

Main SDK 1047/2013 up.

## 12.6.2008/400

### Government Decree on the safety of machinery

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Government's decision, which is made of Social Affairs and Health Ministry, provided a number of technical conformity of equipment on 26 November 2004 of the Act ([1016/2004](#)) § 4 of paragraph 2 and § 5 subsection 2, as well as consumer products and services safety of 30 January 2004 of the Act ([75/2004](#)) § 40 of the Treaty:

#### Chapter 1

##### General provisions

###### § 1

###### Purpose of the Regulation

This regulation implements machinery and amending Directive 95/16/EC of the European Parliament and Council Directive 2006/42/EC.

The Regulation provides for the design and construction of the essential health and safety requirements, as well as the showing of conformity, marketing and deployment.

###### § 2

###### Scope of the Regulation

Apply to the following technical equipment:

- 1) machinery;
- 2) interchangeable equipment;
- 3) safety components;
- 4) lifting accessories;
- 5) lifting chains, ropes and webbing;
- 6) removable mechanical transmission devices;
- 7) the partially completed machinery.

###### § 3

###### Scope of the exclusions



This Regulation shall not apply to:

- 1) safety components intended for use in the identical components as spare parts, which are supplied by the manufacturer of the original machine;
- 2) The fairgrounds or amusement parks for special machines;
- 3) for nuclear purposes, specially designed or put into service on machines where the event of failure may cause an emission of radioactivity;
- 4) weapons, firearms, including;
- 5) The following means of transport:
  - a) agricultural and forestry Directive 2003/37/EC for the risks covered, with the exception of machinery mounted on these vehicles;
  - b) for motor vehicles and their trailers, which include motor vehicles and their trailers on the approximation of the laws of the Member States of Council Directive 70/156/EEC, with the exclusion of machinery mounted on these vehicles;
  - c) vehicles, which include a two-or three-wheel motor vehicles and amending European Parliament and Council Directive 2002/24/EC, with the exclusion of machinery mounted on these vehicles;
  - d) exclusively intended for competition in motor vehicles, and
  - e) air, water and rail networks with means of transport, with the exception of these modes of transport machinery mounted;
- 6) seagoing vessels and mobile offshore units and machinery installed on board such vessels or units;
- 7), especially in military or police purposes designed and constructed for;
- 8) The temporary use in laboratories for research especially designed and constructed for machines;
- 9) mine winding gear;
- 10) machinery intended to move performers during artistic performances;
- 11) The following categories of electrical and electronic products, in so far as they fall within certain voltage electrical equipment on the approximation of the Parliament and Council Directive 2006/95/EC applies:
  - a) for home use, home appliances,
  - b) audio and video equipment,
  - c) information technology equipment,
  - d) the usual office equipment,



- e) low-voltage switchgear and control gear,
  - f) electric motors, as well as
- 12) The following types of high voltage electrical equipment:

- a) switch gear and control gear,
- b) the transformers.

If the unit of the danger of the Second Directive provides a similar national special provision shall be applicable instead of this Regulation.

#### **§ 4** **Definitions**

The purposes of this Regulation, the machine § 2 of 1 to 6 points in accordance with the technical equipment.

The following definitions shall apply:

1) The *machine* shall apply:

- a) The assembly of linked parts or components, with or intended to be fitted with a drive system other than directly for human or animal power-operated power transmission system, and at least one of which moves, and which are joined together for a specific application;
- b) a paragraph to that combination, missing only the components to connect it on site or to the power or operating sources;
- c) a or b subparagraph of assembly which is ready to be installed and able to function only when it is attached to the transport, or installed in a building or a structure;
- d) a, b or c referred to in paragraph 7 of the machinery or partly completed machinery referred to combinations of certain activities organized and managed to work as a whole;
- e) the assembly of linked parts or components, at least one of which moves, and which are joined together, intended for lifting loads and whose only power source is directly applied human effort;

2) *interchangeable equipment* means a device intended for introduction of a machine or a tractor, is assembled with that machinery or tractor by the operation of the amendment or a new function, if this unit is not a tool;

3) The *safety component* means a component:

- a) The operating safety function;
- b) which is independently placed on the market;
- c) the failure or malfunction of which endangers the safety of persons, and
- d) which is not necessary machinery to function, or replaced by the normal components machinery to function.



An indicative list of safety components is set out in Annex V;

4) The *lifting* means a component or device that is not attached to the lifting machinery, allowing the load to be held, which is placed in the machine and the load or on the load itself, or which is intended to load an integral part of which is placed on the market separately, slings and their components are as well as lifting accessories;

5) The *lifting chains, ropes and webbing* means as part of lifting appliance or lifting accessories designed and constructed chains, ropes and webbing;

6) The *mechanical transmission* means a removable component for transmitting power between self-propelled machinery or a tractor and another machine by joining them at the first fixed bearing. If it is brought to market with the guard it shall be regarded as one product;

7) *partly complete machinery* means an assembly which is almost machinery but which can not in itself perform a specific function. A drive system is partly completed machinery. Partially finished the machine is only intended to be connected to other computers, or other partially completed machinery or equipment or assembled in such a way that forming machinery to which this Regulation applies;

8) The *placing on the market* refers to a machine or part of the complete machine for the first making available a view to distribution or use, whether for a fee or free of charge;

9) The *manufacturer* shall mean any natural or legal person who designs or manufactures of this Regulation, a machine covered or partly completed machinery and is responsible for ensuring that the machine or part of the complete machine is the provisions of this Regulation, in order to be placed on the market under his own name or trademark or to take for his own use. As defined above by the manufacturer in the absence of any natural or legal person who places on the market or put into service within the scope of this Regulation, the machine or part of the complete machine;

10) *authorized representative* established within the Community shall mean any natural or legal person who has received a written mandate from the manufacturer to do this on behalf of all of this Regulation relating to the obligations and formalities, or a part of them;

11) *The introduction of* the purposes of this Regulation applies, the use of the machine prior to its first use within the Community; (24.3.2011/265)

12) , a *harmonized standard* is a technical specification, set by the European Standardisation (CEN), the European Committee for Electrotechnical Standardization (CENELEC) or the European Telecommunications Standardization (ETSI) has confirmed and approved by the Commission with the authority of technical standards and regulations and of information society services for the provision of information in the the procedures of the European Parliament and Council Directive 98/34/EC, and in accordance with the procedure laid down a non-binding, and (24.3.2011/265)

13) The *essential health and safety requirements* for the purposes of this Regulation the products covered by the design and manufacture of the mandatory provisions designed to ensure that persons and, where appropriate, domestic animals' health and safety, and property and, where applicable, high level of protection.  
(24.3.2011/265)

## Chapter 2



## **Placing on the market and putting into service**

### **§ 5**

#### **The manufacturer or his authorized representative, the obligations**

The manufacturer or his authorized representative shall, before placing the machine into service:

- 1) ensure that the machine complies with Annex I to the essential health and safety requirements;
- 2) ensure that the Annex VII, Part A of the Technical File is available;
- 3) be equipped with relevant information, such as instructions;
- 4) ensure the appropriate conformity assessment procedure § 7 of the Constitution;
- 5) In accordance with Appendix II, paragraph A of the EC declaration of conformity and ensure that it accompanies the machinery, as well as
- 6) affix the CE marking to 9 in accordance with §.

The manufacturer or his authorized representative shall, before partially finished placing on the market provide 8 § obligations referred to.

The manufacturer or his authorized representative is 7 referred to in § procedures for access to or possesses the necessary means to ensure that the machine is described in Annex I to the essential health and safety requirements.

If the machine is also the other aspects of the subject of other affixing the CE marking on the directives or respective national legal provisions, the latter shall indicate that the machine is in those other provisions. However, if one or more of the CE marking on the provisions of the manufacturer or his authorized representative, during a transitional period, to choose which arrangements to apply, the CE marking shall indicate conformity to the provisions only of which the manufacturer or his authorized representative. EC declaration of conformity shall notify the applicable national provisions in the respective Directives applied, as published in the Official Journal of the European Union.

### **§ 6**

#### **Use of harmonized standards**

If the machine has been manufactured in accordance with harmonized standards, the references of which have been published in the Official Journal of the European Union, it shall be deemed to comply with the harmonized standard covered by the essential health and safety requirements.

## **Chapter 3**

### **The conformity assessment**

#### **§ 7**

##### **Proof of compliance**

The manufacturer or his authorized representative shall certify that the machine is in accordance with the requirements of this Regulation, apply one of paragraphs 2, 3 and 4 set out in subsection conformity assessment procedures.



If the machine is not listed in Annex IV, the manufacturer or his authorized representative shall be applied in accordance with Annex VIII to the manufacture of machinery, internal checks on the conformity assessment procedure.

If a machine is listed in Annex IV and is manufactured in accordance with harmonized standards, and these standards cover all the relevant essential health and safety requirements, the manufacturer or his authorized representative shall apply one of the following procedures:

- 1) of Annex VIII to the machine's internal control of production conformity assessment procedure based;
- 2) Annex IX of the EC-type examination procedure, and Annex VIII, point 3 of the manufacturing process to ensure the machine, or
- 3) Annex X of the full quality assurance procedure.

If a machine is listed in Annex IV and has not been made, or is only partly in accordance with harmonized standards, or if the harmonized standards do not cover all the relevant essential health and safety requirements or if that do not have the harmonized standards exist, the manufacturer or his authorized representative need to use one of the following procedures:

- 1) Annex IX of the EC-type examination procedure, and Annex VIII, point 3 of the manufacturing process to ensure the machine, or
- 2) of Annex X of the full quality assurance procedure.

## **8 §**

### **Partly completed machinery to the procedure for**

Partly completed machinery or his authorized representative shall, before placing it on the market obliged to ensure that the Annex VII, point B as described in the relevant technical documentation described in Annex VI, assembly instructions, and Annex II Section B of incorporation have been developed.

Assembly instructions and the declaration of incorporation must be accompanied by partly completed machinery. When the machine is connected to a partially finished into the final machinery, these documents must be included in the technical file to the machine.

## **§ 9**

### **CE marking**

The CE conformity marking consisting of the initials "CE" in Annex III to the model.

The CE marking shall be affixed to the machinery visibly and legibly and indelibly in accordance with Annex III.

Do not subject to any markings, signs and inscriptions which may be the meaning or form of the CE marking. Any other marking may be affixed to the machine, if they do not impair the CE marking visibility, legibility and meaning.

## **§ 10**

### **The appropriateness of the label**



The label is not appropriate if:

- 1) the CE marking has been affixed pursuant to this Regulation to products that are not covered by this Regulation;
- 2) that the CE marking is missing or EC declaration of conformity is missing, or
- 3) The machine is attached to a non-CE-marked and this marking is prohibited § 9 of subsection 3.

## **§ 11**

### **Information, warnings and instructions for language**

Machine attached to the information and warnings must be Annex I, section 1.7.1. in accordance with the instructions and the machine must be Annex I, section 1.7.4. in accordance with the language. Finland placed on the market or to be put into the machine information, warnings and instructions must always be in Finnish and Swedish. If the machine is introduced only in the monolingual region, information, warnings and instructions may be the official language of the municipalities in the region, only in Finnish or Swedish.

## **Chapter 4**

### **Entry into force provisions**

#### **§ 12**

##### **Entry into force**

This Regulation shall enter into force on 29 December 2009.

Prior to the entry into force of Regulation can be taken for its implementation.

#### **§ 13**

##### **Repeals**

This Regulation repeals the following government decisions, with subsequent amendments:

- 1) The safety of machinery, 21 December 1994, the Government's decision (1314/1994) ;
- 2) The application of the Occupational Safety and Health fixing and their inspection on 4 September 1997 the Government's decision (862/1997) , as well as
- 3) used for the carriage of passengers and their rakennushisseistä audit of 17 December 1980 on the Government Decision (982/1980) .

#### **§ 14**

##### **Transitional provision**

Notwithstanding this regulation in Finland to 29 June 2011 on the market and putting into service of a detonating explosive blasting firearms tools for auxiliary equipment and the necessary means of bolts, screws and cartridges, as well as storage and packing containers that meet the Occupational Safety and Health application fixing and the control of the Government Decision (862/1997) the requirements laid down.

## *Annex I*

### **MACHINE DESIGN AND CONSTRUCTION OF ESSENTIAL HEALTH AND SAFETY**



## GENERAL PRINCIPLES

1 The manufacturer of machinery or his authorized representative must ensure that a risk assessment is done in order to machine the applicable health and safety requirements can be determined. The machinery must then be designed and constructed taking into account the risk assessment results.

The above risk assessment and risk reduction is an iterative process, the manufacturer or his authorized representative shall:

- Determine the limits of the machinery, including the intended use and reasonably foreseeable misuse;
- Identify the potential hazards of the machine and related incidents;
- Estimate the risks, taking into account the possible injury or damage to health severity and probability;
- Evaluate the risks, to determine whether the risk of this Directive, the aim of the reduced, and
- Eliminate the hazards or reduce the risks associated with these hazards by application of protective measures 1.1.2. paragraph b subparagraph order of priority established.

2 The essential health and safety requirements set out in this paragraph apply only if the corresponding hazard exists for the machinery in question when it is used by the manufacturer or his authorized representative under the conditions foreseen or foreseeable abnormal situations. In any event, 1.1.2. set out in section 1.7.3 of the principles of safety. and 1.7.4. referred to in paragraph marking of machinery and instructions obligations.

3 Of this Annex, the essential health and safety requirements are mandatory. In view of the art, it may be possible that a set therein can not be achieved. In this case, the machine is designed and constructed to meet these objectives as far as possible.

4 This appendix is divided into several parts. The first part is of general application and applies to all kinds of machines. Other parts refer to certain kinds of more specific hazards. However, it is essential that this Annex as a whole, in order to be sure that all the relevant essential requirements. When designing must take into account the general part and the requirements of one or more of the requirements of these general principles of paragraph 1 in accordance with the risk assessment carried out according to the results. Environmental protection with the essential health and safety requirements apply only to 2.4. referred to in paragraph machines. (24.3.2011/265)

## 1 ESSENTIAL HEALTH AND SAFETY

### 01.01. GENERAL

#### 1.1.1. Definitions

Purposes of this Annex:

- a) The *hazard* of injury or damage to health possible source;
- b) the *danger zone* or around machinery in which a person is exposed to health or safety;
- c) the *exposed person* a person who is wholly or partially in a danger zone;



- d) the *user* person or persons installing, operating, adjusting, maintaining, cleaning, repairing or moving machinery;
- e) *the risk of* an adverse event possibly related to an injury or damage to health of the probability and severity of;
- f) the *cap* part of the machinery that is used as a physical barrier to provide protection;
- g) *a safety device to* device (other than a guard) which, either alone or in conjunction with a guard to reduce the risk;
- h) *referred to the use of* the machine instructions for use of the information provided in accordance with and
- i) the *reasonably foreseeable misuse of* the machine in a way not intended in the instructions, but which may result from readily predictable human behavior.

### 1.1.2. Principles of safety

- a) Machinery must be designed and constructed so that it is fit for purpose and can be used, adjusted and maintained without putting persons at risk when these operations are carried out as intended, but also taking into account any reasonably foreseeable misuse.

Aim of measures taken must be to eliminate any risk throughout the foreseeable lifetime, including transportation, assembly, dismantling, disabling and scrapping.

- b) In selecting the most appropriate methods, the manufacturer or his authorized representative must apply the following principles in the following order:

- Eliminate or reduce risks as far as possible (inherently safe machinery design and construction);
- Take the necessary protective measures in relation to risks that can not be eliminated, and
- Inform users of the residual risks due to any shortcomings of the protective measures adopted, indicate whether any particular training is required and specify the need for personal protective equipment.

- c) When designing and constructing machinery and when drafting the instructions of the manufacturer or his authorized representative must take into account its intended use but also any reasonably foreseeable misuse.

Machinery must be designed and constructed in such a way that it is not abnormal use if such use would engender a risk. The instructions for use of the machine, if necessary, the user's attention to be paid to the uses that have been found to be feasible in practice, and in which the machinery should not be used.

- d) machinery must be designed and constructed in such a way that the PPE is necessary or foreseeable use of the user due to the limiting factors are taken into account.

- e) Machinery must be supplied with all the special equipment and accessories, which are necessary to enable it to be adjusted, maintained and used safely.

### 1.1.3. Materials and products



The machine materials of construction or use of used or generated must not endanger the health and safety. In particular, the machine with the use of liquids or gases, shall be designed and constructed in such a way as to prevent the filling, use, recovery or draining due to the risks.

#### *1.1.4. Lighting*

If the lack of illumination may cause a risk despite ambient lighting of normal intensity is turned on, the machine is fitted with a suitable for the operations, the machine belonging to lighting.

Machinery must be designed and constructed so as not harmful to cause nuisance, that dazzle and due to the lighting of the hazardous moving parts stroboscopic.

Internal frequent inspection and adjustment, as well as parts requiring maintenance areas must be provided with appropriate lighting.

#### *1.1.5. Design of machinery to facilitate its handling*

Machinery or each component must be handled and transported safely, and be packaged or designed so that it can be stored safely and without damage.

Machine or its parts during transport, sudden movements or of hazards due to instability may not be possible if the machine or its parts are handled according to instructions.

If the machinery or its various component weight, size or shape prevents them from being moved by hand, the machinery or each component part must:

- Fitted with lifting lugs for attachment;
- Designed in such a way that it can be fitted with such attachments, or
- Be shaped in such a way that standard lifting gear can easily be attached.

Where machinery or one of its component parts is to be moved by hand, it must either be easily movable, or equipped for picking up and moving.

Also the light of potentially dangerous tools or machinery parts, dealing with the implementation of special arrangements.

#### *1.1.6. Ergonomics*

Under the intended conditions of use, the discomfort, fatigue and physical and psychological stress minimized by taking into account, inter alia, the following ergonomic principles:

- To take into account the variability of the operator's physical dimensions, strength and stamina;
- The user's body parts must have sufficient space to move around;
- Avoiding a machine-determined work rate;



- To avoid long-term monitoring that requires concentration, and
- Man-machine-interface to the machine to the foreseeable characteristics.

#### *1.1.7. Operating positions*

The operating position must be designed and constructed in such a way as to avoid any exhaust gases or lack of oxygen due to the risks.

If the machine is to be used in a hazardous environment, the health and safety risks arising from, or if the machinery itself gives rise to a hazardous environment, shall take appropriate measures to ensure that the operator has good working conditions and is protected against foreseeable hazards.

Place of use must be fitted with an adequate cabin, which is designed, constructed or equipped so that it meets the above requirements. The exit must be such that the rapid evacuation is possible. It is also possible, have a emergency exit, which is different from the usual exit.

#### *1.1.8. Seating*

If necessary, and working conditions so permit, form part of the machine is working places so designed that they can be fitted with seats.

If the operator is intended to sit during operation and the operating position is an integral part machine, the seat must be provided with the machine.

Operator's seat must be such as to maintain a stable position. In addition, the seat and its distance from the control devices must be able to adjust to the wearer.

If the machinery is subject to vibrations, the seat must be designed and constructed in such a way as to reduce the vibrations transmitted to the lowest level that is reasonably possible. The seat mountings must withstand all stresses to which they can be subjected. If the user is not under your feet on the floor, there is a slip-resistant material footrests covered.

### **02.01. CONTROL SYSTEMS**

#### *1.2.1. Control system security and reliability*

Control systems must be designed and constructed in such a way as to prevent incidents from occurring. Above all, they must be designed and constructed in such a way that:

- They can withstand the intended operating stresses and external influences;
- The control system hardware or software failure does not cause a hazardous situation;
- Errors in the control system logic do not lead to hazardous situations, and
- Reasonably foreseeable human error during operation does not lead to dangerous situations.

Particular attention should be paid to:



- The machinery must not start unexpectedly;
- The machinery must not change in an uncontrolled way when such change may result in a hazardous situation;
- It must not be prevented from stopping if the stop command has already been given;
- No moving part of the machinery or piece held should not be dropped or thrown out;
- No moving part of the automatic or manual stopping must not be hindered;
- The protective devices must remain fully effective or give a stop command, and
- Safety-related parts of control systems must be used in a uniform manner of machinery or partly completed machinery to form a complete assembly.

The wireless control, an automatic stop when correct control signals are not received, or if the connection is lost.

### *1.2.2. Controls*

Control devices must be:

- Be clearly visible and identifiable, using pictograms where appropriate;
- Positioned in such a way that they can be safely operated without hesitation or loss of time and without ambiguity;
- Designed in such a way that the movement of their impact;
- Located outside the danger zones, except where necessary for certain control devices such as emergency stop or a portable programming device;
- Positioned in such a way that their operation can not cause additional risk;
- Designed or protected in such a way that the desired effect, where a risk is involved, can only be achieved by a deliberate action, and
- Constructed to withstand foreseeable forces. Particular attention should be paid to emergency stop devices liable to be subjected to considerable forces.

If the control device is designed and constructed to perform several different functions, namely where there is no completely unambiguous, the function performed must be clearly identified and shall be ensured.

Control devices must be so arranged that their layout, travel and resistance to operation are compatible with the action to be performed, taking account of ergonomic principles.

Machinery must be necessary for the safe use of pointing devices. The user must be able to read them from the control site.

The user must be able to each control position to ascertain that there is no one in the danger zones, or the control



system must be designed and constructed in such a way that starting is prevented while someone is in the danger zone.

If neither of these options is possible, before the machinery starts, issue a warning sound or visual warning signal. The exposed persons must have time to leave the danger zone or prevent the machinery starting up.

If necessary, ensure that the machinery can be controlled only from control positions located in one or more predetermined zones or locations.

If the control there is more than one, the control system must be designed so that a single control location will prevent the use of other, stop and emergency stop devices with the exception of.

If you have two or more operating positions, each position must be provided with all the required control devices without the operators hindering or putting each other into a dangerous situation.

### *1.2.3. The launch of*

Starting the machine can only be possible in such a way, for the purpose control device.

The same requirement applies when restarting after a stoppage, it was whatever the cause, and a significant change in the operating conditions.

Restarting or a change in operating conditions can, however, deliberately using a device other than for the purpose referred to in the control unit if this does not lead to a hazardous situation.

In automatic mode, the machine start-up, restarting after a stop or a change in operating conditions may be possible without intervention, provided this does not lead to a hazardous situation.

Where machinery has several starting controls and the operators can therefore put each other in danger, rule out such risks need to install additional hardware. If you start or pause the interest of safety function in a particular order, these functions making the correct order to ensure special equipment.

### *1.2.4. Arrest*

#### *1.2.4.1. Normal stop*

The machine shall have a control device whereby it can be safely to a complete stop.

Each workstation must be fitted with a control device to stop the existing hazards, depending on whether all or only part of the machine's functions in such a way that the machinery is rendered safe.

Machine stop operation of the device must be the primary boot device in relation to operations.

Once the machinery or its hazardous functions have stopped, the energy supply to the actuators concerned must be cut off.

#### *1.2.4.2. Operational stop*

If, for operational reasons, a stop control that does not cut off the energy supply to the actuators, the stop



condition must be monitored and maintained.

#### 1.2.4.3. The emergency stop

The machine must have one or more emergency stop devices to enable actual or impending danger to be averted.

The following exceptions apply:

- Machines in which an emergency stop device would not lessen the risk, either because it would not reduce the stopping time or because it would not enable the special measures are needed to manage the risk, or
- Portable hand-held or hand-guided machines.

The device must:

- Have clearly identifiable, clearly visible controls that are quickly available;
- Stop the hazardous process as quickly as possible without creating additional risks, and
- Where necessary, trigger certain safeguard movements or permit the triggering.

When the emergency stop device active operation following a stop command is extinguished, that command must be sustained by engagement of the emergency stop device until that engagement is specifically overridden. The device locking must not be possible without triggering a stop command. The device exemption from the stop position of the interlocking shall be possible only by an appropriate operation, and disengaging the device must not restart the machinery but only permit restarting.

The emergency stop function must be available at all times and activities, regardless of the operating mode.

Emergency stop devices must be other safeguarding measures and not a substitute for them.

#### 1.2.4.4. The combination of machine

Case of machinery or equipment, certain parts are designed to work together, they must be designed and constructed in such a way that the stop controls, emergency stop devices, including stop not only the machinery itself but also all related equipment, if its continued operation can be dangerous.

#### 1.2.5. *The control or operating modes*

The control or operating mode selected must override all other control or operating modes, with the exception of the emergency stop.

If the machine has been designed and built in such a way that it is possible to use in several control or operating modes requiring different protective measures and work procedures, it must be a mode selector which can be locked in each position. Each position of the selector must be clearly identifiable and must correspond to a single operating or control mode.

The selector may be replaced by another selection method which enables certain functions of the machine is



restricted to certain user groups.

If certain features of the cover is moved or removed, or a protective device disabled, the control or operating mode selector must simultaneously:

- Disable all other control or operating modes;
- Permit the operation of hazardous functions only by control devices requiring sustained action;
- Permit the operation of hazardous functions only in reduced risk conditions while preventing linked sequences hazards of, and
- Prevent any operation of hazardous functions by voluntary or involuntary action on the machine's sensors.

If these four conditions can not be fulfilled simultaneously, the control or operating mode selector must activate other protective measures that are designed and built to ensure a safe intervention.

In addition, the user must be able to manually control the operation of the parts he is working on.

#### *1.2.6. Power supply problems*

Of the power supply interruption, after an interruption or fluctuation in whatever manner may not lead to dangerous situations.

Particular attention should be given to the following:

- The machinery must not start unexpectedly;
- The machinery must not change in an uncontrolled way when such change may result in a hazardous situation;
- It must not be prevented from stopping if the stop command has already been given;
- No moving part of the machinery or piece held should not be dropped or thrown out;
- No moving part of the automatic or manual stopping shall not be impaired, and
- The protective devices must remain fully effective or give a stop command.

### 03.01. PROTECTION AGAINST MECHANICAL HAZARDS

#### *1.3.1. The risk of loss of stability*

Machinery and its components and connecting elements must be stable enough to avoid overturning, falling or uncontrolled movements of transportation, assembly, dismantling and any other action involving the machinery.

Unless the shape of the machinery itself or its intended installation does not offer sufficient stability, must have the appropriate mounting structures, and be supported by documentation.

#### *1.3.2. Risk of failure during operation*



Various parts of machinery and their linkages must be able to withstand the use of encumbrances.

Materials used by the manufacturer or his authorized representative working environment foreseen by the nature of particular phenomena of fatigue, aging, corrosion, and wear.

The instructions must give the necessary safety inspections and maintenance procedures, and, how much time they have to do. They shall identify and define the wear parts for replacement.

If the risk of rupture or disintegration remains despite the measures taken, the parts must be installed, located or protected so that the fragments will be contained, preventing hazardous situations.

Liquids and gases, in particular the high-pressure pipe and tubing is able to withstand the foreseen internal and external stresses and must be firmly attached or protected to ensure that the risk of rupture.

When the material to be processed is fed to the tool automatically, the following conditions must be met in order to avoid risks to persons:

- When the workpiece comes into contact with the tool must have reached normal operating condition, and
- When the tool starts and stops, intentionally or accidentally, the feed movement and the tool movement must be coordinated manner.

#### *1.3.3. Due to falling or ejected objects risks*

Safeguards need to be prevented from falling or ejected objects risks.

#### *1.3.4. To surfaces, edges or corners of the risks*

As far as the use of permits, palpable in the parts of the machine must not have sharp edges, sharp angles and no rough surfaces likely to cause injury.

#### *1.3.5. Interconnected equipment related risks*

If an inter-connected machines are intended to carry out several different operations with removal of the piece between each handwritten, they shall be designed and constructed in such a way that each element can be used separately without the other elements constituting a risk for exposed persons.

To achieve this, the unprotected functional components must be able to start and stop separately.

#### *1.3.6. Variations in operating conditions due to the risks*

If the machine is intended for use with a variety of operating conditions, it must be designed and constructed in such a way that these conditions are required options and settings can be done safely and reliably.

#### *1.3.7. Risks arising from moving parts*

Moving parts of machinery must be designed and constructed so that contact which could lead to accidents and potentially lead to prevent risks, or if the risks can not be removed, the machine is fitted with guards or protective devices.



All the necessary steps shall be taken, involved in the work of moving parts do not get stuck. If a blockage is likely despite the precautions taken, if necessary, the appropriate specific protective devices and tools to ensure that the equipment to be safely unblocked.

These specific protective devices and their usage The instructions and, where possible, the label on the machine.

#### *1.3.8. Choice of protection of moving parts to combat the risk*

Moving parts of the machine against risks arising from the planned guards and safety devices should be selected on the basis of the type of risk. The following guidelines must be used to facilitate their selection.

##### *1.3.8.1. Moving transmission parts*

Guards designed to protect persons against moving transmission parts hazards must be either 1.4.2.1. fixed guards as referred or 1.4.2.2. referred to in paragraph Interlocking movable guards.

If access is envisaged to be often repeated, should be used as Interlocking movable guards.

##### *1.3.8.2. Involved in the process of moving parts*

Guards or protective devices, which are intended to protect persons against moving parts involved in the process hazards must be:

- Either 1.4.2.1. fixed guards as referred;
- 1.4.2.2. referred to in paragraph Interlocking movable guards;
- 1.4.3. referred to in security devices, or
- Combination of the above.

If a certain process of moving parts directly involved can not be completely inaccessible during operation owing to operations requiring operator intervention making, they must be equipped with:

- Fixed guards or interlocking movable guards preventing access to the moving parts, parts that are not used in the work, and
- 1.4.2.3. referred adjustable guards restricting access to those moving parts where access is necessary.

#### *1.3.9. Uncontrolled movements of the risks posed by*

When a part of the machine is stopped, any other than on the control devices, the stop position out of the movement must be prevented or must be such that it does not cause any danger.

### **01.04. GUARDS AND REQUIRED CHARACTERISTICS**

#### *1.4.1. General requirements*

Guards and protection devices must:



- Be of robust construction;
- Remain firmly in place;
- Be such as to avoid causing any additional risk;
- Be such that it is not easy to by-pass or render non-operational;
- Be located at an adequate distance from the danger zone;
- Cause minimum obstruction to the production process, and
- Permit the insertion or replacement of tools and for maintenance purposes by restricting access only to the point where this work is done, if possible without the guard is removed or the protective device off.

In addition, guards must, where possible, protect the machine from flying or falling of materials or objects and machine-made emissions.

#### *1.4.2. Special requirements for guards*

##### *1.4.2.1. Fixed guards*

Fixed by opening or removing the system shall be possible only with tools.

Fixing systems must remain attached to the guards or to the machinery when the guards are removed.

Possible, guards must be incapable of remaining in place without their fixings.

##### *1.4.2.2. Interlocking movable guards*

Interlocking movable guards must, where possible, remain attached to the machinery when open, and be designed and constructed in such a way that they can be adjusted only by means of an intentional measures.

Interlocking movable guards must be associated with an interlocking device that prevents the start of hazardous machinery functions until the guard is closed, and gives a stop command whenever they are no longer closed.

If the user can reach the danger zone before the hazardous machinery functions due to the risk has passed, movable guards must switch the device also have a guard locking device that prevents hazardous machinery functions from starting until the guard is closed and locked, and keeps the guard closed and locked until the hazardous machinery functions due to accident risk has been eliminated.

Interlocking movable guards must be designed in such a way that one of their components prevents the absence or failure of the hazardous machinery functions starting or stops.

##### *1.4.2.3. Adjustable guards restricting access*

Adjustable guards restricting access to those areas of the moving parts strictly necessary for the work must be adjustable manually or automatically according to the type of work, and readily adjustable without the use of tools.



### *1.4.3. Safety devices for special requirements*

Safety equipment must be designed and incorporated into the control system so that:

- Moving parts can not start up while they are within your reach;
- Persons can not reach moving parts while the parts are moving, and
- One of their components the absence or failure prevents starting or stops the moving parts.

Devices must be adjustable only by an appropriate operation.

## 05.01. OTHER HAZARDS OF RISKS

### *1.5.1. The power supply*

The machine has an electricity supply, it must be designed, constructed and equipped so that all hazards of an electrical nature are or can be prevented.

The machine is subject to Directive 2006/95/EC or the corresponding national safety requirements imposed by the Act. However, the obligations of the machine conformity assessment and the placing on the market or putting regard to electrical hazards are governed solely by this setting.

### *1.5.2. Static electricity*

Machinery must be designed and constructed in such a potentially dangerous electrostatic charges to exclude or limit, or be fitted with a discharging system.

### *1.5.3. Energy supply other than*

The machine, which is the power source of energy other than electricity shall be designed, constructed and equipped in such a way that any and all such sources of energy-related risks are avoided.

### *1.5.4. Installation errors*

If certain components are installed or removed to an improper installation of a source of risk must be made impossible in parts of the design and construction of, or, if this is not possible, by information given on the parts themselves or their housings. The same information must be given on moving parts or their housings where the direction of movement must be known in order to avoid the risk.

If necessary, the instructions must give further information on these risks.

Where a faulty connection can cause a risk, incorrect connections must be made impossible by design or, if this is not possible, the information given on the parts to be connected, and the connectors if necessary.

### *1.5.5. Extreme temperatures*

High or very low temperature to machinery parts or materials in contact with or proximity arising from any accident to avoid the risk measures must be taken.



Hot or very cold material being ejected in order to prevent or protect against shall take the necessary measures.

#### *1.5.6. Fire*

Machinery must be designed and constructed in such a way as to avoid fire or overheating posed by the machinery itself or produced or by gases, liquids, dust, vapors or other substances.

#### *1.5.7. Explosion*

Machinery must be designed and constructed in such a way as to avoid any risk of explosion posed by the machinery itself or produced or by gases, liquids, dust, vapors or other substances.

The machine must be the specific Community directives or respective national laws in accordance with the explosion risks, due to its use in a potentially explosive atmosphere.

#### *1.5.8. Noise*

Machinery must be designed and constructed in such a way that the emission of airborne noise risks have been reduced to the lowest level taking account of technical progress and the availability of means of reducing noise, in particular at source.

The noise emission may be assessed using similar machinery comparative emission data.

#### *1.5.9. Shake*

Machinery must be designed and constructed in such a way that the machine risks resulting from vibrations have been reduced to the lowest level taking account of technical progress and the availability of means of reducing vibration, in particular at source.

The vibration emission may be assessed using similar machinery comparative emission data.

#### *1.5.10. Radiation*

Machine unwanted radiated emissions must be eliminated or reduced to levels that do not have adverse effects on persons.

Any functional ionizing radiation emissions must be limited to the lowest level that is sufficient in the proper functioning of the adjustment, operation and cleaning.

If a risk exists, the necessary protective measures.

Functional non-ionizing radiation emissions during setting, operation and cleaning must be limited to levels that do not have adverse effects on persons.

#### *1.5.11. External radiation*

Machinery must be designed and constructed in such a way that external radiation does not interfere with its operation.



### *1.5.12. Laser radiation*

Laser equipment is used should take into account the following factors:

- Laser equipment on machinery must be designed and constructed to prevent any accidental radiation;
- Laser equipment on machinery must be protected in such a way that the effective radiation, radiation produced by reflection or diffusion and secondary radiation damage health, and
- Laser equipment on board is the observation or adjustment of optical devices must be such that the laser radiation pose a risk to your health.

### *1.5.13. Hazardous materials and substances into the risks*

Machinery must be designed and constructed in such a way as to avoid it produces hazardous materials and substances caused by inhalation, ingestion, skin, eyes and mucous membranes and the skin penetration of the risks involved.

Where a hazard can not be eliminated, the machine is so equipped that hazardous materials and substances can be contained, evacuated, precipitated by water spraying, filtered or treated by another equally effective method.

If the process is not totally enclosed during normal operation, collection or evacuation must be situated in such a way as to achieve the maximum effect.

### *1.5.14. Risk of being trapped in a machine*

Machinery must be designed, constructed or equipped in such a way that a person can not be trapped within it or, if this is not possible, in such a way that a person can call for help.

### *1.5.15. Of slipping, tripping or falling*

Machine parts, which can be enabled in order to move about or stand must be designed and constructed in such a way that they can be of slipping, tripping or falling over, or that from them may fall.

These parts must be fitted with the structure accessible to the user, which gets a hold of, and with grabbing the user to maintain their stability.

### *1.5.16. A lightning strike*

Machinery in need of protection against the effects of lightning while being used must be equipped with a system for conducting the resultant electrical charge to the ground.

## **01.06. MAINTENANCE**

### *1.6.1. Maintenance*

Adjustment and maintenance points must be located outside danger zones. Adjustment, maintenance, repair, cleaning and maintenance operations must be done while the machine is stopped.



If one or more of the above conditions can not be satisfied for technical reasons, measures must be taken to ensure that these operations can be done safely (see section 1.2.5. Above).

Automated machinery and, if necessary, other machinery must be the ability to connect troubleshooting device.

Automatic machines are often interchangeable components must be able to be removed and replaced easily and safely. Components must be available so that these tasks can be the necessary technical means to make the specified guidelines.

#### *1.6.2. Access to operating positions and servicing points*

Machinery must be designed and constructed in such a way that it is possible to secure access to all areas where the lack of user activity it is necessary to use the machine, adjustment and maintenance.

#### *1.6.3. Isolation of energy sources*

Machinery must be fitted to isolate it from all energy sources. Such isolators must be clearly identified. They must be capable of being locked if reconnection could endanger persons. Isolators must also be capable of being locked when the user can not be any of the points to which he has access, to check that the energy is still cut off.

If the machine can be plugged into a power source, removal of the plug is sufficient, provided that the operator can check from any place to which he has access that the plug remains removed.

After the energy is cut off must be able to dissipate normally circuits of the machinery energy remaining or stored without the risk to persons.

By derogation from the requirements of the preceding paragraphs in such districts, for example, to hold parts, protect information, the inside of the light interiors, will remain connected to their energy sources. Then the user must ensure the safety of specific measures.

#### *1.6.4. Operator intervention to operate the machinery*

Machinery must be designed, constructed and equipped in such a way that the user's intervention in its activities will be limited. If the user's intervention to operate the machinery can not be avoided, it should be able to easily and safely.

#### *1.6.5. Cleaning of internal parts*

Machinery must be designed and constructed in such a way that the dangerous substances or preparations contained the insides can be cleaned without the need to go to the machine. Required jam engineering is also able to make the machine from the outside. If it is impossible to avoid entering the machinery, the machinery must be designed and constructed in such a way that it can be cleaned safely.

### 07.01. DETAILS

#### *1.7.1. The attached information and warnings*

The attached information and warnings should preferably be presented in an easily understandable symbols or pictograms. Written or verbal information and warnings must be expressed in one or more of the Member State



in the official Community language in which it is placed on the market or put into service, in addition, they can be expressed as understood by the other official Community languages.

#### 1.7.1.1. Information and communication equipment

Information needed to control the machine is unambiguous and easy to understand format. It must not be so much that they unduly burden the users.

Displays or other user and the machine between the interactive means of communication must be understandable and easy to use.

#### 1.7.1.2. Warning devices

If the failure of unsupervised operation of the machine may compromise the health and safety of persons, must bear such a way that it gives the correct sound or light signal as a warning.

If the machine is equipped with warning devices, they must be clear and conspicuous. The operator must be able at any time to check the above warning devices.

Colors and safety signs of the specific Community Directives must be respected.

#### 1.7.2. *Warning of residual*

The machine is equipped with the necessary warnings and warning devices if the inherent safe design, protection of technical measures and complementary protective measures adopted, despite the risks remain.

#### 1.7.3. *Marking of machinery*

All machinery must be marked visibly, legibly and indelibly with the following minimum information:

- The manufacturer's name and full address and in this Regulation referred to an authorized representative data;
- Name of the machine;
- CE marking (see Annex III);
- Designation of series or type;
- Serial number, and
- Year of construction, ie the year in which the manufacturing process is completed.

Affixing the CE marking shall be prohibited in the machinery or post dated.

For use in a potentially explosive atmosphere machinery designed and constructed must also be marked accordingly.

Machinery must also bear all of its type and the safe use of essential information. This information applies to 1.7.1. the requirements laid down.



Where a machine part must be handled during use with lifting equipment, its mass must be indicated legibly, indelibly and unambiguously.

#### *Section 1.7.4. Instructions*

Each machine must be accompanied by instructions for one or more of the Member State in the official Community language in which it is placed on the market or put into service.

Instructions accompanying the machinery must be "original" or "original instructions". In the case of translation must be accompanied by the original instructions.

By way of exception to the instructions by the manufacturer or his authorized representative designated by the use of experts, can be supplied in only one Community language which the experts understand.

The guidelines are drawn up in accordance with the principles set out below.

##### *1.7.4.1. Guidelines for managing the general principles of*

- a) The instructions must be drawn up by one or more of the official languages. The manufacturer or his authorized representative check one or more translation of the phrase "original instructions".
- b) If the "Original instructions" does not exist in the language or languages in which the machinery is to be used, the manufacturer or his authorized representative or the machine in the linguistic area to bring a person must be provided by a translation into the language or languages. The translations must bear the words "original instructions".
- c) The instructions must take into account not only the machine intended for use in the reasonably foreseeable misuse.
- d) In the event the machine is intended for non-professional use, the user is the wording and layout prepared taking into account the level of general education and acumen that can reasonably be expected from such operators.

##### *1.7.4.2. The contents of*

Each instruction manual must contain, where at least the following information:

- a) the manufacturer and his authorized representative, and full address;
- b) the name of the machine as it is marked on the machine itself, except for the serial number (see 1.7.3. above);
- c) the EC declaration of conformity, or a document setting out the contents of the EC declaration of conformity, showing the machinery, not necessarily including the serial number and the signature;
- d) a general description of the machine;
- e) the drawings, diagrams, descriptions and explanations necessary for the use, maintenance and repair, as well as check the correct functioning necessary;



- f) a description of one or more of the work place by operators may be using;
- g) a description of the intended use of the machine;
- h) warnings machinery must not be that experience has shown might occur;
- i) assembly, installation and connection instructions, including drawings, diagrams, and the means of attachment of the chassis or installation on which the machinery is to be installed;
- j) The installation and assembly instructions aimed at reducing noise or vibration;
- k) using the machine, and the instructions for use and, where appropriate, the training of operators;
- l) information about the residual risks that remain despite the inherent safe design measures, safeguarding and complementary protective measures, despite the measures;
- m) instructions on the protective measures to be taken by the user, including, where appropriate personal protective equipment;
- n) fitted to the machinery essential characteristics of tools;
- o) the conditions under which the machinery meets the requirement of stability during use, transportation, assembly, dismantling when out of service, testing or foreseeable breakdowns;
- p) machine that transport, handling and storage operations to ensure the safety of the guidelines laying down the machinery and its various parts where they are regularly to be transported separately;
- q) the procedures to be followed in event of an accident or breakdown, if a blockage is likely to approach, to enable the equipment to be safely unblocked;
- r) of the adjustment and maintenance operations should be carried out by the user, as well as the preventive maintenance measures that should be taken into account;
- s) instructions designed to enable adjustment and maintenance to be carried out safely, including the protective measures that should be taken during these operations;
- t) the specifications of spare parts, which are used, when these affect the health and safety;
- u) the following information on airborne noise emissions:
  - A-weighted emission sound pressure level at workstations, where this exceeds 70 dB (A). If this level does not exceed 70 dB (A), it must be notified,
  - C-weighted peak sound pressure value at workstations, where this exceeds 63 Pa (130 dB in 20 MPa),
  - Machine A-weighted sound power level, where the A-weighted emission sound pressure level at workstations exceeds 80 dB (A).

The above values are either the machine actually measured values, or those determined from measurements that



have been made technically comparable machinery which adequately represents the manufactured items.

Very large machinery, in the case of the A-weighted sound power level can be indicated instead of the A-weighted emission sound pressure levels at specified positions around the machinery.

If harmonized standards are not applied, sound levels must be measured using the most appropriate method. Noise emission levels are declared, the uncertainty related to these values always be identified. Measurements of operating conditions and measurement methods used must be described.

If one or more of the work are undefined or can not be defined, A-weighted sound pressure levels shall be measured at a distance of one meter from the machine, and 1.60 m above the floor or access platform. The maximum sound pressure position and value must be reported.

Where specific Community Directives lay down other sound pressure levels or sound power levels of the measurement standards shall apply those directives or the corresponding provisions of this paragraph;

v) where machinery is likely to emit non-ionizing radiation which may cause harm to persons, in particular persons with active or non-active implantable medical devices, information concerning the operator and exposed persons radiation.

#### 1.7.4.3. Sales Material

Sales literature describing the machinery must not be a health and safety matters relating to contradict the instructions. Performance characteristics of machinery sales material must include the same information on emissions as in the instructions.

## 2 CERTAIN CATEGORIES OF SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY

Foodstuffs machinery, machinery for cosmetics or pharmaceutical products, hand-held hand or hand-guided machinery, portable fixing machinery and other impact machinery, wood and similar physical characteristics of materials for working machines, as well as pesticide application equipment must comply with all of this chapter with the essential health and safety requirements of (see . General Principles, point 4). (24.3.2011/265)

### 02.01. FOOD AND COSMETICS OR PHARMACEUTICAL PRODUCTS MACHINES

#### 2.1.1. General

The machine, which is intended for food or cosmetics or pharmaceutical products, the processing must be designed and constructed in such a way as to avoid the risk of disease or infection.

The following requirements must be met:

- a) materials in contact or intended to come into contact with foodstuffs or cosmetics or pharmaceutical products must satisfy the relevant Directives. Machinery must be designed and constructed in such a way that these materials can be cleaned before each use. If this is not possible, use disposable parts;
- b) for all foodstuffs or cosmetics or pharmaceutical products in contact with the surfaces of disposable parts with the exception of surfaces, it is



- Be smooth and without ridges nor crevices which could harbor organic materials. The same applies to their joinings,
- Be designed and constructed so as to reduce the projections, edges and recesses to a minimum,
- Be such that they can be easily cleaned and disinfected after removing easily dismantled parts. The inside surfaces with a radius sufficient to allow thorough cleaning to make;

c) foodstuffs, cosmetics or pharmaceutical products as well as cleaning, disinfecting and rinsing derived from liquids, gases and aerosols must be able to exit from the machinery (if possible, in a "clean-up" - position);

d) machinery must be designed and constructed so as to prevent any substances or living creatures, in particular insects, entering, or any organic matter from accumulating in areas that can not be cleaned;

e) machinery must be designed and constructed in such a way that no ancillary substances hazardous to health, including the lubricants used, can come into contact with foodstuffs, cosmetics or pharmaceutical products. Where necessary, machinery must be designed and constructed in such a way that this requirement is met, may be constantly adjusted.

### *2.1.2. Instructions*

The machine, which is intended for food and cosmetics or pharmaceutical products, the processing, the instructions must indicate recommended products for cleaning, disinfecting and rinsing, as well as methods for easily accessible areas but also for areas to which access is not possible or advisable.

## **02.02. PORTABLE HAND MACHINES OR HAND CONTROL EQUIPMENT**

### *2.2.1. General*

The portable hand held machine or hand-guided machinery must meet the following requirements:

- According to the type of machinery, the supporting surface of sufficient size and sufficient number of handles and the appropriate size support, which are arranged in such a way that the machine ensure the stability of the intended operating conditions;
- If the handles can not be removed from the extract in complete safety, the machine is fitted with manually operated start and stop controls, which must be organized in such a way that they can be used for releasing the handles, except in cases where it is technically impossible or where there is an independent control system;
- Present no risks of accidental starting, or the risk that the continued operation after the operator has released the handles. If this requirement is not technically feasible, shall take all measures having equivalent effect, and
- Where appropriate, of the danger zone and the machine the machining operation can be monitored.

Portable hand grips shall be designed and constructed so that the starting and stopping straightforward.

#### *2.2.1.1. Instructions*

The instructions must give the following information portable hand held machine or hand-guided machinery



vibrations emitted by:

- The hand-arm vibration total value, if it exceeds 2,5 m/s<sup>2</sup>. If this value does not exceed 2,5 m/s<sup>2</sup>, this must be mentioned;
- Uncertainty of measurement.

The above values are either the machine actually measured values or determined from measurements that have been made technically comparable machinery which adequately represents the manufactured items.

Where the harmonized standards are not applied, the vibration must be measured using the most appropriate method for the machine.

Measurement of current operating conditions and application method or the harmonized standard will be provided.

### *2.2.2. Portable fixing machines*

#### *2.2.2.1. General*

Portable fixing machinery must be designed and constructed so that:

- Energy is transmitted to the impacted element mounting device to the non-parting portion networks;
- If the device is not set to the correct position and with sufficient pressure to, enabling device prevents impact;
- To prevent accidental tripping. If necessary, the launch will be possible only in certain, enabling device and the control device after a sequence of actions;
- Prevent injury from tripping during the treatment or impact;
- Charging and discharging can be done easily and safely.

The machine is able to be installed, if necessary, one or more of a shield. The machine manufacturer must submit the appropriate guards.

#### *2.2.2.2. Instructions*

The instructions must give the necessary information relating to:

- The accessories and interchangeable equipment that can be used in the machine;
- Suitable fastening elements or other impacted elements that are used in the machine;
- Where appropriate, the suitable cartridges.

## **03.02. WOOD AND PHYSICAL CHARACTERISTICS SIMILAR MATERIAL MACHINE TOOLS**

Wood and similar physical characteristics materials must meet the following requirements:



- a) Machinery must be designed, constructed and equipped in such a way that the piece being machined can be placed and can be guided in safety. If the piece is hand-held on the desktop, the desktop must be sufficiently stable during the work and must not impede the movement of the piece.
- b) where the machinery is to be used in conditions involving workpieces or parts of this risk must be designed, constructed and equipped in such a way as to prevent such ejection, or, if this is not possible, so that the ejection does not engender risks for the operator and exposed persons.
- c) The machine shall have an automatic brake that stops the tool in a sufficiently short time if there is a risk of touching the tool whilst it runs down.
- d) If the tool is not fully automated machine, the machine must be designed and constructed in such a way that the risk of accidental injury is eliminated or reduced.

## 2.4 PESTICIDE APPLICATION EQUIPMENT (24.3.2011/264)

### 2.4.1 *Definition*

Of pesticide application machine means a machine that is specifically designed for plant protection products on the market on 21 October 2009 of the European Parliament and of the Council Regulation (EC) No 1107/2009, Article 2, paragraph 1, of plant protection products distribution.

### 2.4.2 *General*

Pesticide application, the machine manufacturer or his authorized representative shall ensure that the risk of accidental environmental exposure to pesticides is estimated to general principles in section 1 of the risk assessment and mitigation in accordance with the.

Of pesticide application machinery must be designed and constructed in the first paragraph of the risk assessment, taking into account so that the machine can be operated, adjusted and maintained without exposure of the environment to pesticides unintentionally.

Spills should always be avoided.

### 2.4.3 *Controls and Monitoring*

It must be possible to easily and accurately control and monitor the application of pesticides from and stop it immediately.

### 2.4.4 *Filling and emptying*

Machinery must be designed and constructed so that its precise filling with the necessary quantity of pesticide and its complete emptying and to prevent pesticide spills and contamination of the water source during these operations.

### 2.4.5 *Application of pesticides*

#### 2.4.5.1 Application rate



The machine is equipped so that the application rate can be adjusted easily, accurately, and reliably.

#### 2.4.5.2 Pesticide Distribution, fate and transport

Machinery must be designed and constructed so as to ensure that the pesticide is deposited on target areas, to minimize losses to other areas and to prevent drift of pesticide to the environment. If necessary, must be ensured an even distribution and homogeneous.

#### 2.4.5.3 Tests

In order to ensure that the relevant parts of the machinery responsible for 2.4.5.1 and 2.4.5.2 the requirements of the manufacturer or his authorized representative shall perform or have performed on each of the aircraft type in the appropriate tests.

#### 2.4.5.4 Losses during stoppage

Machinery must be designed and constructed so as to prevent the loss of the pesticide application function is stopped.

### 2.4.6 Maintenance

#### 2.4.6.1 Cleaning

Machinery must be designed and constructed in such a way that it is easy and thorough cleaning without polluting the environment.

#### 2.4.6.2 Service

Machinery must be designed and constructed in such a way that the replacement of worn parts is the contamination of the environment.

### 2.4.7 Inspections

It must be possible to connect easily check the correct functioning of the necessary measuring instruments.

### 2.4.8 nozzles, strainers and filters

Nozzles, strainers and filters must be marked so that their type and size can be clearly seen.

### 2.4.9 Indication of pesticide in use

The machine must be fitted with a specific mounting on which the user can place the name of the pesticide.

### 2.4.10 Help

The instructions shall include the following information:

1) precautions to be taken during mixing, loading, application, emptying, cleaning, servicing and transport, in order to avoid contamination of the environment;



- 2) The detailed conditions of use the different operating environments, including the corresponding preparation and adjustments to ensure that the pesticide on target areas while minimizing losses in other areas, to prevent drift to the environment and, if appropriate, an even distribution and homogeneous deposition;
- 3) the nozzles, strainers and filters, types and sizes that can be used with the machinery;
- 4) The cost of the machine and affect the correct functioning parts, such as nozzles, strainers and filters, checks and the parts of the vaihtamiskriteerit and methods;
- 5) calibration, daily maintenance, winter storage, and other checks necessary to ensure the proper operation of machines;
- 6) The types of pesticides that may cause incorrect functioning of the machinery;
- 7) The reference to the fact that the user is kept up to date referred to in paragraph 2.4.9 on the specific mounting used for the name of the pesticide;
- 8) any special equipment or accessories, and user interface and the necessary precautions to be taken;
- 9) The reference to the fact that the machinery may be subject to national requirements in relation to the specified bodies carried out regular inspections of the Community framework for pesticide achieve the sustainable use of 21 October 2009 of the European Parliament and of the Council Directive 2009/128/EC in accordance with
- 10) The machine features that must be checked to ensure proper functioning of machines and
- 11) The instructions for connecting the necessary measuring instruments.

### 3 MOBILITY OF MACHINERY OFFSET HAZARDS DUE TO SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY

Hazards due to the movement of the machines must be accessible to all in this chapter with the essential health and safety requirements (see General Principles, point 4).

#### 03.01. GENERAL

##### 3.1.1. Definitions

a) *its mobility Machinery presenting hazards due to:*

- The machine, the operation of which requires either mobility while working, or continuous or semi-continuous movement between a succession of fixed working locations, or
- A machine that is in use is not transferred, but which can be transferred from place to place facilitating.

b) *The driver* of the machine responsible for the movement, which can travel with the machine, foot, causing the engine or operate the machine from a remote location.

#### 03.02. WORK POSITIONS



### *3.2.1. Control location*

The control place must be such as visibility, the driver can operate the machine and its tools in their foreseeable conditions of use, safety for himself and the exposed persons. Where necessary, appropriate devices to inadequate direct vision remedy hazards.

The driver passes through the plane ride control position must be designed and constructed in such a way that the driver no control location risks from inadvertent contact with the wheels and tracks.

Ride-operator's control position must be designed and constructed in such a way that it can be fitted with a cab, provided that it does not increase the risk and there is room. The cab must incorporate a place for the instructions needed for the driver.

### *3.2.2. Seating*

The machine nomadic users and other persons seating is designed and equipped with a restraint system that persons in their seats, if there is a risk that they may be crushed parts of the machine and the ground machine roll or tip over, especially in the case of 3.4.3. or 3.4.4. protective structure referred to for the machine. This does not, however, restrict the movements necessary for the seats, or the structure caused by the suspension movement. Such restraint systems should not be installed if they increase the risk.

### *3.2.3. Other persons*

If the operating conditions in accordance with the machine can be transported or it can work on a temporary or a regular person, other than the driver, they need appropriate places, so that they can be transported or to work on it without risk.

Described in 3.2.1. the second and third subparagraph shall also apply to persons other than the driver seats reserved.

## 03.03. CONTROL SYSTEMS

Where necessary controls to prevent unauthorized use.

Remote controls, each control unit must clearly identify what the machine is controlled by the unit.

The remote control system must be designed and constructed in such a way as to affect only the machinery and its operation.

Remote-controlled machinery must be designed and constructed in such a way that it responds only to the intended control units signals.

### *3.3.1. Controls*

The driver must be able to use all machine operations control devices required to control locations, with the exception of activities that can be used safely only by control devices located elsewhere. These functions include, in particular, those for which operators other than the driver are responsible or for which the driver has to leave the place to manage them safely.



Where there are pedals must be designed, constructed and installed in such a way that the driver can use them safely and that the improper use of risk as small as possible. They must have a slip-resistant surface and be easy to clean.

Where their operation can lead to hazards, notably dangerous movements, the control device must return to the neutral position as soon as they are released, with the exception of controls, those with preset positions.

Wheeled machinery, the steering is designed and constructed in such a way that it reduces the guide wheels caused by shocks to the steering wheel or lever force of sudden movements.

Differential lock devices shall be designed and positioned in such a way that the differential unlocked when the machinery is moving.

In paragraph 1.2.2. sixth paragraph, which concerns or audible signals, applies only to withdrawal.

### *3.3.2. Start-up and movement*

Ride a self-propelled machine can move only if the driver is at the controls.

If the machine is equipped with operational reasons, devices which exceed its normal clearance zone (eg stabilizers, jib, etc.), the driver must be able to easily check before moving the machinery, that such devices are located and the business can be done safely.

This also applies to all other parts, which have to be in particular positions, locked if necessary, so that business can be done safely.

Movement of the machinery must depend on the aforementioned parts in a safe position, where there is no other risks.

The machine must not leave the unintended movement of the motor.

### *3.3.3. The drive function*

Self-propelled machinery and its trailers must meet the require-stop, braking and immobilisation so as to ensure safety under all the operating, loading, speed, ground and gradient conditions, without prejudice to the provisions of road traffic.

The driver must be able to slow down and stop self-propelled machinery using it primarily referred to the unit. The machine must be fully independent and easily accessible by a control unit equipped with an emergency device slowing down and stopping, if the security required by the main unit failure or the failure of the energy supply.

Where safety so requires, a parking device must be provided to render stationary machinery immobile. This unit can be combined with one another in the second paragraph, if it is purely mechanical.

Remote-controlled machinery must be equipped with devices using the machine can be automatically and immediately and for preventing potentially dangerous operation in the following cases:

- If the driver loses control;



- If it receives a stop signal;
- If the safety-related part failure is detected, or
- If no validation signal is detected within a specified period of time.

The drive function does not apply to 1.2.4. points.

#### *3.3.4. Pedestrian-controlled machinery Movement*

Pedestrian-controlled self-propelled machinery must be possible only if the driver sustained action on the relevant control device. The machine is not allowed to start, especially when starting the engine.

Pedestrian controlled machine control systems must be designed in such a way that inadvertent movement of the machine towards the driver risks, in particular the compression and injury from rotating tools, is minimized.

Machine speed has to be dimensioned taking into account the driver on foot.

If the machine can be attached to a rotary tool to actuate shall not be possible when the reverse gear is engaged, except where movement of the tool. In the latter case, the reversing speed must be low enough so as not to endanger the driver.

#### *3.3.5. Control circuit failure*

If you do have power steering, no power steering failure in the power supply must not prevent machinery from being steered during the time required to stop it.

### 03.04. PROTECTION AGAINST MECHANICAL HAZARDS

#### *3.4.1. Uncontrolled movements*

Machinery must be designed, constructed and where appropriate placed on its mobile support so that when moved, the uncontrolled oscillations do not affect its stability or exert excessive strain on its structure.

#### *3.4.2. Moving transmission parts*

By way of derogation 1.3.8.1. shall, in the engine compartment moving parts hinder movable guards do not need to be connected to the operation of the machine, if they can be opened only by a control point the tool, a key or a control device, provided that the control can be locked in place in the cockpit.

#### *3.4.3. Roll-over and tip-over*

If a self-propelled machine operator, as well as one or more users or any other person's place is a plane ride, and there is a machine or tip to crash risk, the machine is fitted with an appropriate protective structure, unless this increases the risk.

This structure must be such that in the event of rollover or it affords the ride-on with sufficient safety status.

The manufacturer or his authorized representative must, for each type of structure, or have performed the



appropriate tests to verify that the design meets the requirements set out in the second subparagraph.

#### *3.4.4. Falling objects*

If a self-propelled machine operator, as well as one or more users or any other person's place is a plane ride, and falling objects or materials may pose a risk, the machine must be designed and constructed in such a way that these risks are taken into account, and if this is its size, it is possible shall be provided with appropriate protective structure.

This structure must be such that the falling objects or material, it guarantees the ride-on with sufficient safety status.

The manufacturer or his authorized representative must, for each type of structure, or have performed the appropriate tests to verify that the design meets the requirements set out in the second subparagraph.

#### *3.4.5. Access Roads*

The handrails and steps must be designed, constructed and installed in such a way that the operators use them instinctively and do not use the control devices to assist.

#### *3.4.6. Towing Equipment*

Used to tow or to be towed must be fitted with towing or coupling devices designed, constructed and located to ensure easy and secure connection and disconnection and to prevent accidental disconnection during use.

If the towbar load requires, such machinery must be equipped with a bearing surface suited to the load and the ground.

#### *3.4.7. The self-propelled machinery or a tractor and the machine connected to the power transmission between the*

PTO drive shafts that connect the self-propelled machinery or a tractor engine is connected to the first fixed bearing shall be designed and constructed in such a way that all the moves during operation is protected over its whole length.

The PTO side attached to the PTO shaft is protected against power take-off side, either self-propelled machinery or a tractor guard fixed and linked or offering equivalent protection by any other device.

This cover can be opened to allow access to the PTO is possible. Cover in place there must be enough so that the drive shaft damaging the shield machine or a tractor is moving.

Connected to the machinery side, the input shaft must be protected against the machine attached to protect.

Torque limiters or freewheels may be fitted to universal joint transmissions only on the side adjoining the driven machine. The PTO shaft is marked accordingly.

Connected to the machine, the operation of which requires a removable mechanical transmission device to connect it to self-propelled machinery or a tractor is fitted with a pivot shaft mounting system that the propeller shaft and its guard are not damaged by contact with the ground or part of the machine when the machine is



disconnected.

The outside parts of the guard must be designed, constructed and installed in such a way that they can not turn the PTO shaft included. When the axle is equipped with simple joints, the cap is covered with a cardan shaft to the end of the inner fork and wide-angle joints, at least the outer joint of the middle of the conflict.

If access to working positions are close to the drive shaft, they must be designed and constructed so that the shaft can not be used as steps, unless designed and constructed for that purpose.

### 3.5. PROTECTION FROM THE RISKS

#### 3.5.1. Batteries

The battery housing must be designed and constructed in such a way as to prevent the electrolyte being ejected on to the operator roll or tip over, and the accumulation of vapors in places occupied by operators.

Machinery must be designed and constructed in such a way that the battery can be disconnected from the circuit easily accessible by a device intended for this purpose.

#### 3.5.2. Fire

Depending on the hazards anticipated by the manufacturer and the size of the machine to allow either allow easily accessible fire extinguishers, or be fitted with a fixed fire-fighting systems.

#### 3.5.3. Emissions of hazardous substances

In paragraph 1.5.13. The second and third subparagraphs shall not apply to the machine, which is the main function of the spraying. However, the user is protected from exposure to such hazardous emissions against.

### 06.03. INFORMATION AND INDICATIONS

#### 3.6.1. Signs, signals and warnings

All machinery must, where appropriate, use, adjustment, and maintenance instruction plates, or plates, to enable people to health and safety. They must be chosen, designed and constructed in such a way that they are clearly visible and indelible.

Off-hand drive machine must have the following equipment, without prejudice to the provisions of the Road Traffic:

- An acoustic warning device to alert persons;
- The anticipated operating conditions with a light signaling system, with the exception of a machine that is intended solely for underground working and having no electrical power;
- Where appropriate connection between a trailer and the machine signaling system operation.

Remote-controlled machinery which under normal conditions of use, exposes persons to the risk of impact or crushing must be fitted with appropriate signaling devices to signal its movements or with means to protect



persons against such hazards. The same applies to a machine with the use of a constant repetition of the same axis, if the driver does not have direct visibility of the rear area.

The machine is so constructed that the warning and signaling devices can not be deactivated. If security is therefore necessary, these devices must be provided so that their functional status can be checked, and their failure must be made apparent.

If the machinery or its tools is particularly hazardous, signs on the signs which warn of approaching the machinery while it is working. Signs must be legible at a sufficient distance to ensure the safety.

### *3.6.2. Entries*

All machinery must be marked legibly and indelibly with the following information:

- Rated power in kilowatts (kW);
- The most usual configuration mass in kilograms (kg);

and, if necessary:

- The maximum bet to hook, in Newtons (N);
- Maximum vertical load on the coupling hook, in Newtons (N).

### *Section 3.6.3. Instructions*

#### *3.6.3.1. Shake*

The instructions must give the following information and hand-body vibration:

- Hand-arm vibration total value, if it exceeds 2,5 m/s<sup>2</sup>. If this value is not exceeded, it must be mentioned;
- The whole-body vibration acceleration, the maximum weighted root mean square (RMS value), if it exceeds 0,5 m/s<sup>2</sup>. If this value is not exceeded, it must be mentioned;
- Uncertainty of measurement.

The above values are either the machine actually measured values, or those determined from measurements that have been made technically comparable machinery which adequately represents the manufactured items.

Where the harmonized standards are not applied, the vibration must be measured using the most appropriate method for the machine.

Measurements of operating conditions and measurement methods used must be described.

#### *3.6.3.2. Versatility*

A multi-purpose machine instructions, depending on the equipment used and interchangeable equipment instructions must contain the information necessary for the basic machine and attached to the interchangeable



equipment for the safe fitting and use.

## 4 SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS TO OFFSET THE HAZARDS

Machines, which involve increasing the risks to comply with all of this with the relevant essential health and safety requirements (see General Principles, point 4).

### 01.04. GENERAL

#### 4.1.1. Definitions

- a) *to raise the* purposes of movement, for the transfer of goods or persons of unit loads consisting given moment, which requires to change the level.
- b) *guided load* means the load where the total movement takes place determined by fixed points along rigid or flexible guides.
- c) *The capacity factor* means the arithmetic ratio between the manufacturer or his authorized representative up to the maximum load to which a component is able to hold it and the maximum working load marked on the component.
- d) *The test coefficient* refers to the static or dynamic tests on lifting equipment or lifting the load used the arithmetic ratio between the lifting device or accessory or marked with the maximum permissible workload.
- e) *In the static test* means the test during which lifting machinery or lifting accessory is first inspected and subjected to the maximum working load multiplied by the appropriate static test coefficient. After removing the load of the lifting machinery or lifting accessories are checked again, thus ensuring that no damage has occurred.
- f) *The dynamic test* means the test during which lifting machinery in all its possible configurations at the maximum working load multiplied by the appropriate dynamic test coefficient taking into account the dynamic behavior of the lifting device to ensure proper functioning.
- g) *The carrier* means the part of the machinery on or in which lifted persons or goods.

#### 4.1.2. Protection against mechanical hazards

##### 4.1.2.1. Lack of stability risks

Machinery must be designed and constructed in such a way that the 1.3.1. stability required by section maintained both in service and out of service, including all transportation, assembly and dismantling phases, foreseeable component failures and also during the instruction manual tasks during the tests. For this purpose, the manufacturer or his authorized representative shall apply the appropriate verification methods.

##### 4.1.2.2. Guide rails and rail tracks equipment

The machine is fitted with guide rails and tracks with impressive devices to prevent derailment.

If, despite such devices derailment or a rail or of a running component failure is possible, the machine must be



equipped with devices to prevent the device, component or load from falling or the machinery from overturning.

#### 4.1.2.3. Mechanical strength

Machinery, lifting accessories and their components must be capable of use both in and, when not in use, the loadings, the installation and operating conditions, and in all relevant configurations, taking into account climatic factors and forces exerted by persons. This requirement must also be satisfied during transport, assembly and dismantling.

Machinery and lifting accessories must be designed and constructed so as to prevent failure from fatigue and wear, taking due account of their intended use.

The materials used must be chosen for the operating environments, with particular regard to corrosion, abrasion, impacts, extreme temperatures, fatigue, brittleness and aging.

Machinery and lifting accessories must be designed and constructed to withstand the overload in the static tests without permanent deformation or patent defect. Strength calculations must take into account the static test coefficient chosen in order to ensure adequate levels of security. In general, the coefficients can be used for the following values:

a) manually-operated machinery and lifting accessories: 1,5

b) other machinery: 1,25.

Machinery must be designed and constructed in such a way that it passes without failure, the dynamic tests carried out using the maximum working load multiplied by the dynamic test coefficient. This dynamic test coefficient is chosen so as to guarantee an adequate level of safety. This factor is usually 1.1. In general, tests are carried out at the indicated nominal speeds. If the machine control circuit allows the number of simultaneous movements, the tests shall be carried out under the least favorable conditions, usually combining the movements concerned.

#### 4.1.2.4. Pulleys, drums, wheels, ropes and chains

Pulleys, drums and wheels must have a diameter commensurate with the size of the ropes or chains with which they are appropriate.

Drums and wheels must be designed, constructed and installed in such a way that they ropes or chains can be wound up without getting out of their uraltaan.

Directly for lifting or supporting the use of ropes must not include any splicing other than at their ends. Splicings tolerated in installations which are designed to be modified regularly according to needs of use.

Ropes and their endings have a working coefficient chosen so as to guarantee an adequate level of safety. This factor is usually 5

Lifting chains have a working coefficient chosen so as to guarantee an adequate level of safety. This factor is usually 4



The manufacturer or his authorized representative shall perform or have performed each directly for lifting the load used in the wire rope and chain and cable terminals to the appropriate tests to verify that an adequate working coefficient has been attained.

#### 4.1.2.5. Lifting accessories and their components

Lifting accessories and their components must be sized fatigue and aging processes in the light of such a number of operating cycles, which corresponds to the expected life of the application referred to in the specified operating conditions.

In addition:

- a) steel rope and rope-end combination coefficient is chosen so as to guarantee an adequate level of safety, this factor is usually 5 Ropes must not comprise any splices or loops other than at their ends;
- b) where chains with welded links must be short linked. The chains have a working coefficient chosen so as to guarantee an adequate level of safety. This coefficient is usually 4;
- c) for textile ropes or slings is the capacity factor depends on the material, method of manufacture, dimensions and use. This coefficient is chosen so as to guarantee an adequate level of safety. In general, the coefficient is 7, provided the materials used are very good quality and the manufacturing process is suitable for the intended use. If this is not the case, the coefficient is usually set to a higher level in order to ensure an equivalent level of safety. Textile and rakseissa not be any knots, connections or splicing with the exception of the sling, except in the case of an endless sling;
- d) all metallic components that make up the sling, or used with, a working coefficient chosen in such a way as to ensure an adequate level of safety. This coefficient is usually 4;
- e) multilegged sling maximum working load shall be determined taking into account the capacity factor of the weakest leg, the number of legs and a reduction factor which depends on the means of fixation;
- f) The manufacturer or his authorized representative shall perform or have performed for every a, b, c and d of component appropriate tests to verify that an adequate working coefficient has been attained.

#### 4.1.2.6. Control of movements

Movements must act in such a way that the machine into which they are installed is kept safe.

- a) Machinery must be designed and constructed or fitted with devices that the extent of the movement of its components will remain within the specified limits. Before the operation of such devices must, where necessary, issue a warning.
- b) Where several fixed or rail-mounted machines can be maneuvered simultaneously in the same place, exposing the risks caused by the collision, the machinery must be designed and constructed in such a way that they can be installed on systems to avoid this risk.
- c) Machinery must be designed and constructed in such a way that the loads can not creep dangerously or fall freely and unexpectedly, even in the event of a partial or complete failure, or when the user stops operating the



machine.

d) Under normal operating conditions may not be possible to lower the load solely by friction brake, except in the case of machinery whose function requires it to operate in this way.

e) Holding devices must be designed and constructed in such a way that inadvertent dropping of the loads is avoided.

#### 4.1.2.7. Movements of loads during handling

Driving position of machinery must be placed in such a way as to ensure the widest possible view of the moving parts of trajectories in order to avoid the possible risk of causing collisions with persons, equipment or other at the same time running the machines.

A machine with guided loads must be designed and constructed so as to prevent the load, the unit or the counterweights by movement of persons from being injured.

#### 4.1.2.8. Fixed landings machines

##### 4.1.2.8.1. Of the carrier

The fixed stop between the levels of the moving machine the load-carrying unit, stop levels and stop levels must be controlled by means of rigid conductors. Scissor systems are also regarded as rigid guidance.

##### 4.1.2.8.2. Access to the carrier unit

Where persons have access to the carrier, the machinery must be designed and constructed so as to ensure that the carrier move to it when getting up, especially during loading and unloading.

Machinery must be designed and constructed in such a way as to ensure that the carrier and the landing level height difference between the risk of tripping.

##### 4.1.2.8.3. The moving carrier due to contact with the risks

Access to the carrier flow during normal operation must be prevented, if it is necessary to 4.1.2.7. the second paragraph of requirement.

If inspection or maintenance, there is a risk that the carrier under or on top of a person could be trapped carrier and any fixed parts, sufficient free space must be provided either in the form of safety zones or blocking the movement of the mechanical equipment.

##### 4.1.2.8.4. The load falling off the carrier

Machinery must be designed and constructed in such a way that the risk of load falls the carrier is prevented.

##### 4.1.2.8.5. Landings

Levels arrest of the persons risk of contact with the moving carrier or other moving parts must be prevented.



People falling carrier of the path when the unit is not at a landing shall be prevented by installing guards. These guards must not open into the travel mode. They must be fitted with an interlocking device controlled by the carrier according to the location that prevents hazardous movements, until the guards are closed and locked, and hazardous opening of a guard until the unit is stopped at the corresponding stop level.

#### *4.1.3. Fitness for purpose*

The manufacturer or his authorized representative shall ensure that appropriate measures have been taken or that they are made to ensure that the ready to use both hand and power-driven machinery or lifting accessories can be safely used in their specified functions when lifting machinery or lifting accessories are placed on the market or put into service for the first time .

In section 4.1.2.3. referred to in the static and dynamic tests have been carried out on all lifting equipment for the ready to use.

If the machine can not be assembled in the manufacturer or his authorized representative areas, appropriate measures must be made on the spot. Otherwise, the measures can be done either in the manufacturer's premises or at the site.

### 02.04. NON hand-held MACHINERY REQUIREMENTS

#### *4.2.1. Control of movements*

Machinery or its equipment controlling movements of the devices must be. However, for partial or complete movements in which there is no load or the machinery colliding risk, the said devices may be replaced by control devices authorizing automatic stops at pre-selected positions without, to-run control device.

#### *4.2.2. Load control*

The machine has a maximum working load of not less than 1000 kg, or the overturning moment of not less than 40 000 Nm must be fitted to warn the driver and dangerous movements prevention devices

- Of overloading, either the maximum permitted working load or the maximum working torque being exceeded as a result of, or
- Overturning moment being exceeded.

#### *4.2.3. Of cable-controlled systems*

Lifting, lowering or raising and lowering ropes must be equipped with counterweights or by a device that makes it possible to continue the management of the tension of the rope.

### 03.04. INFORMATION AND INDICATIONS

#### *4.3.1. Lifting chains, ropes and webbing*

Each length of lifting chain, rope or belt, which is not part of an assembly must bear a mark or, where this is not possible, a plate or irremovable ring, indicating the manufacturer or his authorized representative and the relevant certificate number.



The certificate mentioned above must include at least the following information:

- a) the manufacturer and, where appropriate, his authorized representative, his name and address;
- b) a description of the chain or rope which includes:
  - Nominal,
  - The structure,
  - Preparation of material, and
  - Any material made of special metallurgical treatment;
- c) the test method used;
- d) a chain or rope should be referred to the maximum allowable load. Possible depending on the application can be given range of values.

#### *4.3.2. Lifting accessories*

Lifting accessories must show the following particulars:

- Identification of the material where this information is needed for safe use;
- The maximum working load.

If lifting accessories is not possible to make notes, these must be firmly attached disk or other equivalent, in which the first paragraph to be provided.

The information must be legible and located in a place where they will not be lost due to wear, and where they do not compromise the lifting strength of the accessory.

#### *4.3.3. Lifting*

Machinery must be marked very clearly the maximum working load. The marking shall be clearly legible, indelible, and it should not be in code form.

If the maximum working load depends on the configuration, each driving position must be provided with a load for each configuration is primarily the work load, in diagrammatic form or by means of tables form.

For lifting goods only intended for the machine is equipped with a load-carrying unit, which allows access to persons, must bear a clear and indelible warning prohibiting the lifting of persons. This warning must be visible at each place where access is possible.

### 04.04. INSTRUCTIONS

#### *4.4.1. Lifting accessories*

Each lifting accessory or each commercially indivisible batch of lifting accessories must be accompanied by



instructions including at least the following information:

- a) purpose;
- b) the use (particularly for lifting accessories such as magnetic or vacuum, which do not fully comply with section 4.1.2.6. requirements of subparagraph e);
- c) the assembly, operating and maintenance instructions, and
- d) the static test coefficient.

#### *4.4.2. Lifting*

Lifting machinery must be accompanied by instructions containing the following information:

- a) Specifications and in particular,
  - The maximum working load and, where appropriate, a copy of 4.3.3. described in the second paragraph or load table,
  - Support or attachment points, the forces and, if necessary characteristics of the tracks,
  - Where appropriate, the definition and the method of installation;
- b) operating and maintenance log the contents of the latter is not supplied with the device;
- c) advice for use when the user's direct line of sight to the load missing;
- d) where appropriate, a test report for the manufacturer or his authorized representative carried out by or static and dynamic tests;
- e) the necessary instructions for 4.1.3. The measures referred to before first putting those devices that are assembled in the manufacturer's premises ready for use.

## 5 UNDERGROUND WORK MACHINERY INTENDED FOR ADDITIONAL ESSENTIAL HEALTH AND SAFETY

Intended for underground work must meet all the machines in this chapter with the essential health and safety requirements (see General Principles, point 4).

### 05.01. Lack of stability RISKS

Powered roof supports must be designed and constructed in such a way as to maintain a given direction when moving and not slip before and while they are under load and after the load has been removed. They must be equipped with anchorages upper plates of the individual hydraulic subsidies for the.

### 05.02. GETTING AROUND

Powered roof supports must allow for unhindered movement.



### 03.05. CONTROLS

The rail mounted machine accelerator and brake controls must be hand-operated. Enabling devices may be foot-operated.

Powered roof supports control devices must be designed and installed in such a way that during the exchange, operators are sheltered by a support. Control devices must be protected against any accidental release.

### 04.05. STOP

Self-propelled, track-running underground working of the driven machine must be equipped with an enabling movement of the machinery driving circuit so that the movement is stopped if the driver is no longer driving the movement.

### 05.05. FIRE

In such a machine, which is highly flammable parts must be 3.5.2. in the second indent of a fixed fire extinguishing system.

Underground working of the engine braking system shall be designed and constructed in such a way that it does not produce sparks or cause fires.

Combustion engines for use in underground work of a machine referred to may be fitted only with engines using fuel with a low vaporising pressure and which caused sparks of electricity are not possible.

### 06.05. EXHAUST EMISSIONS

Engine exhaust emissions must not be directed upwards.

## 6 SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR MACHINERY PARTICULAR HAZARDS DUE TO THE LIFTING OF PERSONS

Machinery presenting hazards due to the lifting of persons must meet all of this Chapter, the relevant essential health and safety requirements (see General Principles, point 4).

### 01.06. GENERAL

#### *6.1.1. Mechanical strength*

The carrier, which may be the pelastautumislukut must be designed and constructed to offer the space and strength corresponding to the maximum permitted number of persons and the maximum working load.

In paragraph 4.1.2.4. and 4.1.2.5. components set out in the use of the coefficients are not sufficient to lift persons referred to in engines, and they tend to be doubled. Persons or persons and goods intended for lifting equipment must be installed in the carrier bearing or support system, which is designed and constructed in such a way as to ensure an adequate overall level of safety and to prevent the carrier falling.

If the carrier is used for suspension ropes or chains, will usually require at least two of their attachment to the cables or chains.



### *6.1.2. Other than human strength Loading control for machinery*

Referred to in 4.2.2. shall apply in the maximum working load and overturning moment, unless the manufacturer can show that the risk of overloading or overturning.

## 02.06. CONTROLS

Where safety requirements do not impose other solutions, the carrier must generally be designed and constructed in such a way that persons in the carrier can control the upward and downward movements and, if necessary, other movements.

Those control devices must be able to use to get the same movement driven by other devices, with the exception of emergency stop devices.

Controls for these movements must be run type except where the carrier itself is completely enclosed.

## 06.03. Carrier in or on Risks to persons

### *Section 6.3.1. Carrier of the movement of the risks posed by*

Machinery for lifting persons must be designed, constructed or equipped in such a way that the load-carrying unit of acceleration or deceleration of any risk to personnel.

### *6.3.2. The carrier Risk of persons falling*

The carrier must not tilt the machine and the unit during the movement so much so that the unit would cause for falling.

Where the carrier is designed as a work station, to ensure stability and to prevent hazardous movements.

If the above-1.5.15. The measures referred to are not adequate, carriers must be fitted with a sufficient number of suitable anchorage points for the number of persons allowed. The anchorage points must be strong enough to withstand the use of fall protection.

The floor or the ceiling if any, pelastautumisluukut or side doors must be designed and constructed in such a way that they can not inadvertent opening and must open in a direction that there is no risk of falling, should they open unexpectedly.

### *Section 6.3.3. On the carrier due to objects falling risk*

If on the carrier and objects falling and endangering persons, the unit must be equipped with a protective roof.

## 04.06. Fixed landings MACHINES

### *6.4.1. The load-carrying in or on the risks to persons*

The carrier must be designed and constructed in such a way as to prevent risks arising in or on persons or objects in or on fixed or moving elements. To meet this requirement, the carrier itself must be completely enclosed with doors fitted with an interlocking device that prevents hazardous movements of the carrier unless



the doors are not closed. The doors must remain closed if the carrier stops between landings where a risk of falling.

Machinery must be designed, constructed and, where necessary, be fitted with devices to prevent the load-carrying unit uncontrolled movements up or down. These devices must be able to stop its maximum working load and at the foreseeable maximum speed.

Stop function may not cause, whatever the load for harmful braking.

#### *6.4.2. Controls levels*

Levels of the control equipment, with the exception of emergency equipment used, must not initiate the load-carrying unit, if the carrier are used to control devices or the unit is not level.

#### *6.4.3. Access the carrier is*

Levels and the load-carrying unit guards must be designed and constructed so as to ensure safe transfer to and from the reference to the goods and persons to be lifted.

### 06.05. POSTS

The carrier must ensure the security of the necessary information, including the unit's maximum number of passengers and the maximum working load.

## *Annex II*

### **INSURANCE**

#### **1 CONTENTS**

##### **A. MACHINERY EC Declaration of Conformity**

This declaration and translations thereof must be drawn up under the same conditions as the instructions (see Annex I, section 1.7.4.1. Paragraph a and b), and must be typewritten or else handwritten in capital letters.

This declaration relates exclusively to the machinery as it is placed on the market, and does not cover the end-user to the following components which are added or created by the measures.

EC declaration of conformity must contain the following information:

- 1) The manufacturer's name and full address, and, where appropriate, his authorized representative;
- 2) the name and address of who is authorized to compile the technical file. A person must be established in the Community;
- 3) the designation and identification, including generic denomination, function, model, type, serial number and commercial name;
- 4) an explicit declaration that the machine complies with the provisions of this Regulation or the relevant directive



(2006/42/EC), the relevant provisions and, if necessary, a similar notice other Directives or relevant provisions with which the machinery complies. These references must be those of the European Union in the Official Journal published these texts;

- 5) if applicable, the name, address and identification number, which is set out in Annex IX to the EC type-examination, the EC type-examination certificate;
- 6) if applicable, the name, address and identification number, which has been approved by Annex X to the full quality assurance procedure;
- 7), where appropriate, reference to harmonized standards which have been used;
- 8) where appropriate, reference to other technical standards and specifications used;
- 9) the adoption of the declaration of conformity the time and place;
- 10) the name and signature of who is authorized to draw up the declaration by the manufacturer or his authorized representative on behalf of.

## B. SEMI-FINISHED THE MACHINERY OF INCORPORATION

This declaration and translations thereof must be drawn up under the same conditions as the instructions (see Annex 1, section 1.7.4.1. Paragraph a and b), and must be typewritten or else handwritten in capital letters.

Of incorporation must contain the following information:

- 1) part of the complete machine manufacturer's name and full address, and, where appropriate, his authorized representative;
- 2) the name and address of who is authorized to compile the relevant technical documentation. This person has to be established in the Community;
- 3) The part of the complete machine description and identification, including generic denomination, function, model, type, serial number and commercial name;
- 4) a declaration of this Regulation, the essential requirements are applied and fulfilled and that the relevant technical documentation has been prepared in accordance with Annex VII, Part B, and, if necessary assurance that the machine is ready to part with other relevant directives. These references must be those of the European Union in the Official Journal published these texts;
- 5) a commitment to provide this incomplete machine, relevant information on the national authorities a reasoned request. This shall include the transfer modalities and shall not prejudice the final part of the machine manufacturer's intellectual property rights;
- 6) a statement that the partly completed machinery must not be put into service until the final machinery into which it is to be accompanied, if necessary, reported to be of this Regulation or the corresponding provisions of the Directive;
- 7) the adoption of a declaration of incorporation time and place;



8) the name and signature of the person empowered to draw up the declaration by the manufacturer or his authorized representative on behalf of.

## 2 STORAGE

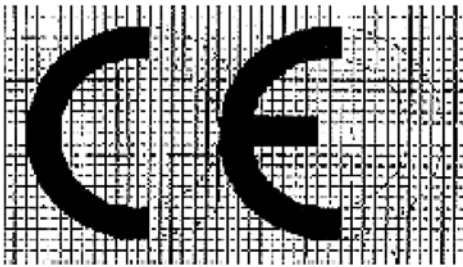
The manufacturer of machinery or his authorized representative shall keep the original EC declaration of conformity for at least ten years from the last date of manufacture of the machine.

Partly completed machinery manufacturer or his authorized representative shall keep the original declaration of incorporation for at least ten years, partly completed machinery from the last date of manufacture.

### *Annex III*

#### **CE MARKING**

The CE conformity marking consisting 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.

CE marking in different parts must be substantially the same vertical dimension, which may not be less than 5 mm. This minimum dimension may be waived for small-scale machinery.

The CE marking shall be affixed by the manufacturer or his authorized agent's name in the immediate vicinity using the same technique.

If it is applied in § 7 of the 3 or 4 referred to in subsection full quality assurance procedure, the CE marking shall be accompanied by the identification number of the notified body.

### *Annex IV*

#### **CATEGORIES OF MACHINERY TO WHICH ONE § 7 OF 3 OR 4 referred to in subsection PROCEDURE:**

1 wood and similar physical characteristics or for working with meat materials, and similar physical characteristics, materials, working with the following types (single or multi-blade) Circular saws

01.01. sawing fixed blade or stationary blades with permanent-saws with a fixed bed or support with manual feed of the workpiece or with a demountable power feed

02.01. sawing fixed blade or blades in place of permanent cutting, which is a manual reciprocating saw-bench or carriage



03.01. sawing fixed blade or blades in place of permanent cutting, having a built-in mechanical feed device for the supply or unloading,

01.04. sawing movable blade knives with cutting, having mechanical movement of the blade and the feed or unloading;

2 Hand-fed surface planing machines for woodworking;

3 woodworking for one-side dressing with a mechanical feed device, with manual loading or unloading;

4 wood and similar physical characteristics or for working with meat materials, and similar physical characteristics, materials, working with the following types of band saws with manual loading or unloading

01.04. sawing machinery with fixed blade saws with a fixed or reciprocating-movement bed or support,

02.04. sawing machinery with blade can be attached to carriage with reciprocating motion;

5 wood or similar physical characteristics, the materials for working with 1-4 and 7 of the types referred to a combination of machines;

6 used woodworking hand fed tenoning;

7 wood and similar physical characteristics of materials used in the fed vertical spindle molding machines for working;

8 woodworking used in portable chain saws;

9 cold working of metals presses and press brakes, with manual loading or unloading, whose movable working parts may have a travel exceeding 6 mm and a speed exceeding 30 mm / s;

10 Plastic Injection or compression molding machines with loading or unloading for woodworking;

11 Rubber Injection or compression molding machines with loading or unloading for woodworking;

12 The following types of underground working of the machines:

12.1. locomotives and brake-vans,

12.2. hydraulic powered roof supports;

13 household waste at the collection of cars to be loaded by hand, incorporating a compression mechanism;

14 PTO drive shafts including their guards;

15 PTO yleissuojukset;

16 huoltoneuvot vehicles;

17 persons or persons and goods hoists for which a risk of falling more than three meters above the ground;



- 18 portable cartridge-operated fixing and other impact machinery;
- 19 designed to detect persons safety equipment;
- 20 Power-operated interlocking movable guards designed to be used in 9, 10 and 11, referred to as safeguards in machinery;
- 21 Logic units to ensure safety functions;
- 22 crash-resistant protective structures (ROPS), as well as
- 23 falling object protective structures (FOPS).

#### *Annex V*

#### **INDICATIVE LIST OF § 4, subsection 2 3 REFERRED TO SAFETY COMPONENTS:**

- 1 PTO shaft guards;
- 2 designed to detect persons safety equipment;
- 3 Power-operated interlocking movable guards designed to be used in Annex IV, 9, 10 and 11, referred to as safeguards in machinery;
- 4 Logic units to ensure safety functions;
- 5 machine control of dangerous movements for valves with a failure detection function;
- 6 extraction systems for machinery emissions;
- 7 guards and safety devices designed to protect persons working processes of moving parts involved;
- 8 lifting appliances and motion control monitoring equipment;
- 9 equipment, with the aim of keeping people stick to their seats;
- 10 emergency stop devices;
- 11 discharge systems potentially dangerous electrostatic charges to prevent the occurrence;
- 12 Annex I, 1.5.7., 3.4.7. and 4.1.2.6. referred to in paragraph energianrajoittimet and warning devices;
- 13 the noise emission and vibration reduction systems and equipment;
- 14 crash-resistant protective structures (ROPS);
- 15 falling object protective structures (FOPS);
- 16 two-hand control devices;



17 the following list includes Components for machinery designed for lifting persons or to calculate the different levels of:

- a) The landing doors locking devices,
- b) devices to prevent the carrier falling or unchecked upward movements,
- c) overspeed limitation devices;
- d) non-linear, or with damping of the return movement of energy-accumulating shock absorbers,
- e) energy-dissipating shock absorbers,
- f) to jacks of hydraulic power safety devices fitted, when used in devices to prevent falls;
- g) the tether types of electronic security equipment with electronic or electrical components.

#### *Annex VI*

##### **PARTIALLY COMPLETED THE MACHINE ASSEMBLY INSTRUCTIONS**

Part of the complete machine assembly instructions must contain a description of the conditions which must be satisfied in order to partly completed machinery can be connected properly to the final machine so that health and safety is not compromised.

These instructions must be final by the machine manufacturer or his authorized representative official Community language acceptable.

#### *Annex VII:*

##### **A. Technical file for machinery**

This section describes the technical procedure for compiling a file. The technical file must demonstrate that the machinery complies with this Regulation and the corresponding requirements of the Directive. It must, to the extent it is necessary to make this assessment, cover the machine design, manufacture and operation.

The technical file must be submitted in one or more of the official languages, with the exception of instructions for the machine, which is subject to Annex I, Section 1.7.4.1. specific provisions set out in section.

1 The technical file has the following components:

- a) a construction file including:
  - A general description of the machine,
  - The overall drawing of the machine and the control circuits, drawings, as well as the pertinent descriptions and explanations of the operation of the machine,
  - Full detailed drawings, accompanied by any calculation notes, test results, certificates and results, etc., required to check the conformity of the machinery with the essential health and safety requirements,



- The risk assessment documentation showing the procedure followed, including the
  - i) a list of the essential health and safety requirements which apply to the machinery,
  - ii) a description of the security measures which have been implemented to eliminate identified hazards or to reduce risks and, where appropriate, an indication of the residual risks associated with the machinery,
- The standards and other technical specifications that shows the essential health and safety requirements covered by these standards,
- The technical report giving the results of tests that have been done either by the manufacturer or the manufacturer or his authorized representative chosen by the Department of
- A copy of the instructions for the machinery,
- Part of the complete machine, as required to incorporation for partly completed machinery and the relevant assembly instructions,
- Where appropriate, copies of machinery or other products incorporated into the EC declaration of conformity,
- A copy of the EC declaration of conformity;
- b) for series manufacture, the internal measures that will be implemented to ensure that the machinery remains of this Regulation or the corresponding provisions of the Directive.

The manufacturer shall be made on components, fittings or the completed machinery necessary research and tests machinery to determine whether by its design or construction, installation and safe for use. The relevant reports and results shall be included in the technical file.

2 Paragraph 1, of a technical file must be available to the competent authorities of the Member States for at least ten years from the machine, or in series produced in the last date of manufacture of the song.

The technical file does not need to be kept within the Community, nor does it have to be permanently available in material form. EC declaration of conformity of the designated person must be able to compile the technical file and made available within a period that is commensurate with its complexity.

The technical file does not have to include detailed plans of subassemblies or any other specific information that is used in the manufacture of the machinery unless they are particularly necessary for the essential health and safety requirements to establish conformity.

3 If the technical file can not be presented to the competent national authorities requested that the appropriate criteria, may constitute sufficient grounds for doubting the conformity of the machinery with the essential health and safety requirements.

#### **B. The incomplete machine RELEVANT TECHNICAL DOCUMENTS**

This section describes the relevant technical documentation procedure for compiling. The documentation must show what this regulation or the corresponding provisions of the Directive are applied and fulfilled. It must cover part of the complete machine design, manufacture and operation to the extent necessary to determine whether it



is with the essential health and safety requirements. The documents must be submitted in one or more of the official languages.

The documents include the following:

a) a construction file including:

- Part of the complete machine overall drawing of the drawings of the control circuits,
- Full detailed drawings, accompanied by any calculation notes, test results, certificates and results, etc., required to check whether a partially completed machinery with the essential health and safety requirements,
- The risk assessment documentation showing the procedure followed, including the

i) a list of the essential health and safety requirements applied and fulfilled,

ii) a description to eliminate identified hazards or reduce the risk of the protective measures implemented and, where appropriate, an indication of the residual risks,

iii) the standards and other technical specifications, so that it turns out the essential health and safety requirements covered by these standards,

iv) a technical report showing the manufacturer or the manufacturer or his authorized representative chosen by the institution's test results,

v) a copy of the part of the complete machine assembly instructions;

b) for series manufacture, the internal measures that will be implemented to ensure that the partly completed machinery remains in conformity with the essential health and safety requirements applied.

The manufacturer shall be made on components, fittings or the partly completed machinery necessary research and tests machinery to determine whether by its design or construction, assembled and used safely. The relevant reports and results shall be included in the technical file.

The relevant technical documentation must be available to the competent authorities for at least ten years after partial or complete machine, the production of the series, the last date of manufacture of the song produced, and on request presented to the appropriate authorities. They do not need to keep within the Community, nor do they need to be permanently available in material form. Incorporation of a designated person must be able to put together and presented to the appropriate authorities.

If the relevant technical documentation can not be presented to the competent national authorities caught them on appropriate grounds, may constitute sufficient grounds for doubting the conformity of partly completed machinery applied and notified to the essential health and safety requirements with regard to.

## *Annex VIII*

### **MACHINE INTERNAL PRODUCTION CONTROL OF CONFORMITY ASSESSMENT**

1 This Annex describes the procedure whereby the manufacturer or his authorized representative, who takes



care of paragraphs 2 and 3 from the obligations, ensures and declares that the machine meets these requirements applicable to machinery Regulation or the corresponding requirements of the Directive.

2 The manufacturer or his authorized representative shall be set out in Annex VII, Part A, the technical file for each series of the representative type.

3 The manufacturer shall take all measures necessary to ensure that the manufacturing process ensures compliance of the manufactured machinery to be set out in Annex VII, Part A of the technical file and of this Regulation or the corresponding provisions of the Directive.

### *Annex IX*

#### **EC TYPE-EXAMINATION**

EC type-examination is the procedure whereby a notified body ascertains and declares that the machinery referred to in Annex IV, a representative model (hereinafter referred to as "type") complies with this Regulation or with the corresponding requirements of the Directive.

1 The manufacturer or his authorized representative shall be set out in Annex VII, Part A, a technical file for each type.

2 The manufacturer or his authorized representative must be submitted by the EC type-examination of the application for a notified body.

The application must include:

- Manufacturer and, where appropriate, his authorized representative, his name and address;
- A written declaration that the same application has not been lodged with any other notified body;
- The technical file.

In addition, the applicant must provide the notified body a sample of the type. The notified body may request further specimens if needed for the test program so require.

3 The notified body must:

03.01. examine the technical file, as well as the fact that the type has been manufactured in accordance with specified the elements which have been designed with the relevant harmonized standards according to the requirements, as well as the elements which have been designed without applying the relevant standards requirements;

03.02. carry out or arrange for the appropriate inspections, measurements and tests to check whether the solutions of this Regulation, or its equivalent, with the essential health and safety requirements of the harmonized standards are not applied;

03.03. when it is used in the harmonized standards, carry out or have carried out the appropriate inspections, measurements and tests to verify that those standards were actually applied;



03.04. agree with the applicant the location where the check that the type has been manufactured in accordance with the technical file and make the necessary inspections, measurements and tests.

4 If the type of this Regulation or the corresponding provisions of the Directive, the notified body shall issue an EC type-examination certificate. The certificate shall include the manufacturer and his authorized representative, the name and address of the approved type necessary for identification of the conclusions of the examination and issuing the certificate.

The manufacturer and the notified body shall keep a copy of this certificate, the technical file and all relevant documents to 15 years of issue.

5 If the type is not of this Regulation or the corresponding provisions of the Directive, the notified body shall refuse to issue an EC type-examination certificate, giving detailed reasons for its refusal. It shall inform the applicant, the other notified bodies and the Member State which has notified it.

6 The applicant must inform the notified body that holds the EC type-examination certificate of the technical file, any changes made to the approved type. Examine the changes, and then either confirm that the EC type-examination certificate remains in force, or enter a new EC type-examination certificate where such changes may affect whether the essential health and safety requirements or the intended conditions of use of the.

7 The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EC type-examination certificate. The Commission and the Member States may, on reasoned request, obtain a copy of the technical file and the body made tests.

8 EC type-examination procedures of documentation and correspondence be written in the official Community language which the notified body is established or in a notified body approved by the official Community languages.

#### 9 EC type-examination certificate

09.01. The notified body has the ongoing responsibility of ensuring that the EC type-examination certificate remains valid. The manufacturer must be notified of any significant changes which affect the validity of the certificate. The notified body shall withdraw certificates which are no longer valid.

09.02. The engine manufacturer has the ongoing responsibility to ensure that the machine is state of the art of the.

09.03. The manufacturer shall request from the notified body for EC type-examination certificate, the validity of the five-year intervals.

Where a notified body finds that the certificate remains valid, taking into account the prior art, it shall renew the certificate for a further five years.

The manufacturer and the notified body shall keep a copy of this certificate, the technical file and all the relevant documents for 15 years for issuing the certificate.

09.04. If the EC-type examination certificate is not renewed, the manufacturer shall cease the placing on the market of the machinery.



## *Appendix X*

### **FULL QUALITY ASSURANCE**

This Annex describes in Annex IV of conformity assessment of machinery using a full quality assurance system, and the procedure by which a notified body assesses and approves the quality system and monitors its application.

1 The manufacturer shall be applied in the design, manufacture and final product inspection and testing as specified in point 2 an approved quality system, and the manufacturer is monitored pursuant to paragraph 3.

#### 2 Quality management system

02.01. The manufacturer or his authorized representative shall assess the quality system with the notified body of his choice.

The application shall include:

- Manufacturer and, where appropriate, his authorized representative, his name and address;
- The places of design, manufacture, inspection, testing and storage sites;
- Annex VII, Part A, the technical file described in Annex IV for each of the machine group for one model, which he plans to manufacture;
- The quality system documentation;
- A written declaration that the same application has not been lodged with any other notified body.

02.02. The quality system must ensure that the machinery of this Regulation or the corresponding provisions of the Directive. All manufacturer approved by the elements, requirements and provisions have been documented in a systematic and orderly manner in the measures, procedures and written instructions. The quality system documentation must be such as to a common understanding of the different procedures and quality measures, such as quality programs, plans, manuals and documentation.

In particular, an adequate description of:

- The quality objectives, the organizational structure, responsibilities and powers of machinery design and quality;
- The technical design specifications, including standards to be applied, and if the harmonized standards are not applied in full, the means used to ensure compliance with this Regulation or its equivalent conformity with the essential health and safety requirements are complied with;
- The design control and design verification techniques, processes and systematic actions that will be used in this Regulation, designing machinery covered;
- The corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;



- The examinations and tests that will be carried out before, during and after, and their frequency;
- The quality records, such as inspection reports and test data, calibration data, and the qualifications of the personnel records;
- The means to monitor the machinery of the required design and quality achievement, as well as the effective operation of the quality system.

03.02. The notified body shall assess the quality system to determine whether it 2.2. the requirements referred to.

The quality system parts, which comply with the relevant harmonized standard is assumed to be 2.2. referred to the respective requirements.

The auditing team must have at least one member with experience in machinery technology assessment. The assessment procedure must include an inspection visit to the manufacturer's premises. During the evaluation, the evaluation team shall be 2.1. second paragraph, third indent, of the technical examination of the records to ensure that they have appropriate health and safety requirements.

The decision must be notified to the manufacturer or his authorized representative. The notification must contain the conclusions of the examination and the reasoned assessment decision.

02.04. The manufacturer must undertake to fulfill the quality system as approved and to maintain the obligations arising from the quality system adequate and efficient.

The manufacturer or his authorized representative must keep the notified body that has approved the quality system with a notified body of planned changes.

The notified body shall evaluate the modifications proposed and decide whether the modified quality system will still 2.2. requirements referred to, or whether it is necessary to make a new assessment.

It must notify its decision to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

3 The notified body responsible for the control of

03.01. The purpose of surveillance is to make sure that the manufacturer duly fulfills the obligations arising out properly.

03.02. The manufacturer must allow the notified body access for inspection purposes the design, manufacture, inspection, testing and storage and provide it with all necessary information, in particular:

- A description of the quality management system;
- The design part of the quality management system of the required documents. These include, for example, analyzes, calculations, tests, etc.;
- The quality system relating to manufacture of the required documents. Such as inspection reports and test data, calibration data, and the qualifications of the personnel documents.



03.03. The notified body shall conduct periodic audits to ensure that the manufacturer maintains and applies the quality system. It shall submit the audit report to the manufacturer. Periodic inspections shall be such that a full reassessment is carried out every three years.

03.04. The notified body may make unannounced visits to the manufacturer. The need for these additional visits, and the frequency will be determined by the notified body inspections of the system. The visits monitoring system takes into account the following factors:

- The results of previous surveillance visits;
- Follow up corrective action requirements;
- The adoption of the system, where the specific requirements
- Significant changes in manufacturing process, measures or techniques.

During such visits the notified body may carry out, or have carried out tests to verify that the quality system is functioning properly. The notified body must provide the manufacturer with a visit report and test if the test is done.

4 The manufacturer or his authorized representative must, for ten years after the last date of manufacture of the national authorities:

- 2.1 above. The documents referred to, as well as
- In paragraph 2.4. , third and fourth subparagraphs, and 3.3. and 3.4. notified body referred to the decisions and reports.

European Parliament and Council Directive 2006/42/EC (32006L0042), OJ L 157, 9.6.2006, p 24

**Change Entry into force and application of:**  
**24.3.2011/265:**

This Regulation shall enter into force on 15 June 2011.

European Parliament and Council Directive 2009/127/EC, OJ No L 310, 25.11.2009, p 29-33

**26.5.2011/574:**

This Regulation shall enter into force on 1 June 2011.

European Parliament and Council Directive 2009/127/EC, OJ No L 310, 25.11.2009, p 29-33 Social Affairs and Health Tuula Juha Rehula Government Secretary Anders

[Finlex](#) > [Legislation](#) > [Updated law](#) > [2008](#) > 12.6.2008/400

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