

"QUESTIONS AND ANSWERS" - A COMPILATION OF POSITIONS RELATING TO THE IMPLEMENTATION OF DIRECTIVE 89/686/EEC (PPE).

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Q.0 To be or not to be a 'PPE'?

A.0 The [table](#) lists products and the opinion of the PPE Expert Group as to them falling under the PPE Directive or not

Q.1 *The text of the original question and answer has been extended following the consultative meeting with the Group of PPE- Experts, Brussels, 5- 6/12/2000*

Scope of the Directive 89/686/EEC regarding motorcyclists' garment and additional protection features?

A.1 As far as protective clothing (including gloves and boots, etc.) shelters from climate conditions such as heat, cold and humidity it is an object for private use. As such it does not fall under the scope of the PPE Directive (Annex I .3, 89/686/EEC).

If a manufacturer explicitly claims, or implies in sale literature and /or advertisement, that a garment offers protection because of specific additional features, these additional features shall be qualified as "PPE". As such they must comply with the provisions of the PPE Directive. The specific features may materialise in e.g. impact protectors for limb and/or back, pads for elbow and /or shoulder and protection from cuts and abrasions (not exclusive listing of examples).

It follows that protectors to be placed in non-protective garments are PPE: the manufacturer has to provide the

		information related to the PPE as specified in the Directive together with the garment. For these protectors, as for any other detachable PPE, the information about the correct way of placing, fixing and detaching these PPE must be given by the manufacturer.
Q.2	<i>(Room for future question)</i>	
Q.3	<i>(Room for future question)</i>	
Q.4	What is the certification category for anti-vibration equipment?	A.4 Equipment designed and manufactured to protect against vibration is not specifically mentioned in Article 8(3) or (4) and is therefore covered by category II.
Q.5	What is the certification category for shoes protecting against static electricity?	A.5 Shoes designed and manufactured to protect against static electricity are category II items of PPE due to the fact that they are worn in an environment with potential risks of explosion.
Q.6	<i>(Room for future question)</i>	A.6
Q.7	Does the directive cover products designed and manufactured for the firefighters, or are they excluded from it because used for military or police purposes ?	<p>A.7 The firefighters are never considered as “armed or police forces”; the equipment they use are PPE with regard to the directive. Depending on their nature, they have to be considered as category II or III.</p> <p>Note : this answer is very general and excludes all exceptions; for instance, the equipment used by the firefighters from Paris or by the sailors firefighters from Marseille have to be conform with the directive 89/686/EEC, even if both bodies belong directly to the French Ministry of Defence.</p> <p>[See also the answer given by Mr. Bangemann on behalf of the Commission the 1st of July 1996 to the written question E-1173/96 of Mr. Gerhard Schmid].</p>
Q.8	If an optometrist or optician assembles a pair of plano sunglasses with an additional protective feature (other than against the sun), which procedure must he or she follow ?	A.8 If plano sunglasses are used for other type of protection (impact protection, lasers, heat...) the assembly, i.e. glasses + frame, should follow the procedures indicated in the directive for the corresponding category of risk involved.
Q.9	If an optometrist or optician assembles a frame and plano lenses and if he or she tints the lenses to create a pair of sunglasses, which procedure must he or she follow ?	A.9 After glasses are tinted, the assembly is considered as a pair of sunglasses; If the protection provided is against sunlight, the assembly is considered in category I.

<p>Q.10 If an optometrist or optician creates a pair of plano sunglasses using a non-CE marked frame and/or non CE-marked lenses provided by the patient, which procedure must he or she follow ?</p>	<p>A.10 The assembler must make an EC declaration of conformity (Annex VI of the PPE directive). Since the assembly is sunglasses, it shall be in category I.</p>
<p>Q.11 In the case of PPE consisting of a combination of several items, what is the notified body responsible for conducting the EC type-examination required to check?</p>	<p>A.11 The notified body must check that all the essential health and safety requirements have been correctly applied for those items covered by categories II and III and for the whole combination. For this purpose, it does not need to repeat the tests already carried out by a notified body or tests recognised by a notified body. Moreover, with regard to Articles 11A and 11B, it is not required to test performance except for those parts directly covered by category III.</p>
<p>Q.12 What view should be taken of lumbar supports and arm supports used to protect the back or joints when carrying out strenuous tasks?</p>	<p>A.12 These items are for medical use and so do not come under the Directive.</p>
<p>Q.13 How can the ambiguity between respirators (face masks) worn for comfort and protective respirators be removed?</p>	<p>A.13 Protective respirators (face masks), however they are described, which are intended to protect the wearer are covered by the Directive on PPE and must therefore meet all the essential health and safety requirements set out in the Directive which apply to them.</p>
<p>Q.14 Should emergency parachutes be classed as "equipment for protection against falls from a height"?</p>	<p>A.14 No. The Directive stipulates that such equipment must be attached to a reliable anchorage point. Emergency and other parachutes, hang-gliders, etc., are not PPE.</p>
<p>Q.15 Are crampons, ropes and other equipment used to get out of the water after falling through ice PPE?</p>	<p>A.15 This equipment is designed to protect the user from drowning in the event of falling through ice. It is category II PPE.</p>
<p>Q.16 Should bullet-proof clothes or jackets for security guards be regarded as PPE?</p>	<p>A.16 These are items of protective clothing and therefore category II PPE. They are not covered by the exclusion relating to the armed forces or forces of law and order. Only bullet-proof clothing and jackets specifically designed for the said forces are excluded from the scope of the Directive.</p>
<p>Q.17 How to proceed legally, technically and in practice to assess the conformity with the PPE Directive of protective</p>	<p>A.17 (1) Legally – On the basis of the PPE categorisation document, these products are classified in the category corresponding to the specific risk involved (EC type</p>

glasses with corrective functions?

examination). Only the elements relating to protection must be taken into account when applying Directive 89/686/EEC. For this purpose reference may be made to the appropriate specifications and test methods indicated in the EN and prEN standards prepared by CEN/TC 85 "Equipment for eye protection".

- The corrective aspects are covered by Directive 93/42/EEC on medical devices, and must be certified on the basis of a declaration of conformity with reference to the essential requirements of that Directive and to the specifications of CEN/TC 170.
- The complete spectacle intended as a Personal Protective Equipment requires conformity with the PPE Directive before the manufacturer can apply the CE marking to the product and draw up and sign an EC declaration of conformity.

(2) Technically

Broadly speaking, a single model of frame can give rise to a wide range of frame/lens combinations, depending on the frame itself (colour, size) and the type of lens (materials, corrective values, inter-axis distance, size). To perform the EC type examination it is neither possible nor necessary to test all potential combinations. Since tests on a statistical sample would produce only an average production value, unsatisfactory in terms of safety assessment, the EC type examination should test the safety features of the most critical combinations.

(3) In practice

When the manufacturer supplies a finished product he is responsible for both CE marking and declaration of conformity.

When the manufacturer supplies products which require further processing, frames and lenses are considered as interchangeable components within the meaning of Article 1(2,c) of the Directive.

Frame and lenses, including uncut lenses, may therefore be certified separately as PPE.

The optician may make the final assembly of the separately certified products without having to submit such a final assembly to additional tests by a notified body provided both following conditions are met :

a) the assembled spectacle is covered within the ranges of lens and frame specifications for which an EC certification of the complete spectacle has been issued.

b) the optician does not perform operations which significantly alter the safety properties of

the product (e.g. thermal soaking of lenses to provide additional shock resistance)

In such a case CE-marking of frames and lenses (even unfinished glass) is carried out by the manufacturers of these components and not by the optician. The optician delivers a document indicating the origin and the conformity of the frames and lenses.

If both conditions 3a) and 3b) above are not met, the optician is considered to be the manufacturer and is submitted to all the obligations of the manufacturer as set out in the Directive.

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Q.18 What is the certification category for diving suits?

A.18 They belong in category II.

They cannot be considered as:

- "protection against atmospheric agents of a neither exceptional nor extreme nature, for professional use" classified as category I, or
- clothing for "use in low-temperature environments the effects of which are comparable to those of an air temperature of -50°C or less" classified as category III.

Q.19 Should rope clamps be classed as PPE?

A.19 A rope clamp is a mechanical device which, when attached to a rope or an accessory cord of appropriate diameter, will lock under load in one direction and slip freely in the opposite direction. Whilst they do not provide absolute protection, rope clamps improve safety, in particular when abseiling. Rope clamps must be classified as PPE.

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Q.20 Should buoyancy aids used for learning and training in swimming, such as foam boards, floating belts, pull-buoys, etc be classed as PPE?

A.20 Buoyancy aids, including those used when learning swimming, are classed as PPE only if they are to be worn by the user, conceived so as to stay in place in the correct position on the user's body during the foreseeable period of use while providing proper safety. Consequently, foam boards, for example, are not PPE because those devices are held, not worn. "Tyre type" buoys are not truly worn and cannot be maintained in place. Current floating belts, because they do not give positive support to the upper part of the body and because their correct positioning is both difficult to ascertain and maintain, are not PPE. Swimming-suits with incorporated floats are dealt with in question 28.

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<p>Q.21 Should the notified body carrying out EC type-examination verify the information drawn up by the manufacturer and supplied with the equipment?</p>	<p>A.21 Article 10(4) does not specifically mention verification of the information drawn up by the manufacturer and supplied with the equipment. EC type-examination comprises examination of the technical file (which does not include the information supplied with the equipment, see Annex III) and of the model (type). However, when examining the model submitted for EC type-examination, the notified body must check that the model can be used safely in accordance with its intended purpose. To do so, the body must check the information referred to in Annex II, point 1.4, which includes instructions for installation, use, etc.</p> <p>The information supplied with the equipment must be submitted to the notified body together with the technical file and the model of the equipment.</p>
<p>Q.22 (Room for future question)</p>	
<p>Q.23 Should rescue equipment be regarded as PPE?</p>	<p>A.23 If the equipment is worn <i>before</i> the accident which prompts the rescue, it is PPE and covered by the Directive. If the rescuer places it on the person requiring rescue <i>after</i> the accident occurs, it is not. For instance, a wet suit worn continuously to prevent hypothermia in the event of falling into water is PPE. A sling used to rescue an unconscious person from an inaccessible spot is not.</p>
<p>Q.24 Are protective clothes for water-skiing PPE ?</p>	<p>A.24 PPE must correspond to the definitions of Article 1 of Directive 89 / 686/EEC and insure an adequate protection against incurred risks (Annex II, 1). Wearing a protective garment for water-skiing protects against risks aimed at Appendix II, section 3.1, notably against mechanical shocks. PPE definition criteria are thus respected.</p>
<p>Q.25 Are resuscitation masks PPE?</p>	<p>A.25 If one considers that resuscitation masks are first held in hand by the rescuer, then maintained on the mouth of the victim, then the question is to know if the equipment is both functional and protective. Resuscitation masks must protect a rescuer practising mouth-to-mouth resuscitation from contagion, by contact with the mouth of the victim and via the respiratory tracts, while allowing adequate artificial breathing (air must pass through towards the victim). A resuscitation masks presenting this double feature is a PPE.</p>
<p>Q.26 (Room for future question)</p>	<p>A.26</p>

<p>Q.27 Which references are to be used when there are no standards?</p>	<p>A.27 In every case, whether a harmonised standard exists or not, it is the requirements of the directive which must be satisfied. Respecting a harmonised standard gives only an assumption of conformity to the directive. Other standards than harmonised standards do not give a presumption of conformity but may provide usable references. When harmonised standards are lacking, other standards, the state of the art, pertinent technical documentation or analogies with regard to equipment for which a standard exists provide useful references on how to demonstrate respect of the essential requirements.</p>
<p>Q.28 Are swimming-suits with incorporated floats PPE ?</p>	<p>A.28 Swimming-suits with incorporated floats are PPE. It follows that such products which would not be admitted as PPE cannot be sold under whichever denomination (for example toys, novelty or textile products). They must in all cases be submitted to Notified Bodies for approval as PPE.</p> <p>Special attention will have to be given by both manufacturers and Notified Bodies to the risks deriving from a high centre of gravity of young children.</p> <p>Notified bodies will have to check on a case-by-case basis whether the safety properties of the submitted swimming-suits with floats give sufficient warranties to allow their being put on the market. In this case in particular, safety properties are to be understood in the broadest sense, as the intrinsic qualities and accompanying elements which make a safe intended use possible and restrict to the maximum extent possible unsafe use. They include conception, manufacture, instruction notice with gravity centre diagram, safety warning labelled on the product.</p> <p>Approval date: 03/2000</p>
<p>Q.29 Does the PPE directive impose that the pictograms illustrating the scope of risks to be covered be marked on the PPE itself?</p>	<p>A.29 No. Annex II point 2.12 only specifies under which conditions the use of pictograms on the PPE is allowable.</p> <p>Approval date : 10/2001</p>
<p>Q.30 Under which conditions can a refurbished PPE to be placed on the market be certified when this refurbished PPE corresponds to an approved type?</p>	<p>A.30 A refurbished or modernised equipment, whether or not it includes new parts, is to be considered as a new PPE. As such it must be compliant with the Directive. For PPE of category 2, no extra controls than those necessary for the type-examination are required. For PPE of category 3, the Notified body must be informed that refurbishing has been used in the production. In both cases, by CE marking its products, the manufacturer will be declaring the equipment is compliant.</p> <p>Approval date: 10/2001</p>

<p>Q.31 Does the release of a revised harmonised standard imply the withdrawal of the presumption of conformity of PPE built under the old standard?</p>	<p>A.31 Under elaboration.</p>
<p>Q.32 How does a manufacturer have to handle the case of minor changes that do not alter the performances of the PPE as to its health and safety characteristics?</p>	<p>A.32 When minor changes do not alter the health and safety characteristics of PPE, this should be declared in writing by the manufacturer to the Notified Body together with a technical documentation of the changes and a request for extension. The Notified Body may request an adequate sample of the modified PPE to be checked against the original type.</p>
<p>Q.33 How can a manufacturer satisfy the demand for special PPE when the limited quantities to be produced do not cover the cost of an approval?</p>	<p>A.33 PPE produced in small series that :</p> <ol style="list-style-type: none"> 1) are submitted to an examination by a Notified Body (cat. 2 and 3) and 2) have to undergo destructive testing <p>should as far as possible be built on the basis of an accepted EC type with variations that do not alter said PPE's safety and health characteristics</p> <p>The delegations agreed with the Commission expressing the view that the reply only provided a partial answer to this issue, but that no more could be done for the time being. This issue should be dealt with in the draft revision of the Directive. The proposed text was agreed with changes (cf. Doc. 2001-10 rev.2).</p>
<p>Q.34 What is the category of gloves protecting against temperatures of more than 50°C and intended for private users?</p>	<p>A.34 Under elaboration.</p>