

dti

PRODUCT STANDARDS

The Supply of Machinery
(Safety) Regulations 1992
(As Amended)

FREQUENTLY ASKED QUESTIONS
- DTI VIEW

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SUPPLY OF MACHINERY (SAFETY) REGULATIONS 1992 FREQUENTLY ASKED QUESTIONS - DTI VIEW

Foreword

This guide is intended as a source of quick reference, providing the current opinion of the Department to those questions which have been most frequently asked of the Department of Trade and Industry (DTI). It does not have any legal standing and should not be used as a substitute for the Regulations themselves. It is only a guide and in any case of doubt independent advice (including legal advice) should be sought. Ultimately that interpretation would be a matter for the courts. Please note that it is the Regulations themselves which implement the EC Machinery Directive in the United Kingdom (UK). The topics are therefore grouped together in the form in which they appear in the UK Regulations. The Directive itself is applicable in all member States of the EC as well as the European Economic Area (EEA); Accordingly, references to the Community or EC in this Guide include the EEA unless the context otherwise requires. The Guide itself comprises the questions and DTI's views, and Annex (Article 100a of the Treaty of Rome).

Where possible the European common view discussed and agreed in the Article 6.2 Standing Committee has been included in this Guide but many of the questions submitted by member States have not yet been the subject of an agreed view by all member States in the Standing Committee. As they are discussed and/or agreed, this Guide will be updated to reflect any change from the current position.

Current Legislation (UK) and EC Directives

The Supply of Machinery (Safety) Regulations 1992 (S.I. 1992/3073)
The Supply of Machinery (Safety) (Amendment) Regulations 1994 (S.I. 1994/2063)
European Directives 89/392/EEC, 91/368/EEC, 93/44 EEC, 93/68/EEC) - copies are available from The Stationery Office (formerly HMSO).

List of Abbreviations Used in the Text

BSI	-	British Standards Institute
CEN	-	European Committee for Normalisation (i.e. standardisation)
CPD	-	Construction Products Directive
DA	-	Draft Commission Answer
DTI	-	Department of Trade and Industry
EC	-	European Community
EEA	-	European Economic Area
EHSRs	-	Essential Health and Safety Requirements
EMC	-	Electromagnetic Compatibility
EN	-	European Norm (i.e. transposed harmonised standards)
EU	-	European Union
HSE	-	Health and Safety Executive
HMSO	-	Her Majesty's Stationery Office (now known as "The Stationery Office")
PrEN	-	Provisional European Standard
S.I.	-	Statutory Instrument
UK	-	United Kingdom

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Annex. (Article 100a of the Treaty of Rome)

1. QUESTIONS AND THE DTI VIEW

PART I

1. Citation, commencement and revocation.

Q1. When did The Supply of Machinery (Safety) Regulations 1992 come into force?

V. These Regulations came into force on 1 January 1993 and are now mandatory. An amendment was made on 26 July 1994. These became mandatory on 1 January 1997. These Regulations were made under the powers contained in the European Communities Act 1972. The Directive which it implements is 89/392/EEC as amended by Directives 91/368/EEC, 93/44/EEC and 93/392/EEC. The Statutory Instruments applicable are numbers 1992/3073 and 1994/2063, both available from The Stationery Office. Their address is as follows: Publications Centre, PO Box 276, London SW8 5DT, tel: 0171-873 9090 fax: 0171-873 8200. Since 1 January 1996 Roll over Protective Structures (ROPS) and Falling Objects Protective Structures (FOPS) have been included within the scope of these Regulations.

Q2. What is the jurisdiction of these Regulations?

V. These apply in the UK. If the supply to a country outside the EC was via the UK, however, regulation 6 (as amended) could be applicable to exclude the machinery from the provisions of these Regulations, provided no CE marking was affixed to that machinery and the supplier believed (with reasonable cause) that the machinery was not to be put into service in the UK or another EC State, but, for example in the Channel Islands. That machinery would, of course, have to comply with the relevant law of the country (outside the EC) where the supply is to take place. It is, however, recommended that independent legal advice be sought in each case. A similar situation also applies to The Isle of Man and Gibraltar. The Regulations would, however, apply to the supply of machinery on "non-mobile" offshore units on the Continental Shelf.

2. Interpretation

Q3. What Directive does the Supply of Machinery (Safety) Regulations implement?

V. This legislation implements the EC Machinery Directive. The "Machinery Directive" means Council Directive 89/392/EEC as amended by Council Directives 91/368/EEC, 93/44/EEC and Article 6 of 93/68/EEC, and is a "New Approach Directive" (see Q4).

Q4. What does the term "New Approach Directive" mean?

V. Under the terms of Article 100 of the Treaty of Rome, which deals with free trade, directives were made by the European Commission and member States requiring unanimity. This approach, however, sometimes did not work in practice because the veto mechanism enabled any individual state to pursue its own vested interests by blocking a proposal. Also, each of the Article 100 directives covered a comparatively narrow product range and had detailed and prescriptive technical Annexes which took a long time to agree and which would need to be amended by further legislation if developments in the state of the art required this. New powers were consequently introduced in the Treaty of Rome to

facilitate the adoption of harmonising measures throughout the Community. These powers using Article 100a of the Treaty of Rome allow the harmonisation of standards across the Community in respect of a range of products using a process requiring agreement by a qualified majority of member States. The advantages of moving towards a system of directives based on standards is intended to enable manufacturers / suppliers to take full advantage of the Single Market; as when once a product complies with an agreed transposed European harmonised standard for the purposes of a directive, it may be type approved against that standard and enjoy a presumption of conformity with the requirements of the directive (albeit a rebuttable presumption). In addition, the more prescriptive approach of Article 100 directives could be avoided and an approach based on minimum requirements and general principles, supported by more detailed mandated standards could be achieved. In addition, these New Approach Directives also required that achieving improved harmonised standards should not place financial, legal or administrative constraints on the creation and development of small and medium sized businesses. A full text of Article 100a appears in the Annex to this Guide. These directives also prescribe EHSRs which, while not reducing safety levels already in place in any member State, seek to raise these to the highest level. These New Approach Directives also introduce equipment-specific harmonised standards called ENs. This forms best practice guidance for compliance with EHSRs.

Directives are adopted by the European Council of Ministers with the agreement of the European Parliament. It is then the responsibility of individual member States to transpose them into their own national law. It is therefore the Regulations with which UK suppliers and manufacturers must comply.

Q5. What is the relationship between standards and CEN?

V. The European Committee for Standardisation (CEN) is mandated by the European Commission to draft **harmonised standards** for the purposes of Article 100a Directives and, if these are used by manufacturers of machinery, will be one of the ways in which compliance with the EHSRs can be achieved. If a reference to a harmonised standard is published in the Official Journal of the European Communities then its use provides “a presumption of conformity” (rebuttable) of satisfying the EHSRs. **If, however, a harmonised CEN standard does not exist, it is still possible for machinery to be certified and CE marked.**

Q6. Does other existing health and safety UK / GB legislation continue to apply or do these Regulations replace it?

V. Much UK health and safety legislation such as the Health and Safety at Work etc. Act 1974 remains on the statute book. However, relevant machinery (see Question 22), must comply with the Regulations. Products which fully comply with the Supply of Machinery (Safety) Regulations enjoy free access to the market in the UK as far as product safety is concerned.

*Q7. Do **harmonised standards** supersede existing legislation?*

V. Harmonised standards are not legislation (Note: unless incorporated in the legislation) and do not replace existing legislation. Subject to the transitional arrangements (see Q42), machinery first supplied after 1 January 1993 in the UK has to satisfy the requirements of these Regulations assuming that the product is within their scope. Using a harmonised

standard is one of the ways of complying with the EHSR addressed by that standard. However, the use of such standards is voluntary (see Q5). They do, however, replace British Standards on the same subject.

Q8. Is it possible for other member States or EEA States to interpret the Directive differently and therefore insist on additional technical requirements?

V. If you are supplying relevant machinery to other member or EEA States, you will need to satisfy their enforcement authorities that it complies with the requirements of the Directive which they have been bound to implement in their national law. The use of harmonised standards where available should reduce the scope for differences of interpretation on technical matters as they apply universally. In addition the European Commission is issuing non legally binding opinions on difficult questions of interpretation after consultation with member States in the advisory committee set up under the Directive (the Article 6.2 Standing Committee). If you consider your machine complies with the Directive but is being denied access to the market of other member or EEA States and you have done all you can to resolve the issue with the authorities, the DTI's Action Single Market Unit should be informed immediately. Their address is Bay 211, Kingsgate House, London SW1E 6SW.

Q9. How can manufacturers contribute to the standards making process?

V. The Commission has mandated the European Committee for Standardisation (CEN) to produce standards in support of the Machinery Directive. These are, therefore, being progressed and CEN is undertaking consultation accordingly. The European Committee for Electrotechnical Standardisation (CENELEC) is also producing some mandated standards. If a manufacturer feels that any European Standard (EN) fails fully to reflect the EHSRs of the Machinery Directive, they should advise the British Standards Institute's (BSI) UK representative at CEN. The EN for each product should incorporate the relevant EHSRs of the Regulations. Any correspondence should be addressed to the BSI Information Centre, Engineering Department, 389 Chiswick High Road, Chiswick, London W4 4AL.

The making of standards is basically a process independent of government and is primarily a partnership between the standards making bodies and industry, which, as the main beneficiary, has the principal responsibility for funding and ensuring the smooth running of the standards making process. The DTI is concerned that in some areas these standards have not yet been developed and has taken every available opportunity to press the European Commission to use their authority with CEN to secure progress.

CEN is, however, an independent European Standards making body and the DTI's influence is therefore limited. Compliance is, however, against the Directive and implemented by the Regulations not the standard. Provided, therefore, the machine is not one of those specified in Schedule 4 to the Regulations, it may be certified by the manufacturer against the EHSRs as set out in Schedule 3 to the Regulations (as amended). This means that any delay in the development of harmonised standards should not, therefore, prejudice compliance.

*Q10. How can compliance with the **EHSRs** be achieved?*

V. EHSRs basically set safety requirements to be attained by manufacturers who have considerable flexibility as to the way in which they meet them. If a machine or safety component is not classified under Schedule 4 to the Regulations (as amended), the

manufacturer can decide how best to comply. If it is so classified, then specific provisions apply as set out in Schedule 4.

For machinery or safety components listed in Schedule 4 and manufactured in accordance with transposed harmonised standards, the “responsible person” (see Q12) may choose between :

- i) drawing up and forwarding the technical file to a body appointed by a member State for the purposes of the conformity assessment procedures (an “approved body”). The approved body will acknowledge receipt of the file as soon as possible and keep it;
- ii) submitting the technical file to an approved body. The approved body will verify that the transposed harmonised standards have been correctly applied and draw up a certificate of adequacy for the file, sending a copy to the “responsible person”; or
- iii) submitting to an approved body an example of the machinery or safety component for EC type-examination.

For machinery or safety components listed in Schedule 4 but not manufactured in conformity with transposed harmonised standards, the “responsible person” must first submit an example of the machinery or safety component for EC type examination.

EC type-examination is a procedure, carried out by an approved body, to ascertain and certify that an example of machinery or safety component satisfies the relevant provisions of the Directive.

In the UK, the Secretary of State for Trade and Industry is responsible for appointing approved bodies for the purposes of the Machinery Directive. The European Commission publishes EC wide lists of such bodies in the Official Journal of The European Communities. A list - “Machinery Directive: UK Approved Bodies” is also available from DTI’s Business in Europe Hotline on 0117-944 4888.

Q11. How does a manufacturer determine whether a product is “safe”?

V. A risk assessment has to be carried out by the manufacturer in order to identify hazards and risks to health and safety of persons exposed to them. He must then do all he can to eliminate them in accordance within the principles of safety integration listed in the EHSRs. (See pr EN 1050 for more details). It may not always be possible to remove all hazards and in such circumstances they should be eliminated as far as possible, protection provided and information about residual hazards provided (see paragraph 1.1.2 of the EHSRs which contains the principles of safety integration i.e. intrinsically safe design, guard, instructions for use). The manufacturers may also use national standards as a guide in the absence of harmonised CEN standards.

*Q12. What are the definition and duties of the **Responsible Person**?*

V. The responsibility for demonstrating that the machinery or safety component, to which the Directive / Regulations apply, satisfies the requirements of the Regulations implementing the Directive rests on the manufacturer or the importer into the EC (who is

described in the UK Regulations as the “**responsible person**”). The definition of the “responsible person” in regulation 2 specifies certain other persons, who may also satisfy those requirements. One of those persons might fulfil the duties of the “responsible person” in some cases.

For the purposes of the Regulations (as amended) “**responsible person**” means in relation to relevant machinery, including relevant safety components,

- (a) **the manufacturer of that machinery;**
 - (b) **the manufacturer’s authorised representative established in the Community; or**
 - (c) **where the manufacturer is not established in the Community and either -**
 - (i) **he has not appointed an authorised representative in the Community; or**
 - (ii) **his authorised representative established in the Community is not the supplier of that machinery,**
- the person who first supplies the relevant machinery in the Community.**

This expression “**the manufacturer of that machinery or safety component**” should be interpreted as it is written - without restriction although the obligations of regulation 11(1) (as amended) might also be fulfilled by one of those other alternative persons coming within the definition of “responsible person” depending on the circumstances of each case. Therefore, in this context, manufacturers outside the EEA can perform the duties of a “responsible person” including drawing up the EC declaration of conformity for the purposes of regulation 22. However, if these manufacturers do not fulfil all those duties then either the manufacturer’s representative established in the EEA or the person importing into the EEA (as appropriate) as specified in the definition in regulation 2(2) must fulfil those obligations which have not been met by the manufacturer. While it follows that an importer must be satisfied that the product concerned complies with the Regulations, the Regulations do not impose any duty upon a manufacturer to disclose the contents of his technical file to the importer. However, any failure by the “responsible person” to make the technical file available to an enforcement authority would negate the presumption of conformity provided in regulation 26 and, if the importer is in fact the “responsible person” who issues the declaration of conformity, he is required to ensure that the technical file (or a copy of it if the original is retained by / submitted to an approved body) is readily available to the enforcement authorities (see regulation 24).

Whatever the circumstances, it should in addition be noted that under regulation 11(2) (as amended) any person supplying relevant machinery or a safety component in the UK is under a duty to ensure that it is safe and must be able to demonstrate to the satisfaction of the enforcement authorities that it is safe. It follows that such persons must be able to assure themselves that they have or can gain access to all the information they might need to demonstrate this.

The importer - whether he is an authorised representative or anyone else - must also ensure that the manufacturer will supply to the European safety authorities any information that they may need to see.

Q13. What is the definition of an "authorised representative established in the EC"?

V. The authorised representative is described in the European Commission's publication "Guide to the implementation of Community harmonisation directives" based on the new approach and the global approach - referred to as the New Approach Guide (it is not a legally binding document but has been issued by way of guidance in respect of "New Approach" Directives with regard to the Single Market), as a person within the Community appointed by the manufacturer to act on his behalf in carrying out certain tasks required by the Directive, which have been delegated to him by the manufacturer. The DTI consider that any person (including a company) can act as an "authorised representative" for the purposes of the Machinery Directive as long as he is established in the EEA. There is nothing in the Directive to prevent anyone from having more than one authorised representative established in the EEA.

Q14. Is it possible for a user or dealer to fit guards to a machine as the authorised representative of the manufacturer?

V. The first Preliminary Observation to Annex 1 of the Machinery Directive indicates that "the obligations laid down by the essential health and safety requirements apply only when the corresponding hazard exists for the machinery in question when it is used under the conditions foreseen by the manufacturer". It therefore follows that if a hazard is foreseen by the manufacturer which requires the fitting of a safeguard, it should be fitted prior to the machinery being placed on the market in an EEA State. However, if such machinery is manufactured without guarding in another EEA State, it is considered that a person in the UK (whether as an importer or end user) might affix the necessary safeguard prior to supplying the machinery in the UK provided he acts as an "authorised representative" of the manufacturer in that respect. In this situation, the "authorised representative" would be a "responsible person" for the purposes of these Regulations, and would need to comply with their requirements. The "authorised representative" would need to be given authority on behalf of the manufacturer to affix the CE marking. The manufacturer would still have obligations to design and manufacture in accordance with the requirements of the Regulations.

Should an end user in the UK obtain such machinery without guarding direct by way of import from outside the EEA, they should ensure that it complies with the provisions of the Regulations including the affixing of a safeguard before it is put into service. Once again, the end user would be a "responsible person" with the consequent obligations.

Q15. How can importers assure themselves that non-EC manufacturers have carried out the duties of the "responsible person"?

V. The "responsible person" must, if supplying machinery in the UK, ensure that it is safe and be able to demonstrate this to the satisfaction of the relevant enforcement authorities. If imported from a third country outside the EEA Regulation 11(1) would apply as this is the provision which ensures that a product when placed on the market within the EU satisfies the general requirements for placing on the market. Regulation 11(2) (as amended) states that any person supplying machinery in the UK, which would include all those further down the supply chain, is under a duty to ensure that it is safe and must be able to demonstrate this to the satisfaction of the enforcement authorities. It follows that such suppliers must be able to assure themselves that they have or can gain access to all the information they might need to demonstrate this. In order for an importer to carry out his

duties effectively he will need access to the technical data of the product. As a minimum, reference to the declaration of conformity should be made as a method of ensuring that the non-EEA manufacturers have at least indicated that they understood what they had to do to comply with the Regulations. This provision does not, however, apply to the supply of any machinery or a safety component which has previously been put into service in the EC or, and after 1 January 1994, the EEA.

Q16. Are stair lifts covered by these Regulations in view of the complex relationship between this and other European Directives?

V. Yes. (In response to a request from the European Council, however, the European Commission is studying the position to assess whether special equipment for lifting handicapped people still needs to be brought within the scope of the Machinery Directive by means of an amending directive. This will need further discussion and consideration at European level.) A copy of a more detailed paper is available upon request.

*Q17. When is the **CE marking** affixed?*

V. Regulation 25 details the circumstances in which the CE marking is affixed. Essentially, it may only be applied to machinery (not safety components) which satisfy the EHSRs that apply to it and which is safe. In addition, the “responsible person” must have carried out the appropriate conformity assessment procedures. The CE marking must be affixed in the prescribed manner. The relevant applicable requirements of other Directives should also be fully complied with before the CE marking is affixed.

Q18. If equipment has been previously supplied in the EC prior to January 1993, can the same type of equipment continue to be supplied without it having to carry the CE marking or to have a technical file, and if machinery was already in stock prior to the end of 1994, does it require the CE marking?

V. If first supplied or put into service in the EC before 1 January 1993, (or, in the case of a safety component and certain machinery, before 1 January 1995) the machinery does not have to conform with the Directive and the Regulations. However the regulations refer to individual items of machinery and not “types”, so machines supplied after the expiration of the transitional arrangements on 1 January 1995 which are identical to ones supplied under those arrangements in accordance with national legislation in force at 31 December 1992 must conform with the requirements of the Regulations. The only exclusions are for those individual items of machinery already in use prior to 1 January 1993. (Different transitional arrangements / dates apply in the case of a safety component and certain machinery.)

In the case of machinery in stock prior to the end of 1994, provided it complies with the relevant “health and safety provisions” (i.e. relevant national legislation in force on 31 December 1992 e.g. Section 6 of the Health and Safety at Work etc. Act) and was supplied before 1 January 1995, CE marking is not required. It should be noted in that respect that “supply” as defined in the Regulations includes “offering to supply, agreeing to supply, exposing for supply and possessing for supply”. In certain circumstances, therefore, machinery held in stock by the manufacturer on 31 December 1994 may also be excluded. The regulations regarding “supply” may also be different in other member States and prior legal advice should be sought.

Q19. If a machine has already been CE marked in another EC / EEA country, does it need to be freshly marked when imported into the UK?

V. No. Provided that it has already been CE marked in accordance with the requirements of the Directive, in another member State, this is not necessary.

Q20. Is it possible to manufacture a machine in one EEA state and have guards supplied and fitted in the EEA country of destination?

V. An installer or assembler of a product *may* be regarded as a manufacturer. However, such persons can only be responsible for the work they carry out; the manufacturers of the component items of plant must have met requirements as appropriate to them. For example, a complex assembly line may comprise of several different items of machinery and other plant. The manufacturers of each plant item should have met relevant requirements and completed appropriate declarations of conformity or incorporation before supplying such plant to the installer. The installer, as “manufacturer” of the final plant may only take on responsibility for assembly and the central controls and associated wiring depending on contractual obligations. It is the Department’s view that whoever is designated as the “responsible person” should issue the declaration of conformity and affix the CE marking. The “responsible person” must ensure that all EHSRs (including those relating to guarding) are complied with prior to issuing the certificate and affixing the marking. This applies to countries in the EEA as well as the EU.

Q21. What form should the instructions take and are translations necessary?

V. This is set out in section 1.7.4 of the EHSRs which is set out in Schedule 3 to the Regulations (as amended). Section 1.7.4 (b) was amended in 1994 and as regards translations of instructions, now states that on being put into service, all machinery must be accompanied by a translation of the instructions in the language or languages of the country in which the machinery (or safety component) is to be used and by the instructions in the original language. This translation must be done either by the manufacturer or his authorised representative established in the Community or by the person introducing the machinery (or safety component) into the language area in question. By way of derogation from this requirement, the maintenance instructions for use by specialised personnel employed by the manufacturer or his authorised representative established in the Community may be drawn up in only one of the Community languages understood by that personnel.

PART II

3. Relevant Machinery

Q22. What items are covered by these Regulations and are there any general exclusions?

V. All machinery as defined in regulation 4 falls within the scope of these Regulations. There are, however, some general exclusions, which are described in regulations 6 to 10 as well as some specific items excluded by regulation 5 which are set out in Schedule 5 to the Regulations (as amended). Safety components as defined in Schedule 4 are also included within the scope of the Regulations. These can be components placed on the market independently, for the purpose of being assembled with the sole purpose of fulfilling a safety function when in use and the failure or malfunctioning of which endangers the

safety or health of exposed persons. Safety components are not machinery as defined under the Regulations but the requirements of the Regulations indicating the conformity assessment procedures and the EC Declaration of Conformity as defined in Regulation 22 of the regulations (as amended) apply. Such a declaration must state the safety function fulfilled by the safety component (unless this is obvious) and that the safety component complies with the essential health and safety requirements applying to it. A “safety component” should not, however, be CE marked for the purposes of the Regulations (as amended).

Also, those valves which meet the definition of “relevant machinery” in regulation 4 are covered by the Regulations (unless one of the exclusions in regulations 5 to 10 applies). If sold as a stand-alone item they are not generally considered to be within the scope of these Regulations as they do not perform a function consistent with the definition. If, however, their sole function is to act as a safety component for relevant machinery then the provisions of the Regulations would apply.

Q23. In Schedule 4 what is meant by "presses, including press-brakes, for the cold working of metal, requiring type examination when not manufactured to transposed harmonised standards"? In the case of presses, does the ruling apply to a) presses for cold working of metal, b) presses, including press brakes, c) presses with manual loading and/or unloading, d) presses whose movable working parts may have a travel exceeding 6mm and a speed exceeding 30mm per second?

V. The DTI has taken the view that paragraph 9 of Schedule 4 to the Regulations (as amended) has to be read narrowly. This means that only presses (and press brakes) for cold working of metals with manual loading and/or unloading whose movable working parts may have a travel exceeding 6mm and a speed exceeding 30mm per second, require special attestation procedures. Some support for that might be gained from the other provisions of the Schedule (which is taken from Annex IV of the Machinery Directive, as amended). For example, most of the other paragraphs relate to single types of saws / sawing machines set out in sub paragraphs to paragraph 1 of the Schedule / Annex and, logically, that format would have been adapted in the case of presses / press brakes if the individual meanings set out in the question had been intended. The DTI has consistently argued very strongly to keep machinery listed under Schedule 4 of the Regulations as narrow as possible as the DTI is aware of the unwelcome costs for manufacturers whose machinery falls within this category. The answer of the Article 6.2 Committee must therefore be seen against this background. Their conclusions were that while “press brakes” were mentioned, if the legislator had wanted to widen the scope to include such items as guillotine-shears and punching machines, he would have said so (see European Agreed Answer A.45).

4. Definition of “machinery”

Q24. How does the definition of machinery relate to component parts of machines, and what are the procedures that should be followed?

V. Regulation 4 defines machinery in different ways. One of these definitions relates to an assembly of linked parts or components at least one of which moves under power. When components are incorporated into another machine covered by these Regulations, they should be accompanied by a declaration of incorporation (pursuant to regulation 23) and the entire assembly should be CE marked as a single entity. If, subsequently, an additional

component is added which is, in itself, a machine which could be used in a stand-alone capacity, the “responsible person” needs to ensure that the correct conformity assessment procedures have been followed. In this instance if the product can be used in a stand-alone capacity the manufacturer should have prepared a declaration of incorporation but **not** applied a CE marking if the end use is known. If, however, the same item is covered by the definition of machinery in regulation 4, and is sold as a stand alone item, it should be accompanied by an EC declaration of conformity and CE marked accordingly.

Q25. If two or more units are electronically linked together, in, for example a shop, does this arrangement require an additional CE marking and, if so, who would be responsible for applying the CE marking, at what point would it be made and what technical file would be required? In that connection if an item of machinery which is already CE marked is attached to another machine, also CE marked, what procedures need to be followed?

V. If two machines, both CE marked in their own right are linked together to form an integral whole, then the assembler would have to CE mark the system. A single CE marking is sufficient, but a technical file as defined by regulation 14 would need to be prepared for the overall assembly. The CE marking can be applied using either the EHSRs of the Regulations (as amended) or transposed harmonised European Standards where these are appropriate. In addition, applicable requirements of other European Directives need to be taken into account before CE marking is applied.

In the case of complex assemblies the installer would need to ensure that the composite assembly, which is, effectively a new machine, complies with the EHSRs as detailed in Schedule 3 to the Regulations. A new declaration of conformity would need to be prepared and the CE marking affixed. The Regulations do not, however, apply to used machinery but in these circumstances when installing a CE marked machine to existing / used machinery the installer would have to ensure that the machinery is safe. The Health and Safety Executive can provide more detailed advice on technical aspects. At all times it should be remembered that if a machine is within the scope of the Directive (as amended) an EC declaration of conformity would be required for the entire assembly if they function as an integrated whole.

Q26. Are computers covered by these Regulations?

V. Computers are “electrical equipment” as defined by the Electrical Equipment (Safety) Regulations 1994 which implements the Low Voltage Directive (Council Directive 73/23/EEC as published in the Official Journal No L 77 dated 26 March 1973 (page 29)). Article 1 of the Low Voltage Directive states that “For the purposes of this Directive “electrical equipment” means any equipment designed for use with a voltage rating of between 50 and 1000 V for alternating current and between 75 and 1500 V for direct current...”. The principal risk to safety is electrical and computers are therefore excluded from the Regulations under regulation 10. If, however, a computer is incorporated into the control system of a machine, the entire product must comply with the Regulations (as amended). In any event, computers must comply with Regulations which implement the relevant Community Directives such as that relating to electromagnetic compatibility (EMC).

Q27. Within the tipping gear industry, who is responsible for declaring the conformity of tipping gear under these Regulations and affixing the CE marking?

V. It is the DTI's view that tipping gear comprising of hydraulic ram, control circuitry and power source taken together does meet the definition of "relevant machinery" set out in these Regulations and compliance is therefore necessary. The DTI also considers that the option of issuing a declaration of incorporation (and therefore not affixing the CE marking) is not available to manufacturers of tipping gear i.e. it is not justified by the fact that the machinery into which the tipping gear will be incorporated (e.g. a road going vehicle) is excluded by virtue of Schedule 5 to the Regulations. The DTI therefore concludes that manufacturers of tipping gear should issue an EC declaration of conformity and affix the CE marking. The DTI is also aware that it is not possible for tipping gear to fully comply with the Regulations given that they require manufacturers to ensure that machinery they supply is safe. This apparatus cannot be certified as safe until it has been assembled with a chassis and other parts to comprise the complete vehicle. Conformity can, however, be achieved provided clear instructions are provided in respect of the proper installation and maintenance for its intended use as supplied. In addition, in Article 1(3), of the Directive, lorries do not come within under the scope of the Directive likewise bare chassis designed to be equipped are not covered by the Directive either.

Equipment such as that for unloading the lorry in the case of dumping cylinders or lifting in the case of lorry loading cranes or tail lifts may not be covered by Article 1(3) of the Directive. When the type of equipment described above is placed on the market separately (lorry loading cranes, tail lifts etc.) and installed on the chassis by a garage (acting on the instructions of the user in every case) or by the user himself, they would comprise "interchangeable equipment" within the meaning of the Directive. The equipment manufacturer must, therefore, have affixed the CE marking to them, attached an EC Declaration of Conformity and drawn up the technical file. The instructions must include detailed assembly instructions and indicate any potential incompatibility.

When such equipment is installed on the chassis by the equipment or chassis manufacturer (skip tilting devices, refuse collection hoppers, concrete mixers, fire fighting equipment etc.) the assembler is the manufacturer within the meaning of the Directive and is responsible for the procedures for certification of conformity to the essential requirements for the equipment and functions mounted on the lorry or chassis. In such cases the general "transport" function of the lorry is often performed entirely by the equipment. Finally, certain vehicles, even converted ones such as highway emergency vehicles or ambulances keep transport as their sole function and do not come under the Machinery Directive (see Article 1(3) which lists the specific exclusions and states "means of transport, i.e. vehicles and their trailers intended solely for transporting passengers by air or on road rail or water networks, as well as means of transport in so far as such means are designed for transporting goods by air, on public road or rail networks or on water. Vehicles used in the mineral extraction industry shall not be excluded").

Q28. Are self contained refrigeration systems in refrigerated lorries covered by these Regulations?

V. Vehicles are generally excluded from the Regulations as they are "means of transport" (as defined in Schedule 5 to the Regulations as amended) but any equipment which falls within the definition of "relevant machinery" and which is fitted to such vehicles would have to comply. More detailed information on the technical aspects can be obtained from

the Health and Safety Executive. In connection with such systems, the following will normally be considered within the scope of the Regulations:

- self-contained refrigeration systems with compressed refrigerant circuits in mechanically refrigerated lorries are covered by the Machinery Directive.

European Provisional Answer 39 provides more detail on this issue.

Q29. If an importer wishes to supply an item such as hydraulic hoists, which cannot perform any of the functions for which they are intended until the Customer fits them to a machine, either for civilian or military use, does this mean that the CE marking is not required?

V. The items concerned would be covered by regulation 4, except in cases where their use was for military purposes. In these circumstances they would be exempt under Schedule 5 to the Regulations. Regulation 4 however, defines the scope of relevant machinery and should such items be used in conjunction with other machines which require conformity under the Regulations, a declaration of incorporation would be required, and therefore the CE marking should not be affixed to such items.

General exclusions

5. Excluded Machinery

Q30. Is offshore equipment covered by these Regulations?

V. Under regulation 6(1) (as amended) the basic position is that the Regulations apply to the supply of all relevant products except those which the supplier believes (with reasonable cause) will be put into service outside the EEA. There is, also a distinction to be made between “mobile” and “non mobile” units with the latter being within the scope of the Directive / Regulations. In that connection, some assistance might be drawn from The Operational Safety Health and Welfare Regulations 1976 which define “fixed installation” and “mobile installation”. There is further difference between equipment temporarily and permanently placed on board such units. Equipment placed on an accommodation platform would cease to be regarded as mobile once it was affixed to a platform. It is therefore important to draw a distinction between a drilling rig, which may only be in one location for a short time before moving elsewhere, and a production platform which, even though it might in some cases have similar characteristics to a drilling rig, will remain in position for as long as it is required in order to extract oil / gas from the relevant field. The latter is thus considered to be a permanent structure and covered by the terms of this Directive. Seagoing vessels and mobile offshore units, however, are not covered by the terms of these Regulations due to their temporary location and the DTI’s interpretation is that equipment carried on board such units is therefore also exempt and does not, therefore require the CE marking. However, there are special circumstances in cases where a mobile unit remains fixed in place for a significant time and is used for exploration / production purposes. European Answer 85 suggests that equipment mounted in such units is within the scope of the Directive and therefore these Regulations.

Q31. Do winches require the CE Marking?

V. In most cases the CE marking is required but the exclusions in Schedule 5 should be noted, in particular, the reference to those machines designed specially and constructed for military purposes.

Q32. Are paint spray guns covered by these Regulations?

V. In the opinion of the DTI and the Health and Safety Executive, these items do not fall within the scope of the Machinery Directive (and therefore these Regulations) or the Simple Pressure Vessels Directive. However, it is considered that an air compressor unit consisting of a prime mover (e.g. typically an electric motor or petrol or diesel engine) providing mechanical energy to drive the compressor, plus usually an air receiver, would come within the scope of both the Machinery and Simple Pressure Vessels Directives. Such an air compressor unit would typically be used to supply compressed air to a conventional airspray gun but the gun itself would not be within the scope of either Directive (see European Provisional Answer 114).

Q33. Does the installation of building services plant such as heating and ventilation fall within the scope of these Regulations?

V. The question covers too wide a range of products to have a single answer. At least the following distinctions can be drawn from Commission Provisional Answer 39. This states that :

“Packaged air-conditioning units (installed adjacent to windows) are covered by the Low-Voltage Directive;

- in the case of collective air-conditioning units delivered complete but in several components, the only work required on site being to connect the tubes, the parts accessible to users or to maintenance staff must comply with the requirements of the Machinery Directive and the CE marking must be affixed on or beside the manufacturer’s plate;
- collective air-conditioning systems and cold room refrigeration systems assembled on site from components supplied by one or several manufacturers are covered by the Construction Products Directive (89/106/EEC) and the Machinery Directive. Before affixing the CE marking, the final installer must check that both Directives have been complied with”.

The treatment of building services plants such as air conditioning has been discussed repeatedly in meetings of the Article 6.2 Standing Committee which meets periodically to discuss the implementation and operation of the Machinery Directive. However, as yet there is no definitive answer and in the meantime the DTI’s view would be that manufacturers may have to comply with both the Construction Products Directive (CPD) as well as the Machinery Directive in certain instances. This is because with air conditioning in particular, machinery is only excluded to the extent that the risks are covered by other Directives. The CPD does not wholly cover the risks of air conditioning systems. The Heating and Ventilation and Air Conditioning Manufacturers Association (Tel: 01628 810423) can provide further advice, and the Health and Safety Executive should be consulted on the technical

aspects of enforcement. However, manufacturers should seek / rely on their own advice in the particular circumstances of each case pending any further clarification.

Q34. Is refurbished equipment (originally manufactured) before 1 January 1995 exempt from the EC Machinery Directive and therefore these Regulations?

V. When a machine that has been overhauled or reconditioned outside the Community re-enters the Community, it must be regarded as being placed on the market and put into service for the first time in the Community. The fact that it originated in the Community does not alter this reasoning. The Machinery Directive 89/392/EEC therefore applies and the CE marking and EC declaration of conformity are required. The reconditioner must be in possession of and keep the full technical file referred to in Annex V (PA 45).

The point at which a machine becomes “new” will depend on the particular circumstances of each case but in the opinion of the UK authorities it becomes new if the reconditioning changes the specification of the product, the nature of the hazards or increases the levels of risk associated with the machinery.

Regulation 11 (4) states that “the requirements of this regulation do not apply in relation to supply of relevant machinery or a relevant safety component which has previously been put into service in the Community or, after 1 January 1994, the European Economic Area”. This would include machinery which was in use in the Community before January 1993. When used machinery is overhauled and no components are changed (or used parts are merely replaced by identical new parts), the machinery remains the same and the Regulations do not apply. It is, however, recognised that reconditioned machines being sold as “new” will have to comply with the requirements of the Regulations although the point at which the machine becomes “as new” is not clear.

In addition regulation 8A states that regulation 8 will apply to safety components from 31 December 1996. Before this date compliance with those safety provisions in force prior to 14 June 1993 is sufficient.

If used machinery is overhauled and no components are changed (or used parts are merely replaced by identical new parts) the machinery basically remains the same and the Regulations do not apply in the event of any further “supply” of that machinery.

In addition, European Provisional Answer 22 states:

“If the work is carried out on a new machine, it seems hard to imagine that there will be no consultation between the original manufacturer and the reconditioner. One part of the risks is dealt with by the original manufacturer and the other part by the reconditioner. Only **one** person can sign the declaration of conformity, and that person is then responsible for the finished machine’s conformity with the Directive and must be qualified to respond to a substantiated request for the technical file. Only **one** CE marking is affixed to the machinery.

If the work is done without the agreement of the original manufacturer, the reconditioner assumes responsibility for all the machine and must therefore reconstitute the technical file for the assembly.”

Q35. Do lorry mounted truck mixers fall within the scope of the Regulations?

V. Most vehicles are exempt from these Regulations as they are “means of transport” but any such equipment fitted would have to conform with the Regulations.

Q36. Are hand operated winches exempt from the Regulations?

V. Manufacturers of hand powered winches only have to comply with the Regulations if they are to be used for lifting or lowering of loads in which case the limitations on their use should be made clear in the instructions.

Q37. Do refurbished machines need comply with these Regulations?

V. Regulation 11(4) of these Regulations states that they do not apply to machinery which has already been used within the EC (see next question below). This however, only applies where general overhaul is undertaken and matching spare parts replaced as necessary. If the machine is reconditioned by installing new equipment which changes the specification of that machine, it becomes, effectively, a new machine supplied to the market for the first time and therefore a CE marking is required.

Q38. If equipment currently in service, is refurbished, at a manufacturer’s premises and brought back into service, are the original requirements sufficient or does the equipment now need to meet the terms of these Regulations?

V. Under the terms of regulation 11(4), if the machine was made in the EC before 1993 and refurbished prior to 1 January 1995, the Regulations do not apply provided national requirements met the health and safety provisions of the Health and Safety at Work etc. Act 1974. If, however, the refurbishment means that it is effectively a new product, the Regulations do apply and their requirements must be met and a CE marking is therefore necessary.

Q39. Is office machinery covered by these Regulations?

V. In most instances, electrical office equipment would fall under the Electrical Equipment (Safety) Regulations 1994 which implement the EC Low Voltage Directive in the United Kingdom.

Q40. What lifting equipment is covered by the Regulations?

V. Various forms of lifting equipment are covered by the Regulations. In particular, vehicles servicing lifts which are stationary equipment designed to raise vehicles in order to facilitate repair or maintenance operations under the vehicles are included within Schedule 4 to the Regulations and therefore require third party testing. Other items included within Schedule 4 include motorised container lifting devices fitted to a refuse collection vehicle. Tail lifts are also considered to be “machinery” within the meaning of the Regulations as they have different functions to the lorry to which they are attached, are in motion throughout their use and present significant health and safety hazards. The Regulations may apply to lifting accessories are covered by the Directive and the manufacturer should therefore have a technical file. The following, however are excluded from Schedule 4 although within the scope of the Regulations:

- Lift trucks used to set vehicles down on a raised, fixed, woodbench
- car jack elevators
- jacks
- vehicle tippers.

It should however, be noted that vehicle tippers are considered to have a sufficient safety risk (as they are capable of manual operation) to an operator and therefore fall under Schedule 4 to the Regulations (and thus require third party testing), as the operator could fall into the tipper because the rear wall is low.

6. Machinery for export to a third country

Q41. If an item is imported into the UK and is covered by these Regulations, can it be sold to a third country without a CE Marking?

V. If the item of equipment is not intended for sale or use either in the UK or another EEA state then the Regulations do not apply. The Health and Safety Executive should be consulted about any ancillary health and safety issues which may apply. Please also see the answer to question 2.

Transitional exclusions (see also regulations 7 and 8)

No specific questions

7. Machinery first supplied or put into service before 1 January 1993

No specific questions

8. Exclusion until 31 December 1994 of machinery which complies with health and safety provisions in force in a member state on 31 December 1992

Q42. Are roll over protection structures (ROPS) and falling object protection structures (FOPS) excluded from the terms of these Regulations and if not, what transitional arrangements apply?

V. The European Commission has now issued its opinion on the correct method of interpreting the provisions in the Directive 89/392/EEC (as amended by 91/368/EEC and also 93/44/EEC) as it applies to these structures. ROPS and FOPS are protective devices fitted to certain kinds of industrial vehicles and equipment to protect workers against injury should the vehicles or equipment either roll over during use or be subjected to falling objects, particularly those dislodged during industrial activity. The Directive harmonises the EHSRs for the design and manufacture of certain kinds of machinery and equipment so that different sets of national regulations cannot create technical barriers to trade when machinery is placed on the market for the first time in the EEA.

As with many EC Directives, the Directive had a transition period during which manufacturers could choose to apply either existing national regulations as at a specified date or the provisions of the Directive. At the end of the transition period the Directive's provisions became mandatory and hence the provisions of the Regulations are mandatory.

There is confusion as to how the Directive applies to certain ROPS and FOPS because the First Amending Directive 91/368/EEC brings them within the scope of the Directive as “machinery” and the second amending Directive (93/44/EEC) also refers to them as “safety components” for the purposes of Annex IV to the Directive. There are different transition periods specified.

Whilst the interpretation of the respective provisions of the Directive would ultimately be for the courts, the Commission has expressed the opinion that the measures for incorporation into national law applying to ROPS and FOPS (which are supplied separately as “safety components”) are those laid down by 89/392/EEC last amended by 93/44/EEC which should:

- from 1 January 1995 ensure the implementation of amended Directive 89/392/EEC for ROPS and FOPS placed on the market separately, (i.e. as safety components),
- allow the manufacturers to apply either 89/392/EEC or the national regulations in force on 14 June 1993 for such ROPS and FOPS during the period 1 January 1995 to 31 December 1996,
- from 1 January 1997 ensure the application of modified Directive 89/392/EEC only, for these structures.

The DTI supports the Commission's opinion which is reflected in the amendment to these Regulations made by S.I. 1994/2063.

This means that ROPS and FOPS if supplied separately, even if supplied by the manufacturer of the base machine are deemed to be “safety components placed on the market separately” as referred to in Directive 93/44. They must, therefore, comply with the Regulations (as amended) and, as they are listed in Schedule 4, must either comply with the relevant harmonised standards or have been submitted for EC type examination and must be accompanied by an EC declaration of conformity and have a manufacturer's plate **but not bear the CE marking (unless required pursuant to another Community Directive)**.

If a manufacturer sells machinery with ROPS and/or FOPS structures already fitted, this should be indicated in the description of the machinery (and in the EC declaration of conformity). The structure is not dealt with separately from the machinery and is not subject to a separate certification procedure. The transition period for the supply of ROPS and FOPS with certain construction plant has now expired.

Q43. If an item of machinery was supplied and put into service prior to 1 January 1995, does it have to comply with the Directive?

V. Under the terms of regulation 8, subject to compliance with health and safety law on 31 December 1992, it was not necessary for compliance with the Regulations if a firm order for a machine was placed on or before 31 December 1994. In that event, the Regulations, under the definition of “supply” would allow for the machine to be exempt from the new Regulations and subject only to those relevant at the time of placement of the order.

Q44. If someone proposes to buy non CE marked items of machinery in the UK (i.e. machinery which does not comply with the provisions of the Machinery Directive) can he do so under the terms of these Regulations, and if he does buy that machinery, what form of enforcement would there be?

V. All machines supplied in the UK market have to be safe. Although the Regulations became mandatory in respect of machinery on 1 January 1995, it is our view, given the definition of “supply” in the Regulations, and the provisions of regulation 8, that non CE marked machinery can be legally supplied in the UK provided the “supply” in the Community / EEA first took place on or before 31 December 1994 and the relevant health and safety provisions were met. Such non CE marked machinery if supplied for use at work in Great Britain would however, be subject to Section 6 of the Health and Safety at Work etc. Act 1974. The Health and Safety Executive are responsible for enforcement of all legislation in this area in Great Britain and, in instances of non compliance, the action taken by Inspectors ranges from advice to prosecution. (There are separate enforcement arrangements, but similar legislation, in Northern Ireland.) It is, however important to stress that only machines supplied within the EEA prior to 1 January 1995 have this particular exemption. Any other machine first supplied or put into service in the UK would need to be CE marked in accordance with the Regulations before it was placed on the UK market unless another exemption applied.

9. Exclusion of Specific Machinery

No specific questions

10. Machinery where risks are wholly covered by other Directives

Q45. What is the relationship between these Regulations and those relating to forms of “electrical equipment” and is it necessary to comply with both sets of Regulations?

V. Regulation 10 (1) (b) states that the Regulations do not apply to “machinery which is electrical equipment in so far as the risks to such equipment are mainly of an electrical origin.” Most such items will fall under the EC Low Voltage Directive, which is implemented in the UK by the Electrical Equipment (Safety) Regulations 1994 (S.I. 1994/3260). A leaflet outlining the overlap between these two sets of Directives and Regulations is available from the Standards and Technical Regulations Directorate of the DTI. It is not a definitive ruling but provides a degree of guidance to suppliers and manufacturers. The risk assessment will in most cases determine the correct route to be followed and the EHSRs which would need to be observed.

PART III

GENERAL REQUIREMENTS

11. General Duty

Q46. If an item of machinery will be provided specifically for internal use by the manufacturer of the machinery and not intended to be sold into any market, do the Regulations still apply?

V. Yes. Compliance with the Regulations will be necessary. Regulation 11(3) (as amended) states that “(a) where a person being the manufacturer of relevant machinery or a relevant safety component, himself puts that relevant machinery or relevant component into service in the course of business; or (b) where a person, having imported relevant machinery or relevant safety component from a country or territory outside the European Economic Area himself puts that relevant machinery or relevant safety component into service in the course of a business, for the purposes of these Regulations that person shall be deemed to have supplied that relevant machinery or relevant safety component to himself ”.

Q47. If a supplier from outside the EEA wishes to export machinery into the UK does the machinery concerned have to meet all the requirements of these Regulations?

V. Yes. Although Regulation 11(4) exempts machinery put into service within the EEA on or after 1 January 1994, from these Regulations, any equipment from outside this area must comply fully with these Regulations.

Q48. What are the Regulations regarding the supply of second-hand machinery?

V. Regulation 11(4) (as amended) provides that the requirements (of the Regulations) do not apply in relation to the supply of relevant machinery which has already been used in the Community on or after 1 January 1994, in the EEA. Used machinery imported into the UK from outside the EEA must be brought into conformity with the Regulations unless it has previously been used as indicated above.

Q49. Does a machine require third party approval before the EC declaration of conformity is drawn up?

V. Provided the item of machinery is not listed in Schedule 4 to the Regulations, then self-certification is permissible. If it falls within Schedule 4, testing by an approved body will be required where the product is not, or only partly, manufactured in accordance with transposed harmonised standards or where there are no such standards. In cases where such a product is manufactured in accordance with all relevant transposed harmonised standards (ENs) this can be taken as a presumption of conformity with the Directive and should be stated on the EC declaration of conformity and in the technical file but no testing of the product by an approved body is required. Regulation 14 outlines this in more detail.

Q50. If an importer obtains machinery from another EEA State, which has not been CE marked, is it possible for the importer to do so?

V. It is suggested that legal advice be taken by the importer on the status of the organisation vis a vis the supplier. For example, if the product (to be supplied) was in stock within another EEA State on or after 1 January 1994 but before 1 January 1995 (when the provisions of the Regulations became mandatory) and the manufacturer has not become familiar with the provisions of the Directive and has not, therefore assessed his products to ensure that they conformed to its provisions, the failure to affix the CE marking to the machinery will constitute an offence under the Regulations. An importer into the UK in these circumstances should, therefore, ascertain in advance whether the suppliers in that other EEA State are manufacturing in accordance with the Directive and if they are not, to make it a condition of a contract that the products to be supplied / imported do so comply.

Q51. When machinery is imported, who should sign the EC declaration of conformity?

V. The responsible person as defined in Regulation 2.

Q52. Which equipment should be considered as “incorporated” into approved machinery and how does this relate to the type approval of the plant as a whole?

V. In the Regulations, “machinery” is defined as “an assembly of linked parts or components at least one of which moves, including, without prejudice to the generality of the foregoing, the appropriate actuators control and power circuits, joined together for a specific application.....”. When machinery is sold as equipment to be incorporated into a machine covered by the Regulations, it can be sold with a declaration of incorporation. When a declaration of incorporation is issued, CE marking should not be affixed. If, however, machinery is sold as stand alone equipment, it should be sold with an EC declaration of conformity and the CE marking affixed. The best method to ensure compliance will depend on the circumstances of each case, and it is suggested that legal advice be sought at an early stage to clarify this matter. It should, however, be noted that if the whole assembly (of linked parts) is CE marked, then the entire assembly would need to comply with the essential health and safety requirements as set out in these Regulations.

Q53. Are auctioneers classified as suppliers under the terms of these Regulations?

V. The position of an auctioneer will depend on the circumstances of each case and auctioneers should seek their own legal advice as regards their position and responsibility in the particular circumstances of that case. (There may also be responsibilities in other areas such as “health and safety” and “sale of goods”.) However, if a manufacturer of machines goes bankrupt with completed machinery ready for supply, or where an auctioneer buys a factory / plant and auctions the equipment or alternatively, enters into a joint venture with, for example, a machine tool dealer, in order to auction off the contents, in those events the responsibility for complying with the provisions of the Regulations would fall upon the “responsible person” which is likely to be the person disposing of the factory / plant or the facility / contents to the auctioneer for onward “supply”. In such cases, the auctioneer (as a supplier but not the “responsible person”) would have to ensure that the product was “safe” as defined in regulation 2 under the requirements of regulation 11(2) (as amended).

In the case of a manufacturer who goes bankrupt with unfinished machinery in the factory / plant should an auctioneer purchase, for example, that factory where there were unfinished products which he then completed prior to disposal, it is possible that the auctioneer might in those circumstances be regarded as the “manufacturer” for the purpose of the Regulations. In that case, clearly he would have the obligations of a “responsible person” before the finished product was supplied.

Q54. Are photocopies of the signature of the “responsible person” acceptable?

V. This is most commonly used when declarations of conformity or incorporation are required. This is not precluded by the Directive / Regulations but the latest view on this issue among member States is that this is not recommended. It is considered dangerous because it is for the manufacturer to establish that fraud has been committed and this becomes virtually impossible if he himself uses photocopies.

12. Requirements for Supply of Relevant Machinery

Q55. For the purposes of the Regulations, what constitutes “safe”?

V. All equipment to which the Regulations apply, has to satisfy the EHSRs specified in Schedule 3 to the Regulations (as amended) which relate to the equipment. Regulation 2(2) also defines “safe” as “when the machinery is properly installed and maintained, and used for the purposes for which it is intended, there is no risk (apart from one reduced to a minimum) of its being the cause or occasion of death or injury to persons or, where appropriate, to domestic animals or damage to property, and cognate expressions which shall be construed accordingly. For the purposes of this definition, when considering whether or not a risk has been reduced to a minimum, regard shall be had to the practicability of so reducing that risk at the time of the construction of the relevant machinery”.

Conformity assessment procedures

13. Relevant Machinery other than Section 4 machinery

No specific questions

14. Schedule 4 Machinery manufactured in accordance with transposed harmonised standards.

No specific questions but see Q23 as a typical example of a machine requiring third party testing.

15. Schedule 4 Machinery not manufactured in accordance with transposed harmonised standards.

No specific questions

16. Modifications to relevant machinery

Q56. If an item of Schedule 4 machinery has already been CE marked either by self certification or after third party assessment an approved body, if modifications are made, is a new EC type examination necessary?

V. If the type of Schedule 4 machinery which has been affixed with the CE marking is significantly modified, the EHSRs would need to be met and new documentation including an EC declaration of conformity prepared. In the case of modifications to machinery which has already received an EC type examination certificate from an approved body, it may have to be type examined again depending on the circumstances. Reference should be made to the approved body who retains the technical file or has issued the certificate of adequacy / EC type examination certificate in respect of the machinery and should have the technical expertise to advise whether the modification changes the specification of the machine to the point where it becomes a new machine and whether the safety risk has increased.

Q57. If changes are made to the machine without the consent of the original manufacturer, who is responsible for compliance with these Regulations?

V. Whoever carries out the change (if it amounts to a significant modification) should assume responsibility for the machine by complying with the Regulations which would include the drawing up of a new EC declaration of conformity and amending the technical file as necessary. In the case of Schedule 4 machinery, the Approved Body should be informed of the modification and they will arrange for any additional testing that may be required.

17. Approved bodies

Q58. How does an organisation become a UK Approved Body?

V. In order to become an Approved Body in the UK, an organisation must first have been assessed by the United Kingdom Accreditation Service (UKAS) or such other body as may have been appointed for that purpose, on behalf of the Secretary of State for Trade and Industry. The minimum requirements for Approved Bodies are set out in Annex VII of the Directive. These bodies must be independent and have no interest in the products they examine. There is guidance on the appointment of Notified Bodies. The contact point within UKAS on this matter is Mr Peter Key, Building 202, Queens Road, Teddington, Middlesex TW11 0NA (Tel: 0181-943 7068). A manufacturer can use any Notified Body within the EEA.

18. United Kingdom Approved bodies

Q59. From where can one obtain details of UK Notified Bodies?

V. The DTI publish a list of UK Notified Bodies which by definition have been approved to undertake third party EC type examination for machinery and have been notified to the European Commission. Please write to Mrs M Joshi, Standards and Technical Regulations Directorate, DTI, 3rd Floor Red, 151 Buckingham Place Road, London SW1W 9SS.

19. Fees

No specific questions

20. Certificate of Adequacy

No specific questions

21. EC Type-Examination

Q60. If a manufacturer or supplier has complied with all the necessary actions under the Regulations and considers that the product meets all the "relevant essential necessary health and safety requirements", can the EC type examination of Schedule 4 machinery be waived on grounds of cost, and can self certification therefore be used?

V. Under the Directive, manufacturers of most machinery are able to self certify that their machinery complies with the essential health and safety requirements. The items listed at Schedule 4 to the Regulations, however, require the intervention of a third party to ensure

compliance. Machinery supplied in these instances must be sent to an approved body for EC type examination or alternatively, if manufactured in accordance with transposed harmonised standards, the technical file should be sent to an approved body for retention or verification / certificate of adequacy (see Q10). It is, however, appreciated by the Department that this can lead to unwanted expense and that the UK expressed those reservations in discussions.

Q61. If a supplier and distributor imports machines and subsequently modifies them, is there any method that would preclude other importers from obtaining such machinery direct from the manufacturer and can a distributor, who purchases a machine from a manufacturer resell it showing their name and address in place of the manufacturer's before placing on the market?

V. European Answer A.56 states that the Directive requires the name and address of the manufacturer only to be marked on machinery that is finished and ready for use. So for Original Equipment Manufacturers (OEMs) there is no problem: the one who carried out the certification procedures (the manufacturer of the machinery or of the complex assembly) is the one who has to supply his name. The Directive makes no further stipulation. The owners of trade marks covering finished machinery must take responsibility for all the obligations placed on the manufacturer by the Directive; in particular, they must draw up and sign the EC declaration of conformity, affix the CE marking, draw up the instructions and **be in possession of** the technical file referred to in Annex V or VI as appropriate. This procedure requires the actual manufacturer to provide the trade mark owner with all the information needed for the technical file. Should an importer wish to substitute his own name or that of the distributor in place of the manufacturer, the DTI would interpret this as supply of a new machine and the named organisation would need to comply with all provisions of these Regulations.

As far as the United Kingdom is concerned, the Regulations can only be enforced if the supply is to or from the UK. In these circumstances the company importing the product and placing their own brand name on it is responsible for ensuring that the product is in full conformity with the Regulations.

Declaration and marking procedures

22. EC declaration of conformity

Q62. If a national administration within the EC insists on different information in the EC declaration of conformity before an item can be placed on the market in that country, does it have to conform with their regulations or will adherence to the EC Machinery Directive suffice?

V. If the machinery is within the scope and fully complies with the Directive, no EEA State should prevent its placing on the market and its subsequent commissioning. The EC declaration of conformity, should, however, contain enough information to identify the machine and it should be retained in the technical file of the completed machinery. The Directive does not require the serial numbers of equipment to be included although a company may supply these. If equipment to be supplied is incomplete, but classified as machinery, the EHSRs should be complied with as far as possible. A declaration of incorporation can then be issued. In these circumstances, the Health and Safety Executive

should be consulted. The Directive is comprehensive for all matters relating to health and safety and these in turn include a reference to national environmental laws. In the case of the latter, it is therefore possible that additional testing could be required by some Member States under existing national provisions.

Q63. Is there a standard format for the declaration forms (EC declaration of conformity or declaration of incorporation)?

V. There is no such requirement in the Regulations. The Directive allows flexibility by setting out the contents but not specifying a format. The DTI has supported this flexible approach and has been content to leave presentation to industry as long as they follow the Regulations closely. The DTI is, however, aware that some manufacturers may wish to use ready made “documentation”. Whilst the DTI is not in a position to endorse any product / documentation further information can be obtained from organisations such as Formecon Services Ltd, Gateway, Crewe, Cheshire CW1 1YN, who, it is understood, provide such a service and there may be other suppliers of whom the Department is not at present aware who can provide similar facilities.

Q64. Who can sign the EC Declaration of Conformity?

V. Regulation 22(1) only requires that the person authorised to sign on behalf of the “responsible person” is identified. Accordingly, that person needs to be formally authorised unless he is himself the “responsible person”.

Q65. Can an EC declaration of conformity be written on company headed notepaper?

V. Such action is compatible with regulation 22 and the Directive.

Q66. If a company manufactures machinery outside the EEA, can they sign the EC declaration of conformity for relevant machinery to be supplied in the UK?

V. Yes, but importers into the UK must ensure that the machinery they supply in the UK conforms with the Regulations in all its respects.

Q67. Are separate EC declarations of conformity required for each machine?

V. These declarations should be issued as separate documents in respect of each machine although this is not stated explicitly in the Directive. A declaration of conformity when issued with a machine, confirms that it complies with the relevant health and safety requirements (Commission answer A.66 has more details). Where appropriate, transposed harmonised standards or national standards and technical specifications should be listed on the EC declaration of conformity when complying with the Regulations and as appropriate state conformity with the EHSRs of the Machinery Directive.

23. Declaration of Incorporation

Q68. When is the Declaration of Incorporation used?

V. Regulation 23 defines the different categories of machinery which require a declaration of incorporation. These are:

- Relevant machinery intended for incorporation into other machinery,
- Relevant machinery which is intended for assembly with other machinery,
- Machinery which cannot function independently,
- Machinery which is not interchangeable equipment.

This means that when such items as pumps, which meet the definition of machinery are sold other than as “safety components” to be incorporated into another item of machinery covered by the Regulations, a Declaration of Incorporation may be drawn up by the supplier and a CE marking is **not** to be affixed. It is assumed that such items will be limited by design or intended use to functioning in or in conjunction with another machine or being integrated within an assembly of machines.

Q69. Does a Declaration of Incorporation have to be issued in respect of each machine supplied?

V. Whilst the Directive does not identify a “declaration of incorporation” (as such) reference is made to a declaration in Annex IIB but it is not explicit whether this has to be issued for each machine to which the declaration relates. The DTI’s understanding however, is that a declaration of incorporation should be issued with each such machine. It should, however, be noted that the declarations can cover a series of machines (e.g. by serial numbers) which should reduce the overall cost of compliance. In other words the same procedures as that followed for producing an EC declaration of conformity should be adhered to.

24. Retention of Documentation

Q70. How should the technical file be prepared?

V. It had been suggested that the technical file should be presented in two parts, one containing all the data needed by the competent authorities to ascertain compliance with the Directive and a second part containing more precise technical data such as calculation notes, non compulsory test reports, certificates of origin of components or materials.

This is **not** the case. The European Commission is currently considering this matter and their provisional conclusions are that the Directive, and therefore these Regulations, do not require the technical file to be filed in two parts. The technical file need only be supplied in response to a substantiated request from an enforcement authority or an approved body. This implies that the manufacturer is required only to supply the part of the file concerned by such a request. Regulations 13(3) and 14(3) provide for the file being drawn up. It must be drawn up in an official language of the member State in which the approved body is established (in the United Kingdom, English) or in such other language as is acceptable to the approved body, which will be another language of the Community. The same criteria applies to equipment supplied to countries within the EEA but not the EC. The Regulations as amended cover the drawing up and / or submission of a technical file to an approved body in regulations 13 to 15 (inclusive) for appropriate action under regulation 18. The conformity procedures will depend on the nature and circumstances of the machine to be supplied.

25. The CE Mark

Q71. What is the basis on which a technical file must be prepared, how long is it to be retained and who retains custody?

V. Regulation 24(1) states that “a responsible person who issues EC declarations of conformity or declarations of incorporation..... in the United Kingdom shall retain on his premises the technical file or a copy of the technical file submitted to an approved body, as the case may be, which relates to the relevant machinery in respect of which such declarations are made so that such file is available to the enforcement authorities for a period of 10 years beginning with the date on which the last unit of relevant machinery to which the file relates is produced”. This means that the technical file should reside with the manufacturer or with the responsible person who has been mandated by the manufacturer to ensure EC type examination tasks are carried out.

The technical file must be supplied in response to a substantiated request from an enforcement agency. Regulation 13 states that this file must be supplied in one of the Community languages - see paragraph 1.7.4 of Schedule 3 to these Regulations (since the Agreement on the European Economic Area entered into force, the language of one of the signatory countries). European Answer A.63 refers to this.

Q72. Does the year of manufacture need to be inserted after the CE marking?

V. It must not be shown on machines supplied after 1 January 1997. Transitional arrangements applied between 1 January 1995 and 1 January 1997 whereby in the case of the CE mark, the year of manufacture should be affixed together with the last two digits of the year of manufacture. The main provision of the amendment to the Regulations in this area means that from 1 January 1997, however, this requirement will be for the letters “CE” alone to be affixed. The various components of the CE marking must have substantially the same vertical dimension which may not be less than 5mm. This minimum dimension may be waived for small-scale machinery. The year of construction can therefore be shown elsewhere on the machine, if the “responsible person” so chooses provided it is not likely to deceive any person as regards the meaning and form of the CE marking or reduce the visibility / legibility of that marking.

Q73. Should an importer be concerned with the CE marking and why is it necessary?

V. An importer must ensure that the necessary stages are followed to ensure a CE marking has been or can be affixed to relevant machinery if it is intended to offer the product for sale in any EEA State. The importer should therefore check in advance with the manufacturer if outside the EEA to ensure that the CE marking has been or can be “properly affixed”. It is also relevant to stress that the affixing of the CE marking enables the machine to be offered for sale in any EEA State in the absence of any evidence that the machine does not comply with the provisions of the Directive and thus enabling barriers to trade to be lifted by reducing the need for repetitive type examination. It is not, however, a quality mark.

Q74. Is it possible for the CE marking to be fitted retrospectively?

V. This can be done, in the case of machinery which was in the supply chain prior to 1 January 1993, provided it is carried out by the manufacturer and that all the provisions

of the Regulations are met. It is important to stress that the CE marking is a claim to have met all necessary requirements of relevant Single Market legislation which in this case are these Regulations. If other legislation applied, these provisions too, would have to be met. Please note, however, that only machinery which was in the supply chain may be retrospectively marked. New items will have to be CE marked at the time of manufacture.

Q75. Are any noise tests required to ensure health and safety requirements are met before the CE marking is affixed?

V. The Regulations require the manufacturer or importer of machinery rather than the end user (unless he is also the manufacturer or importer) to ensure that the relevant EHSRs are met. These include some provisions on noise. There is, however, no requirement in the Regulations for employers to arrange audiometric testing of employees who are exposed to high sound levels. The Noise at Work Regulations, however, provide for such testing. Details of these Regulations can be obtained from the Health and Safety Executive, who can be contacted on the telephone numbers shown in the DTI guidance booklet "Machinery - Guide to UK Regulations".

Q76. How large should the CE marking be?

V. Apart from the letters "CE" shown in the format outlined in Schedule 2 to the Regulations (as amended) there are no restrictions. The minimum dimension of 5mm may be waived for small-scale machinery.

Supplementary procedures

26. Conditions for relevant machinery being taken to comply with the relevant essential health and safety requirements

No questions identified

27. Judicial review of decisions of approved bodies.

Q77. What is the procedure should an approved body refuse to issue a certificate to a customer?

V. Under regulation 27, if a notified body refuses to issue a such a certificate, the appellant may seek to challenge that decision by making an application for leave to judicially review it.

PART IV

ENFORCEMENT

28. Application of Schedule 6

Q78. Who is responsible for enforcement of these Regulations in the United Kingdom?

V. The Health and Safety Executive (HSE) and Trading Standards Officers enforce these Regulations respectively in the workplace and domestically in Great Britain, and provide

technical advice to the DTI on enforcement issues. The HSE, in enforcing these Regulations will also take into account compliance with the relevant provisions of the Health and Safety at Work (HSW) etc. Act 1974. In both instances, their approach to enforcement is to ensure that primarily the machinery meets the EHSRs of these Regulations, but should not impose an additional burden on industry and that the machine is safe. In the case of Northern Ireland, enforcement is carried out by the Department of Economic Development and the Department of Agriculture in relation to machinery and safety components for use at work and district councils in relation to machinery and safety components for domestic use.

29. Offences

No questions identified

30. Penalties

No questions identified

31. Defence of due diligence

No questions identified

32. Liability of persons other than the principal offender

No questions identified

33. Consequential disapplication of United Kingdom law

No questions identified

34. Relevant machinery which is electrical equipment

Q79. In which cases do the provisions of these Regulations apply, and in which instances do those of the Electrical Equipment (Safety) Regulations 1994 apply?

V. Where the safety risk of the electrical equipment / machinery product is not mainly of electrical origin, then the provisions of the Regulations apply. Electrical equipment is defined in Article 1 of Council Directive 73/23 EEC, as published in the Official Journal, No L77 dated 26 March 1973 (page 29), which is implemented by the Electrical Equipment (Safety) Regulations 1994. In that event the 1994 Regulations would not apply. However, regulation 10(1)(b) of these Regulations disapplies their own provisions where the safety risks of machinery which is “electrical equipment” is mainly of electrical origin. In such circumstances the 1994 Regulations would apply to the machinery (see Q45).

ARTICLE 100a

1. By way of derogation from Article 100 and save where otherwise provided in this Treaty, the following provisions shall apply for the achievement of the objectives set out in Article 7a. The Council shall, acting in accordance with the procedure referred to in Article 189b and after consulting the Economic and Social Committee, adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market.

2. Paragraph 1 shall not apply to fiscal provisions, to those relating to the free movement of persons nor to those relating to the rights and interests of employed persons.

3. The Commission, in its proposals envisaged in paragraph 1 concerning health, safety and environmental protection and consumer protection, will take as a base a high level of protection.

4. If, after the adoption of a harmonisation measure by the Council acting by a qualified majority, a Member State deems it necessary to apply national provisions on grounds of major needs referred to in Article 36, or relating to protection of the environment or the working environment, it shall notify the Commission of these provisions. The Commission shall confirm the provisions involved after having verified that they are not a means of arbitrary discrimination or a disguised restriction on trade between Member States.

By way of derogation from the procedure laid down in Articles 169 and 170, the Commission or any Member State may bring the matter directly before the Court of Justice if it considers that another Member State is making improper use of the powers provided for in this Article.

5. The harmonisation measures referred to above shall, in appropriate cases, include a safeguard clause authorising the Member States to take, for one or more of the non-economic reasons referred to in Article 36, provisional measures subject to a Community control procedure.