ready for use
1. The flux transmitted by PPE to the user must be sufficiently low to prevent the cold accumulated during wear at any point on the part of the body being protected, including the tips of fingers and toes in the case of hands or feet, from attaining, under any circumstances, the pain or health-impairment threshold;
2. PPE must as far as possible prevent the penetration of such liquids as rain water and must not cause injuries resulting from contact between its cold protective integument and the user.
If PPE incorporates a breathing device, this must adequately fulfil the protective function assigned to it under the foreseeable conditions of use.
The manufacturer's notes accompanying each PPE model intended for brief use in
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low-temperature environments must provide all relevant data concerning the maximum permissible user exposure to the cold transmitted by the equipment
The manufacturer must design the PPE such that in the foreseeable conditions of use:
- the loss of body heat does not cause hypothermia, pain or harmful effects, in particular

to the user's extremities (e.g. tips of fingers and toes);
- it prevents the penetration of liquids, such as rain water, likely to cause injuries(e.g. by proper coverage of body parts to be protected);
- any part of the PPE which might be cooled down to harmful temperature must not be in direct contact with the user.
PPE against cold incorporating a breathing device must be designed such that, in the foreseeable conditions of use, it will fulfil the requirements of a respiratory protective device: e.g. the temperature of breathable air flow is physiologically acceptable.
With regards to PPE for brief use in cold environments, the manufacturer must provide enough information so that the user can determine for each of his intended action, the maximum effective protection time and/or maximum acceptable use time from a physiological point of view.

3.8 Protection against electric shock

PPE designed to protect all or part of the body against the effects of electric current must be sufficiently insulated against the voltages to which the user is likely to be exposed under the most unfavourable foreseeable conditions.
To this end, the constituent materials and other components of these PPE classes must be so chosen or designed and incorporated as to ensure that the leakage current measured through the protective integument under test conditions at voltages correlated with those likely to be encountered in situ is minimized and, at all events, below a maximum conventional permissible value which correlates with the tolerance threshold.
Together with their packaging, PPE types intended exclusively for use during work or activities in electrical installations which are or may be under tension must bear markings indicating, in particular, their protection class and (or) corresponding operating voltage, their serial number and their date of manufacture; a space must also be provided outside the protective integument of such PPE for the subsequent inscription of the date of entry into service and those of the periodic tests or inspections to be periodic tests or inspections to be conducted.
The manufacturer's notes must indicate, in particular, the exclusive use for which these PPE types are intended and the nature and frequency of the dielectric tests to which they are to be subjected during their useful life.

To identify the "most unfavourable foreseeable conditions", the manufacturer will need to consider:
- the risk of direct contact to a live conductor;

- the possible harmful electrical parameters and threshold limit values;
- moistness of the skin;
- the effect, during normal use of the PPE, of contact with chemicals used such as solvents, of mechanical degradation/ageing and of climatic environmental factors
PPE marking intended for professional use to protect against electrical risks is intended to ensure their traceability and to give information on their scope of use and necessary periodic checking.
In addition to the electrical "main risk", other risks related to short-circuiting (such as thermal and mechanical risks) also need to be taken into account.
The manufacturer needs to clearly indicate the following in the instructions for use (amongst

other information necessary to ensure safe use:
• maximum voltage for the class considered;
• storage;
• controls to be carried out (visual examination and gloves inflation) and their periodicity (in any case before each intended use);
• instructions for the maintenance of PPE.
Moreover, precautions of use, in particular aimed at preserving the electrical insulation properties of the PPE or against the risks of deterioration need to be indicated e.g. use of overgloves
to reduce the risk of punctures, cuts, abrasion, chemical attacks.

3.9 Protection against radiation

3.9.1 non-ionizing radiation

PPE designed to prevent acute or chronic eye-damage from sources of non-ionizing radiation must be capable of absorbing or reflecting the majority of the energy radiated in the harmful wavelengths without unduly affecting the transmission of the innocuous part of the visible spectrum, the perception of contrasts and the ability to distinguish colours where required by the foreseeable conditions of use.

To this end, protective glasses must be so designed and manufactured as to possess, for each harmful wave, a spectral transmission factor such that the radiant-energy illumination density capable of reaching the user's eye through the filter is minimized and, under no circumstances, exceeds the maximum permissible exposure value.

Furthermore, the glasses must not deteriorate or lose their properties as a result of the effects of radiation emitted under the foreseeable conditions of use and all marketed specimens must bear the protection-factor number corresponding to the spectral distribution curve of their transmission factor.

Glasses suitable for radiation sources of the same type must be classified in the ascending order of their protection factors and the manufacturer's notes must indicate, in particular, the transmission curves which make it possible to select the most appropriate PPE bearing in mind such inherent factors of the effective conditions of use as distance to source and the spectral distribution of the energy radiated at that distance.

The relevant protection-factor number must be marked on all specimens of filtering glasses by the manufacturer.

When designing PPE for protection for eye protection against non-ionising radiations, the manufacturer will, in particular, need to consider, the following:
- the spectral and additional characteristics of the radiation sources;
- the illumination of the environment;
- the distance of the wearer from the source(s);
- the need to allow colour recognition (e.g. warning signals or t° identification of materials at elevated temperatures)
- the effect of ageing and of radiations on the efficiency of the PPE exposed e.g. to sun, UV, IR radiations or laser sources. The transmission characteristics of the PPE shall remain at the requested level during all the service time of the products;
- the updated exposure limit values.

The exposure limit values of the eye to the non ionising radiations are laid down in scientific publications and national regulations to which the manufacturer can refer. In particular in:
□ Directive 2004/40/EC of the EU Parliament and Council lays on the minimum health and safety requirements regarding the exposure of workers to the risks arising from exposure to magnetic fields (0 Hz to 300 GHz). It covers the microwaves and ultra high frequency waves (UHF) and the very high frequency rays (VHF) domains.
□ The guidelines of the International Commission on Non-Ionizing Radiation Protection (ICNIRP) who regularly publish updated limiting exposure and recommend exposure limits values. A new directive, on the minimum health and safety requirements regarding the exposure of workers to the risks arising from exposure to optical radiation is currently under preparation.
Where this requirement refers to "radiation sources of the same type" it relates, for example, to those of the same nature (e.g. infra-red radiations) or of the same type of operations (e.g. radiations produced by arc and gas welding stations and associated processes).
This obliges the manufacturer to include the transmission curves in the instructions for use. The knowledge of the transmission curve is useful for the user only when the optical filter concerned cannot be characterised by a standardised scale or shade number.
In other cases, the supply of such curves is not of great use. They do not allow for the selection of appropriate filters without a computer for calculation and or the knowledge of other additional information such as the spectral irradiance or the spectral luminance of the radiant sources and of the spectral transmission values of the filters. Subject to these caveats, the transmission curves shall be made available to users on demand. The preferred option is that the manufacturer gives the standardised scale or shade number.
The manufacturer needs to give information on the scale or shade numbers of PPE and replaceable spare parts and of the corresponding field of use by means of informative markings on the PPE and in the instructions for use. When the PPE forms a single unit with non replaceable filters (e.g. laser eye protectors), the marking(s) can be placed on the frame.
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3.9.2 Ionizing radiation

3.9.2.1 Protection against external radioactive contamination

PPE constituent materials and other components designed to protect all or part of the body against radioactive dust, gases, liquids or mixtures thereof must be so chosen or designed and incorporated as to ensure that this equipment effectively prevents the penetration of the contaminants under the foreseeable conditions of use.

Depending on the nature or condition of these contaminants, the necessary leaktightness can be provided by the impermeability of the protective integument and/or by any other appropriate means, such as ventilation and pressurization systems designed to prevent the back-scattering of these contaminants.

Any decontamination measures to which PPE is subject must not prejudice its possible re-use during the foreseeable useful life of these classes of equipment.

The instructions for use need in particular to specify the procedure of decontamination which the PPE can withstand without significant degradation of its level of protection (in the case of re-usable PPE only).

3.9.2.2 Limited protection against external irradiation

PPE intended to provide complete user protection against external irradiation or, failing this, adequate attenuation thereof, must be designed to counter only weak electron (e.g. beta) or weak photon (e.g. X, gamma) radiation.
The constituent materials and other components of these PPE classes must be so chosen or designed and incorporated as to provide the degree of user protection required by the foreseeable conditions of use without leading to an increase in exposure time as a result of the impedance of user gestures, posture or movement (see 1.3.2).
PPE must bear a mark indicating the type and thickness of the constituent material(s) suitable for the foreseeable conditions of use.
PPE in conformity with this requirement constitute the ultimate recourse in the event of deterioration of the characteristics of the enclosures ensuring collective protection. The equivalent thickness of lead is given according to this limited energy so that the intended user is not exposed beyond the lawful exposure limit values.
Lead and heavy metals are used only to attenuate X or gamma rays. In the case of beta radiation, use of this type of protection should be avoided as the heavy metal will stop the beta radiation but will also cause a breaking x-ray called "Bremsstrahlung". There is no specific protection against beta radiation other than equipment made of elastomers or polymers which help stop some of the radiation (the level of protection will depend on the material, its thickness and the energy of the radiation emitted).
The level of protection offered by a PPE is characterised by the determination of equivalent lead thickness of a lead sheet receiving the same rate of attenuation of the ionizing radiations. If the PPE comprises several components, each component and their assembly shall offer the requested level of protection whatever the posture taken by the user.
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The thickness considered here can be expressed in term of lead equivalent thickness. The aim is to supply useful information to the user on the attenuation of the ionizing radiations offered by the PPE.
The lead equivalent thickness always has to be given with the energy of the radiation at which it has been verified.
3.10 Protection against dangerous substances and infective agents
3.10.1 Respiratory protection
PPE intended for the protection of the respiratory tract must make it possible to supply the user with breathable air when the latter is exposed to a polluted atmosphere and/or an atmosphere having inadequate oxygen concentration.
The breathable air supplied to the user by the PPE must be obtained by appropriate means, for example after filtration of the polluted air through the protective device or appliance or by a piped supply from an unpolluted source.
The constituent materials and other components of these PPE classes must be so chosen or designed and incorporated as to ensure appropriate user respiration and respiratory hygiene for the period of wear concerned under the foreseeable conditions of use.
The leak-tightness of the face-piece and the pressure drop on inspiration and, in the case of the filtering devices, purification capacity must be such as to keep contaminant penetration from a polluted atmosphere low enough not to be prejudicial to the health or hygiene of the user.

The PPE must bear the manufacturer's identification mark and details of the specific characteristics of that type of equipment which, in conjunction with the instructions for use, will enable a trained and qualified user to employ the PPE correctly.

The manufacturer's notes must also in the case of filtering devices, indicate the deadline for the storage of filters as new and kept in their original packaging.

It is advisable to design the PPE so that exposure to contaminants is clearly under the necessary limit values. Air supplied needs to be a suitable temperature and humidity so that the comfort of the intended user is not affected, it does not cause harmful effects or endanger the safe operation of the device.

Minimum oxygen concentration of the inhaled air has to be sufficient taking into account the demands of the tasks of the user. The amount of re-breathed exhalation air needs to be minimised to avoid the accumulation of carbon dioxide inside the mask. For very short periods of use, such as in escape apparatus, higher carbon dioxide concentrations may be accepted.

The filtration efficiency of the contaminants is dependent on the size, distribution and nature of the aerosols or gases and vapours as well as of the characteristics of the filtering element.

Filtration efficiency changes has to be considered in the design of the device and adequate instructions given.

The breathable gas supply in compressed air or oxygen breathing apparatus is to be ensured by proper design of the mechanical and operational strength and function. The risks caused by the wrong combination of the air supply systems of the breathing apparatus have to be eliminated as far as possible by design. If not possible, adequate information on safe combinations shall be given by the manufacturer.

The respiratory protective device cannot contain or release any substances which are known to be harmful. All of the materials used should be listed in the information for the user. The release of harmful filtering material from the filter has to be eliminated.

The design, adjustments and size range or overpressure inside the face-piece has to prevent face seal leakage as far as possible. The maximum breathing rate needs to be considered in the foreseeable use situation and the device designed that the breathing resistance is not too high. The foreseeable work load can also cause face-piece leakage due to higher under-pressure inside the mask. Moreover, the effect of the increase of the breathing resistance of particle filters during normal use of filtering face piece respirators should also be carefully considered. The magnitude of the penetration between the body of the mask and the face of the user is proportional to the square root of the resistance. Therefore, the higher the resistance of the filter, the greater the face penetration. This needs to be clearly explained in instructions for use accompanying particle filters and face masks.

The manufacturer is required to mark all respiratory protective devices, their components and important spare parts so that it is clear to which device these belong to. These markings also have to be described in the instructions for use.

All filters have to be marked with relevant pictograms and information on the deadline for the storage of the filters when kept sealed in their original packaging.

The essential requirement 2.3 applies to all respiratory protective devices. This requirement foresees the use of anti fogging products or lenses when necessary. This is essential for full face masks intended for use in very polluted and foggy atmospheres where it is not possible to

remove the apparatus in order to clean it.
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3.10.2 Protection against cutaneous and ocular contact
PPE intended to prevent the surface contact of all or part of the body with dangerous substances and infective agents must be capable of preventing the penetration or diffusion of such substances through the protective integument under the foreseeable conditions of use for which the PPE is placed on the market.
To this end, the constituent materials and other components of these PPE classes must be so chosen, or designed and incorporated as to ensure, as far as possible, complete leak-tightness, which will allow where necessary prolonged daily use or, failing this, limited leaktightness necessitating a restriction of the period of wear.
Where, by virtue of their nature and the foreseeable conditions of their use, certain dangerous substances or infective agents possess high penetrative power which limits the duration of the protection provided by the PPE in question, the latter must be subjected to standard tests with a view to their classification on the basis of efficiency. PPE which is considered to be in conformity with the test specifications must bear a mark indicating, in particular, the names or, failing this, the codes of the substances used in the tests and the corresponding standard period of protection.
The manufacturer's notes must also contain, in particular, an explanation of the codes (if necessary), a detailed description of the standard tests and all appropriate information for the determination of the maximum permissible period of wear under the different foreseeable conditions of use.
The protective part of this PPE will prevent adequately direct contact of the harmful substance (chemicals, biological agents, …) with the skin or eyes.
PPE protecting against dangerous substances needs to have penetration and permeation properties suitable according to the risk and tasks for which they are designed. This will be the case at least during the use time indicated in the instruction for use. In practice all materials have limited protection over time and thus relevant information and warnings are needed in the instructions for use.
It is not possible to test the protection efficiency against all (mixtures of) substances in all ambient conditions. Therefore tests with representative chemicals will give an indication to the user. In the instructions for use these test substances are to be clearly mentioned so that the end user can select suitable PPE for his tasks. The meaning of these results (e.g. breakthrough time) need to be explained to make it clear for them user. On that basis the user will be able to evaluate the protection and protection time in his/her own working situation.
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3.11 Safety devices for diving equipment
1. Breathing equipment
The breathing equipment must make it possible to supply the user with a breathable gaseous mixture, under foreseeable conditions of use and taking account in particular of the maximum depth of immersion.

2. Where the foreseeable conditions of use so require, the equipment must comprise:
(a) a suit which protects the user against the pressure resulting from the depth of immersion
(see 3.2) and/or against cold (see 3.7);
(b)an alarm designed to give the user prompt warning of an approaching failure in the supply of breathable gaseous mixture (see 2.8);
(c)a life-saving suit enabling the user to return to the surface (see 3.4.1).

The term "diving equipment" is restricted to equipment used for the diving in a sub aqueous (i.e. water) medium.

Respiratory tracts are subjected to the effect of the pressure. Breathing apparatus must therefore be provided with a system automatically ordering the regulation of the feeding system in a breathable gas mixture.

Whether in a sub aqueous medium or pressurised dry medium, the user is always exposed to pressure. The flexible combinations used in practice cannot ensure a protection against the pressure within the meaning of requirement 3.2. This requirement, with regard to the pressure, imposes only that the combinations will not induce new risks arising from the equipment itself. The warning device forms integral part of the breathing apparatus aimed to article 3.11, first subparagraph.

The life saving suit which allows for the rapid escape of the diver should not be confused with the diving suit. This rescue equipment (called a "buoyancy compensator") is worn independently and over the diving suit which provides the diver with means for controlling buoyancy, for holding him in a head-up position at the surface even if he is unconscious and in cases of emergency for returning at the surface.

APPENDIX C: HARMONIZED PPE STANDARDS

Titles and references of harmonized standards under Directive 89/686/EEC for Personal protective equipment (PPE)[1]

ESO	Reference and title of the harmonized standard (and reference document)	First publication OJ	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard
CEN	EN 132:1998 Respiratory protective devices - Definitions of terms and pictograms	04/06/1999	EN 132:1990 Note 2.1	Date expired (30/06/1999)
CEN	EN 133:2001 Respiratory protective devices - Classification	10/08/2002	EN 133:1990 Note 2.1	Date expired (10/08/2002)
CEN	EN 134:1998 Respiratory protective devices - Nomenclature of components	13/06/1998	EN 134:1990 Note 2.1	Date expired (31/07/1998)
CEN	EN 135:1998 Respiratory protective devices - List of equivalent terms	04/06/1999	EN 135:1990 Note 2.1	Date expired (30/06/1999)
CEN	EN 136:1998 Respiratory protective devices - Full face masks - Requirements, testing, marking	13/06/1998	EN 136:1989 EN 136-10:1992 Note 2.1	Date expired (31/07/1998)
	EN 136:1998/AC:2003			
CEN	EN 137:2006 Respiratory protective devices - Self-contained open-circuit compressed air breathing apparatus with full face mask - Requirements, testing, marking	23/11/2007	EN 137:1993 Note 2.1	Date expired (23/11/2007)
CEN	EN 138:1994 Respiratory protective devices - Fresh air hose breathing apparatus for use with full face mask, half mask or mouthpiece assembly - Requirements, testing, marking	16/12/1994		
CEN	EN 140:1998 Respiratory protective devices - Half masks and quarter masks - Requirements, testing, marking	06/11/1998	EN 140:1989 Note 2.1	Date expired (31/03/1999)
	EN 140:1998/AC:1999			
CEN	EN 142:2002 Respiratory protective devices -	10/04/2003	EN 142:1989	Date expired (10/04/2003)

[1] Source: http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/personal-protective-equipment/index_en.htm

	Mouthpiece assemblies - Requirements, testing, marking		Note 2.1	
CEN	EN 143:2000 Respiratory protective devices - Particle filters - Requirements, testing, marking	24/01/2001	EN 143:1990 Note 2.1	Date expired (24/01/2001)
	EN 143:2000/A1:2006	21/12/2006	Note 3	Date expired (21/12/2006)
	EN 143:2000/AC:2005			
CEN	EN 144-1:2000 Respiratory protective devices - Gas cylinder valves - Part 1: Thread connections for insert connector	24/01/2001	EN 144-1:1991 Note 2.1	Date expired (24/01/2001)
	EN 144-1:2000/A1:2003	21/02/2004	Note 3	Date expired (21/02/2004)
	EN 144-1:2000/A2:2005	06/10/2005	Note 3	Date expired (31/12/2005)
CEN	EN 144-2:1998 Respiratory protective devices - Gas cylinder valves - Part 2: Outlet connections	04/06/1999		
CEN	EN 144-3:2003 Respiratory protective devices - Gas cylinder valves - Part 3: Outlet connections for diving gases Nitrox and oxygen	21/02/2004		
	EN 144-3:2003/AC:2003			
CEN	EN 145:1997 Respiratory protective devices - Self-contained closed-circuit breathing apparatus compressed oxygen or compressed oxygen-nitrogen type - Requirements, testing, marking	19/02/1998	EN 145:1988 EN 145-2:1992 Note 2.1	Date expired (28/02/1998)
	EN 145:1997/A1:2000	24/01/2001	Note 3	Date expired (24/01/2001)
CEN	EN 148-1:1999 Respiratory protective devices - Threads for facepieces - Part 1: Standard thread connection	04/06/1999	EN 148-1:1987 Note 2.1	Date expired (31/08/1999)
CEN	EN 148-2:1999 Respiratory protective devices - Threads for facepieces - Part 2: Centre thread connection	04/06/1999	EN 148-2:1987 Note 2.1	Date expired (31/08/1999)
CEN	EN 148-3:1999	04/06/1999	EN 148-3:1992	Date expired

	Respiratory protective devices - Threads for facepieces - Part 3: Tread connection M 45 x 3		Note 2.1	(31/08/1999)
CEN	EN 149:2001+A1:2009 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking	06/05/2010	EN 149:2001 Note 2.1	Date expired (06/05/2010)
CEN	EN 166:2001 Personal eye-protection - Specifications	10/08/2002	EN 166:1995 Note 2.1	Date expired (10/08/2002)
CEN	EN 167:2001 Personal eye-protection - Optical test methods	10/08/2002	EN 167:1995 Note 2.1	Date expired (10/08/2002)
CEN	EN 168:2001 Personal eye-protection - Non-optical test methods	10/08/2002	EN 168:1995 Note 2.1	Date expired (10/08/2002)
CEN	EN 169:2002 Personal eye-protection - Filters for welding and related techniques - Transmittance requirements and recommended use	28/08/2003	EN 169:1992 Note 2.1	Date expired (28/08/2003)
CEN	EN 170:2002 Personal eye-protection - Ultraviolet filters - Transmittance requirements and recommended use	28/08/2003	EN 170:1992 Note 2.1	Date expired (28/08/2003)
CEN	EN 171:2002 Personal eye-protection - Infrared filters - Transmittance requirements and recommended use	10/04/2003	EN 171:1992 Note 2.1	Date expired (10/04/2003)
CEN	EN 172:1994 Personal eye protection - Sunglare filters for industrial use	15/05/1996		
	EN 172:1994/A1:2000	04/07/2000	Note 3	Date expired (31/10/2000)
	EN 172:1994/A2:2001	10/08/2002	Note 3	Date expired (10/08/2002)
CEN	EN 174:2001 Personal eye-protection - Ski goggles for downhill skiing	21/12/2001	EN 174:1996 Note 2.1	Date expired (21/12/2001)
CEN	EN 175:1997 Personal protection - Equipment for eye and face protection during welding and allied processes	19/02/1998		
CEN	EN 207:2009	06/05/2010	EN 207:1998	Date expired

	Personal eye-protection equipment - Filters and eye-protectors against laser radiation (laser eye-protectors)		Note 2.1	(30/06/2010)
	EN 207:2009/AC:2011			
CEN	EN 208:2009 Personal eye-protection - Eye-protectors for adjustment work on lasers and laser systems (laser adjustment eye-protectors)	06/05/2010	EN 208:1998 Note 2.1	Date expired (30/06/2010)
CEN	EN 250:2000 Respiratory equipment - Open-circuit self-contained compressed air diving apparatus - Requirements, testing, marking	08/06/2000	EN 250:1993 Note 2.1	Date expired (19/07/2000)
	EN 250:2000/A1:2006	21/12/2006	Note 3	Date expired (21/12/2006)
CEN	EN 269:1994 Respiratory protective devices - Powered fresh air hose breathing apparatus incorporating a hood - Requirements, testing, marking	16/12/1994		
CEN	EN 340:2003 Protective clothing - General requirements	06/10/2005	EN 340:1993 Note 2.1	Date expired (06/10/2005)
CEN	EN 342:2004 Protective clothing - Ensembles and garments for protection against cold	06/10/2005		
	EN 342:2004/AC:2008			
CEN	EN 343:2003+A1:2007 Protective clothing - Protection against rain	08/03/2008	EN 343:2003 Note 2.1	Date expired (08/03/2008)
	EN 343:2003+A1:2007/AC:2009			
CEN	EN 348:1992 Protective clothing - Test method: Determination of behaviour of materials on impact of small splashes of molten metal	23/12/1993		
	EN 348:1992/AC:1993			
CEN	EN 352-1:2002 Hearing protectors - General requirements - Part 1: Ear-Muffs	28/08/2003	EN 352-1:1993 Note 2.1	Date expired (28/08/2003)
CEN	EN 352-2:2002 Hearing protectors - General requirements - Part 2: Ear-plugs	28/08/2003	EN 352-2:1993 Note 2.1	Date expired (28/08/2003)

CEN	EN 352-3:2002 Hearing protectors - General requirements - Part 3: Ear-muffs attached to an industrial safety helmet	28/08/2003	EN 352-3:1996 Note 2.1	Date expired (28/08/2003)
CEN	EN 352-4:2001 Hearing protectors - Safety requirements and testing - Part 4: Level-dependent ear-muffs	10/08/2002		
	EN 352-4:2001/A1:2005	19/04/2006	Note 3	Date expired (30/04/2006)
CEN	EN 352-5:2002 Hearing protectors - Safety requirements and testing - Part 5: Active noise reduction ear-muffs	28/08/2003		
	EN 352-5:2002/A1:2005	06/05/2010	Note 3	Date expired (06/05/2010)
CEN	EN 352-6:2002 Hearing protectors - Safety requirements and testing - Part 6: Ear-muffs with electrical audio input	28/08/2003		
CEN	EN 352-7:2002 Hearing protectors - Safety requirements and testing - Part 7: Level-dependent ear-plugs	28/08/2003		
CEN	EN 352-8:2008 Hearing protectors - Safety requirements and testing - Part 8: Entertainment audio ear-muffs	28/01/2009		
CEN	EN 353-2:2002 Personal protective equipment against falls from a height - Part 2: Guided type fall arresters including a flexible anchor line	28/08/2003	EN 353-2:1992 Note 2.1	Date expired (28/08/2003)
CEN	EN 354:2010 Personal fall protection equipment - Lanyards	09/07/2011	EN 354:2002 Note 2.1	Date expired (09/07/2011)
CEN	EN 355:2002 Personal protective equipment against falls from a height - Energy absorbers	28/08/2003	EN 355:1992 Note 2.1	Date expired (28/08/2003)
CEN	EN 358:1999 Personal protective equipment for work positioning and prevention of falls from a height - Belts for work positioning and restraint and work positioning lanyards	21/12/2001	EN 358:1992 Note 2.1	Date expired (21/12/2001)
CEN	EN 360:2002	28/08/2003	EN 360:1992	Date expired

	Personal protective equipment against falls from a height - Retractable type fall arresters		Note 2.1	(28/08/2003)
CEN	EN 361:2002 Personal protective equipment against falls from a height - Full body harnesses	28/08/2003	EN 361:1992 Note 2.1	Date expired (28/08/2003)
CEN	EN 362:2004 Personal protective equipment against falls from a height - Connectors	06/10/2005	EN 362:1992 Note 2.1	Date expired (06/10/2005)
CEN	EN 363:2008 Personal fall protection equipment - Personal fall protection systems	20/06/2008	EN 363:2002 Note 2.1	Date expired (31/08/2008)
CEN	EN 364:1992 Personal protective equipment against falls from a height - Test methods	23/12/1993		
	EN 364:1992/AC:1993			
CEN	EN 365:2004 Personal protective equipment against falls from a height - General requirements for instructions for use, maintenance, periodic examination, repair, marking and packaging	06/10/2005	EN 365:1992 Note 2.1	Date expired (06/10/2005)
	EN 365:2004/AC:2006			
CEN	EN 367:1992 Protective clothing - Protection against heat and fire - Method of determining heat transmission on exposure to flame	23/12/1993		
	EN 367:1992/AC:1992			
CEN	EN 374-1:2003 Protective gloves against chemicals and micro-organisms - Part 1: Terminology and performance requirements	06/10/2005	EN 374-1:1994 Note 2.1	Date expired (06/10/2005)
CEN	EN 374-2:2003 Protective gloves against chemicals and micro-organisms - Part 2: Determination of resistance to penetration	06/10/2005	EN 374-2:1994 Note 2.1	Date expired (06/10/2005)
CEN	EN 374-3:2003 Protective gloves against chemicals and micro-organisms - Part 3: Determination of resistance to permeation by chemicals	06/10/2005	EN 374-3:1994 Note 2.1	Date expired (06/10/2005)
	EN 374-3:2003/AC:2006			
CEN	EN 379:2003+A1:2009	06/05/2010	EN 379:2003	Date expired

	Personal eye-protection - Automatic welding filters		Note 2.1	(06/05/2010)
CEN	EN 381-1:1993 Protective clothing for users of hand-held chainsaws - Part 1: Test rig for testing resistance to cutting by a chainsaw	23/12/1993		
CEN	EN 381-2:1995 Protective clothing for users of hand-held chain saws - Part 2: Test methods for leg protectors	12/01/1996		
CEN	EN 381-3:1996 Protective clothing for users of hand-held chain-saws - Part 3: Test methods for footwear	10/10/1996		
CEN	EN 381-4:1999 Protective clothing for users of hand-held chainsaws - Part 4: Test methods for chainsaw protective gloves	16/03/2000		
CEN	EN 381-5:1995 Protective clothing for users of hand-held chain saws - Part 5: Requirements for leg protectors	12/01/1996		
CEN	EN 381-7:1999 Protective clothing for users of hand-held chainsaws - Part 7: Requirements for chainsaw protective gloves	16/03/2000		
CEN	EN 381-8:1997 Protective clothing for users of hand-held chain saws - Part 8: Test methods for chain saw protective gaiters	18/10/1997		
CEN	EN 381-9:1997 Protective clothing for users of hand-held chain saws - Part 9: Requirements for chain saw protective gaiters	18/10/1997		
CEN	EN 381-10:2002 Protective clothing for users of hand-held chainsaws - Part 10: Test method for upper body protectors	28/08/2003		
CEN	EN 381-11:2002 Protective clothing for users of hand-held chainsaws - Part 11: Requirements for upper body protectors	28/08/2003		
CEN	EN 388:2003 Protective gloves against mechanical risks	06/10/2005	EN 388:1994 Note 2.1	Date expired (06/10/2005)
CEN	EN 397:2012+A1:2012	20/12/2012	EN 397:2012	30/04/2013

	Industrial safety helmets		Note 2.1	
CEN	EN 402:2003 Respiratory protective devices - Lung governed demand self-contained open-circuit compressed air breathing apparatus with full face mask or mouthpiece assembly for escape - Requirements, testing, marking	21/02/2004	EN 402:1993 Note 2.1	Date expired (21/02/2004)
CEN	EN 403:2004 Respiratory protective devices for self-rescue - Filtering devices with hood for escape from fire - Requirements, testing, marking	06/10/2005	EN 403:1993 Note 2.1	Date expired (06/10/2005)
CEN	EN 404:2005 Respiratory protective devices for self-rescue - Filter self-rescuer from carbon monoxide with mouthpiece assembly	06/10/2005	EN 404:1993 Note 2.1	Date expired (02/12/2005)
CEN	EN 405:2001+A1:2009 Respiratory protective devices - Valved filtering half masks to protect against gases or gases and particles - Requirements, testing, marking	06/05/2010	EN 405:2001 Note 2.1	Date expired (06/05/2010)
CEN	EN 407:2004 Protective gloves against thermal risks (heat and/or fire)	06/10/2005	EN 407:1994 Note 2.1	Date expired (06/10/2005)
CEN	EN 420:2003+A1:2009 Protective gloves - General requirements and test methods	06/05/2010	EN 420:2003 Note 2.1	Date expired (31/05/2010)
CEN	EN 421:2010 Protective gloves against ionizing radiation and radioactive contamination	09/07/2011	EN 421:1994 Note 2.1	Date expired (09/07/2011)
CEN	EN 443:2008 Helmets for fire fighting in buildings and other structures	20/06/2008	EN 443:1997 Note 2.1	Date expired (31/08/2008)
CEN	EN 458:2004 Hearing protectors - Recommendations for selection, use, care and maintenance - Guidance document	06/10/2005	EN 458:1993 Note 2.1	Date expired (06/10/2005)
CEN	EN 464:1994 Protective clothing - Protection against liquid and gaseous chemicals, including aerosols and solid particles - Test method: Determination of leak-tightness of gas-tight suits (Internal pressure test)	16/12/1994		
CEN	EN 469:2005 Protective clothing for firefighters -	19/04/2006	EN 469:1995	Date expired (30/06/2006)

	Performance requirements for protective clothing for firefighting		Note 2.1	
	EN 469:2005/A1:2006	23/11/2007	Note 3	Date expired (23/11/2007)
	EN 469:2005/AC:2006			
CEN	EN 471:2003+A1:2007 High-visibility warning clothing for professional use - Test methods and requirements	08/03/2008	EN 471:2003 Note 2.1	Date expired (30/06/2008)
CEN	EN 510:1993 Specification for protective clothing for use where there is a risk of entanglement with moving parts	16/12/1994		
CEN	EN 511:2006 Protective gloves against cold	21/12/2006	EN 511:1994 Note 2.1	Date expired (21/12/2006)
CEN	EN 530:2010 Abrasion resistance of protective clothing material - Test methods	09/07/2011	EN 530:1994 Note 2.1	Date expired (09/07/2011)
CEN	EN 564:2006 Mountaineering equipment - Accessory cord - Safety requirements and test methods	08/03/2008	EN 564:1997 Note 2.1	Date expired (08/03/2008)
CEN	EN 565:2006 Mountaineering equipment - Tape - Safety requirements and test methods	08/03/2008	EN 565:1997 Note 2.1	Date expired (08/03/2008)
CEN	EN 566:2006 Mountaineering equipment - Slings - Safety requirements and test methods	08/03/2008	EN 566:1997 Note 2.1	Date expired (08/03/2008)
CEN	EN 567:1997 Mountaineering equipment - Rope clamps - Safety requirements and test methods	10/08/2002		
CEN	EN 568:2007 Mountaineering equipment - Ice anchors - Safety requirements and test methods	08/03/2008	EN 568:1997 Note 2.1	Date expired (08/03/2008)
CEN	EN 569:2007 Mountaineering equipment - Pitons - Safety requirements and test methods	08/03/2008	EN 569:1997 Note 2.1	Date expired (08/03/2008)
CEN	EN 659:2003+A1:2008 Protective gloves for firefighters	20/06/2008	EN 659:2003 Note 2.1	Date expired (30/09/2008)
	EN 659:2003+A1:2008/AC:2009			

CEN	EN 702:1994 Protective clothing - Protection against heat and flame - Test method: Determination of the contact heat transmission through protective clothing or its materials	12/01/1996		
CEN	EN 795:1996 Protection against falls from a height - Anchor devices - Requirements and testing	12/02/2000		
	EN 795:1996/A1:2000	24/01/2001	Note 3	Date expired (30/04/2001)
Warning: This publication does not concern the equipment described in classes A (structural anchors), C (anchor devices employing horizontal flexible lines) and D (anchor devices employing horizontal rigid anchor rails) referred to in paragraphs 3.13.1, 3.13.3, 3.13.4, 4.3.1, 4.3.3, 4.3.4, 5.2.1, 5.2.2, 5.2.4, 5.2.5, 5.3.2 (in respect of class A1), 5.3.3, 5.3.4, 5.3.5, 6 (in respect of classes A, C and D), Annex A (paragraphs A.2, A.3, A.5 and A.6), Annex B, and Annex ZA (in respect of classes A, C and D), in respect of which there shall be no presumption of conformity with the provisions of Directive 89/686/EEC.				
CEN	EN 812:2012 Industrial bump caps	20/12/2012	EN 812:1997 Note 2.1	30/04/2013
CEN	EN 813:2008 Personal fall protection equipment - Sit harnesses	28/01/2009	EN 813:1997 Note 2.1	Date expired (28/02/2009)
CEN	EN 863:1995 Protective clothing - Mechanical properties - Test method: Puncture resistance	15/05/1996		
CEN	EN 892:2012 Mountaineering equipment - Dynamic mountaineering ropes - Safety requirements and test methods	20/12/2012	EN 892:2004 Note 2.1	30/04/2013
CEN	EN 893:2010 Mountaineering equipment - Crampons - Safety requirements and test methods	09/07/2011	EN 893:1999 Note 2.1	Date expired (09/07/2011)
CEN	EN 943-1:2002 Protective clothing against liquid and gaseous chemicals, including liquid aerosols and solid particles - Part 1: Performance requirements for ventilated and non-ventilated "gas-tight" (Type 1) and "non-gas-tight" (Type 2) chemical protective suits	28/08/2003		
	EN 943-1:2002/AC:2005			
CEN	EN 943-2:2002 Protective clothing against liquid and gaseous chemicals, including liquid	10/08/2002		

	aerosols and solid particles - Part 2: Performance requirements for "gas-tight" (Type 1) chemical protective suits for emergency teams (ET)			
CEN	EN 958:2006+A1:2010 Mountaineering equipment - Energy absorbing systems for use in klettersteig (via ferrata) climbing - Safety requirements and test methods	09/07/2011	EN 958:2006 Note 2.1	Date expired (09/07/2011)
CEN	EN 960:2006 Headforms for use in the testing of protective helmets	21/12/2006	EN 960:1994 Note 2.1	Date expired (31/12/2006)
CEN	EN 966:2012+A1:2012 Helmets for airborne sports	20/12/2012	EN 966:2012 Note 2.1	30/04/2013
CEN	EN 1073-1:1998 Protective clothing against radioactive contamination - Part 1: Requirements and test methods for ventilated protective clothing against particulate radioactivate contamination	06/11/1998		
CEN	EN 1073-2:2002 Protective clothing against radioactive contamination - Part 2: Requirements and test methods for non-ventilated protective clothing against particulate radioactive contamination	28/08/2003		
CEN	EN 1077:2007 Helmets for alpine skiers and snowboarders	08/03/2008	EN 1077:1996 Note 2.1	Date expired (08/03/2008)
CEN	EN 1078:2012+A1:2012 Helmets for pedal cyclists and for users of skateboards and roller skates	20/12/2012	EN 1078:2012 Note 2.1	30/04/2013
CEN	EN 1080:1997 Impact protection helmets for young children	14/06/1997		
	EN 1080:1997/A1:2002	28/08/2003	Note 3	Date expired (28/08/2003)
	EN 1080:1997/A2:2005	19/04/2006	Note 3	Date expired (30/06/2006)
CEN	EN 1082-1:1996 Protective clothing - Gloves and arm guards protecting against cuts and stabs by hand knives - Part 1: Chain mail gloves and arm guards	14/06/1997		

CEN	EN 1082-2:2000 Protective clothing - Gloves and arm guards protecting against cuts and stabs by hand knives - Part 2: Gloves and arm guards made of material other than chain mail	21/12/2001		
CEN	EN 1082-3:2000 Protective clothing - Gloves and arm guards protecting against cuts and stabs by hand knives - Part 3: Impact cut test for fabric, leather and other materials	21/12/2001		
CEN	EN 1146:2005 Respiratory protective devices - Self-contained open-circuit compressed air breathing apparatus incorporating a hood for escape - Requirements, testing, marking	19/04/2006	EN 1146:1997 Note 2.1	Date expired (30/04/2006)
CEN	EN 1149-1:2006 Protective clothing - Electrostatic properties - Part 1: Test method for measurement of surface resistivity	21/12/2006	EN 1149-1:1995 Note 2.1	Date expired (31/12/2006)
CEN	EN 1149-2:1997 Protective clothing - Electrostatic properties - Part 2: Test method for measurement of the electrical resistance through a material (vertical resistance)	19/02/1998		
CEN	EN 1149-3:2004 Protective clothing - Electrostatic properties - Part 3: Test methods for measurement of charge decay	06/10/2005		
CEN	EN 1149-5:2008 Protective clothing - Electrostatic properties - Part 5: Material performance and design requirements	20/06/2008		
CEN	EN 1150:1999 Protective clothing - Visibility clothing for non-professional use - Test methods and requirements	04/06/1999		
CEN	EN 1384:2012 Helmets for equestrian activities	20/12/2012	EN 1384:1996 Note 2.1	30/04/2013
CEN	EN 1385:2012 Helmets for canoeing and white water sports	20/12/2012	EN 1385:1997 Note 2.1	30/04/2013
CEN	EN 1486:2007 Protective clothing for fire-fighters - Test	08/03/2008	EN 1486:1996	Date expired (30/04/2008)

	methods and requirements for reflective clothing for specialised fire-fighting		Note 2.1	
CEN	EN 1497:2007 Personal fall protection equipment - Rescue harnesses	08/03/2008		
CEN	EN 1621-1:2012 **(new)** Motorcyclists' protective clothing against mechanical impact - Part 1: Motorcyclists' limb joint impact protectors - Requirements and test methods	This is the first publication	EN 1621-1:1997 Note 2.1	30/06/2013
CEN	EN 1621-2:2003 Motorcyclists' protective clothing against mechanical impact - Part 2: Motorcyclists' back protectors - Requirements and test methods	06/10/2005		
	EN 1621-2:2003/AC:2006			
CEN	EN 1731:2006 Personal eye protection - Mesh eye and face protectors	23/11/2007	EN 1731:1997 Note 2.1	Date expired (23/11/2007)
CEN	EN 1809:1997 Diving accessories - Buoyancy compensators - Functional and safety requirements, test methods	13/06/1998		
CEN	EN 1827:1999+A1:2009 Respiratory protective devices - Half masks without inhalation valves and with separable filters to protect against gases or gases and particles or particles only - Requirements, testing, marking	06/05/2010	EN 1827:1999 Note 2.1	Date expired (06/05/2010)
CEN	EN 1836:2005+A1:2007 Personal eye-equipment - Sunglasses and sunglare filters for general use and filters for direct observation of the sun	08/03/2008	EN 1836:2005 Note 2.1	Date expired (31/03/2008)
CEN	EN 1868:1997 Personal protective equipment against falls from a height - List of equivalent terms	18/10/1997		
CEN	EN 1891:1998 Personal protective equipment for the prevention of falls from a height - Low stretch kernmantel ropes	06/11/1998		
CEN	EN 1938:2010 Personal eye protection - Goggles for motorcycle and moped users	09/07/2011	EN 1938:1998 Note 2.1	Date expired (09/07/2011)
CEN	EN ISO 4869-2:1995	15/05/1996		

	Acoustics - Hearing protectors - Part 2: Estimation of effective A-weighted sound pressure levels when hearing protectors are worn (ISO 4869-2:1994)			
	EN ISO 4869-2:1995/AC:2007			
CEN	EN ISO 4869-3:2007 Acoustics - Hearing protectors - Part 3: Measurement of insertion loss of ear-muff type protectors using an acoustic test fixture (ISO 4869-3:2007)	08/03/2008	EN 24869-3:1993 Note 2.1	Date expired (08/03/2008)
CEN	EN ISO 6529:2001 Protective clothing - Protection against chemicals - Determination of resistance of protective clothing materials to permeation by liquids and gases (ISO 6529:2001)	06/10/2005	EN 369:1993 Note 2.1	Date expired (06/10/2005)
CEN	EN ISO 6530:2005 Protective clothing - Protection against liquid chemicals - Test method for resistance of materials to penetration by liquids (ISO 6530:2005)	06/10/2005	EN 368:1992 Note 2.1	Date expired (06/10/2005)
CEN	EN ISO 6942:2002 Protective clothing - Protection against heat and fire - Method of test: Evaluation of materials and material assemblies when exposed to a source of radiant heat (ISO 6942:2002)	28/08/2003	EN 366:1993 Note 2.1	Date expired (28/08/2003)
CEN	EN ISO 9185:2007 Protective clothing - Assessment of resistance of materials to molten metal splash (ISO 9185:2007)	08/03/2008	EN 373:1993 Note 2.1	Date expired (08/03/2008)
CEN	EN ISO 10256:2003 Head and face protection for use in ice hockey (ISO 10256:2003)	06/10/2005	EN 967:1996 Note 2.1	Date expired (06/10/2005)
CEN	EN ISO 10819:1996 Mechanical vibration and shock - Hand-arm vibration - Method for the measurement and evaluation of the vibration transmissibility of gloves at the palm of the hand (ISO 10819:1996)	03/12/1996		
CEN	EN ISO 10862:2009 Small craft - Quick release system for trapeze harness (ISO 10862:2009)	06/05/2010		
CEN	EN ISO 11611:2007 Protective clothing for use in welding and allied processes (ISO 11611:2007)	08/03/2008	EN 470-1:1995 Note 2.1	Date expired (30/04/2008)
CEN	EN ISO 11612:2008	05/06/2009	EN 531:1995	Date expired

	Protective clothing - Clothing to protect against heat and flame (ISO 11612:2008)		Note 2.1	(05/06/2009)
CEN	EN 12083:1998 Respiratory protective devices - Filters with breathing hoses, (Non-mask mounted filters) - Particle filters, gas filters, and combined filters - Requirements, testing, marking	04/07/2000		
	EN 12083:1998/AC:2000			
CEN	EN ISO 12127-2:2007 Clothing for protection against heat and flame - Determination of contact heat transmission through protective clothing or constituent materials - Part 2: Test method using contact heat produced by dropping small cylinders (ISO 12127-2:2007)	08/03/2008		
CEN	EN 12270:1998 Mountaineering equipment - Chocks - Safety requirements and test methods	16/03/2000		
CEN	EN 12275:1998 Mountaineering equipment - Connectors - Safety requirements and test methods	16/03/2000		
CEN	EN 12276:1998 Mountaineering equipment - Frictional anchors - Safety requirements and test methods	24/02/2001		
	EN 12276:1998/AC:2000			
CEN	EN 12277:2007 Mountaineering equipment - Harnesses - Safety requirements and test methods	23/11/2007	EN 12277:1998 Note 2.1	Date expired (23/11/2007)
CEN	EN 12278:2007 Montaineering equipment - Pulleys - Safety requirements and test methods	23/11/2007	EN 12278:1998 Note 2.1	Date expired (30/11/2007)
CEN	EN ISO 12401:2009 Small craft - Deck safety harness and safety line - Safety requirements and test methods (ISO 12401:2009)	06/05/2010	EN 1095:1998 Note 2.1	Date expired (06/05/2010)
CEN	EN ISO 12402-2:2006 Personal flotation devices - Part 2: Lifejackets, performance level 275 - Safety requirements (ISO 12402-2:2006)	21/12/2006	EN 399:1993 Note 2.1	Date expired (31/03/2007)
	EN ISO 12402-2:2006/A1:2010	09/07/2011	Note 3	Date expired (09/07/2011)

CEN	EN ISO 12402-3:2006 Personal flotation devices - Part 3: Lifejackets, performance level 150 - Safety requirements (ISO 12402-3:2006)	21/12/2006	EN 396:1993 Note 2.1	Date expired (31/03/2007)
	EN ISO 12402-3:2006/A1:2010	09/07/2011	Note 3	Date expired (09/07/2011)
CEN	EN ISO 12402-4:2006 Personal flotation devices - Part 4: Lifejackets, performance level 100 - Safety requirements (ISO 12402-4:2006)	21/12/2006	EN 395:1993 Note 2.1	Date expired (31/03/2007)
	EN ISO 12402-4:2006/A1:2010	09/07/2011	Note 3	Date expired (09/07/2011)
CEN	EN ISO 12402-5:2006 Personal flotation devices - Part 5: Buoyancy aids (level 50) - Safety requirements (ISO 12402-5:2006)	21/12/2006	EN 393:1993 Note 2.1	Date expired (31/03/2007)
	EN ISO 12402-5:2006/A1:2010	09/07/2011	Note 3	Date expired (09/07/2011)
	EN ISO 12402-5:2006/AC:2006			
CEN	EN ISO 12402-6:2006 Personal flotation devices - Part 6: Special purpose lifejackets and buoyancy aids - Safety requirements and additional test methods (ISO 12402-6:2006)	21/12/2006		
	EN ISO 12402-6:2006/A1:2010	09/07/2011	Note 3	Date expired (09/07/2011)
CEN	EN ISO 12402-8:2006 Personal flotation devices - Part 8: Accessories - Safety requirements and test methods (ISO 12402-8:2006)	02/08/2006	EN 394:1993 Note 2.1	Date expired (31/08/2006)
	EN ISO 12402-8:2006/A1:2011	11/11/2011	Note 3	Date expired (11/11/2011)
CEN	EN ISO 12402-9:2006 Personal flotation devices - Part 9: Test methods (ISO 12402-9:2006)	21/12/2006		
	EN ISO 12402-9:2006/A1:2011	11/11/2011	Note 3	Date expired (11/11/2011)
CEN	EN ISO 12402-10:2006 Personal flotation devices - Part 10: Selection and application of personal flotation devices and other relevant	02/08/2006		

	devices (ISO 12402-10:2006)			
CEN	EN 12477:2001 Protective gloves for welders	10/08/2002		
	EN 12477:2001/A1:2005	06/10/2005	Note 3	Date expired (31/12/2005)
CEN	EN 12492:2012 Mountaineering equipment - Helmets for mountaineers - Safety requirements and test methods	20/12/2012	EN 12492:2000 Note 2.1	30/04/2013
CEN	EN 12628:1999 Diving accessories - Combined buoyancy and rescue devices - Functional and safety requirements, test methods	04/07/2000		
	EN 12628:1999/AC:2000			
CEN	EN 12841:2006 Personal fall protection equipment - Rope access systems - Rope adjustment devices	21/12/2006		
CEN	EN 12941:1998 Respiratory protective devices - Powered filtering devices incorporating a helmet or a hood - Requirements, testing, marking	04/06/1999	EN 146:1991 Note 2.1	Date expired (04/06/1999)
	EN 12941:1998/A1:2003	06/10/2005	Note 3	Date expired (06/10/2005)
	EN 12941:1998/A2:2008	05/06/2009	Note 3	Date expired (05/06/2009)
CEN	EN 12942:1998 Respiratory protective devices - Power assisted filtering devices incorporating full face masks, half masks or quarter masks - Requirements, testing, marking	04/06/1999	EN 147:1991 Note 2.1	Date expired (04/06/1999)
	EN 12942:1998/A1:2002	28/08/2003	Note 3	Date expired (28/08/2003)
	EN 12942:1998/A2:2008	05/06/2009	Note 3	Date expired (05/06/2009)
CEN	EN 13034:2005+A1:2009 Protective clothing against liquid chemicals - Performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (Type 6 and Type PB [6] equipment)	06/05/2010	EN 13034:2005 Note 2.1	Date expired (06/05/2010)

CEN	EN 13061:2009 Protective clothing - Shin guards for association football players - Requirements and test methods	06/05/2010	EN 13061:2001 Note 2.1	Date expired (06/05/2010)
CEN	EN 13087-1:2000 Protective helmets - Test methods - Part 1: Conditions and conditioning	10/08/2002		
	EN 13087-1:2000/A1:2001	10/08/2002	Note 3	Date expired (10/08/2002)
CEN	EN 13087-2:2012 Protective helmets - Test methods - Part 2: Shock absorption	20/12/2012	EN 13087-2:2000 Note 2.1	30/04/2013
CEN	EN 13087-3:2000 Protective helmets - Test methods - Part 3: Resistance to penetration	10/08/2002		
	EN 13087-3:2000/A1:2001	10/08/2002	Note 3	Date expired (10/08/2002)
CEN	EN 13087-4:2012 Protective helmets - Test methods - Part 4: Retention system effectiveness	20/12/2012	EN 13087-4:2000 Note 2.1	30/04/2013
CEN	EN 13087-5:2012 Protective helmets - Test methods - Part 5: Retention system strength	20/12/2012	EN 13087-5:2000 Note 2.1	30/04/2013
CEN	EN 13087-6:2012 Protective helmets - Test methods - Part 6: Field of vision	20/12/2012	EN 13087-6:2000 Note 2.1	30/04/2013
CEN	EN 13087-7:2000 Protective helmets - Test methods - Part 7: Flame resistance	10/08/2002		
	EN 13087-7:2000/A1:2001	10/08/2002	Note 3	Date expired (10/08/2002)
CEN	EN 13087-8:2000 Protective helmets - Test methods - Part 8: Electrical properties	21/12/2001		
	EN 13087-8:2000/A1:2005	06/10/2005	Note 3	Date expired (06/10/2005)
CEN	EN 13087-10:2012 Protective helmets - Test methods - Part 10: Resistance to radiant heat	20/12/2012	EN 13087-10:2000 Note 2.1	30/04/2013

CEN	EN 13089:2011 Mountaineering equipment - Ice-tools - Safety requirements and test methods	09/07/2011		
CEN	EN 13138-1:2008 Buoyant aids for swimming instruction - Part 1: Safety requirements and test methods for buoyant aids to be worn	05/06/2009	EN 13138-1:2003 Note 2.1	Date expired (05/06/2009)
CEN	EN 13158:2009 Protective clothing - Protective jackets, body and shoulder protectors for equestrian use: For horse riders and those working with horses, and for horse drivers - Requirements and test methods	06/05/2010	EN 13158:2000 Note 2.1	Date expired (06/05/2010)
CEN	EN 13178:2000 Personal eye-protection - Eye protectors for snowmobile users	21/12/2001		
CEN	EN 13274-1:2001 Respiratory protective devices - Methods of test - Part 1: Determination of inward leakage and total inward leakage	21/12/2001		
CEN	EN 13274-2:2001 Respiratory protective devices - Methods of test - Part 2: Practical performance tests	21/12/2001		
CEN	EN 13274-3:2001 Respiratory protective devices - Methods of test - Part 3: Determination of breathing resistance	10/08/2002		
CEN	EN 13274-4:2001 Respiratory protective devices - Methods of test - Part 4: Flame tests	10/08/2002		
CEN	EN 13274-5:2001 Respiratory protective devices - Methods of test - Part 5: Climatic conditions	21/12/2001		
CEN	EN 13274-6:2001 Respiratory protective devices - Methods of test - Part 6: Determination of carbon dioxide content of the inhalation air	10/08/2002		
CEN	EN 13274-7:2008 Respiratory protective devices - Methods of test - Part 7: Determination of particle filter penetration	20/06/2008	EN 13274-7:2002 Note 2.1	Date expired (31/07/2008)
CEN	EN 13274-8:2002 Respiratory protective devices - Methods of test - Part 8: Determination of dolomite dust clogging	28/08/2003		

CEN	EN 13277-1:2000 Protective equipment for martial arts - Part 1: General requirements and test methods	24/02/2001		
CEN	EN 13277-2:2000 Protective equipment for martial arts - Part 2: Additional requirements and test methods for instep protectors, shin protectors and forearm protectors	24/02/2001		
CEN	EN 13277-3:2000 Protective equipment for martial arts - Part 3: Additional requirements and test methods for trunk protectors	24/02/2001		
	EN 13277-3:2000/A1:2007	23/11/2007	Note 3	Date expired (31/12/2007)
CEN	EN 13277-4:2001 Protective equipment for martial arts - Part 4: Additional requirements and test methods for head protectors	10/08/2002		
	EN 13277-4:2001/A1:2007	23/11/2007	Note 3	Date expired (31/12/2007)
CEN	EN 13277-5:2002 Protective equipment for martial arts - Part 5: Additional requirements and test methods for genital protectors and abdominal protectors	10/08/2002		
CEN	EN 13277-6:2003 Protective equipment for martial arts - Part 6: Additional requirements and test methods for breast protectors for females	21/02/2004		
CEN	EN 13277-7:2009 Protective equipment for martial arts - Part 7: Additional requirements and test methods for hand and foot protectors	06/05/2010		
CEN	EN ISO 13287:2012 **(new)** Personal protective equipment - Footwear - Test method for slip resistance (ISO 13287:2012)	This is the first publication	EN ISO 13287:2007 Note 2.1	30/04/2013
CEN	EN 13356:2001 Visibility accessories for non-professional use - Test methods and requirements	21/12/2001		
CEN	EN 13484:2012 Helmets for users of luges	20/12/2012	EN 13484:2001 Note 2.1	30/04/2013

CEN	EN 13546:2002+A1:2007 Protective clothing - Hand, arm, chest, abdomen, leg, foot and genital protectors for field hockey goal keepers, and shin protectors for field players - Requirements and test methods	23/11/2007	EN 13546:2002 Note 2.1	Date expired (31/12/2007)
CEN	EN 13567:2002+A1:2007 Protective clothing - Hand, arm, chest, abdomen, leg, genital and face protectors for fencers - Requirements and test methods	23/11/2007	EN 13567:2002 Note 2.1	Date expired (31/12/2007)
CEN	EN 13594:2002 Protective gloves for professional motorcycle riders - Requirements and test methods	28/08/2003		
CEN	EN 13595-1:2002 Protective clothing for professional motorcycle riders - Jackets, trousers and one piece or divided suits - Part 1: General requirements	28/08/2003		
CEN	EN 13595-2:2002 Protective clothing for professional motorcycle riders - Jackets, trousers and one-piece or divided suits - Part 2: Test method for determination of impact abrasion resistance	28/08/2003		
CEN	EN 13595-3:2002 Protective clothing for professional motorcycle riders - Jackets, trousers and one-piece or divided suits - Part 3: Test method for determination of burst strength	28/08/2003		
CEN	EN 13595-4:2002 Protective clothing for professional motorcycle riders - Jackets, trousers and one-piece or divided suits - Part 4: Test method for determination of impact cut resistance	28/08/2003		
CEN	EN 13634:2010 Protective footwear for motorcycle riders - Requirements and test methods	09/07/2011	EN 13634:2002 Note 2.1	Date expired (09/07/2011)
CEN	EN 13781:2012 Protective helmets for drivers and passengers of snowmobiles and bobsleighs	20/12/2012	EN 13781:2001 Note 2.1	30/04/2013
CEN	EN 13794:2002 Respiratory protective devices - Self-contained closed-circuit breathing apparatus for escape - Requirements,	28/08/2003	EN 1061:1996 EN 400:1993 EN 401:1993	Date expired (28/08/2003)

	testing, marking		Note 2.1	
CEN	EN 13819-1:2002 Hearing protectors - Testing - Part 1: Physical test methods	28/08/2003		
CEN	EN 13819-2:2002 Hearing protectors - Testing - Part 2: Acoustic test methods	28/08/2003		
CEN	EN 13832-1:2006 Footwear protecting against chemicals - Part 1: Terminology and test methods	21/12/2006		
CEN	EN 13832-2:2006 Footwear protecting against chemicals - Part 2: Requirements for footwear resistant to chemicals under laboratory conditions	21/12/2006		
CEN	EN 13832-3:2006 Footwear protecting against chemicals - Part 3: Requirements for footwear highly resistant to chemicals under laboratory conditions	21/12/2006		
CEN	EN 13911:2004 Protective clothing for firefighters - Requirements and test methods for fire hoods for firefighters	06/10/2005		
CEN	EN 13921:2007 Personal protective equipment - Ergonomic principles	23/11/2007		
CEN	EN 13949:2003 Respiratory equipment - Open-circuit self-contained diving apparatus for use with compressed Nitrox and oxygen - Requirements, testing, marking	21/02/2004		
CEN	EN ISO 13982-1:2004 Protective clothing for use against solid particulates - Part 1: Performance requirements for chemical protective clothing providing protection to the full body against airborne solid particulates (type 5 clothing) (ISO 13982-1:2004)	06/10/2005		
	EN ISO 13982-1:2004/A1:2010	09/07/2011	Note 3	Date expired (09/07/2011)
CEN	EN ISO 13982-2:2004 Protective clothing for use against solid particulates - Part 2: Test method of	06/10/2005		

	determination of inward leakage of aerosols of fine particles into suits (ISO 13982-2:2004)			
CEN	EN ISO 13995:2000 Protective clothing - Mechanical properties - Test method for the determination of the resistance to puncture and dynamic tearing of materials (ISO 13995:2000)	06/10/2005		
CEN	EN ISO 13997:1999 Protective clothing - Mechanical properties - Determination of resistance to cutting by sharp objects (ISO 13997:1999)	04/07/2000		
	EN ISO 13997:1999/AC:2000			
CEN	EN ISO 13998:2003 Protective clothing - Aprons, trousers and vests protecting against cuts and stabs by hand knives (ISO 13998:2003)	28/08/2003	EN 412:1993 Note 2.1	Date expired (28/08/2003)
CEN	EN 14021:2003 Stone shields for off-road motorcycling suited to protect riders against stones and debris - Requirements and test methods	06/10/2005		
CEN	EN 14052:2012+A1:2012 High performance industrial helmets	20/12/2012	EN 14052:2012 Note 2.1	30/04/2013
CEN	EN 14058:2004 Protective clothing - Garments for protection against cool environments	06/10/2005		
CEN	EN ISO 14116:2008 Protective clothing - Protection against heat and flame - Limited flame spread materials, material assemblies and clothing (ISO 14116:2008)	28/01/2009	EN 533:1997 Note 2.1	Date expired (28/01/2009)
	EN ISO 14116:2008/AC:2009			
CEN	EN 14120:2003+A1:2007 Protective clothing - Wrist, palm, knee and elbow protectors for users of roller sports equipment - Requirements and test methods	23/11/2007	EN 14120:2003 Note 2.1	Date expired (31/12/2007)
CEN	EN 14126:2003 Protective clothing - Performance requirements and tests methods for protective clothing against infective agents	06/10/2005		
	EN 14126:2003/AC:2004			

CEN	EN 14143:2003 Respiratory equipment - Self-contained re-breathing diving apparatus	06/10/2005		
CEN	EN 14225-1:2005 Diving suits - Part 1: Wet suits - Requirements and test methods	06/10/2005		
CEN	EN 14225-2:2005 Diving suits - Part 2: Dry suits - Requirements and test methods	06/10/2005		
CEN	EN 14225-3:2005 Diving suits - Part 3: Actively heated or cooled suits (systems) - Requirements and test methods	06/10/2005		
CEN	EN 14225-4:2005 Diving suits - Part 4: One atmosphere suits (ADS) - Human factors requirements and test methods	06/10/2005		
CEN	EN 14325:2004 Protective clothing against chemicals - Test methods and performance classification of chemical protective clothing materials, seams, joins and assemblages	06/10/2005		
CEN	EN 14328:2005 Protective clothing - Gloves and armguards protecting against cuts by powered knives - Requirements and test methods	06/10/2005		
CEN	EN 14360:2004 Protective clothing against rain - Test method for ready made garments - Impact from above with high energy droplets	06/10/2005		
CEN	EN 14387:2004+A1:2008 Respiratory protective devices - Gas filter(s) and combined filter(s) - Requirements, testing, marking	20/06/2008	EN 14387:2004 Note 2.1	Date expired (31/07/2008)
CEN	EN 14404:2004+A1:2010 Personal protective equipment - Knee protectors for work in the kneeling position	06/05/2010	EN 14404:2004 Note 2.1	Date expired (31/07/2010)
CEN	EN 14435:2004 Respiratory protective devices - Self-contained open-circuit compressed air breathing apparatus with half mask designed to be used with positive pressure only - Requirements, testing, marking	06/10/2005		
CEN	EN 14458:2004 Personal eye-equipment - Faceshields and	06/10/2005		

	visors for use with firefighters' and high performance industrial safety helmets used by firefighters, ambulance and emergency services			
CEN	EN ISO 14460:1999 Protective clothing for automobile racing drivers - Protection against heat and flame - Performance requirements and test methods (ISO 14460:1999)	16/03/2000		
	EN ISO 14460:1999/A1:2002	10/08/2002	Note 3	Date expired (30/09/2002)
	EN ISO 14460:1999/AC:1999			
CEN	EN 14529:2005 Respiratory protective devices - Self-contained open-circuit compressed air breathing apparatus with half mask designed to include a positive pressure lung governed demand valve for escape purposes only	19/04/2006		
CEN	EN 14593-1:2005 Respiratory protective devices - Compressed air line breathing apparatus with demand valve - Part 1: Apparatus with a full face mask - Requirements, testing, marking	06/10/2005	EN 139:1994 Note 2.1	Date expired (02/12/2005)
CEN	EN 14593-2:2005 Respiratory protective devices - Compressed air line breathing apparatus with demand valve - Part 2: Apparatus with a half mask at positive pressure - Requirements, testing, marking	06/10/2005	EN 139:1994 Note 2.1	Date expired (02/12/2005)
	EN 14593-2:2005/AC:2005			
CEN	EN 14594:2005 Respiratory protective devices - Continuous flow compressed air line breathing apparatus - Requirements, testing, marking	06/10/2005	EN 139:1994 EN 270:1994 EN 271:1995 EN 1835:1999 EN 12419:1999 Note 2.1	Date expired (02/12/2005)
	EN 14594:2005/AC:2005			
CEN	EN 14605:2005+A1:2009 Protective clothing against liquid chemicals - performance requirements for clothing with liquid-tight (Type 3) or spray-tight	06/05/2010	EN 14605:2005 Note 2.1	Date expired (06/05/2010)

	(Type 4) connections, including items providing protection to parts of the body only (Types PB [3] and PB [4])			
CEN	EN 14786:2006 Protective clothing - Determination of resistance to penetration by sprayed liquid chemicals, emulsions and dispersions - Atomizer test	21/12/2006		
CEN	EN ISO 14877:2002 Protective clothing for abrasive blasting operations using granular abrasives (ISO 14877:2002)	28/08/2003		
CEN	EN ISO 15025:2002 Protective clothing - Protection against heat and flame - Method of test for limited flame spread (ISO 15025:2000)	28/08/2003	EN 532:1994 Note 2.1	Date expired (28/08/2003)
CEN	EN ISO 15027-1:2012 **(new)** Immersion suits - Part 1: Constant wear suits, requirements including safety (ISO 15027-1:2012)	This is the first publication	EN ISO 15027-1:2002 Note 2.1	31/05/2013
CEN	EN ISO 15027-2:2012 **(new)** Immersion suits - Part 2: Abandonment suits, requirements including safety (ISO 15027-2:2012)	This is the first publication	EN ISO 15027-2:2002 Note 2.1	31/05/2013
CEN	EN ISO 15027-3:2012 **(new)** Immersion suits - Part 3: Test methods (ISO 15027-3:2012)	This is the first publication	EN ISO 15027-3:2002 Note 2.1	31/05/2013
CEN	EN 15090:2012 Footwear for firefighters	20/12/2012	EN 15090:2006 Note 2.1	30/04/2013
CEN	EN 15151-1:2012 Mountaineering equipment - Braking devices - Part 1: Braking devices with manually assisted locking, safety requirements and test methods	20/12/2012		
CEN	EN 15333-1:2008 Respiratory equipment - Open-circuit umbilical supplied compressed gas diving apparatus - Part 1: Demand apparatus	20/06/2008		
	EN 15333-1:2008/AC:2009			
CEN	EN 15333-2:2009 Respiratory equipment - Open-circuit umbilical supplied compressed gas diving	06/05/2010		

	apparatus - Part 2: Free flow apparatus			
CEN	EN 15613:2008 Knee and elbow protectors for indoor sports - Safety requirements and test methods	05/06/2009		
CEN	EN 15614:2007 Protective clothing for firefighters - Laboratory test methods and performance requirements for wildland clothing	23/11/2007		
CEN	EN ISO 15831:2004 Clothing - Physiological effects - Measurement of thermal insulation by means of a thermal manikin (ISO 15831:2004)	06/10/2005		
CEN	EN 16027:2011 Protective clothing - Gloves with protective effect for association football goal keepers	16/02/2012		
CEN	EN ISO 17249:2004 Safety footwear with resistance to chain saw cutting - (ISO 17249:2004)	06/10/2005		
	EN ISO 17249:2004/A1:2007	23/11/2007	Note 3	Date expired (23/11/2007)
CEN	EN ISO 17491-3:2008 Protective clothing - Test methods for clothing providing protection against chemicals - Part 3: Determination of resistance to penetration by a jet of liquid (jet test) (ISO 17491-3:2008)	28/01/2009	EN 463:1994 Note 2.1	Date expired (28/02/2009)
CEN	EN ISO 17491-4:2008 Protective clothing - Test methods for clothing providing protection against chemicals - Part 4: Determination of resistance to penetration by a spray of liquid (spray test) (ISO 17491-4:2008)	28/01/2009	EN 468:1994 Note 2.1	Date expired (28/02/2009)
CEN	EN ISO 20344:2011 Personal protective equipment - Test methods for footwear (ISO 20344:2011)	16/02/2012	EN ISO 20344:2004 Note 2.1	Date expired (30/06/2012)
CEN	EN ISO 20345:2011 Personal protective equipment - Safety footwear (ISO 20345:2011)	16/02/2012	EN ISO 20345:2004 Note 2.1	30/06/2013
CEN	EN ISO 20346:2004 Personal protective equipment - Protective footwear (ISO 20346:2004)	06/10/2005	EN 346:1992 EN 346-2:1996	Date expired (06/10/2005)

			Note 2.1	
	EN ISO 20346:2004/A1:2007	08/03/2008	Note 3	Date expired (31/03/2008)
	EN ISO 20346:2004/AC:2007			
CEN	EN ISO 20347:2012 Personal protective equipment - Occupational footwear (ISO 20347:2012)	20/12/2012	EN ISO 20347:2004 Note 2.1	30/04/2013
CEN	EN ISO 20349:2010 Personal protective equipment - Footwear protecting against thermal risks and molten metal splashes as found in foundries and welding - Requirements and test method (ISO 20349:2010)	09/07/2011		
CEN	EN 24869-1:1992 Acoustics - Hearing protectors - Subjective method for the measurement of sound attenuation (ISO 4869-1:1990)	16/12/1994		
Cenelec	EN 50286:1999 Electrical insulating protective clothing for low-voltage installations	16/03/2000		
	EN 50286:1999/AC:2004			
Cenelec	EN 50321:1999 Electrically insulating footwear for working on low voltage installations	16/03/2000		
Cenelec	EN 50365:2002 Electrically insulating helmets for use on low voltage installations	10/04/2003		
Cenelec	EN 60743:2001 Live working - Terminology for tools, equipment and devices IEC 60743:2001	10/04/2003	EN 60743:1996 Note 2.1	Date expired (01/12/2004)
	EN 60743:2001/A1:2008 IEC 60743:2001/A1:2008	09/07/2011	Note 3	Date expired (09/07/2011)
Cenelec	EN 60895:2003 Live working - Conductive clothing for use at nominal voltage up to 800 kV a.c. and ± 600 kV d.c. IEC 60895:2002 (Modified)	06/10/2005	EN 60895:1996 Note 2.1	Date expired (01/07/2006)
Cenelec	EN 60903:2003 Live working - Gloves of insulating material IEC 60903:2002 (Modified)	06/10/2005	EN 50237:1997 + EN 60903:1992 + A11:1997	Date expired (01/07/2006)

			Note 2.1	
Cenelec	EN 60984:1992 Sleeves of insulating material for live working IEC 60984:1990 (Modified)	04/06/1999		
	EN 60984:1992/A11:1997	04/06/1999	Note 3	Date expired (04/06/1999)
	EN 60984:1992/A1:2002 IEC 60984:1990/A1:2002	10/04/2003	Note 3	Date expired (06/10/2005)

(1) ESO: European Standardisation Organisation:

CEN: Avenue Marnix 17, B-1000, Brussels, Tel.+32 2 5500811; fax +32 2 5500819 (http://www.cen.eu)

CENELEC: Avenue Marnix 17, B-1000, Brussels, Tel.+32 2 5196871; fax +32 2 5196919 (http://www.cenelec.eu)

ETSI: 650, route des Lucioles, F-06921 Sophia Antipolis, Tel.+33 492 944200; fax +33 493 654716, (http://www.etsi.eu)

APPENDIX D: CATEGORIES OF PPE

Categories of PPE under the European Directive

	Type of PPE	Category
1. Equipment for hearing protection		
1.1	All equipment protecting hearing (whether worn in or over the ear)	II
Except		
1.2	Ear plugs intended for swimmers to prevent water entering the ears	0
2. Equipment for eye protection		
2.1	All eye protectors and filters	II
Except:		
2.2	Eye protectors and filters designed and manufactured for use in high-temperature environments the effects of which are comparable to those of an air temperature of 100 °C or more and which may or may not be characterised by the presence of infra-red radiation, flames or the projection of large amounts of molten material	III
2.3	Eye protectors and filters designed and manufactured to provide protection against ionizing radiation	III
2.4	Eye protectors and filters designed and manufactured to provide protection against electrical risks	III
2.5	Swimming and/or diving goggles and masks	I
2.6	Eye protectors and filters designed and manufactured exclusively to provide protection against sunlight, sun glasses (not corrective) for private and professional use. This includes cases where glasses are tinted after manufacturing or any other assembly after manufacturing (e.g. assembly of sunlight protective lenses in a non CE marked frame)	I
2.7	Ski goggles of all types, except corrective spectacles	I
2.8	Corrective spectacles including corrective sunglasses Note: where corrective spectacles provide protection other than protection against sunlight (e.g. against impact, abrasive projections, etc.), they are classified as personal protective equipment of the category corresponding to the hazard in question solely in respect of their protective features.	0
2.9	Visors incorporated into helmets designed and manufactured for use with two- or three-wheeled motor vehicles	0
3. Equipment for protection against falls from a height		
3.1	All protective equipment designed and manufactured to provide protection against falls from a height, for private or professional use (working at heights, falling off boats, mountaineering, rock climbing, speleology, etc.). This category also includes equipment for working at a height and with support (harnesses, thigh straps, belts, etc.) Note: this equipment includes harnesses (thigh straps, shoulder belts, etc.) and all accessories intended for attaching a person to a structure, with the exception of anchorage points forming an integral part of the structure or rock face. - For example: for professional use: lanyards, mobile fall arresters, karabiners, energy absorbers, connectors, anchor points, etc. - For mountaineering, rock climbing, and speleology: connectors (simple ropes), ropes for abseiling (double ropes), slings, climbing karabiners, rope clamps, chocks, pitons, ice pitons, gripping devices for use on artificial climbing walls, etc. Note: the categorization is not influenced by the fact that the equipment is factory made/assembled or produced/assembled by the (employer) user himself (e.g. double lanyards).	III

Note: "O" in the Category column indicates a product that is not covered under the PPE Directive. It may be covered under another EU Directive, with requirements for certification and marking.

Categories of PPE under the European Directive

Type of PPE		Category
Except:		
3.2	Anchorage points forming an integral part of the structure or rock face Example: Anchor devices of classes A, C and D according to EN 795:199625	0
3.3	Equipment for accessing or leaving positions at a height (winch seats, descenders not fitted with a built-in speed-regulating system, etc.)	0
3.4	Equipment for climbing, rock climbing, speleology etc. (ice-axes, hammers, descenders not fitted with a built-in speed-regulating system, rope-climbing equipment, etc.)	0
3.5	Support equipment (harnesses, etc.) designed and manufactured for use with parachutes, paragliders, hanggliders, etc. and which cannot be used for purposes other than those for which they were designed	0
3.6	Emergency parachutes	0
4. Equipment for head protection		
4.1	All helmets, including sports helmets	II
Except:		
4.2	Helmets designed and manufactured for use in high-temperature environments the effects of which are comparable to those of an air temperature of 100°C or more and which may or may not be characterised by the presence of infra-red radiation, flames or the projection of large amounts of molten material	III
4.3	Helmets designed and manufactured to provide protection against electrical risks	III
4.4	Light headgear designed and manufactured to provide scalp protection	I
4.5	Helmets designed and manufactured for riders of 2- or 3- wheeled motor vehicles, including racing helmets Note: car racing helmets are not excluded from the PPE directive and thus PPE category II.	0
4.6	Helmets designed and manufactured specifically for use by the armed forces or in the maintenance of law and order	0
5. Equipment for part or whole face protection		
5.1	All equipment	II
Except:		
5.2	Equipment designed and manufactured for use in high-temperature environments the effects of which are comparable to those of an air temperature of 100°C or more and which may or may not be characterised by the presence of infra-red radiation, flames or the projection of large amounts of molten material	III
5.3	Equipment designed and manufactured for use in low-temperature environments the effects of which are comparable to those of an air temperature of -50°C or less	III
5.4	Equipment designed and manufactured to provide protection against electrical risks	III
5.5	Visors designed and manufactured for incorporation into helmets used by riders of 2- or 3-wheeled motor vehicles, including racing visors	0

Note: "O" in the Category column indicates a product that is not covered under the PPE Directive. It may be covered under another EU Directive, with requirements for certification and marking.

Categories of PPE under the European Directive

	Type of PPE	Category
6. Protective clothing		
6.1	All items of clothing and/or accessories (whether or not detachable) designed and manufactured to provide specific protection • Remark: this category includes also: protective clothing used for sports activities such as diving suits, protective clothes for waterskiing, etc.; • bullet-proof clothing used by other than the armed forces (for instance security guards); • clothing protecting against infective agents used by other than the armed forces.	II
Except:		
6.2	Clothing and/or accessories (whether or not detachable) designed and manufactured to provide protection against electrical risks	III
6.3	Clothing and/or accessories (whether or not detachable) designed and manufactured for use in high-temperature environments the effects of which are comparable to those of an air temperature of 100 °C or more and which may or may not be characterized by the presence of infrared radiation, flames or the projection of large amounts of molten material	III
6.4	Clothing and/or accessories (whether or not detachable) designed and manufactured for use in low-temperature environments the effects of which are comparable to those of an air temperature of -50 °C or less	III
6.5	Clothing and/or accessories (whether or not detachable) designed and manufactured to provide only limited protection against chemical attack or against ionising radiation Note: the manufacturer shall indicate the products against which protection is provided, and the time for which such protection lasts.	III
6.6	Clothing and/or accessories (whether or not detachable) designed and manufactured to provide complete insulation from the atmosphere	III
6.7	Clothing and/or accessories (whether or not detachable) designed and manufactured to provide protection against weather conditions which are neither exceptional nor extreme, for professional use	I
6.8	Clothing and/or accessories (whether or not detachable) designed and manufactured to provide protection against mechanical action the effects of which are superficial	I
6.9	Clothing and/or accessories (whether or not detachable) designed and manufactured to provide protection against risks arising from handling hot components which do not expose the user to a temperature of over 50 °C or to dangerous impacts	I
6.10	Clothing and/or accessories (whether or not detachable) designed and manufactured specifically for use by the armed forces or in the maintenance of law and order, including bullet-proof clothing or jackets, clothing protecting against biological contamination or ionising radiation Remark: the given examples of garments used by others than armed forces or maintenance of law and order, are PPE and to be categorised depending on the type of risk they provide protection against.	0
6.11	Clothing and/or accessories (whether or not detachable) designed and manufactured to provide protection against adverse atmospheric conditions for private use	0
6.12	Ordinary clothing and/or accessories (whether or not detachable) or sports clothing and/or accessories (not providing specific protection), including uniforms	0
6.13	Motorcyclists' garments and additional protection. See point 14	

Note: "O" in the Category column indicates a product that is not covered under the PPE Directive. It may be covered under another EU Directive, with requirements for certification and marking.

Categories of PPE under the European Directive

	Type of PPE	Category
7. Respiratory protective equipment		
7.1	All respiratory protective equipment (however described) designed and manufactured to provide protection against solid aerosols, liquid aerosols or gases All respiratory protective equipment designed and manufactured to provide full insulation from the atmosphere; all respiratory protective equipment designed and manufactured for use in diving	III
Except:		
7.2	All respiratory protective equipment designed and manufactured specifically for use by the armed forces or in the maintenance of law and order	0
7.3	Surgical masks Note: where such masks are intended to protect the wearer against microbial and viral infections, etc. they are in certification category III (personal protection rather than medical use).	0
7.4	Nose plugs intended for swimmers to prevent water entering the nose	0
8. Equipment for leg and/or foot and anti-slip protection		
8.1	All equipment and/or accessories (whether or not detachable) designed and manufactured specifically to protect the foot and/or the leg and to provide anti-slip protection Note: Protection against static electricity is included in this category since this equipment is used in environments with potential risk of explosion.	II
Except:		
8.2	Equipment and/or accessories (whether or not detachable) designed and manufactured to provide protection against electrical risks for work involving dangerous voltages, or used to provide insulation against high voltages	III
8.3	Equipment and/or accessories (whether or not detachable) designed and manufactured for use in high-temperature environments the effects of which are comparable to those of an air temperature of 100 °C or more and which may or may not be characterised by the presence of infra-red radiation, flames or the projection of large amounts of molten material	III
8.4	Equipment and/or accessories (whether or not detachable) designed and manufactured for use in low-temperature environments the effects of which are comparable to those of an air temperature of -50 °C or less	III
8.5	Equipment and/or accessories (whether or not detachable) designed and manufactured to provide only limited protection against chemical attack or ionising radiation Note: the manufacturer shall indicate the products against which protection is provided, and the time for which such protection lasts.	III
8.6	Sports equipment (in particular sport shoes) and/or accessories (whether or not detachable) designed and manufactured to protect against minor impacts and vibrations which do not affect vital areas of the body and whose effects cannot cause irreversible lesions Note: sport shin-guards (e.g. for football, hockey) and protective equipment are generally category 2 unless designed only for protection against minor impacts.	I
8.7	Equipment and/or accessories (whether or not detachable) designed and manufactured to provide protection against weather conditions which are neither exceptional nor extreme, for professional use	I
8.8	Equipment and/or accessories (whether or not detachable) designed and manufactured to provide protection against atmospheric conditions, for private use	0

Note: "O" in the Category column indicates a product that is not covered under the PPE Directive. It may be covered under another EU Directive, with requirements for certification and marking.

Categories of PPE under the European Directive

	Type of PPE	Category
8.9	Equipment and/or accessories (whether or not detachable) designed and manufactured specifically for use by the armed forces or in the maintenance of law and order, including equipment protecting against biological contamination or ionising radiation	0
8.10	Some shoes, in particular sports shoes, contain components intended to absorb shock when walking, running, etc. or to ensure a good grip or stability. These components are to be regarded as being intended to increase comfort Note: this category includes in particular football and spiked running shoes.	0
9. Equipment for hand and arm protection		
9.1	All equipment and/or accessories (whether or not detachable) designed and manufactured specifically to protect the arm and/or the hand Note: this includes all garments protecting the hand or part of the hand, including gloves, fingerless gloves, mittens, garments protecting the fingers only or the palm only, etc.	II
Except:		
9.2	Equipment and/or accessories (whether or not detachable) designed and manufactured to provide protection against electrical risks for work involving dangerous voltages, or used to provide insulation against high voltages.	III
9.3	Equipment and/or accessories (whether or not detachable) designed and manufactured for use in high-temperature environments the effects of which are comparable to those of an air temperature of 100 °C or more and which may or may not be characterised by the presence of infra-red radiation, flames or the projection of large amounts of molten material, including fire-fighters' equipment.	III
9.4	Equipment and/or accessories (whether or not detachable) designed and manufactured for use in low-temperature environments the effects of which are comparable to those of an air temperature of -50 °C or less	III
9.5	Equipment and/or accessories (whether or not detachable) designed and manufactured to provide only limited protection against chemical attack or ionising radiation Note: the manufacturer shall indicate the products against which protection is provided and the time for which such protection lasts.	III
9.6	Equipment and/or accessories (whether or not detachable) designed and manufactured to protect against cleaning materials of weak action (for dishwashing, cleaning etc.), for professional use	I
9.7	Equipment and/or accessories (whether or not detachable) designed and manufactured to provide protection against mechanical action the effects of which are superficial (pricks due to sewing, gardening, dirty work, sports (including bag gloves for boxing), etc.)	I
9.8	Equipment and/or accessories (whether or not detachable) designed and manufactured to protect against heat and risks encountered in the handling of hot components which do not expose the user to a temperature exceeding 50 °C or to dangerous impacts and against unexceptional cold weather, for professional use	I
9.9	Gloves and finger guards for medical use in the patient's environment	0
9.10	Gloves designed and manufactured to provide protection against adverse atmospheric conditions, damp and water or heat or cold for private use	0
9.11	Equipment and/or accessories (whether or not detachable) designed and manufactured specifically for use by the armed forces or in the maintenance of law and order, including equipment protecting against biological contamination or ionising radiation	0
9.12	Boxing gloves Note: bag gloves are PPE category I	0

Note: "O" in the Category column indicates a product that is not covered under the PPE Directive. It may be covered under another EU Directive, with requirements for certification and marking.

Categories of PPE under the European Directive

Type of PPE		Category
9.13	Dry gloves for divers	II

PART 2: per type of risk

Remark: the tables in this part contain all type of PPE and are not in contradiction with the tables in part 1. These are only given for further clarification.

Type of PPE		Certification category
10. Equipment designed to prevent drowning or for use as buoyancy aids		
10.1	All equipment designed and manufactured to prevent drowning or for use as buoyancy aids, including swimming aids and inflatable buoys which are not regarded as toys (for use exclusively in shallow water) • Note: Includes crampons, ropes and other equipment used to get out of water after falling through ice. • Also included: swimming suits with incorporated floats. • Also included: swimming armbands	II
Except:		
10.2	Life-buoys and life-jackets for emergency use by ship and aircraft passengers Note: the terms "ship" and "aircraft" refer exclusively to those carrying passengers and to seagoing vessels subject to the international conventions of the IMO. Pleasure craft (motor boats and sailing boats), fishing boats, working boats, etc. are not included in this category.	0
10.3	Buoyancy aids that are not worn but held by the user (such as foam boards, etc.)	0
10.4	Buoyancy aids that are not designed to be kept in place while worn or assure the upright position of the wearer (such as 'tyre type' buoys, floating belts, etc.)	0
11. Equipment for protection against electrical risks		
11.1	Equipment for protection against electrical risks Note: Dangerous voltages means a voltage equal to or exceeding 50 V alternating current or 75 V direct current	III
Except:		
11.2	Hand-held insulating tools	0
11.3	Protective equipment (such as shoes, garments, etc.) against static electricity Note: this equipment is used in environments with potential risk of explosion.	II
12. Equipment designed and manufactured to protect against the result of mechanical action		
12.1	All PPE designed and manufactured to protect the wearer against vibrations	II
12.2	PPE designed and manufactured to protect the skin of the user against friction (e.g. patches)	I
12.3	PPE designed and manufactured to protect the wearer against increased risk levels arising from impacts with other persons or from falling while performing sports (e.g. backprotectors for mountainbikers, football shin-guards, ice hockey protectors, ...)	II

Note: "O" in the Category column indicates a product that is not covered under the PPE Directive. It may be covered under another EU Directive, with requirements for certification and marking.

Categories of PPE under the European Directive

Type of PPE		Certification category
12.4	PPE designed and manufactured to protect the wearer against impacts resulting from g-forces (e.g. karting collar, racing neck braces, ...)	II
Except:		
12.5	Equipment protecting against minor impacts and vibrations which do not affect vital areas of the body and whose effects cannot cause irreversible lesions (such as light anti-scalping helmets, gloves, light footwear, etc.)	I
12.6	Sports equipment protecting against minor impacts from falling (protection against bruises, abrasion, light burns, ...), such as volleyball knee pads, ...	I
12.7	Some equipment designed and manufactured to enhance comfort and performance such as footwear and gloves, e.g. running shoes and sport gloves containing components intended to absorb shock when walking, running etc. or to ensure a good grip or stability	0
13. Rescue equipment		
13.1	Resuscitation masks: if the mask has, apart from allowing adequate artificial breathing, also a protective function for the rescuer (protection against contagion by contact with the mouth of the victim for instance) then they are PPE	Depending on the type of protection
13.2	If the rescue equipment is worn before the accident which prompts the rescue, then it is PPE Example: a wet suit worn continuously to prevent hypothermia in the event of falling into water is PPE.	Depending on the type of protection
Except:		
13.3	If the rescue equipment is placed on the person after the accident occurs, it is not a PPE Example: a sling used to rescue an unconscious person from an inaccessible point.	0
14. Motorcyclists' equipment		
14.1	Motorcyclists' helmets	0
14.2	Motorcyclists' garments and additional protection such as gloves for private use as long as only protection against climatic conditions are provided	0
Except:		
14.3	Motorcyclists' garments and additional protection (e.g. gloves, boots) only protecting against climatic conditions for professional use	I
14.4	Motorcyclists' garments and additional protection (e.g. gloves, footwear) for which additional protection is provided (e.g. impact protectors for limb or back, pads for elbow or shoulders, protection against cuts and abrasion, ...)	II.
15. High visibility clothing and accessories		
15.1	High visibility clothing	II
15.2	High visibility accessories (e.g. free hanging accessories such as dangling tags)	II
Except:		
15.3	High visibility gadgets (e.g. reflective keyrings, backpacks with reflective and/or fluorescent material, ...)	0

Note: "O" in the Category column indicates a product that is not covered under the PPE Directive. It may be covered under another EU Directive, with requirements for certification and marking.

APPENDIX E: CONFORMITY ASSESSMENT MODULES

Annex 7

Contents of conformity assessment procedures

Council Decision 93/465/EEC lays down the modules for conformity assessment, which are further defined in each directive. This annex is intended to give an overview of the tasks that are to be carried out under the responsibility of the manufacturer and the notified body, and the tasks that the manufacturer can delegate to the authorised representative. However, there are differences between the conformity assessment procedures adopted by the directives, which are not taken into account in this general presentation. Furthermore, the tasks to be carried out by the importer or the person responsible for placing on the market are described in Section 3.3. of the Guide.

Module	Manufacturer	Manufacturer or the authorised representative	Notified body
A	• establishes a technical documentation as regards the design, manufacture and operation of the product • takes all measures necessary to ensure that the manufacturing process assures compliance of the products with the technical documentation and with the applicable requirements (i.e. operates a quality system)	• ensures and declares that the products concerned satisfy the requirements • affixes the CE marking to each product • draws up a declaration of conformity • keeps a copy of the declaration of conformity and the technical documentation at the disposal of the surveillance authorities	
Aa1	In addition to the responsibilities as in module A: • carries out, or has carried out on his behalf, one or more tests for each product manufactured • chooses a notified body on whose responsibility the tests are carried out	In addition to the responsibilities as in module A: • affixes the notified body's identification number to follow the CE marking, if the notified body intervened during the production stage	• supervises the tests carried out by the manufacturer • supervises the affixing of its identification number, where it was involved in conformity assessment during the production stage • keeps a record of relevant information • communicates to the other notified bodies relevant information (on request)
Aa2	As in module A: • applies for product checks at random intervals	In addition to the responsibilities as in module A: • affixes the notified body's identification number to follow the CE marking	• carries out or has carried out product checks at random intervals, and for this purpose takes samples of final products • supervises the affixing of its identification number • keeps a record of relevant information • communicates to the other notified bodies relevant information (on request)
B	• establishes a technical documentation as regards the design, manufacture and operation of the product	• applies for the EC type-examination • places at the disposal of the notified body one (or more) specimen(s), which is (are) representative of the production envisaged • informs the notified body of all modifications to the approved product • keeps the technical documentation, including a copy of the EC type-examination certificate, at the disposal of the surveillance authorities	• ascertains, by performing or having performed examinations and tests, that the specimen(s) meet(s) the applicable provisions and is manufactured in accordance with the technical documentation • issues an EC type-examination certificate • keeps a copy of the certificate and a record of other relevant technical information • communicates to the other notified bodies the relevant information concerning the EC type-examination certificates (on request)

Module	Manufacturer	Manufacturer or the authorised representative	Notified body
C	• takes all measures necessary to ensure that the manufacturing process assures compliance of the products with the type as described in the EC type-examination certificate and with the applicable requirements (i.e. operates a quality system, which includes establishing the necessary documentation)	• ensures and declares that the products concerned are in conformity with the EC type-examination certificate and satisfy the applicable requirements • affixes the CE marking to each product • draws up a declaration of conformity • keeps relevant technical information and a copy of the declaration of conformity at the disposal of the surveillance authorities	
C*bis*1	As in modules C and Aa1	As in modules C and Aa1	As in module Aa1
C*bis*2	As in modules C and Aa2	As in modules C and Aa2	As in module Aa2
D	• operates an approved quality system for production, final product inspection and testing, which includes the drawing up of a technical documentation (i.e. relevant information for the product category envisaged, documentation concerning the quality system and its updating, technical documentation of the approved type, a copy of the EC type-examination certificate, and the decisions and reports from the notified body) • applies for the assessment of the quality system for the products concerned • ensures and declares that the products concerned are in accordance with the EC type-examination certificate and satisfy the applicable requirements • undertakes to fulfil the obligations arising out of the approved quality system and upholds it so that it remains adequate and efficient • supports the action carried out by the notified body for surveillance purpose • keeps at the disposal of the surveillance authority the documentation concerning the quality system, details of any updating of the quality system, the decisions and reports of the notified body	• affixes the CE marking to each product • affixes the notified body's identification number to follow the CE marking • draws up a declaration of conformity • informs the notified body of any intended updating of the quality system • keeps a copy of the declaration of conformity at the disposal of the surveillance authorities	• assesses the quality system to determine whether it satisfies the applicable requirements, and accordingly takes a decision • supervises the affixing of its identification number • carries out surveillance of the manufacturer by means of periodic and unexpected visits • keeps a record of relevant technical information • communicates to the other notified bodies the relevant information concerning the quality system approvals issued and withdrawn (on request)

Module	Manufacturer	Manufacturer or the authorised representative	Notified body
Dbis	• establishes a technical documentation as regards the design, manufacture and operation of the product • operates an approved quality system for production, final product inspection and testing, which includes the drawing up of a technical documentation (i.e. relevant information for the product category envisaged, documentation concerning the quality system and its updating, and the decisions and reports from the notified body) • applies for the assessment of the quality system for the products concerned • ensures and declares that the products concerned satisfy the requirements • undertakes to fulfil the obligations arising out of the approved quality system and upholds it so that it remains adequate and efficient • supports the action carried out by the notified body for surveillance purpose • keeps at the disposal of the surveillance authority the documentation concerning the quality system, details of any updating of the quality system, the decisions and reports of the notified body	As in module D	As in module D
E	As in module D, but operates an approved quality system for final product inspection and testing	As in module D	As in module D
Ebis	As in module Dbis, but operates an approved quality system for final product inspection and testing	As in module D	As in module D
F	• takes all measures necessary to ensure that the manufacturing process assures conformity of the products with the type as described in the EC type-examination certificate and with the applicable requirements (i.e. operates a quality system, which includes establishing the necessary documentation) Where the statistical verification is used: • presents the products in the form of homogeneous lots and takes all measures necessary in order that the manufacturing process ensures the homogeneity of each lot produced	• applies for certification of conformity • checks and attests that the products are in conformity with the type as described in the EC type-examination certificate and satisfy the applicable requirements • affixes the CE marking to each product • affixes the notified body's identification number to follow the CE marking • draws up a declaration of conformity • keeps relevant technical information (e.g. the notified body's certificate of conformity) and a copy of the declaration of conformity at the disposal of the surveillance authorities	• carries out the appropriate examinations and tests in order to check the conformity of the product with the applicable requirements either by examination and testing of every product, or by examination and testing of products on a statistical basis • supervises the affixing of its identification number • draws up a certificate of conformity relating to the tests carried out • if a lot is rejected, takes appropriate measures to prevent the putting on the market of that lot • keeps a record of relevant technical information • communicates to the other notified bodies relevant information (on request)

Module	Manufacturer	Manufacturer or the authorised representative	Notified body
F*bis*	• establishes a technical documentation as regards the design, manufacture and operation of the product • takes all measures necessary to ensure that the manufacturing process assures conformity of the products with the applicable requirements (i.e. operates a quality system) Where the statistical verification is used: • presents the products in the form of homogeneous lots and takes all measures necessary in order that the manufacturing process assures the homogeneity of each lot produced	• applies for certification of conformity • checks and attests that the products satisfy the applicable requirements • affixes the CE marking to each product • affixes the notified body's identification number to follow the CE marking • draws up a declaration of conformity • keeps a copy of the declaration of conformity, the technical documentation and the notified body's certificate of conformity at the disposal of the surveillance authorities	As in module F
G	• establishes a technical documentation as regards the design, manufacture and operation of the product • ensures and declares that the product concerned conforms to the applicable requirements	• applies for certification of conformity • affixes the CE marking to each product • affixes the notified body's identification number to follow the CE marking • draws up a declaration of conformity • keeps a copy of the declaration of conformity and the technical documentation at the disposal of the surveillance authorities	• examines the individual product, and carries out the appropriate tests to ensure its conformity with the relevant requirements • supervises the affixing of its identification number • keeps a record of relevant information • draws up a certificate of conformity concerning the tests carried out • communicates to the other notified bodies relevant information (on request)
H	• operates an approved quality system for design, manufacture, final product inspection and testing, which includes the drawing up of a technical documentation (i.e. relevant information for the design, the product category envisaged, documentation concerning the quality system and its updating, and the decisions and reports from a notified body) • applies for the assessment of the quality system for the products concerned • ensures and declares that the products concerned satisfy the applicable requirements • undertakes to fulfil the obligations arising out of the approved quality system and upholds it so that it remains adequate and efficient • supports the action carried out by the notified body for surveillance purpose • keeps at the disposal of the surveillance authority the documentation concerning the quality system, details of any updating of the quality system, the decisions and reports of the notified body	As in module D	As in module D

Module	Manufacturer	Manufacturer or the authorised representative	Notified body
Hbis	In addition to responsibilities as in module H: • applies for examination of the design • informs the notified body of any modification to the approved design	As in module D	In addition to responsibilities as in module D: • examines the application • issues an EC design examination certificate, if the design meets the applicable provisions • keeps a record of the EC design examination certificates and the EC design approvals • communicates to the other notified bodies relevant information concerning the EC design examination certificates and the EC design approvals (on request)

APPENDIX F: MODEL SUPPLIER'S DECLARATION OF CONFORMITY

MODEL EC DECLARATION OF CONFORMITY

The manufacturer or his authorized representative established in Community (1)
.....

declares that the new PPE described hereafter (2)
.....

is in conformity with the provisions of Council Directive 89/686/EEC and, where such is the case, with the national standard transposing harmonized standard No ..... (for the PPE referred to in article 8 (3)) is identical to the PPE which is the subject of EC certificate of conformity No..... issued by (3)(4).....

.....
is subject to the procedure set out in article 11 point A or point B (4) of Directive 89/686/EEC under the supervision of the notified body(3)

.....

Done at ....., on .....
Signature (5)

(1) Business name and full address; authorized representatives must also give the business name and address of the manufacturer.
(2) Description of the PPE (make, type, serial number, etc.).
(3) Name and address of the approved body.
(4) Delete whichever is inapplicable.
(5) Name and position of the person empowered to sign n behalf of the manufacturer or his authorized representative.

APPENDIX G: RAPEX RISK ASSESSMENT TOOL

RAPEX Risk Assessment Steps[1]

1. **Describe the product and its hazard.**

   - Describe the product unambiguously; does the hazard concern the entire product or only a (separable) part of the product?
   - Is there only one hazard within the product? Are there several hazards? See table 2 of RAPEX Guidelines.
   - Identify the standard(s) or legislation applicable to the product.

2. **Identify the type of consumer you want to include in your injury scenario with the hazardous product.**

   - Start with the intended user and the intended use of the product for your first injury scenario. Take other consumers (See table 1 in attachment 1 of RAPEX Guidelines) and uses for further scenarios.

3. **Describe an injury scenario in which the product hazard(s) you have selected causes an injury(ies) or adverse health effect(s) to the consumer you selected.**

   - Describe the steps to the injury (ies) clearly and concisely, without exaggerating the details ('shortest path to injury', 'critical path to injury'). If there are several concurrent injuries in your scenario, include them all in that same scenario.
   - When you describe the injury scenario, consider the frequency and duration of use, hazard recognition by the consumer, whether the consumer is vulnerable (in particular children), protective equipment, the consumer's behaviour in the case of an accident, the consumer's cultural background, and other factors that you consider important for the risk assessment.
   - See section 3.3 in attachment 1 and table 2 in attachment 2 of RAPEX Guidelines.

4. **Determine the severity of the injury.**

   - Determine the level of severity (1 to 4) of the injury to the consumer. If the consumer suffers from several injuries in your injury scenario, estimate the severity of all those injuries together.
   - See table 3 in attachment 2 for guidance of RAPEX Guidelines.

5. **Determine the probability of the injury scenario.**

   - Assign a probability to each step of your injury scenario. Multiply the probabilities to calculate the overall probability of your injury scenario.
   - See left-hand side of table 4 in attachment 2 for guidance of RAPEX Guidelines.

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[1] Source: www.oecd.org/sti/consumer/50095691.doc

6. Determine the risk level.

- Combine the severity of the injury and the overall probability of the injury scenario and check the risk level in table 4 in attachment 2 of RAPEX Guidelines.

7. Check whether the risk level is plausible.

- If the risk level does not seem plausible, or if you are uncertain about the severity of injury(ies) or about the probability(ies), move them one level up and down and recalculate the risk. This 'sensitivity analysis' will show you whether the risk changes when your input changes.

- If the risk level remains the same, you can be quite confident of your risk assessment. If it changes easily, you may want to err on the safe side and take the higher risk level as 'the risk' of the consumer product.

- You could also discuss the plausibility of the risk level with experienced colleagues.

8. Develop several injury scenarios to identify the highest risk of the product.

- If your first injury scenario identifies a risk level below the highest risk level set out in these guidelines, and if you think that the product may pose a higher risk than the one identified,

  - Select other consumers (including vulnerable consumers, such as children),
  - Identify other uses (including reasonably foreseeable uses), in order to determine which injury scenario puts the product at its highest risk.

- Please take into account that the highest risk normally refers to a risk of a product that allows for application of the most effective risk management measures. In specific cases, a particular hazard may lead to a less-than-highest risk and require specific risk management measures.

- As a rule of thumb, injury scenarios may lead to the highest risk level set out in these guidelines where:

  - The injury(ies) considered are at least at levels 3 or 4,
  - The overall probability of an injury scenario is at least greater than 1/100.

- See table 4 in attachment 4 for guidance of RAPEX Guidelines.

9. Document and pass on your risk assessment.

- Be transparent and also set out all the uncertainties that you encountered when making your risk assessment.

- Examples for reporting risk assessments are provided in section 6 of attachment 1 of RAPEX Guidelines.