

SAFETY GUIDELINES ON PERSONAL PROTECTIVE EQUIPMENT [PPE]

INTRODUCTION AND BACKGROUND

The EC Directive 89/686/EEC on the approximation of the laws of Member States relating to personal protective equipment was adopted by the Council on 21 December 1989.

Failure to comply with these Regulations may mean that PPE may be prohibited from being placed on the Community /European Economic Area (EEA)* market. If previously placed on the market and non-compliant, PPE may be forfeited. PPE complying with the PPE Directive's requirements may be supplied anywhere in the EEA.

'New Approach' Directives (that is Community laws) set out 'essential requirements' (for safety, for example), written in general terms, which must be met before products may be supplied in the Community. European harmonised standards then fill in the detail. Conformity with such standards is the main way for businesses to comply with the 'essential requirements'. The Directives also say how manufacturers are to show that products meet the 'essential requirements'. Products meeting these requirements carry CE marking, which means that they can be sold anywhere in the Community.

APPLICATION

The law applies to any device or appliance designed to be worn or held by an individual for protection against one or more health and safety hazards.

EXAMPLES OF PPE PRODUCTS COVERED



Safety helmets



Respirators



Ear defenders



Welding masks



Knee pads



Face masks



Protective footwear



Protective gloves

LATVIAN LAW

The safety of personal protective equipment is controlled in Latvia by the following legislation:

- **Consumer Rights Protection Law, 1999**
- **Law on the Safety of Goods and Services, 2004**
- **Cabinet Regulation No 74 – Requirements for Personal Protective Equipment, Conformity Assessment and Market Surveillance, adopted 11th Feb 2003**

This legislation has transposed the requirements of the relevant European Directive into Latvian law. Producers, importers, distributors and suppliers must ensure that they comply fully with the provisions of their national legislation.

EU DIRECTIVE

Definition of PPE

PPE means any device or appliance designed to be worn or held by an individual for protection against one or more health and safety hazards.

PPE also includes:

- a unit constituted by several devices or appliances which have been integrally combined by the manufacturer for the protection of an individual against one or more potentially simultaneous risks;
- a protective device or appliance combined, separably or inseparably, with personal non-protective equipment worn or held by an individual for the execution of a specific activity;
- interchangeable PPE components which are essential to its satisfactory functioning and used exclusively for such equipment.

Any system placed on the market in conjunction with PPE for its connection to another external, additional device is to be regarded as an integral part of that equipment even if the system is not intended to be worn or held permanently by the user for the entire period of risk exposure.

Exclusions

- PPE manufactured for use in a country outside the Community, or imported into the Community for re-export to a country outside the Community.
- Non-compliant PPE for presentation at trade fairs, exhibitions and the like, provided that an appropriate notice is displayed drawing attention to the fact that-
 - the PPE is not in conformity with the provisions of the Directive; and
 - it may not be acquired or used until it has been brought into conformity by the manufacturer or his authorised representative established in the Community.

- PPE designed and manufactured specifically for use by the armed forces or in the maintenance of law and order (helmets)
- PPE for self-defence (e.g. aerosol canisters, personal deterrent weapons etc).
- PPE designed and manufactured for private use against adverse weather; damp and water; and heat.
- PPE intended for the protection or rescue of persons on vessels or aircraft, not worn all the time.
- Helmets and visors intended for users of two or three-wheeled motor vehicles.
- Second-hand PPE, except for that which, since its last use, has been subjected to further manufacture or refurbished and resold as new PPE.

HARMONISED STANDARDS

European harmonised standards are European standards outlining technical specifications which are adopted by CEN and thus through agreement by all members. The references of these are required to be published in the Official Journal of the European Union in order to provide for a presumption of conformity.

PRODUCT CATEGORISATION

The Directive provides exclusive lists of 'simple' and 'complex' design PPE. The responsibility for deciding whether a product is covered by the Directive and if so, to which category that PPE belongs rests with the manufacturer or his authorised representative in the Community.

'SIMPLE' DESIGN PPE

The Directive defines 'simple PPE' (Category I PPE) as PPE models of simple design where the designer assumes that the user can himself 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. This category shall cover exclusively PPE intended to protect the wearer against:

- mechanical action whose effects are superficial (gardening gloves, thimbles)
- cleaning materials of weak action and easily reversible effects (gloves affording protection against diluted detergents)
- 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 (headgear, seasonal clothing, footwear)
- minor impacts and vibrations etc which do not affect vital areas of the body and whose effects cannot cause irreversible lesions (light anti-scalping helmets, gloves, light footwear)
- sunlight (sunglasses). However, this does not include PPE used for high reflecting environment or in altitude.

'COMPLEX' DESIGN PPE

The directive defines 'complex PPE' (Category III PPE) as PPE of complex design intended to protect against mortal danger, or against dangers that may seriously and irreversibly harm health, the immediate effects of which the designer assumes that the user cannot identify in sufficient time. This category shall cover exclusively:

- 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 characterised 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
- PPE to protect against electrical risks and dangerous voltages or that used as insulation in high-tension work.

'INTERMEDIATE' DESIGN PPE

This category includes all models of PPE which are neither covered by the simple design category nor the complex design category (Category II requirements)

Because of uncertainties about the scope of the 'simple' and 'complex' categories of the Directive and the categorisation of products covered by it not only within, but also between, the Member States, the Commission has prepared guidance which is published on their website

http://europa.eu.int/comm/enterprise/mechan_equipment/ppe/index.htm.

One section of this guidance involves clarification of PPE categories as set out in the Directive and matters of interpretation of the Directive. This guidance has been a result of work done by the PPE Standing Committee

GENERAL DUTIES OF MANUFACTURERS, IMPORTERS AND OTHERS

Under the Directive, the onus to comply lies with

- the manufacturer,
- his authorised representative established in the EU (where the manufacturer has appointed such a representative) or,
- the importer responsible for first placing the PPE on the Community market.

The Directive also requires that any person who supplies PPE must ensure that it is safe. The various duties placed on each of these parties are set out below.

The **manufacturer** decides, in the light of all the information available to him, whether the products he manufactures fall within the scope of the Regulations and if so, to which category they fall (i.e. 'complex' design, 'simple' design or 'intermediate'). He must ensure that PPE satisfies the essential health and safety requirements as set out in the Directive. He should then follow the appropriate conformity assessment procedures.

The **manufacturer's authorised representative** (where such a representative exists) is responsible for ensuring that the above-mentioned conformity assessment procedures are carried out fully and correctly, on the manufacturer's behalf.

The **importer** should ensure that all PPE which he brings directly into the European Community, with a view to placing it on the Community market, has been manufactured in accordance with the Directives' requirements and bears the CE marking. This may involve the importer himself arranging for the conformity assessment procedures mentioned above to be undertaken, where this has not been done previously.

All **other suppliers**, i.e. wholesalers, distributors, retailers etc., in the course of a business have a statutory duty to ensure that the equipment that they supply satisfies the safety requirements of the Directive and bears CE marking.

CONFORMITY ASSESSMENT PROCEDURES

The appropriate conformity procedures must be determined in accordance with the PPE category. For simple, complex and intermediate categories of PPE the manufacturer or his authorised representative must draw up technical documentation.

TECHNICAL FILES

It should include the following

- description of and/or sample of the PPE to which the file relates
- list of the basic health and safety requirements relating to the PPE in question and the means used to satisfy these requirements, including: details of any harmonised European standards employed, in full or in part, in the PPE's manufacture
- details of any other national or other standards, or recognised specifications, employed in full or in part in the PPE's manufacture
- any other technical specifications taken into account
- performance characteristics and details of intended use

In case of PPE of other than of 'simple' design, this documentation must also contain

- the manufacturer's technical file comprising of overall and detailed plans of the PPE in question, together with, where appropriate particulars of the calculations employed in the design of the PPE
- the results of the tests of any prototype of the PPE in question, which are necessary to verify its compliance with the relevant basic health and safety requirements
- a description of the control and test facilities used in the manufacturer's plant to check compliance of PPE units with the relevant national standards, or other relevant technical specifications and to maintain the quality of production

ADDITIONAL CONFORMITY ASSESSMENT PROCEDURES

In addition, for respective categories of PPE the following procedures must be applied:

NOTIFIED BODIES

Notified Bodies are appointed by a member state to carry out one or more of the conformity assessment procedures. The name of any such body and the scope of its approval will be notified to the Commission and other member states. Each body is assigned a unique identification number and the details published in the Official Journal.

EC TYPE APPROVAL

PPE of 'intermediate' and 'complex' design, submit the product for EC type examination procedure to a Notified Body.

The application should be accompanied by an appropriate number of specimens of the PPE to which the application relates and include the following details

- the name and address of the manufacturer or where the application is made by an authorised representative, his name and address
- details of the manufacturing site which will produce the PPE to which the application relates
- the manufacturer's technical file

Unless the approved body agrees beforehand, all documentation should be in the official language(s) of the Member State in which that approved body is established. The approved body will examine the manufacturer's technical file to establish that the relevant harmonised European standards and/or technical specifications applied to the PPE are suitable for demonstrating its compliance with the relevant basic health & safety requirements.

It will then instigate appropriate examinations and tests of the specimens provided, to establish their conformity with the technical file.

If the approved body is satisfied that the PPE specimens provided meet fully the appropriate requirements of the Regulations, it will prepare an EC type-examination certificate which it will issue to the applicant. That certificate will reproduce the findings of the examinations and tests, specify any conditions attaching to its issue and incorporate descriptions and drawings necessary for the identification of the approved PPE.

QUALITY CONTROL PROCEDURES

For complex PPE the manufacturer must apply one of the two procedures. This is to ensure that PPE affording protection against mortal danger, or against dangers that may seriously and irreversibly harm the health, continue to be manufactured in such a way as to ensure conformance with the pre-production PPE which successfully passed the EC type-examination.

EC QUALITY CONTROL SYSTEM FOR THE FINAL PRODUCT

Under this system the manufacturer appoints an approved body (not necessarily the same body that carried out the EC type-examination) which will, at least once a year, make all checks necessary to assure itself that the PPE being manufactured:-

- is homogenous,
- conforms with the pre-production PPE for which an EC type examination certificate has been issued,
- meets the relevant basic health and safety requirements of the Directive.

To achieve this, the approved body will select at random, adequate samples of the manufactured PPE and instigate any appropriate tests as may be necessary. It is anticipated that these tests are likely to mirror those conducted under the original EC type- examination.

Where the approved body is not that which issued the relevant EC type-examination certificate, it should be able to identify and consult the issuing body. The manufacturer will be provided with a report of the approved body's investigations and conclusions. If the approved body concludes in this report that it has not been able to satisfy itself that the PPE tested by it fully meets the requirements of the relevant EC type-examination certificate, it will write to the authorities informing them of those findings and consider whether it should revoke that certificate. If it is not the body which issued that certificate, it is required to notify the issuing body of its findings. Upon receipt of such notification the body which issued the original certificate will itself consider revoking the certificate.

SYSTEM FOR ENSURING EC QUALITY OF PRODUCTION BY MEANS OF MONITORING

This system requires the manufacturer to check each item of PPE having had his quality control system approved and periodically audited by a suitably qualified approved body. Whilst it is not a requirement of the Directive, the Commission is generally of the opinion that a quality control system that has been certified as conforming to EN/ISO 9001 may be presumed to meet the requirements for such a system.

APPROVAL OF THE QUALITY CONTROL SYSTEM

This will be undertaken by an approved body of the manufacturer's choice. The manufacturer will provide that body with all relevant information relating to the PPE concerned, including the EC type-examination certificate (together with any documents annexed to it) and the technical file. All relevant information relating to the quality control system shall also be provided, including

- the quality objectives, organisation chart, responsibilities of executives and their powers in respect of product quality
- the checks and tests which the manufacturer requires to be carried out after manufacture;
- the means employed to check the efficient operation of the system.
- its adequacy and efficiency in the manufacture of the PPE concerned.

The approved body will carry out an objective evaluation of the system to ascertain whether it corresponds with the information supplied by the manufacturer pertaining to it and to determine whether the system is such as to ensure that the PPE to be manufactured under it will conform to the PPE approved under the original EC type-examination. The approved body will then provide the manufacturer with a report of its findings and conclusions

If it is satisfied that the system ensures that these requirements are fully met and therefore, that the relevant basic health and safety requirements of the Directive are satisfied, it will approve the system. If it is not so satisfied, it will refuse approval of the system and state its reasons for that decision.

The manufacturer should not make any change to an approved quality control system which would require the information provided to the approved body, about the system in its original application to be amended.

MONITORING OF AN APPROVED QUALITY CONTROL SYSTEM

To ensure that a manufacturer fulfils his obligations under an approved quality control system (including a system which has been modified) the approved body should be able to

- have access to all premises relevant to any investigations necessary for this purpose
- inspect all such premises and things therein
- inspect all documents which are relevant to the investigation including, in particular, those relating to the approved quality control system, technical documentation and quality control manuals.

The approved body will, from time to time, carry out audits to ensure that the manufacturer is maintaining and applying the approved quality control system and provide the manufacturer with an audit report. Unannounced visits to the manufacturer may also be made and a report of any such visit and audit report, if appropriate, shall also be provided to the manufacturer.

EC DECLARATION OF CONFORMITY

For PPE of all categories, the manufacturer or his authorised representative established in the Community must prepare an EC Declaration of Conformity.

CE MARK

Finally they must affix the CE mark to the product. For complex PPE the identification number of the Approved Body involved in the production control phase should be indicated alongside the CE mark.

EXAMPLES OF RECENT RAPEX NOTIFICATIONS OF PRODUCTS THAT FAIL TO MEET THE ESSENTIAL SAFETY REQUIREMENTS OF THE PERSONAL PROTECTIVE EQUIPMENT DIRECTIVE

Helmet for cyclists and users of skateboards and roller blades



There is a risk of injuries because:

- ✦ the helmet is assembled incorrectly
- ✦ the helmet has sharp edges,
- ✦ the protective tape used to fix the upper and lower half of the plastic shield is attached incorrectly and prevents the user from correctly positioning the helmet,
- ✦ the retention system on the helmet does not withstand shock as required by the Standard as the retention system clip could break and the helmet come off,
- ✦ it is possible to open the release system with one hand, and the retention system clip can be broken.

The product does not comply with the relevant European standard EN 1078.

Carabineer



The product poses a risk of injuries because it does not withstand the static strength test which could lead to falls. The test was carried out on the major axis, and it was noted that the connectors break when the following forces are applied:

- ✦ force of the major axis with open gate pen: 6.1 KN (required level: 7 KN)
- ✦ force of the major axis with the gate closed: 18.6 KN (required level: 22 KN)

Sunglasses



The product poses a risk of injuries because there is no warnings "not suitable for directly viewing the sun" or "not suitable for drivers and road users".

These sunglasses are not suitable for drivers and road users given the risk of confusion of the colours of traffic lights.

Consumers are not informed of this restriction on their use.

The product does not comply with the relevant European standard EN 1836.

Motorcycle jacket



The product poses a risk of injuries because after a series of three impacts, each one the equivalent of 50 Joule, the average force registered under the anvil is much higher than the maximum permissible limit (a maximum of 24770N for 18000N). The back protection even cracked after the third impact, therefore making it impossible to carry out all five impact tests required by the standard.

The product does not comply with the relevant European standard EN 1621.

Welding mask with automatic protective filter



When the welding arc is ignited, the filter switches its protection stage automatically from low (bright state) to high (dark state).

There is a risk of damage to the sight of the user because it does not provide protection from 3 spectral light transmission. In addition the instructions for use are incomplete.

The product does not comply with the relevant European standards EN 379, EN 166 and EN 175.

Safety vest for horse riders



The product poses a risk of injuries because of too little shock absorbing material.

The product does not comply with the relevant European standard EN 13158.

MODEL EC DECLARATION OF CONFORMITY

The manufacturer or his authorised representative established in the
Community.....
declares that the new PPE described hereafter

.....
.....
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.....

.....
.....
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 approved body (3).....

Done

at,on

..... Signature

Note:

1. The business name must be name and full address of manufacturer
2. Description of PPE (make, type, serial number)
3. Name and address of the Notified Body
4. Name and position of person empowered to sign on behalf of the manufacturer or his authorised representative

SOURCES OF FURTHER INFORMATION

Europa website for PPE

http://europa.eu.int/comm/enterprise/mechan_equipment/ppe/index.htm

Guidance on applying the PPE Directive

http://ec.europa.eu/enterprise/mechan_equipment/ppe/guide.htm

List of Harmonised Standards for PPE (in Latvian)

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2008:156:0001:0027:LV:PDF>

Directive 89/686/EEC

http://ec.europa.eu/enterprise/mechan_equipment/ppe/dir89-686.htm

List of Notified Bodies

http://ec.europa.eu/enterprise/mechan_equipment/ppe/nb.htm

Useful Contact Points

http://ec.europa.eu/enterprise/mechan_equipment/ppe/contactpoint.htm

RAPEX Notifications

http://ec.europa.eu/consumers/dyna/rapex/rapex_archives_en.cfm

Cabinet Regulation No 74 – Requirements for Personal Protective Equipment, Conformity Assessment and Market Surveillance, adopted 11th Feb 2003