



Department of Trade and Industry

**The Personal Protective Equipment
(EC Directive) Regulations 1992**

Proposal to Amend the Regulations

A Consultation Document

11 December 2000

URN 00/1450

**PERSONAL PROTECTIVE EQUIPMENT (EC DIRECTIVE) REGULATIONS
1992**

PROPOSAL TO AMEND THE REGULATIONS

A CONSULTATION DOCUMENT

Preface

The Department of Trade and Industry (DTI) would welcome your comments on consideration of a proposal to amend the Personal Protection (EC Directive) Regulations 1992 SI No 1992/3139. (Annex A)

The Personal Protective Equipment (EC Directive) Regulations 1992 ("the Principal Regulations") came into force on 1 January 1993 and have been amended on three separate occasions. The Principal Regulations, as they are currently drafted, do not give Trading Standards Departments powers of prosecution under section 12 of the Consumer Protection Act 1987. At the time the Principal Regulations were made such powers were not considered to be appropriate. Trading Standards Officers at present have powers to warn, prohibit, suspend and (in the most serious cases) forfeit and destroy goods. Trading Standards Departments consider that these powers may be unduly draconian. An additional power to prosecute will provide a less draconian enforcement route than forfeiture of PPE leading to its destruction. It should be noted, however, that in practice the powers of prosecution under section 12 will be the ultimate sanction used by Trading Standards Departments in line with good practice, outlined in the Enforcement Concordat.

In order to extend the Principal Regulations to cover this provision it would be necessary to amend for a fourth time. Rather than issuing a separate amendment, in the interests of providing clear, transparent legislation, it is intended to consolidate the Principal Regulations with the existing amendments and the new enforcement power in new Regulations ("the Consolidated Regulations"). The proposed consolidation does not impose additional costs to legitimate businesses, alter the scope or change the essential requirements of the Principal Regulations in any respect. Once the Consolidated Regulations are brought into force, the Principal Regulations and the three existing amending Regulations will be revoked.

The DTI would be grateful if any comments could, where possible, be co-ordinated through the British Safety Industry Federation in the case of comments from industry and through LACOTS for comments from Trading Standards Departments.

Comments are required by 15 February 2001.

Co-ordinated responses should be sent to Harsha Patel at the address below. However, if e-mail is available then such means are preferred. Further copies of the document can be obtained from the same address.

Harsha Patel
Department of Trade and Industry
STRD 4
321 Red Zone
151 Buckingham Palace Road
London SW1W 9SS

Fax: 020 7215 1529

Email: harsha.patel@dti.gov.uk

It should be noted that replies will be treated as open unless respondents state that they wish them or any part of them (including the identity of the respondent) to be treated as confidential.

Department of Trade and Industry, London

Summary of Proposals

THE DRAFT CONSOLIDATED REGULATIONS APPLY TO CERTAIN PPE (AS DEFINED IN REGULATION 2(2)) AND IMPOSE REQUIREMENTS WHICH MUST BE MET IF SUCH PPE IS PLACED ON THE MARKET OR PUT INTO SERVICE IN THE UNITED KINGDOM. THE CONSOLIDATED REGULATIONS WILL CONSOLIDATE THE PRINCIPAL REGULATIONS, AS AMENDED, WHICH IMPLEMENT DIRECTIVE 89/686 ON THE APPROXIMATION OF LAWS OF MEMBER STATES RELATING TO PPE, AS AMENDED ("THE DIRECTIVE").

CITATION, COMMENCEMENT AND REVOCATION

Regulation 1 identifies the Consolidated Regulations, establishes the date for entry into force and revokes the Principal Regulations and the amending Regulations to the Principal Regulations.

INTERPRETATION

Regulation 2 provides interpretation and definitions necessary for the application of the Consolidated Regulations.

APPLICATION

Regulations 3 and 4 provide for the general application of the Consolidated Regulations and PPE which is excepted from the application of the Consolidated Regulations.

EXCLUDED PPE

Regulation 5 excludes from the scope of the Consolidated Regulations PPE listed therein, as derived from Article 1.4 of the Directive.

PPE PLACED ON THE MARKET BEFORE 1 JULY 1992

Regulation 6 excludes from the scope of the Consolidated Regulations PPE placed on the market before the date of application (1 July 1992).

TRANSITIONAL EXCLUSION

Regulation 7 sets out the transitional arrangements whereby PPE placed on the market or put into service on or before 30 June 1995 is excluded from the scope of the Consolidated Regulations provided that it complies with any safety provisions relating to the placing on the market or putting into service in the UK of that PPE which was in force on 30 June 1992.

GENERAL DUTY OF PLACING ON THE MARKET OF PPE

Regulation 8 places a duty on any “responsible person” (defined in regulation 2(2)) who places on the market or puts into service any PPE to comply with certain requirements, set out in regulation 8(2). These include that PPE must satisfy the relevant basic health and safety requirements which are applicable to that class or type of PPE and the appropriate conformity assessment procedure in accordance with regulation 10.

EXCEPTIONS TO PLACING ON THE MARKET IN RESPECT OF CERTAIN PPE

Regulation 9 provides for exceptions from the duties in regulation 8 for PPE which will be put into service outside the Community or imported into the Community for re-export outside the Community.

CONFORMITY ASSESSMENT PROCEDURES

Regulation 10 sets out the conformity assessment procedures for PPE by reference to Schedules 3, 7, 8 and 9.

CE MARKING

Regulation 11 sets out the requirement for CE marking.

APPROVED BODIES

Regulation 12 describes approved bodies.

APPOINTMENT OF APPROVED BODIES

Regulation 13 provides for the Secretary of State to appoint approved bodies.

FEEES

Regulation 14 provides for approved bodies, subject to certain conditions, to charge fees for carrying out their duties under the Consolidated Regulations.

APPLICATION OF SCHEDULE 10 ON ENFORCEMENT

Regulation 15 provides for enforcement of the Consolidated Regulations by reference to Schedule 10 and also includes a requirement that a warning must be given and the opportunity given to the responsible person to remedy non-conformity before enforcement action is taken.

DEFENCE OF DUE DILIGENCE

Regulation 16 provides for a defence of due diligence.

LIABILITY OF PERSONS OTHER THAN THE PRINCIPAL OFFENDER

Regulation 17 provides for liability of persons other than the principal offender.

SCHEDULES

Schedule 1 lists the PPE not covered by the Directive or the Consolidated Regulations (reproduced from Annex I of the Directive).

Schedule 2 sets out the basic health and safety requirements (reproduced from Annex II of the Directive).

Schedule 3 sets out the technical documentation to be supplied by the manufacturer (reproduced from Annex III of the Directive).

Schedule 4 sets out the CE conformity marking and information required (reproduced from Annex IV of the Directive).

Schedule 5 sets out the model EC declaration of conformity (reproduced from Annex VI of the Directive).

Schedule 6 sets out the requirements of CE marking (reproduced from Article 13 of the Directive).

Schedule 7 sets out the EC type-examination procedure (reproduced from Article 10 of the Directive).

Schedule 8 sets out the required checking of PPE manufactured (reproduced from Article 11 of the Directive).

Schedule 9 sets out the EC declaration of production conformity (reproduced from Article 12 of the Directive).

Schedule 10 sets out the arrangements for enforcement.

Schedule 11 sets out the revoked Regulations.

Supplementary Notes

The following are considered to be particularly worthy of note, consideration or comment:

Regulations 12, 13 and 14 provide clarity on the appointment of approved bodies and the circumstances in which they may charge fees for their services. These regulations reflect in greater detail the existing arrangements in place under the Principal Regulations.

Regulations 16 and 17 provide explicitly for the defence of due diligence and for the liability of persons other than the principal offender.

Schedule 10 provides for the enforcement of the Consolidated Regulations through the application of certain provisions of the Consumer Protection Act 1987 ("the 1987 Act"). The applied provisions of the 1987 Act specify offences and the applicable penalties for those offences. In particular, paragraph 1(c) of Schedule 10 indicates that the Consolidated Regulations shall constitute "safety regulations" within the meaning of section 45(1) of the 1987 Act. This means that the Consolidated Regulations are treated as Regulations made under section 11 of the 1987 Act for the purposes of section 12 of the 1987 Act. This introduces the additional prosecution power. Section 12 indicates where a person is contravening safety regulations it will be an offence and also, at paragraph (5) of that section, that a person guilty of an offence under that section shall be liable on summary conviction to imprisonment for a term not exceeding six months or to a fine not exceeding level 5 on the standard scale or to both.

The technical drawing of the CE marking is not included at present but will be copied from the Directive. We are trying to ensure that a clear and legible drawing is inserted in the published Consolidated Regulations.

DRAFT REGULATIONS

Citation, commencement and revocation

1.-(1) These Regulations may be cited as the Personal Protective Equipment (EC Directive) Regulations [2000] and shall come into force on [].

(2) The Regulations specified in Schedule 11 hereto are hereby revoked with effect from the coming into force of these Regulations.

Interpretation

2.-(1) In these Regulations –

- (a) the “PPE Directive” means Council Directive 89/686/EEC on the approximation of the laws of the Member States relating to personal protective equipment(c);
- (b) except for the references to the European Communities in the definition of “the Commission” and in relation to the Official Journal, a reference to the Community includes a reference to the EEA, and a reference to a member State includes a reference to an EEA State: for this purpose –
 - (i) the “EEA” means the European Economic Area;
 - (ii) an “EEA State” means a State which is a Contracting Party to the EEA Agreement; and
 - (iii) the “EEA Agreement” means the Agreement of the European Economic Area signed at Oporto on 2nd May 1992 as adjusted by the Protocol signed at Brussels on 17th March 1993(a); and
- (c) unless the context otherwise requires, a reference to a numbered regulation or Schedule is a reference to the regulation or Schedule so numbered in these Regulations and a reference –

(c) O.J. No. L399, 30.12.89, p.18, as amended by Directive 93/68/EEC (O.J. No. L 220, 30.8.93, pl), Directive 93/95/EEC (O.J. No. L 276, 9.11.93, pl) and Directive 96/58/EC (O.J. No. L236, 18.9.96, p44).

(a) The PPE Directive was added to Chapter XXII of Annex II to the EEA Agreement by item P in Annex 3 to Decision No.7/94 of the EEA Joint Committee of 21 March 1994 (O.J. No.L160, 28.6.94, pl).

- (i) to a paragraph in a regulation is a reference to a paragraph in that regulation;
- (ii) to an Annex is a reference to an Annex to the PPE Directive: for the purposes of these Regulations, Annexes I, II, III, IV and VI are respectively set out in Schedules 1, 2, 3, 4 and 5;
- (iii) to an Article in these Regulations is a reference to the Article so numbered in the PPE Directive and a reference to a section or paragraph of an Article shall be construed accordingly: for the purposes of these Regulations, Articles 10, 11, 12 and 13 are respectively set out in Schedules 7, 8, 9, and 6;
- (iv) to a section or a paragraph in an Annex is a reference to a section or a paragraph in that Annex as set out in the relevant Schedule; and
- (v) to “the Directive” in an Annex or Article is a reference to the PPE Directive.

(2) In these Regulations, unless the context otherwise requires –

“1987 Act” means the Consumer Protection Act 1987^(a);

“approved body” shall be construed in accordance with regulation 12;

“basic health and safety requirements” means the requirements set out in Schedule 2;

“Contracting Parties” are those States which are contracting parties to the EEA Agreement;

“CE marking” means the CE marking referred to in regulation 11 consisting of the initials “CE” in the form shown in Schedule 4;

“the Commission” means the Commission of the European Communities;

“complex PPE” means 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 the user cannot identify in sufficient time: this category shall cover exclusively –

- (a) filtering respiratory devices for protection against solid and liquid aerosols or irritant, dangerous, toxic or radiotoxic gases;
- (b) respiratory protection devices providing full insulation from the atmosphere, including those for use in diving;

^(a) 1987 c.43.

- (c) PPE providing only limited protection against chemical attack or against ionising radiation;
- (d) 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 which may or may not be characterised by the presence of infra-red radiation, flames or the projection of large amounts of molten materials;
- (e) emergency equipment for use in low temperature environments the effects of which are comparable to those of an air temperature of 150°C or less;
- (f) PPE to protect against falls from a height; and
- (g) PPE to protect against electrical risks and dangerous voltages or that used as insulation in high-tension work;

“enforcement authority” shall be construed in accordance with Schedule 10;

“harmonised standard” means a text containing a technical specification or specifications adopted by either or both of the European Committee for Standardisation and the European Committee for Electrotechnical Standardisation upon a remit from the Commission in accordance with Council Directive 98/34/EC laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on information society services(a);

“placing on the market” includes, except for the purposes of regulation 9, putting into service, and cognate expressions shall be construed accordingly;

“PPE” means –

- (a) any device or appliance designed to be worn or held by an individual for protection against one or more health and safety hazards: and shall also include -
 - (i) 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;
 - (ii) a protective device or appliance combined, separately or inseparably, with personal non-protective equipment worn or held by an individual for the execution of a specific activity; and
 - (iii) interchangeable components which are essential to its satisfactory functioning and used exclusively for such equipment;

“responsible person” means –

(a) O.J. No. L204, 22.6.98 p37 as amended by Council Directive 98/48/EC (O.J. No. L217, 20.7.98, p.18).

- (a) the manufacturer or his authorised representative established within the Community; or
- (b) where neither the manufacturer nor his authorised representative is established within the Community, the person who places the PPE on the market;

“simple PPE” means 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 –

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

“transposed harmonised standard” means a standard, the reference number of which is published –

- (a) in the United Kingdom, by the Secretary of State, in such a manner as he considers appropriate; or
- (b) in another member State of the Community,

and which corresponds to a harmonised standard the reference number of which is published in the Official Journal of the European Communities.

(3) For the purposes of these Regulations, PPE shall not be regarded as having been put into service where a person –

- (a) being a manufacturer of PPE for his own use; or
- (b) having imported PPE from a country or territory outside the Community for

his own use,

puts that PPE into service otherwise than in the course of a business.

Application

3.-(1) Subject to paragraph (2) and regulations 4, 5, 6, and 7, these Regulations shall apply to PPE.

(2) These Regulations shall not apply to PPE which is presented at any trade fair, exhibition, demonstration or the like and which is not in conformity with the provisions of the PPE Directive, provided that a visible sign clearly indicates that the PPE in question does not comply with these provisions and it may not be placed on the market until it has been made to comply with them.

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

Excluded PPE

5. These Regulations shall not apply to PPE which is –

(1) of one of the classes specified in the list of excluded products in Schedule 1; or

(2) within the scope of any directive designed to achieve the same objectives as the PPE Directive with regard to placing on the market, free movement of goods and safety of PPE.

PPE placed on the market before 1 July 1992

6. These Regulations do not apply to any PPE which is placed on the market before 1 July 1992

Transitional Exclusion

7.-(1) These Regulations do not apply to any PPE which was placed on the market on or before 30 June 1995 and which complies with any safety provisions with which it would have been required to comply for it to be placed on the market in the United Kingdom on 30 June 1992.

(2) The exclusion provided in paragraph (1) does not apply in the case of any PPE which –

- (a) unless required to bear the CE marking pursuant to any other Community obligation, bears the CE marking or an inscription liable to be confused therewith; or

- (b) bears or is accompanied by any other indication, howsoever expressed, that it complies with the PPE Directive.

General duty of placing on the market of PPE

8.-(1) Subject to regulation 9, no person who is a responsible person shall place on the market any PPE unless the requirements of paragraph (2) have been complied with in relation thereto.

- (2) The requirements of this paragraph, in respect of any PPE, are that-
 - (a) it satisfies the basic health and safety requirements which are applicable to that class or type of PPE and, for the purpose of satisfying those requirements where a transposed harmonised standard covers one or more of the basic health and safety requirements, PPE which conforms to that standard shall be presumed to comply with that or, as the case may be, those basic health and safety requirements;
 - (b) the appropriate conformity assessment procedure, in accordance with regulation 10, has been carried out –
 - (i) by the manufacturer; or
 - (ii) where permitted by procedure, by the manufacturer's authorised representative established in the Community,

save that where the person placing the PPE on the market is neither the manufacturer nor his authorised representative established in the Community the obligation to retain the technical documentation required by the appropriate conformity assessment procedure shall be fulfilled by the person who places that PPE on the market;

- (c) the CE marking has been affixed to it by the manufacturer or his authorised representative in accordance with regulation 11 and Schedule 4 hereto to indicate that it conforms with all the provisions of the PPE Directive including the appropriate conformity assessment procedure and regulation 11 and Schedule 4 shall have effect for that purpose; and
- (d) when properly maintained and used for its intended purpose it does not compromise the safety of individuals, domestic animals or property.

Exceptions to placing on the market in respect of certain PPE

9. For the purposes of regulation 8, PPE shall not be regarded as being placed on the market where that PPE –

- (a) will be put into service in a country outside the Community; or
- (b) is imported into the Community for re-export to a country outside the Community,

save that this paragraph shall not apply if the CE marking, or any inscription liable to be confused therewith, is affixed thereto.

Conformity assessment procedures

10.-(1) For the purposes of regulation 8(2)(b), the appropriate conformity assessment procedure shall be the assembly of such technical documentation as required under Schedule 3 and in the case of -

- (a) simple PPE, the EC declaration of conformity procedure described in Schedule 9;
- (b) the series production of complex PPE, the EC declaration of conformity procedure described in Schedule 9, the EC type-examination procedure described in Schedule 7 and one of the two checking of PPE manufactured procedures described in Schedule 8; and
- (c) the series production of PPE other than simple PPE or complex PPE, the EC declaration of conformity procedure described in Schedule 9 and EC type-examination procedure described in Schedule 7 .

CE marking

11.-(1) Subject to the following paragraphs of this regulation, PPE which either meets the basic health and safety requirements or is presumed to do so in accordance with regulation 8(2)(a) shall bear the CE marking in a visible, legible and indelible form.

(2) Where the manufacturer or his authorised representative established within the Community is required to affix the CE marking to PPE it shall be affixed in accordance with Schedules 4 and 6.

(3) Subject to paragraph (4), where any PPE is subject to any other directive or directives in addition to the PPE Directive which also provides for the affixing of the CE marking, the CE marking shall indicate that the PPE also fulfils the provisions of that other directive or directives.

(4) Where one or more of the other directives referred to in paragraph (3) allow the manufacturer, during a transitional period, to choose which arrangements apply, the CE marking shall indicate conformity to the provisions only of the directive or directives applied by the manufacturer; and, in this case, the particulars of the directive or directives applied, as published in the Official Journal of the European Communities, must be given in the documents, notices or instructions required by the directive or directives and accompanying the PPE in question.

Approved bodies

12. For the purposes of these Regulations, an approved body is a body which has been –

- (a) appointed as a United Kingdom approved body pursuant to regulation 13; or
- (b) appointed by a member State other than the United Kingdom;

to carry out one or more of the conformity assessment procedures specified in regulation 10 and which has been notified by the United Kingdom or by such other member State, as the case may be, to the Commission and the other member States pursuant to Article 9(1) .

Appointment of approved bodies

13.-(1) The Secretary of State may from time to time appoint such persons as he thinks fit to be approved bodies for the purposes of these Regulations.

(2) Such appointment –

- (a) may relate to all descriptions of product or such descriptions (which may be framed by reference to any circumstances whatsoever) of product as the Secretary of State may from time to time determine;
- (b) may be made subject to such conditions as the Secretary of State may from time to time determine, which may include conditions which are to apply upon or following termination of the appointment;
- (c) shall without prejudice to the generality of sub-paragraph (b) and subject to paragraph (4), require that body to carry out the procedures and specific tasks for which it has been appointed including (where so provided as part of those procedures) surveillance to ensure that the manufacturer duly fulfils the obligations arising out of the relevant conformity assessment procedure;
- (d) shall be terminated upon 6 months notice in writing to the Secretary of State, at the request of the approved body; and
- (e) may be terminated at any time by the Secretary of State if it appears to the Secretary of State that any of the conditions of the appointment are not complied with.

(3) Subject to paragraphs (2)(d) and (e), an appointment under this regulation may be for the time being or for such period as may be specified in the appointment.

(4) An approved body appointed by the Secretary of State shall not be required to carry out the functions referred to in paragraph (2)(c) if –

- (a) the documents subject to it in relation to carrying out such functions are not in English or another language acceptable to that body;
- (b) the person making the application has not submitted with its application the amount of the fee which the body requires to be submitted with the application pursuant to regulation 14 ; or

- (c) the body reasonably believes that, having regard to the number of applications made to it in relation to its appointment under these Regulations which are outstanding, it will be unable to commence the required work within 3 months of receiving the application.

(5) If for any reason the appointment of an approved body is terminated under this regulation, the Secretary of State may –

- (a) give such directions (either to the body the subject of the termination or another approved body) for the purposes of making such arrangements for the determination of outstanding applications as he considers appropriate; and
 - (b) without prejudice to the generality of the foregoing, authorise another approved body to take over its functions in respect of such cases as he may specify.
- (6) If an approved body, to whom an application has been made for an EC type-examination certificate pursuant to the EC type-examination procedure (set out in Schedule 7 hereto), is not satisfied that the requirements for such a certificate are met and refuses to issue an EC type-examination certificate it shall inform all other approved bodies of this.
- (7) If an approved body withdraws an EC type-examination certificate it shall inform the Secretary of State.

Fees

14.-(1) Without prejudice to the power of the Secretary of State, where he is appointed as an approved body in the United Kingdom, to charge fees pursuant to regulations made under section 56 of the Finance Act 1973(a) and subject to paragraph (2), an approved body appointed by the Secretary of State may charge such fees in connection with, or incidental to, carrying out the tasks referred to in regulation [13(2)(c)] as it may determine; provided that such fees shall not exceed the sum of the following-

- (a) the costs incurred or to be incurred by the approved body in performing the relevant function; and
- (b) an amount on account of profit which is reasonable in the circumstances having regard to-
 - (i) the character and extent of the work done or to be done by the body on behalf of the applicant; and
 - (ii) the commercial rate normally charged on account of profit for that work or similar work.

(a) 1973 c.51.

(2) The power in paragraph (1) includes the power to require the payment of fees or a reasonable estimate thereof in advance of carrying out the work requested by the applicant.

Application of Schedule 10 on Enforcement

15.- (1) Subject to paragraph (2), Schedule 10 shall have effect for the purposes of providing for enforcement of these Regulations, and for matters incidental thereto.

(2) Except in the case of PPE which when used in accordance with its intended purpose, in the opinion of an enforcement authority, may endanger the safety of persons and, where appropriate, domestic animals or property, where an enforcement authority has reasonable grounds for suspecting that the CE marking has been affixed to the PPE, or its packaging and in relation to which any provision of these Regulations has not been complied with, it may serve notice in writing on the responsible person and, subject to paragraph (3), no other action pursuant to Schedule 10 may be taken, in respect of that PPE until such notice has been given and the person to whom it is given has failed to comply with its requirements.

(3) Notwithstanding the provisions of paragraph (2), for the purposes of ascertaining whether or not the CE marking has been correctly affixed, action may be taken pursuant to section 20 of the Health and Safety at Work etc Act 1974(a) or, in Northern Ireland pursuant to Article 22 of the Health and Safety at Work (Northern Ireland) Order 1978(b) or section 29 of the 1987 Act (c), as they are applied by Schedule 10.

(4) A notice which is given under paragraph (2) shall -

- (a) state that the enforcement authority suspects that the CE marking has not been correctly affixed to the PPE or its packaging;
- (b) specify the respect in which it is so suspected and give particulars thereof;
- (c) require the person to whom the notice is given;
 - (i) to secure that any PPE to which the notice relates conforms as regards the provisions concerning the correct affixation of the CE marking within such period as may be specified in the notice; or
 - (ii) to provide evidence within that period, to the satisfaction of an enforcement authority, that the CE marking has been correctly affixed; and
- (d) warn that person that if the non-conformity continues after, or if satisfactory evidence has not been provided within, the period specified in the notice,

(a) 1974 c.37.

(b) S.I. 1978/1039 (N.I. 9)

(c) 1987 c.43.

further action may be taken under these Regulations in respect of that PPE or PPE of the same type placed on the market by that person.

Defence of due diligence

16.-(1) Subject to the following provisions of this regulation, in proceedings against any person for an offence under Schedule 10 it shall be a defence for that person to show that he took all reasonable steps and exercised all due diligence to avoid committing the offence.

(2) Where in any proceedings against any person for such an offence the defence provided by paragraph (1) involves an allegation that the commission of the offence was due -

- (a) to the act or default of another; or
- (b) to reliance on information given by another,

that person shall not, without leave of the court, be entitled to rely on the defence unless, not less than seven clear days before the hearing of the proceedings (or, in Scotland, the trial diet), he has served notice under paragraph (3) on the person bringing the proceedings.

(3) A notice under this paragraph shall give such information identifying or assisting in the identification of the persons who committed the act or default or gave the information as is in the possession of the person serving the notice at the time he serves it.

(4) It is hereby declared that a person shall not be entitled to rely on the defence provided by paragraph (1) by reason of his reliance on information supplied by another, unless he shows that it was reasonable in all circumstances for him to have relied on the information, having regard in particular -

- (a) to the steps which he took and those which might reasonably have been taken, for the purposes of verifying the information; and
- (b) to whether he had any reason to disbelieve the information.

Liability of persons other than the principal offender

17.-(1) Where the commission by any person of an offence under Schedule 10 is due to an act or default committed by some other person in the course of any business of his, the other person shall be guilty of the offence and will be proceeded against and punished by virtue of this paragraph whether or not proceedings are taken against the first-mentioned person.

(2) Where a body corporate is guilty of an offence under these Regulations (including where it is so guilty by virtue of paragraph (1)) in respect of any act or default which is shown to have been committed with the consent or connivance of, or

to be attributable to any neglect on the part of, any director, manager, secretary or other similar officer of the body corporate or any person who was purported to act in any such capacity he, as well as the body corporate, shall be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

(3) Where the affairs of a body corporate are managed by members, paragraph (2) shall apply in relation to the acts and defaults of a member in connection with his functions of management as if he were a director of the body corporate.

(4) In this regulation, references to a “body corporate” include references to a partnership in Scotland and, in relation to such partnership, any reference to a director, manager, secretary or other similar officer of a body corporate is a reference to a partner.

ANNEX I

**EXHAUSTIVE LIST OF PPE CLASSES NOT COVERED BY THIS
DIRECTIVE**

1. PPE designed and manufactured specifically for use by the armed forces or in the maintenance of law and order (helmets, shields, etc.).
2. PPE for self-defence (aerosol canisters, personal deterrent weapons, etc.).
3. PPE designed and manufactured for private use against:
 - adverse atmospheric conditions (headgear, seasonal clothing, footwear, umbrellas, etc.),
 - damp and water (dish-washing gloves, etc.),
 - heat (gloves etc.).
4. PPE intended for the protection or rescue of persons on vessels or aircraft, not worn all the time.
5. Helmets and visors intended for users of two- or three-wheeled motor vehicles.

SCHEDULE 2 regulations 2(1)(c)(ii), 2(2), 8(2)(a), 11(1) and Schedule 3(3)

ANNEX II

BASIC HEALTH AND SAFETY REQUIREMENTS

1. GENERAL REQUIREMENTS APPLICABLE TO ALL PPE

PPE must provide adequate protection against all risks encountered.

1.1. Design principles

1.1.1. Ergonomics

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

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.

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.

1.2. **Innocuousness of PPE**

1.2.1. **Absence of risks and other 'inherent' nuisance factors**

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

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.

1.2.1.1. **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.

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 minimised; nor must PPE cause movements which endanger the user or other persons.

1.3. **Comfort and efficiency**

1.3.1. **Adaptation of PPE to 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 of use, bearing in mind ambient factors, movements to be made and postures to be adopted. For this purpose, it must be possible to optimise PPE adaptation to user morphology by all appropriate means, such as adequate adjustment and attachment systems or the provision of an adequate

size range.

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.

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.

1.4. Information supplied by the manufacturer

In addition to the name and address of the manufacturer and/or his authorised 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:

- (a) storage, use, cleaning, maintenance, servicing and disinfecting.
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;
- (b) performance as recorded during technical tests to check the levels or classes of protection provided by the PPE in question;
- (c) suitable PPE accessories and the characteristics of appropriate spare parts;

- (d) the classes of protection appropriate to different levels of risk and the corresponding limits of use;
- (e) the obsolescence deadline or period of obsolescence of PPE or certain of its components;
- (f) the type of packaging suitable for transport;
- (g) the significance of any markings (see 2.12).
- (h) where appropriate, the references of the Directives applied in accordance with Article 5(6)(b);
- (i) the name, address and identification number of the notified body involved in the design stage of the PPE.

These notes, which must be precise and comprehensible, must be provided at least in the official language(s) of the member State of destination.

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.

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 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.

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 minimised. 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.

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 manufacturer 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.

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.

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.

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

These PPE classes must be so designed and manufactured as to minimise 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.

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.

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.

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.

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.

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 harmonised 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.

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.

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.

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.

3.1.2.2. Prevention of falls from a height

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 minimised 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.

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.

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.

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.

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.

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 **(1)**. 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.

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.

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

(1) OJ No L 137, 24.5.1986, p28

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 high-temperature 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.

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.

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.

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).

3.7.2. Complete PPE ready for use

Under the foreseeable conditions of 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 low-temperature environments must provide all relevant data concerning the maximum permissible user exposure to the cold transmitted by the equipment.

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 minimised 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 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.

3.9. Radiation protection

3.9.1. Non-ionising radiation

PPE designed to prevent acute or chronic eye-damage from sources of non-ionising 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 minimised 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.

3.9.2. Ionising 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 leak-tightness can be provided by the impermeability of the protective integument and/or by any other appropriate means, such as ventilation and pressurisation 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.

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.

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 facepiece 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.

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 leak-tightness 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.

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).

SCHEDULE 3

regulations 2(1)(c)(ii), 10(1) and Schedule 7(3)

ANNEX III

TECHNICAL DOCUMENTATION SUPPLIED BY THE MANUFACTURER

The documentation referred to in Article 8(1) must comprise relevant data on the means used by the manufacturer to ensure that a PPE complies with the basic requirements relating to it. In the case of PPE models referred to in Article 8(2), the documentation must comprise in particular:

1. the manufacturer's technical file consisting of:
 - (a) overall and detailed plans of the PPE accompanied, where appropriate, by calculation notes and the results of prototype tests in so far as necessary for the verification of compliance with the basic requirements;
 - (b) an exhaustive list of the basic safety requirements and of the harmonised standards or other technical specifications referred to in Articles 3 and 5, taken into account the design of the model;
2. a description of the control and test facilities to be used in the manufacturer's plant to check compliance of production PPE with the harmonised standards or other technical specifications and to maintain quality level;
3. a copy of the information notice referred to in Annex II, 1.4.

SCHEDULE 4 regulations 2(1)(c)(ii), 2(2), 8(2)(c) and 11(2) and Schedule 6(1)

ANNEX IV

CE CONFORMITY MARKING AND INFORMATION

- The CE conformity marking shall consist of the initials "CE " taking the following form:

- If the CE marking is reduced or enlarged the proportions given in the above graduated drawing must be respected.

- The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm. This minimum dimension may be waived for small-scale PPE.

ANNEX VI

MODEL EC DECLARATION OF CONFORMITY

The manufacturer or his authorised representative established in the Community ⁽¹⁾:

.

.

.

declares that the new PPE described hereafter ⁽¹⁾

.

.

.

.

.

is in conformity with the provisions of Council Directive 89/686/EEC and, where such is the case, with the national standard transposing harmonised standard N° (for the PPE referred to in Article 8 (3))

is identical to the PPE which is the subject of EC certificate of conformity N° 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; authorised 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 on behalf of the manufacturer or his authorised representative.

Article 13

1. The CE conformity marking shall consist of the initials “CE” in the form shown in the specimen in Annex IV. In the event of the involvement of a notified body in the production control phase as indicated in Article 11, its identification number shall be added.
2. The CE marking must be affixed to each piece of manufactured PPE so as to be visible, legible and indelible throughout the expected life of the PPE; however, if this is not possible in view of the characteristics of the product, the CE marking may be affixed to the packaging.
3. The affixing of markings on the PPE which are likely to deceive third parties as to the meaning and form of the CE marking shall be prohibited. Any other marking may be affixed to the PPE or its packaging provided that the visibility and legibility of the CE marking is not thereby reduced.
4. Without prejudice to Article 7:
 - (a) where a Member State establishes that the CE marking has been affixed unduly, the manufacturer or his authorised representative established within the Contracting Parties shall be obliged to make the product conform as regards the provisions concerning the CE marking and to end the infringement under the conditions imposed by the Member State;
 - (b) where non-conformity continues, the Member State must take all appropriate measures to restrict or prohibit the placing on the market of the product in question or to ensure that it is withdrawn from the market in accordance with the procedures laid down in Article 7.

Article 10

1. EC type-examination is the procedure whereby the approved inspection body establishes and certifies that the PPE model in question satisfies the relevant provisions of this Directive.
2. Application for EC type-examination shall be made by the manufacturer or his authorised representative to a single approved inspection body in respect of the model in question. The authorised representative shall be established in the Community.
3. The application shall comprise:
 - the name and address of the manufacturer or his authorised representative and of the PPE production plant in question,
 - the manufacturer's technical file referred to in Annex III.

It shall be accompanied by the appropriate number of specimens of the model to be approved.

4. The inspection body of which notification has been given shall conduct the EC type-examination in accordance with the undermentioned procedures:
 - (a) Examination of the manufacturer's technical file
 - It shall examine the manufacturer's technical file to establish its suitability with respect to the harmonised standards referred to in Article 5.
 - Where a manufacturer has not applied, or has only partly applied, the harmonised standards or where there are no such standards, the body of which notification has been given must check the suitability of the technical specifications used by the manufacturer with respect to the basic requirements

before examining the manufacturer's technical file to establish its suitability with respect to these technical specifications.

(b) Examination of the model

- When examining the model, the inspection body shall verify that it has been produced in accordance with the manufacturer's technical file and can be used in complete safety for its intended purpose.

- It shall conduct the necessary examinations and tests to establish the conformity of the model with the harmonised standards.

- Where a manufacturer has not applied or has only partly applied the harmonised standards or where there are no such standards the body of which notification has been given shall conduct the necessary examinations and tests to establish the conformity of the model with the technical specifications used by the manufacturer, subject to their being suitable with respect to these basic requirements.

5. If the model satisfies the relevant provisions, the inspection body shall draw up an EC type-examination certificate and shall notify the applicant to this effect. This certificate shall reproduce the findings of the examination, indicate any conditions attaching to its issue and incorporate the descriptions and drawings necessary for the identification of the approved model. The Commission, the other approved inspection bodies and the other Member States may obtain a copy of the certificate and, in response to a reasoned request, a copy of the manufacturer's technical file and the reports of the examinations and tests conducted. The file shall be held at the disposal of the competent authorities for 10 years following the placing of the PPE on the market.

6. Any inspection body which refuses to issue an EC type-examination certificate shall inform the other approved inspection bodies of this fact. An inspection body withdrawing an EC type-examination certificate shall inform the member State which

approved it, to this effect. That member State shall then inform the other member States and the Commission, setting out the reasons for the decision.

CHECKING OF PPE MANUFACTURED**Article 11****A. 'EC' quality control system for the final product**

1. A manufacturer shall take all steps necessary to ensure that the manufacturing process, including the final inspection of PPE and tests, ensures the homogeneity of production and the conformity of PPE with the type described in the EC type-approval certificate and with the relevant basic requirements of this Directive.
2. A body of which notification has been given, chosen by a manufacturer, shall carry out the necessary checks. Those checks shall be carried out at random, normally at intervals of at least one year.
3. An adequate sample of PPE taken by the body of which notification has been given shall be examined and appropriate tests defined in the harmonised standards or necessary to show conformity to the basic requirements of this Directive shall be carried out to check the conformity of PPE.
4. Where a body is not the body that issued the relevant EC type-approval certificate it shall contact the body of which notification has been given in the event of difficulties in connection with the assessment of the conformity of samples.
5. The body of which notification has been given shall provide the manufacturer with a test report. If the report concludes that production is not homogeneous or that the PPE examined do not conform to the type described in the EC type-approval certificate or the relevant basic requirements, the body shall take measures appropriate to the nature of the fault or faults recorded and inform the member State which gave notification thereof accordingly.
6. The manufacturer must be able to present, on request, the report of the body of

which notification has been given.

B. System for ensuring EC quality of production by means of monitoring

1. The system

(a) Under this procedure the manufacturer submits an application for the approval of his quality-control system to a body of which notification has been given, of his choice.

That application shall include:

- all the information relating to the category of PPE concerned, including, where appropriate, documentation relating to the model approved,
- documentation on the quality-control system,
- the undertaking to maintain the obligations arising from the quality-control system and to maintain its adequacy and efficiency.

(b) Under the quality-control system, each PPE shall be examined and the appropriate tests referred to in Section A paragraph 3 shall be carried out to check their conformity to the relevant basic requirements of this Directive. The documentation on the quality-control system shall in particular include an adequate description of:

- the quality objectives, the organisation chart, the responsibilities of executives and their powers in respect of product quality,
- the checks and tests which must be carried out after manufacture,
- the means to be employed to check the efficient operation of the quality-control system.

(c) The body shall assess the quality-control system to determine whether it satisfies the provisions referred to in paragraph 1 (b). It shall assume that quality-control systems applying the relevant harmonised standard satisfy those provisions. The body carrying out audits shall make all necessary objective evaluations of the components of the quality-control system and shall check in particular whether the system ensures conformity of PPE manufactured with the approved model. The decision shall be communicated to the manufacturer. It shall include the conclusions of the check and the reasoned assessment decision.

(d) The manufacturer shall inform the body which approved the quality-control system of any plan to alter the quality-control system. The body shall examine the proposed changes and decide whether the altered quality-control system satisfies the relevant provisions. It shall communicate its decision to the manufacturer. The communication shall include the conclusions of the check and the reasoned assessment decision.

2. Supervision

(a) The purpose of supervision is to ensure that a manufacturer correctly fulfils the obligations arising from the approved quality-control system.

(b) The manufacturer shall authorise the body to have access, for purposes of inspection, to PPE inspection, testing and storage sites and shall provide the body with all requisite information, in particular:

- documentation on the quality-control system,
- technical documentation,
- quality control manuals.

(c) The body shall periodically carry out audits to ensure that the manufacturer is maintaining and applying the approved quality-control system and shall provide the manufacturer with a copy of the audit report.

(d) In addition, the body may make unannounced visits to the manufacturer. In the course of such visits the body shall provide the manufacturer with a report of the visit and, if appropriate, with an audit report.

(e) The manufacturer must be able to present, on request, the report of the body of which notification has been given.

SCHEDULE 9

regulations 2(1)(c)(iii) and 10(1)(a), (b) and (c)

EC DECLARATION OF PRODUCTION CONFORMITY

Article 12

The EC declaration of conformity is the procedure whereby the manufacturer or his authorised representative established within the Contracting Parties:

1. draws up a declaration using the form laid down on Annex VI certifying that the PPE placed on the market are in conformity with the provisions of the Directive with a view to its submission to the competent authorities;
2. affixes the CE marking of conformity provided for by Article 13 to each PPE.

SCHEDULE 10

regulations 2(2), 15(1), (2) and (3), 16(1) and 17(1)

Enforcement

1. For the purposes of providing for the enforcement of these Regulations-

(a) it shall be the duty of the following authorities to enforce these Regulations within their area-

(i) in Great Britain, weights and measures authorities; and

(ii) in Northern Ireland, every district council;

and “enforcement authority” shall be construed accordingly;

(b) an enforcement authority shall have the same duty to enforce these Regulations as it has in relation to Part II of the 1987 Act, and Part IV, sections 37 and 38 and sub-sections (3) and (4) of section 42 of the 1987 Act shall apply accordingly;

(c) these Regulations shall constitute safety regulations within the meaning of section 45(1) of the 1987 Act for the for the purposes of section 12 of the 1987 Act;

(d) section 13 of the 1987 Act (prohibition notices and notices to warn) shall (to the extent that it does not already do so) apply in relation to products to which these Regulations apply as it applies in relation to relevant goods under that section;

(e) these Regulations shall constitute safety provisions for the purposes of section 14 (suspension notices), 15 (appeals against suspension notices), 16

(forfeiture: England, Wales and Northern Ireland), 17 (forfeiture: Scotland) and 18 (power to obtain information) of the 1987 Act; and

- (f) in England, Wales and Northern Ireland, a magistrates' court may try an information (in the case of England and Wales) or a complaint (in the case of Northern Ireland) in respect of an offence committed under these Regulations if (in the case of England and Wales) the information is laid or (in the case of Northern Ireland) the complaint is laid within twelve months from the time when the offence is committed, and in Scotland summary proceedings for such an offence may be begun at any time within twelve months from the time when the offence is committed.

2. An enforcement authority shall, where action has been taken by it to prohibit or restrict the placing on the market of any product to which these Regulations apply which bears the CE marking, forthwith inform the Secretary of State of the action taken and the reasons for it with a view to this information being passed by the Secretary of State to the Commission.

3. Nothing in these Regulations shall authorise an enforcement authority to bring proceedings in Scotland for an offence.

REGULATIONS REVOKED

1. The Personal Protective Equipment (EC Directive) Regulations 1992**(a)**.
2. The Personal Protective Equipment (EC Directive) (Amendment) Regulations 1993**(b)**.
3. The Personal Protective Equipment (EC Directive) (Amendment) Regulations 1994**(c)**.
4. The Personal Protective Equipment (EC Directive) (Amendment) Regulations 1996**(d)**.

(a) S.I. 1992/3139 as amended by S.I. 1993/3074, S.I. 1994/2326 and S.I. 1996/3039 and extended by section 2(1) of the Economic Area Act 1993 (c.51).

(b) S.I. 1993/3074.

(c) S.I. 1994/2326.

(d) S.I. 1996/3039.