



REPUBLIC OF SERBIA
Ministry of Finance and Economy

HANDBOOK FOR IMPLEMENTATION OF RULEBOOK ON SAFETY OF MACHINERY

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Handbook for implementation of Rulebook on Safety of Machinery

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Content

INSTRUCTIONS FOR IMPLEMENTATION OF RULEBOOK ON SAFETY OF MACHINERY	5
1. Introduction	5
2. Scope of the Rulebook	7
2.1 Products covered by the Rulebook	7
2.2 Products that are not covered	9
3. Essential requirements and risk assessment	11
4. List of Serbian standards accompanying Rulebook and Presumption of Conformity	12
4.1 Technical documentation	12
4.2 Conformity assessment	12
5. Conformity Assessment carried out by the manufacturer	13
6. Conformity Assessment carried out by the designated body	14
7. Marking of conformity and accompanying documentation	17
7.1 Marking	17
7.2 Declaration of conformity	18
7.3 Confirmation of conformity	19
7.4 Certificates	20
7.5 Instruction	20
8. Safeguard clause	21
9. Market surveillance	21
10. Conclusion	22
RULEBOOK ON MACHINERY SAFETY	23

INSTRUCTIONS FOR IMPLEMENTATION OF RULEBOOK ON SAFETY OF MACHINERY

1. INTRODUCTION

The instruction have been prepared in order to help all economic operators (manufactures, importers, machine distributors), and all those involved in design, production and/or trade of machinery, in the implementation of the requirements of this Rulebook, and other stakeholders involved, that is who use the Rulebook on Safety of machinery ("Official Gazette of RS", No. 13/10 – hereinafter referred to as: Rulebook), as conformity assessment designated bodies (hereinafter referred to as: Designated bodies), standardisers, market surveillance authorities, consumer associations and similar.

Intention of the authors of this handbook is to provide short and concise overview in regards to the:

- application of the Rulebook,
- essential requirements,
- list of Serbian standards accompanying the Rulebook,
- technical documentation and risk assessment,
- the means (module) of conformity assessment,
- the principle of conformity marking with Serbian conformity mark,
- documentation accompanying the product,
- the safeguard clause and
- market surveillance.

The Rulebook is in compliance with all principles and essential requirements of Directive 2006/42/EC of the European Parliament and the Council of May 17th 2006 relating to machinery, which confirms commitments undertaken by the Republic of Serbia under the Stabilisation and Association Agreement (SAA), and National Programme for Integration of the Republic of Serbia to the European Union (NPI). Obligations from SAA particularly relate to the part referring to the free movement of goods and, in this sense, the necessity of harmonization of technical legislation of the Republic of Serbia with technical legislation of the European Union (EU) with the aim to remove technical barriers to trade as one of the key elements for ensuring the free movement of goods and creating a single market.

If the Rulebook is defined from the different perspective, that is, if we say that its primary goal is to harmonize the rules governing the marketing of machinery, and at the same time guaranteeing the highest possible level of safety, then it is justified to conclude that the Rulebook actually represents a guideline intended for engineers, which must be applied at the beginning of designing machinery with the main

objective to provide its placing on the market and/or use, and in our conditions it can be said that the very approach of the production is changing.

Rulebook prescribes strengthened exclusive responsibility of the manufacturer that the machinery placed on the market and/or put into use must be in conformity with the essential health and safety protection requirements, which is achieved by prescribed internal control of the production, type examination of machinery and issuance of relevant certificates, as well as to ensure of the quality. This includes the participation of the designated bodies, as so called third party, in conformity assessment, depending on the needs and choices of the manufacturer.

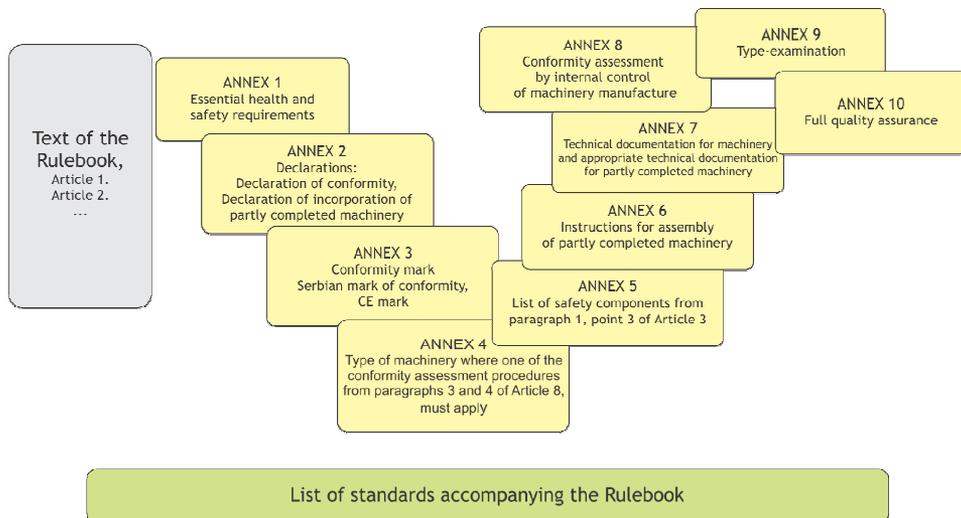
„manufacturer shall mean a legal person, entrepreneur or natural person that makes a product, or person claiming to be manufacturer by placing on the product its business name, name or title, trademark or other distinctive mark or in any other manner“;

*Law on technical requirements for products and conformity assessment
("Official Gazette of RS", No. 36/09)*

Rulebook does not imply how the manufacturer should make a product that will be in conformity with the essential health and safety requirements, but "only" what requirements must be met, and the manner this will be achieved is left to the manufacturer. Among other things, this reflects flexibility of so-called New Approach of the EU.

The intended purpose of the product is of great importance, because it further determines the application of directives or rulebook.

It should be emphasized that the mechanical sector is one of the largest and most competitive industrial sector in the EU, with over 170,000 companies (most of which are SMEs), which count 3.3 million employees. With about 36% of the global market, Europe is the world's largest manufacturer and exporter of machinery. Competitiveness of the machine industry lies in the synthesis of excellent, innovative products, application of know-how technology, skills and abilities to satisfy all customer desires.



Picture 1. The Rulebook structure

2. SCOPE OF THE RULEBOOK

2.1 Products covered by the Rulebook

Article 2 of the Rulebook determines the scope of application. This Rulebook applies to 7 categories of products, namely:

- *machinery;*
- *interchangeable equipment;*
- *safety components;*
- *lifting accessories;*
- *chains, ropes and webbing;*
- *removable mechanical transmission devices;*
- *partly completed machinery.*

Each of seven named categories of products is defined in Article 4 of the Rulebook.

MACHINERY is defined as an assembly, fitted with or intended to be fitted with a drive system other than directly applied human or animal effort, consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application. Therefore, products with parts or components that are not joined in an assembly are not considered to be machinery.

The moving parts of machinery are powered by a drive system using one or more sources of energy such as thermal, electric, pneumatic, hydraulic or mechanical energy. The machinery may have a motor using its own source of energy such as thermal energy or energy provided by a battery. It may be connected to one or more external sources of energy such as a supply of electricity or compressed air. Machinery may use mechanical energy supplied by other equipment such as, for example, towed agricultural machinery that is driven by the power take-off of a tractor, or test beds for motor vehicles that are driven by the vehicles being tested. Machinery may also be powered by natural sources of energy such as wind or water power.

Usually the manufacturer of complete machinery supplies the machinery fitted with its drive system. However machines intended to be fitted with a drive system but supplied without it may also be considered as machinery. This provision takes account, for example, of the fact that certain users of machinery prefer to have a homogeneous stock of motors for their machines in order to facilitate maintenance.

The moving parts of machinery subject to the Rulebook must be driven by a source of energy other than directly applied human or animal effort. Machinery driven by directly applied human or animal effort, such as, for example, hand-driven lawn mowers, hand drills or hand-pushed trolleys, which cease to operate as soon as the manual effort is no longer applied, are not subject of the Rulebook. Lifting machinery is the only exception to this general rule.

On the other hand, the Rulebook is applicable to machinery driven by manual effort which is not applied directly but stored, for example, in springs or in hydraulic or pneumatic accumulators, so that the machinery can function after the manual effort has ceased. A typical example is a hydraulic mechanism for slow and quiet closing the door.

Machinery is also defined as an assembly, missing only the components to connect it on site or to sources of energy and motion.

Means of transport are, in general, excluded from the scope of the Rulebook, but machinery mounted on means of transport is subject to the Rulebook. Examples of machinery mounted on means of transport include, for example, loader cranes, tail lifts, tipper bodies, vehicle or trailer-mounted compressors, vehicle-mounted compaction systems, vehicle-mounted concrete mixers, skip loaders, powered winches, tippers and vehicle-mounted mobile elevating work platforms.

Also, it is implied that the manufacturer of machinery intended to be installed on a means of transport or installed in a building or a structure is responsible for the conformity of the machinery with the relevant essential health and safety requirements. He must affix the conformity mark on the machinery and draw up and sign the Declaration of Conformity. The manufacturer of such machinery must take into account in his

risk assessment all the risks associated with the machine, including those relating to installation of the machinery on the chassis of a vehicle or trailer or on a supporting structure. The machinery manufacturer, in his instructions, should list necessary specifications for the supporting structure and provide precise installation instructions.

The person who installs such a machine on a means of transport or in a building or structure is responsible for carrying out the machinery manufacturers' installation instructions.

Machinery is also defined as assemblies of machinery or partly completed machines that are arranged and controlled so that they function as an integral whole in order to achieve the same purpose. It is referred to the machinery that are assembled together in order to carry out a common function. Assemblies of machinery may be constituted by two units such as, for example, a packaging machine and a labelling machine, or by several units assembled together, for example, in a production line.

A group of machines that are connected to each other but where each machine functions independently of the others is not considered as an assembly of machinery in this sense. However, for the application of the Machinery Directive, such large installations can usually be divided into sections which may be considered as assemblies of machinery, for example, raw material unloading and reception equipment - processing equipment -packaging and loading equipment. **The person constituting an assembly of machinery is considered as the manufacturer of the assembly of machinery and is responsible** for ensuring that the assembly as a whole complies with the health and safety requirements of the Rulebook.

The Declaration of Conformity for complete machines and the Declaration of Incorporation and the assembly instructions for partly completed machinery incorporated into the assembly of machinery must be included in the technical file for the assembly of machinery.

Machinery is also defined as an 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. Examples of such machinery include manually powered hoists and cranes, jacks, lifting tables, pallet and stacker trucks and mobile elevating work platforms. Appliances which do not lift a load but simply maintain it at a given height are not covered by this definition.

INTERCHANGEABLE EQUIPMENT is defined as equipment that is designed and constructed in order to be assembled with machinery after the basic machinery has been put into service. Interchangeable equipment operators assemble on drive or hauling machinery in order to change its function or attribute a new function.

Equipment that is assembled with machinery by the manufacturer when the machinery is placed on the market and that is not intended to be changed by the user is not considered as interchangeable equipment but is considered as part of the machinery. Interchangeable equipment should not be confused with spare parts that do not change the function of the machinery.

Example of interchangeable equipment includes equipment assembled with agricultural or forestry tractors for functions such as: ploughing, harvesting, lifting or loading, and equipment assembled with earth-moving equipment, for functions such as drilling or demolition. Work platforms intended to be assembled with lifting machinery in order to modify its function for the purpose of lifting persons are interchangeable equipment (see Annex 4 of the Rulebook, point 17).

SAFETY COMPONENT is a component:

- which serves to fulfil a safety function;
- which is independently placed on the market;
- the failure and/or malfunction of which endangers the safety of persons;
- which is not necessary in order for the machinery to function, or for which normal components may be substituted in order for the machinery to function.

Safety components are components intended by their manufacturer to be fitted to machinery specifically to fulfil a protective role. Components placed independently on the market that are intended by

the manufacturer for functions that are both safety and operational functions, or that are intended by the manufacturer to be used either for safety or for operational functions are considered as safety components.

The definition of safety component implies that the Rulebook only applies to safety components that are independently placed on the market as such. Safety components manufactured by a machinery manufacturer to be incorporated in his own machinery are not subject of the Rulebook. In cases when such a manufacturer supplies safety components as spare parts to replace the original safety components on machinery he has placed on the market and/or put into use, they are not subject of the Rulebook.

LIFTING ACCESSORIES are components or equipment, including slings and their components, that are not attached to the lifting machinery and which are placed between the machinery and the load, or which are intended to constitute an integral part of the load and which are independently placed on the market.

Lifting machinery usually has a device for holding the load, for example, a hook. Such load holding devices incorporated into lifting machinery are not considered as lifting accessories.

Slings and their components are also considered as lifting accessories. This implies that equipment intended to be used as an independent sling or in a variety of combinations to be made up by a user, for example, to make up a multi-leg sling, is considered as a lifting accessory.

Lifting accessories are subject to certain specific essential health and safety requirements in order to remove hazards due to lifting operations.

CHAINS, ROPES AND WEBBING in terms of this Rulebook are designed and constructed for lifting purposes, as part of lifting machinery or lifting accessories.

Also, as in the previous case, essential health and safety requirements in order to remove hazards due to lifting operations, are applied.

REMOVABLE MECHANICAL TRANSMISSION DEVICES is a removable component for transmitting power between self-propelled machinery or a tractor and another machine by joining them at the first fixed bearing. When it is placed on the market with the guard it shall be regarded as one product.

PARTLY COMPLETED MACHINERY is an assembly which cannot itself perform a specific application, but it is intended to be incorporated into or assembled with other machinery or other partly completed machinery or equipment, thereby forming machinery to which this Rulebook applies. Partly completed machinery must undergo further construction in order to become final machinery that can perform its specific application.

Partly completed machinery should also be distinguished from machinery ready to be installed on a means of transport or in a building or a construction.

Machinery that can itself perform its specific application but is only missing the necessary protective means or safety components is not considered as partly completed machinery.

Drive system that is ready to be fitted to machinery and not to the individual components of such systems, is also partly completed machinery. For example, an internal combustion engine placed on the market ready to be fitted to machinery subject to the Rulebook is considered as partly completed machinery.

Most low voltage electric motors are excluded from the scope of the Rulebook and are subject to the Rulebook on electrical equipment intended for use within certain voltage limits („Official Gazette of RS”, No 13/10).

2.2 Products that are not covered

Rulebook does not apply to the machinery, that is to the products, related to risk referred to Annex 1 of the Rulebook, if those risks are covered by more specific regulations.

The Rulebook does not apply to separate machinery components such as, ball-bearings, pulleys, elastic couplings, solenoid valves, hydraulic cylinders, flange-connected gearboxes and the like, that do not have a specific application and that are intended to be incorporated into machinery. **The complete**

machinery incorporating such components must comply with the relevant essential health and safety requirements. The machinery manufacturer must therefore choose components with adequate specifications and characteristics.

Therefore, the Rulebook does not apply to the following machinery and/or products:

- *safety components intended to be used as spare parts to replace identical*
- *components and supplied by the manufacturer of the original machinery;*
- *specific equipment for use in fairgrounds and/or amusement parks;*
- *machinery specially designed or put into service for nuclear purposes which, in the event of failure, may result in an emission of radioactivity;*
- *weapons, including firearms;*
- *the following means of transport:*
 - *agricultural and forestry tractors for the risks covered by relevant regulations, with the exclusion of machinery mounted on these vehicles;*
 - *motor vehicles and their trailers covered by relevant regulation, with the exclusion of machinery mounted on these vehicles;*
 - *two or three-wheel motor vehicles covered by relevant regulation, with the exclusion of machinery mounted on these vehicles;*
 - *motor vehicle exclusively intended for competition;*
 - *means of transport by air, on water and on rail networks with the exclusion of machinery mounted on these means of transport.*
- *seagoing vessels and mobile offshore units and machinery installed on board such vessels and/or units;*
- *machinery specially designed and constructed for military or police purposes;*
- *machinery specially designed and constructed for research purposes for temporary use in laboratories;*
- *mine winding gear;*
- *machinery intended to move performers during artistic performances;*
- *electrical and electronic products¹ or groups of such products falling under application of other regulations as follows:*
 - *household appliances intended for domestic use²;*
 - *audio and video equipment;*
 - *information technology equipment;*
 - *ordinary office machinery;*
 - *low-voltage switchgear and control gear;*
 - *electric motors.*
 - *high-voltage electrical equipment as follows:*
 - *switch gear and control gear;*
 - *transformers.*

¹ **Electrical machinery that is not in any of the categories listed in this point is in the scope of the Rulebook.**

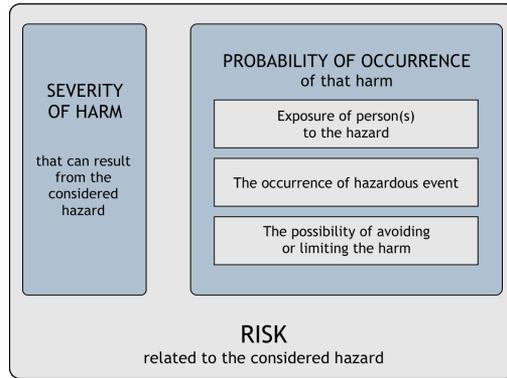
When such machinery has an electrical supply within the voltage limits of the Low Voltage Directive (between 50 and 1000 V for alternating current or between 75 and 1500 V for direct current), it must fulfil the safety objectives of the Rulebook on electrical equipment intended for use within certain voltage limits. However, in that case, Declaration of Conformity for such machinery **should not refer to** Rulebook on electrical equipment intended for use within certain voltage limits, but just to the Rulebook.

² Appliances of housekeeping functions, but also intended for commercial or professional use (hospitality, hospitals, different service providers (hairdresser's, dry cleaning and laundry, ironing, etc.) or for industrial use, are not excluded from the scope of the Rulebook.

3. ESSENTIAL REQUIREMENTS AND RISK ASSESSMENT

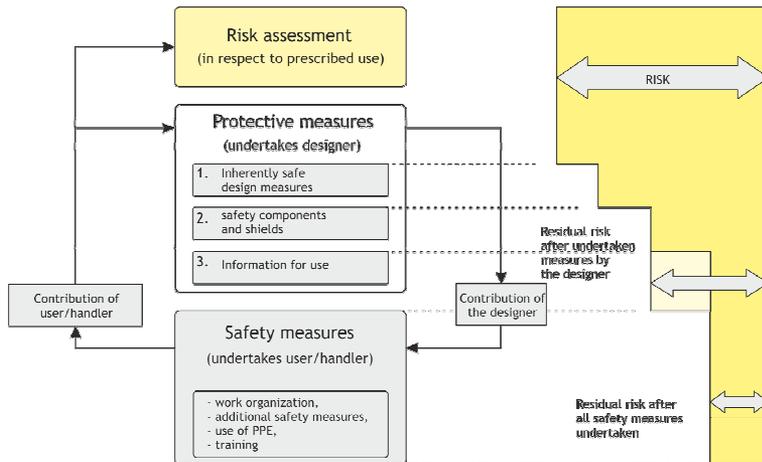
The essential health and safety requirements are set out in Annex 1 introduce four basic principles.

The first one, dealing with **risk assessment**, explains a basic requirement of Annex 1 to identify the hazards and assess the risks associated with machinery in order to identify and apply the relevant essential health and safety requirements.



Picture 2. Elements of risk (SRPS EN 14121-1)

Machinery must be designed and constructed taking into account the results of the risk assessment. Risk reduction measures dealing with the identified hazards should be given an order of priority, in accordance with the principles of safety integration. The risk assessment and its outcome must be documented in the technical documentation for machinery. Serbian standard SRPS EN ISO 14121-1 (A type standard) *Safety of machinery - Risk assessment - Part 1: Principles*, explains the general principles for risk assessment of machinery.



Picture 3. Methodology of risk reduction (SRPS ISO 12100-1)

The other general principles are essential for understanding the status and the implications of the essential health and safety requirements. These general principles must be taken into account when applying each of the essential health and safety requirements to the design and construction of machinery.

4. LIST OF SERBIAN STANDARDS ACCOMPANYING RULEBOOK AND PRESUMPTION OF CONFORMITY

Harmonized standards in the field of machinery are transposed and adopted as Serbian standards by the Institute for Standardization of Serbia. List of adopted Serbian standards in the field of machinery transposing harmonized standards is compiled, updated and published in accordance with the Law on technical requirements for products and conformity assessment and the regulation adopted on the basis of that Law.

4.1 The classification of machinery standards

Serbian standards for machinery are classified into three types, A, B and C. The purpose of this classification is to enable the authors of standards (CEN and CENELEC mandated by European Commission) for particular categories of machinery to use horizontal standards providing tried technical solutions. The horizontal A and B-type standards can also help manufacturers designing machinery for which C-type standards are not available.

A-type standards determine basic concepts, terminology and design principles that are applicable to all categories of machinery. Application of only such standards provides an essential framework for the correct application of the Rulebook, but it is not sufficient to ensure conformity with the relevant essential health and safety requirements of the Rulebook and therefore does not give a full presumption of conformity.

B-type standards deal with specific aspects of machinery safety or specific types of safeguard that can be used for a wide range of categories of machinery. Application of the specifications of B-type standards creates a presumption of conformity with the essential requirements of the Rulebook that they cover when a C-type standard or the manufacturer's risk assessment shows that a technical solution specified by the B-type standard is adequate for the particular category or model of machinery in subject.

C-type standards provide specifications for a specific category of machinery, for example, mechanical presses, combine harvesters or compressors. The different types of machinery that belong to the category covered by a C-standard have a similar purpose and present similar hazards.

4.2 Presumption of conformity

Conformity mark and Declaration of conformity as presumption of conformity of the machinery

This kind of presumption of conformity of machinery with the requirements of the Rulebook is prescribed in provisions of Articles 5 and 6 and indirectly from provision of Article 15 of the Rulebook. Conformity mark, placed on the machinery, and the Declaration of conformity of the machinery are the external appearances that indicate the existence of the presumption of conformity of that machinery with the requirements of the Rulebook.

Application of standards from the List of Serbian standards in the field of machinery as a presumption of conformity of the machinery

It is considered that the machinery complies with the essential requirements referred to in Annex 1, if it is made in accordance with Serbian standards in the field of machinery which transposed appropriate harmonized standards; in other words it could be said that the machinery meets essential requirements until it is proven otherwise. Further, such equipment is placed on the market and/or put into use freely without any restrictions.

On the other hand, when partly completed machinery is concerned, it should be noted that only such partly completed machinery for which the manufacturer or his representative compiled and issued **Declaration on incorporation** of Annex 2 Chapter of the Rulebook, can be placed on the market freely and without any restrictions. This declaration must be stated that the partially completed machinery designed for installation into the machinery or installation to partly completed machinery in order to form a single machine.

If a manufacturer decides not to apply standards from the List of Serbian standards in the field of machinery or to enforce only the parts of a standard, he must include, in the technical documentation, information on the completed risk assessment and the measures taken to achieve compliance with relevant health and safety requirements.

However, in the case of categories of machinery listed in Annex 4 of the Rulebook, the application of standards from the List of Serbian standards in the field of machinery, which include all the essential health and safety requirements relating to the machinery, allows the manufacturer to carry out conformity assessment of the machinery without referring to the designated conformity assessment body.

In conclusion it can be said that the use of Serbian standards from a list of (harmonized) standards is the simplest and fastest tool in the procedure of "proving" the conformity of product with essential requirements.

5. TECHNICAL DOCUMENTATION

In regards to the Rulebook (and all other regulations transposing New Approach and Global Approach Directives) technical documentation **is documentation providing evidence of conformity of the product** with requirements of all relevant technical regulations relating to the given product.

Rulebook in its Annex 7 defines in detail, technical documentation and divides into technical documentation for the machinery and the technical documentation for partly completed machinery.

Drawing up of the technical documentation, actually begins with the first, initial step in the machinery production process, and that is the risk assessment. Machinery manufacturer assess the risk. After the risk assessment, the machinery must be designed and constructed so to take into account the results of this assessment (essential health and safety requirements set out in Annex 1 are mandatory).

Drawing up technical documentation includes knowledge, procedures and skills that mechanical engineers acquire on undergraduate and master studies. This activity does not require any special license.

Essential characteristics:

- ✓ **Technical documentation must confirm that the machinery complies with requirements from the Rulebook;**
- ✓ **Technical documentation includes design, manufacture and operation of the machinery to the extent it is necessary for conformity assessment;**
- ✓ **Technical documentation must be written in Serbian language, or in any of the official languages of the EU, with relevant translation into Serbian;**

It must include:

- **a general description of the machinery,**
- **the overall drawing of the machinery and drawings of the control circuits, as well as the pertinent descriptions and explanations necessary for understanding the operation of the machinery,**
- **full detailed drawings, accompanied by any calculation notes, test results, certificates, etc., which are required to check the conformity of the machinery with the essential health and safety requirements,**
- **the documentation on risk assessment including:**
 - **a list of the essential health and safety requirements which apply to the machinery,**
 - **the description of the protective measures implemented to eliminate identified hazards or to reduce risks and, when appropriate, the indication of the residual risks associated with the machinery,**
- **the standards and other technical specifications applied, indicating the essential health and safety requirements covered by these standards and specifications,**
- **any technical report providing the tests results carried out either by the manufacturer or by a body chosen by the manufacturer or his representative,**

- *the instructions for the machinery,*
- *where appropriate, the declaration of incorporation for included partly completed machinery and the relevant assembly instructions for that machinery,*
- *where appropriate, the declaration of conformity of machinery or other products incorporated into the machinery,*
- *the declaration of conformity;*

In case of series manufacture, the technical documentation includes defined internal measures of the manufacturer that will be implemented to ensure that the machinery is in conformity with the requirements of the Rulebook, that is, the technical documentation.

The technical documentation must be made available to the competent authorities for at least 10 years following the date of manufacture of the machinery or, in the case of series manufacture, of the last unit produced.

The technical documentation must be available to relevant authority at least ten years after the date of the last manufactured specimen of the equipment.

The technical documentation **does not have to:**

- to be kept on the territory of the Republic of Serbia,
- in one locality,
- to be permanently available in material form.

Person specified in Declaration of Conformity of the machinery, must ensure that technical documentation is available, that is, to make it at disposal to competent authorities at their request.

If manufacturer or his representatives is not registered in the Republic of Serbia, all obligations are taken over by importer of machinery in subject.

6. CONFORMITY ASSESSMENT

Rulebook defines different procedures (modules) of conformity assessment of machinery, which must be carried out **before placing machinery on the market or putting into use**. They can be performed by manufacturer or designated body for conformity assessment.

The conformity assessment procedure is mandatory, however, for certain categories of machinery, the manufacturer can choose between several alternative procedures.

6.1 Conformity assessment carried out by the manufacturer

Rulebook defines conformity assessment procedures (paragraph 2 of Article 8) which apply to all categories of machinery, except those listed in Annex 4.

The procedure applied is the procedure for **assessment of conformity with internal checks on the manufacture of machinery** referred to in Annex 8 of the Rulebook. This procedure does not involve the participation of a conformity assessment designated body.

Manufacturers of machinery that are not listed in Annex 4, may seek advice or assistance in part relating to conformity assessment procedures (testing of product and issuance of test report, or similar) from bodies that are designated for certain categories of machinery referred to in Article 11 of the Rulebook or from Annex 4 of the Rulebook, but not from **other accredited on non-accredited** competent conformity assessment bodies in which manufacturer has trust that the appropriate tastings and checks will be done accordingly. This control, performed by the manufacturer, involves three essential elements:

- Technical documentation,
- Declaration of Conformity;
- Marking of conformity and conformity mark.



Picture 4. Internal production control

6.2. Conformity assessment carried out by Designated body

Article 4 of the Rulebook prescribes that conformity assessment body may carry out or participate in the conformity assessment of the machinery, only if it meets the designation requirements laid down in Annex 11 of the Rulebook, and if it is designated by the competent minister in charge of standardization, technical regulations, accreditation and metrology (MoERD) in accordance with the Law on technical requirements for products and conformity assessment and Regulation on the manner of designation and authorization of conformity assessment bodies ("Official Gazette of RS", No. 98/09).

Designated bodies are independent conformity assessment bodies entrusted with the conformity assessment procedures for the specific categories of machinery – by reviewing the technical documentation in accordance with the Article 11 of the Rulebook as well as conformity assessment procedures, type examination of machinery or approval and monitoring of manufacturer's full quality assurance system specifically for categories of machinery listed in Annex4 of the Rulebook, in accordance with Article 8 and Annexes 9 and 10 of the Rulebook.

Conformity assessment procedures performed by designated bodies refer to:

1) Machinery listed in Annex 4, namely:

- Type examination of Annex 9 of the Rulebook - requires from manufacturer to submit a model of the machinery, so that the designated body may perform type examination and determine whether it meets all the applicable essential health and safety requirements. Conformity of the machinery produced after in accordance with the type examined by the designated body, is later performed by the manufacturer himself in the internal control of production.
- Full quality assurance of Annex 10 of the Rulebook - requires the manufacturer to have a full quality assurance system covering the design, manufacture, final inspection and testing of machinery. The system must be assessed and approved by a designated body to ensure that it is adequate to ensure the design and manufacture of machinery that complies with the essential health and safety requirements that are applicable. The Notified Body must also monitor the correct application of the full quality assurance system.

After performed procedures designated body issues **type examination certificate** or **decision (certificate) approving the full quality assurance system**.

2) Machinery listed in Article 11 (where the conformity assessment of machinery internal production control has already been applied):

- examination of technical documentation – **a copy of Declaration of conformity for that machinery is delivered to designated body, along with accompanying technical documentation, for confirming conformity of the machinery with requirements of this Rulebook.**

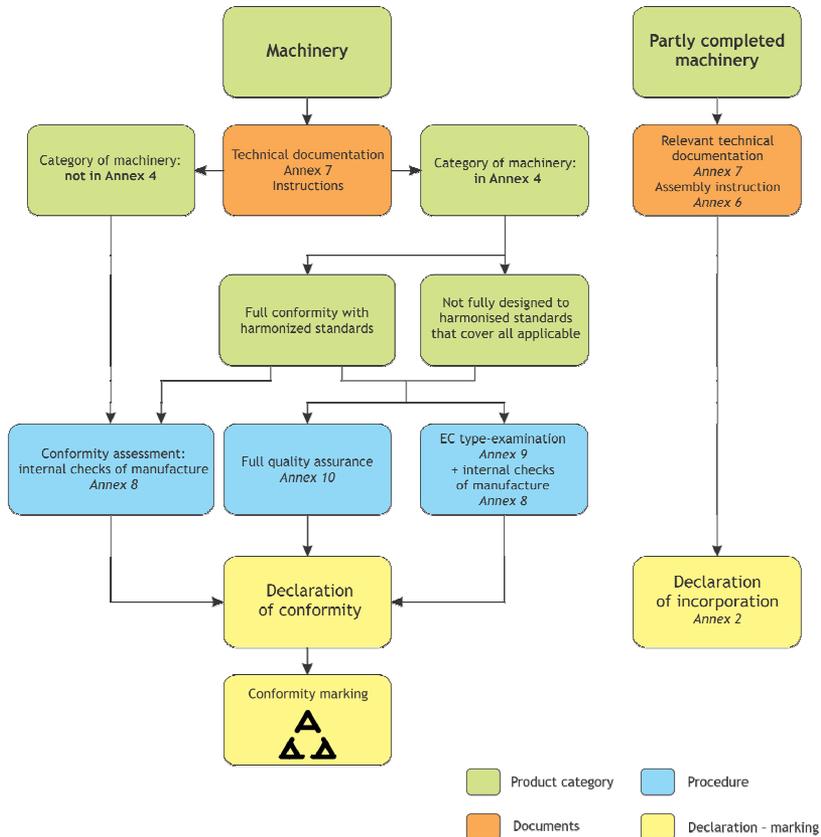
Procedure applies to the following machinery: „electric-powered lifts“ for vertical transport of freight with the cabin inaccessible for people; chains and constituent elements of chains; steel ropes intended for general use and portable tools with electric motors of nominal alternating voltage up 250 V for domestic and similar use.

After this procedure, designated body, if the conformity of the machinery is established, issues Confirmation of conformity of the machinery concerned with the essential requirements referred to in Annex 1.

The confirmation of conformity is a document accompanying the product during import and later during placing on the market of the Republic of Serbia, which serves as proof of conformity and which the supplier of the product is required to make available to the customs officer, or relevant authority upon his request, and also to the user of the machinery. The Designated body keeps a record of issued confirmations and upon request of manufacturer or his representative and/or importer issues the **Extract from records**. The Designated body publishes the records on issued confirmations on its official webpage. It has the same validity period as a confirmation of conformity.

Confirmation of Conformity (and extract from the register of issued certificates) shall be applied in the legal system of the Republic of Serbia until entry into force of ratified International Agreement on Conformity Assessment and Acceptance of Industrial Products with the European Union - ACAA (Agreement on Conformity Assessment and Acceptance of Industrial Products) in part relating to the machinery covered by the Rulebook, and not later than the accession of Serbia to the European Union.

On the basis of the confirmation of conformity or excerpt from the record issued by the designated body, the manufacturer or his authorised representative affixes the **Serbian conformity mark** on the equipment.



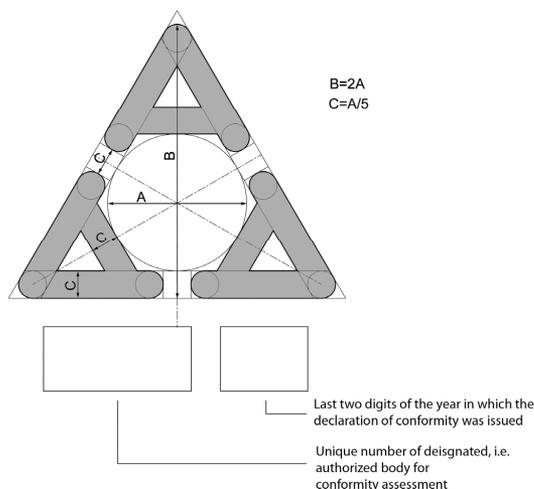
Picture 5. Flowchart of conformity assessment procedure

7. MARKING OF CONFORMITY AND ACCOMPANYING DOCUMENTATION

7.1 Marking

Marking and conformity mark of the machinery are prescribed in Articles 12 and 13 and Annex 3 of the Rulebook.

The machinery that is in compliance with requirements from the Rulebook is marked by conformity mark.



Picture 6. Serbian mark of conformity

The manufacturer, or his authorised representative, or importer (if the manufacturer or his representative is not registered in the Republic of Serbia) shall affix the conformity mark on the machinery, so as to be visible, legible and indelible, in accordance with the regulation governing the manner of affixing and use of conformity marks.

Serbian mark is the only label certifying that the product being placed on the market and/or put into use in the Republic of Serbia, is in compliance with the requirements of Serbian technical regulation, if such regulation provides its affixing.

Together with Serbian mark, a unique number of designated body is affixed, if that body performed and/or participated in conformity assessment, as well as last two digits of the year of issuance of declaration of conformity of drawing up declaration of conformity.

Affixing of conformity mark is performed:

- by pressing, stamping,
- on the place easily accessible for inspection,
- by indentation on the plate,
for importers who are not expected to open products
- by affixing on the product container (or label, slings)
- by affixing on the documentation.

The machinery may be affixed with other signs, symbols, inscriptions or other markings, provided that this does not reduce the visibility, legibility and/or interpretation of a conformity mark.

The machinery cannot be affixed with other signs, symbols, inscriptions or other markings, the labelling of which is prohibited by the law governing technical requirements for products and conformity assessment.

7.2 Declaration of conformity

Declaration of conformity of the machinery

The manner in which the conformity mark has been affixed is the first indication for market surveillance authorities that the product complies with the relevant essential requirements of the appropriate applicable regulations and suggests that it is followed by the declaration of conformity.

The declaration of conformity is a document issued or drawn up by the manufacturer or his representative. This document represents a kind of legal statement by which the manufacturer or his representative confirms:

- that all relevant requirements of the regulation(s) have been fulfilled;
- that he holds technical documentation,
- if necessary, holds other documents of conformity, by which undoubtedly confirms the fulfilment of the requirements of technical regulations,
- that he is held responsible for conformity of the product with the prescribed requirements, and safety of the products.

Declaration of conformity of the machinery must contain the following information:

- 1) business name and full seat address of the manufacturer and, where appropriate, his representative;
- 2) name and address of the person authorised to compile the technical documentation;
- 3) description and identification of the machinery, including generic denomination, function, model, type, serial number and commercial name;
- 4) a sentence expressly declaring that the machinery fulfils all the relevant provisions of this Rulebook and where appropriate, a similar sentence declaring the conformity with other regulations and/or relevant requirements with which the machinery complies. These references must be those of the regulation applied and published in the Official Gazette;
- 5) where appropriate, the name, address and identification number of the designated body which carried out the type-examination referred to in Annex 9 and, if it regards the machinery imported into Republic of Serbia, the number of the type-examination certificate;
- 6) where appropriate, the business name, address of the seat and unique identification number of the designated body referred to in point 5) of this Chapter, which approved the full quality assurance system referred to in Annex 10;
- 7) a reference to the applied Serbian standards for machinery referred to in Article 7 of this Rulebook;
- 8) where appropriate, the reference to other standards and technical specifications when they are applied;
- 9) the place and date of issuance of the declaration;
- 10) the identity and signature of the authorized person, responsible to draw up the declaration on conformity of machinery on behalf of the manufacturer or his representative.

The request from point 1, Chapter A, paragraph 1 of Annex 2 stating that the Declaration and its translations must be written under the same conditions as the instructions, imposes the obligation for Declaration to be made in Serbian language, that is, in addition to the copies of the Declaration in a foreign language, its translation into Serbian must be made.

Declaration must be provided separately, as a single document and when necessary it can be written on instructions but always with the prescribed content.

The Declaration of conformity of partly completed machinery

Annex 2, point 1, Chapter B relates to the Declaration of Incorporation that must be drawn up by the manufacturer of partly completed machinery or his representative and that it must accompany the partly

completed machinery until it reaches the manufacturer of the final machinery into which it is to be incorporated. Declaration of Incorporation then forms a part of the technical documentation for the final machinery. The Declaration of Incorporation is a legal statement by the manufacturer or his representative with the following main purposes:

- to inform the manufacturer of the final machinery which of the applicable essential health and safety requirements of Annex 1 of the Rulebook have been applied and fulfilled and to declare the conformity of the partly completed machinery;
- to undertake to transmit, in response to a request by the relevant authorities, relevant information on the partly completed machinery;
- to indicate that the partly completed machinery must not be put into service until the final machinery into which it is to be incorporated has been declared in conformity with the relevant requirements and/or provisions of the Rulebook.

The Declaration of Incorporation of partly completed machinery must contain the following information:

- 1) business name and full seat address of the manufacturer of partly completed machinery and, where appropriate, his representative;
- 2) name and address of the person authorised to compile the technical documentation;
- 3) description and identification of the machinery, including generic denomination, function, model, type, serial number and commercial name;
- 4) a sentence declaring which essential requirements of this Rulebook are applied and fulfilled and that the relevant technical documentation is compiled in accordance with Annex 7 Chapter B, and, where appropriate, a sentence declaring the conformity of the partly completed machinery with other specific regulations, when they are applied. These references must be those of the regulation applied and published in the Official Gazette;
- 5) a statement of undertaking obligation to respond to a request by the relevant authorities, with appropriate information on the partly completed machinery. This includes the method of transmission and shall be without prejudice to the intellectual property rights of the manufacturer of the partly completed machinery;
- 6) a statement that the partly completed machinery must not be put into service until the final machinery into which it is to be incorporated has been declared in conformity with the provisions of this Rulebook;
- 7) the place and date of issuance of the declaration of incorporation of partly completed machinery;
- 8) the identity and signature of the person authorized to draw up the declaration of incorporation of partly completed machinery on behalf of the manufacturer or his representative.

7.3 Confirmation of Conformity

Confirmation of Conformity is a special type of document of conformity that was like a specific legal institute, introduced in the Serbian technical legislation by "the new technical regulations." The confirmation of conformity is a document certifying the compliance of the product in subject with the requirements of the relevant regulations. It can be issued at the request of various economic operators. The request may be submitted by foreign or domestic manufacturer, agent, representative or branch office or representative of a foreign manufacturer or importer. More on Confirmation of Conformity has been said in Section 6.2 of this handbook.

7.4 Certificates

When on the machinery, falling within one of the categories listed in Annex 4 of the Rulebook, is apply any of the conformity assessment procedures in which a designated conformity assessment body participates (type-examination in Annex 9 of the Rulebook or full quality assurance in Annex 10 of the Rulebook) the resulting document is the appropriate certificate. **There is no requirement that such issued**

certificate is following a product on the market, but **its existence must be clearly indicated** on the declaration of conformity.

7.5 Instructions

Item 1.7.4. of Annex 1 of the Rulebook relates to requirements that manufacturer must meet before the machinery is placed on the market and/or put into use (see paragraph 5.1. of the guide).

In the first paragraph of point 1.7.4 it is stated that the machinery should be followed by the manufacturer's instructions. This implies that the instructions must be made before the machinery is placed on the market and/or put into use, and it must follow the machinery until it reaches the users. Importers and distributors of machinery must therefore ensure the delivery of instructions to the user.

In addition to general requirements for instructions determined in point 1.7.4, additional requirements for instructions are specified in the following points of Annex 1 of the Rulebook:

- Section 2.1.2, 2.2.1.1 and 2.2.2.2 - machinery for foodstuffs and machinery for cosmetics and pharmaceutical products, portable hand-held and hand guided machinery, portable fixing and other impact machinery;

- Section 3.6.3.1 and 3.6.3.2 - mobile machinery and machinery with multiple uses;

- Section 4.4.1 and 4.4.2 - lifting accessories and lifting machinery.

There is a general agreement that all instructions regarding health and safety requirements must be submitted in writing, because it should not be assumed that the user has means to read the given instructions in electronic form or available on the Internet site. However, it is often useful for the instructions to be made available in electronic form and on the Internet as well as in paper form, since this enables the user to download the electronic file if he so wishes and to recover the instructions if the paper copy has been lost. This practice also facilitates the updating of the instructions when this is necessary.

Machinery must be accompanied by original instructions, that is, the instructions prepared by the manufacturer, or his representative, or if they are not registered in the Republic of Serbia, the importer. If the original instructions are not available in the Serbian language, the machinery must be accompanied by translation of the original instructions as well as the original instructions. The purpose of the last request is to allow users to see the original instructions in case of doubt of the accuracy of the translation.

Sub-item d) of point 1.7.4.1 makes a distinction between the machinery intended for professional and unprofessional use. Text and the form of the instructions must be adapted to the target group.

8. SAFEGUARD CLAUSE

Conformity mark that was affixed on the machine and the Declaration of Conformity for machinery are external indicators that confirm the existence of a **presumption of conformity** of machinery with the requirements from the Rulebook.

Therefore, **the delivery or use of machinery, that is placed on the market of the Republic of Serbia**, which meets the requirements of this Rulebook, on which the conformity mark has been affixed, which is accompanied by a declaration of conformity of machinery and used in accordance with the intended purpose or under conditions that can be reasonably predicted, **it cannot be limited nor its free movement can be affected by other requirements and conditions which are not prescribed by the Rulebook.**

Nevertheless, this presumption of conformity can be disproved, so that the free movement of such machinery may still be restricted or prohibited **only if there is a reasonable doubt** that the machinery is unsafe or non-compliance with the essential safety requirements from Annex 1 of the Rulebook, but that restriction, withdrawal, revocation, or some other kind of prohibition on trade can be executed by a competent market surveillance authorities **only according to the procedure and in the manner prescribed by the law** governing technical requirements for products and conformity assessment, or by other appropriate law (Article 15 of the Rulebook - safeguard clause).

9. MARKET SURVEILLANCE

Market surveillance over the implementation of the Rulebook should ensure that the Rulebook is applied in practice and that the machinery placed on the market and/or put into use in the Republic of Serbia is safe.

Market surveillance is carried out *during or after placing those products on the Serbian market, and/or into their intended use*. Market surveillance is different from the conformity assessment because their aim is to ensure conformity of products *before* they are placed on the market and/or put into use.

Market surveillance can be done at any stage after the completion of the machinery design, as soon as the product is made available for distribution or use in the Republic of Serbia. The machinery can be inspected at the premises of manufacturers, importers, distributors or companies that rent, as well as in transit.

The conformity of machinery may also be checked at the user's premises after it has been put into service, but in that case, the market surveillance authorities must be able to distinguish the features that the machinery had when it was supplied by the manufacturer from features that may result from modifications carried out by the user. This may be facilitated by examination of the relevant elements of the manufacturer's technical documentation. The conformity of machinery manufactured by the user for his own use may also be checked after it has been put into use.

Market surveillance of partly completed machinery can be carried out before the partly completed machinery has been incorporated into the final machinery or assembly of machinery. The market surveillance authorities may also carry out checks on machinery or assemblies of machinery into which partly completed machinery has been incorporated. In that case, the market surveillance of the partly completed machinery is an aspect of the market surveillance of the final machinery.

What does relevant market surveillance authority checks?

- Conformity mark and Declaration of conformity.
 - Content of Declaration of conformity of the machinery.
 - Content of Declaration of incorporation of partly completed machinery.
- Instruction
 - Documents relating to machinery listed in Annex 4 of the Rulebook.
 - Type-examination certificate.
 - Full quality assurance certificate.
- Technical documentation - if the relevant market surveillance authority has reasonable doubt in conformity with the essential health and safety requirements, it may require the submission of technical documentation for the machinery and/or relevant technical documentation for partly completed machinery. Such a request may be submitted at any stage of market surveillance procedure.

Actions and measures undertaken by the relevant market surveillance authority in the case of non-compliance of all the products with the requirements from every technical regulation, including non-compliance of machinery with the requirements from the Rulebook, are prescribed by the Law on Technical Requirements for Products and Conformity Assessment, and in the absence of some surveillance measures in that Law, other surveillance measures from the Law on General Product Safety are applied.

10. CONCLUSION

Contrary to the Old Approach, the philosophy of the New Approach implies that the European directives define only essential requirements for product safety, and that the detailed technical content, i.e. elaboration of the essential requirements is contained in the so-called harmonized European standards (that were commissioned by the European Commission from European organizations for standardization). When requirements of the harmonized standards are met, it is considered that the manufacturer fulfils the essential

requirements contained in the New Approach directives (presumption of conformity). Having in mind that fulfilment of requirements from standards is not the only way to ensure conformity with essential requirements; manufacturer can meet essential requirements in another manner. This way the voluntary application of standards is preserved.

Another element of the New Approach represents a way to verify compliance with the essential requirements. Conformity assessment is based on the so-called Global Approach, i.e. modules for conformity assessment. Unlike the Old Approach, compliance with the requirements of the directive is confirmed by the manufacturer – with a declaration of conformity or document of conformity which were issued by designated conformity assessment body, and the government is completely left out from the process of conformity assessment with the prescribed requirements.

In accordance with Directive 2006/42/EC, as the so-called New Approach directive in the field of technical legislation of the EU, as well as the law governing the technical requirements for products and conformity assessment, new essential solutions are anticipated in the field of machinery, types of operators that carry out or participate in the conformity assessment, types of documents of conformity, as well as voluntary application of Serbian standards that transpose harmonized (European) standards in this field (presumption of conformity). This concept differs from concept of direct, mandatory application of standards that rulebooks and ordinances in the field of machinery referred to; they often contained out of date, inconsistent and too detailed technical and technological solutions and rules, which have sometimes presented unnecessary restrictions and burdens for the manufacturers.

RULEBOOK ON MACHINERY SAFETY

("Official Gazette of RS ", No. 13/2010)

I INTRODUCTION PROVISIONS

Article 1

This Rulebook sets out the essential health and safety requirements relating to design and construction of machinery, and other requirements and conditions that shall be met prior to placing machinery on the market or putting into service; the contents of Declaration of Conformity of the machinery and Declaration of Incorporation of partly completed machinery; the contents of technical documentation; conformity assessment procedures; criteria that shall be met by conformity assessment bodies to be notified; conformity mark and conformity marking; confidentiality and safeguard clause.

Scope

Article 2

This Rulebook shall apply to the following machines and products:

- 1) Machinery;
- 2) Interchangeable equipment;
- 3) Safety components;
- 4) Lifting accessories;
- 5) Chains, ropes and webbing;
- 6) Removable mechanical transmission devices;
- 7) Partly completed machinery.

Products excluded from the scope of this Rulebook

Article 3

This Rulebook shall not apply to the following machines and products:

- 1) Safety components intended to be used as spare parts to replace identical components and supplied by the manufacturer of the original machinery;
- 2) Specific equipment for use in fairgrounds and/or amusement parks;
- 3) Machinery specially designed or put into service for nuclear purposes which, in the event of failure, may result in an emission of radioactivity;
- 4) Weapons, including firearms;
- 5) The following means of transport:
 - (1) agricultural and forestry tractors for the risks covered by relevant regulations, with the exclusion of machinery mounted on these vehicles;
 - (2) motor vehicles and their trailers covered by relevant regulation, with the exclusion of machinery mounted on these vehicles;

- (3) two or three-wheel motor vehicles covered by relevant regulation, with the exclusion of machinery mounted on these vehicles;
- (4) motor vehicle exclusively intended for competition;
- (5) means of transport by air, on water and on rail networks with the exclusion of machinery mounted on these means of transport.
- 6) Seagoing vessels and mobile offshore units and machinery installed on board such vessels and/or units;
- 7) Machinery specially designed and constructed for military or police purposes;
- 8) Machinery specially designed and constructed for research purposes for temporary use in laboratories;
- 9) Mine winding gear;
- 10) Machinery intended to move performers during artistic performances;
- 11) Electrical and electronic products or groups of such products falling under application of other regulations as follows:
 - (1) household appliances intended for domestic use;
 - (2) audio and video equipment;
 - (3) information technology equipment;
 - (4) ordinary office machinery;
 - (5) low-voltage switchgear and control gear;
 - (6) electric motors.
- 12) High-voltage electrical equipment as follows:
 - (1) switch gear and control gear;
 - (2) transformers.

This Rulebook shall not apply to machinery with relation to hazards listed in Annex 1 – Essential health and safety requirements relating to design and construction of machinery, which is printed with this Rulebook as its integral part, where the hazards are covered more specifically by other regulations.

Definitions

Article 4

Terms used in this Rulebook shall have the following meaning:

- 1) „machinery” means machines or products listed in Article 2 (1), Points (1) to (6) of this Rulebook, and also:
 - (1) an assembly, fitted with or intended to be fitted with a drive system other than directly applied human or animal effort, consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application;
 - (2) an assembly referred to in the first subparagraph of this Point, missing only the components to connect it on site or to sources of energy and motion;
 - (3) an assembly referred to in the first and second subparagraphs of this Point ready to be installed and able to function only if mounted on a means of transport, or installed in a building or a structure;
 - (4) an assembly referred to in the first, second and thirds subparagraphs of this Point or partially completed machinery which, in order to achieve the same goal, are arranged and controlled so that they function as an integral whole;
 - (5) an assembly of linked parts or components, at least one of which moves, intended for lifting loads and whose only power source is directly applied human effort.
- 2) „interchangeable equipment” means a device mounted on machinery or tractor by the operator in order to change its function or attribute a new function, in so far as this equipment is not a tool;
- 3) „safety components” means a component:
 - (1) which serves to fulfil safety functions;
 - (2) which is independently placed on the market;
 - (3) the failure and/or malfunction of which endangers the safety of persons;
 - (4) which is not necessary in order for the machinery to function, or for which normal components may be substituted in order for the machinery to function.

An indicative list of safety components is listed as Annex 5 – List of safety components, printed with this Rulebook and its integral part;

4) „lifting accessory” means a component or equipment not attached to the lifting machinery, allowing the load to be held, which is placed between the machinery and the load or on the load itself, or which is intended to constitute an integral part of the load and which is independently placed on the market; slings and their components are also regarded as lifting accessories;

5) „chains, ropes and webbing” means chains, ropes and webbing designed and constructed for lifting purposes as part of lifting machinery or lifting accessories;

6) „removable mechanical transmission device” 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. When it is placed on the market with the guard, it shall be regarded as one product;

7) „partly completed machinery” means an assembly which is almost machinery but which cannot in itself perform a specific application; but is only intended to be incorporated into or assembled with other machinery or other partly completed machinery or equipment, thereby forming machinery to which this Rulebook applies. A drive system is partly completed machinery;

8) „placing on the market” means making available for the first time on the market in the Republic of Serbia machinery or partly completed machinery with a view to distribution or use, in return for payment or free of charge;

9) „manufacturer” means any natural or legal person or entrepreneur who designs and/or manufactures machinery or partly completed machinery with a view to its being placed on the market, under his own business name or trademark or other recognisable label or for his own use. In the absence of a manufacturer as defined above, any natural or legal person or entrepreneur who places on the market or puts into service machinery or partly completed machinery shall be considered a manufacturer;

10) „authorised representative” means any legal entity or entrepreneur registered in the Republic of Serbia or natural person who is resident in the Republic of Serbia who has been authorised by the manufacturer to perform on his behalf all or part of the obligations under this Rulebook;

11) „putting into service” means the first use of machinery for its intended purpose in the Republic of Serbia;

12) „harmonised standard” means a standard adopted by European Standards Bodies, namely: the European Committee for Standardisation (CEN), the European Committee for Electrotechnical Standardisation (CENELEC) or the European Telecommunications Standards Institute (ETSI) on the basis of a remit issued by the European Commission, which has been published in the Official Journal of the European Commission.

Terms used in this Rulebook which are not defined under Paragraph 1 of this Article, shall have meanings stipulated by acts regulating technical requirements for products, general safety of products and standardisation.

II PLACING ON THE MARKET AND/OR PUTTING INTO SERVICE Placing into market and/or putting into service

Article 5

Before placing machinery on the market and/or putting it into service, the manufacturer shall:

- 1) ensure that it satisfies the relevant essential health and safety requirements set out in Annex I;
- 2) ensure that the technical documentation referred to in Annex VII, Chapter A – Technical documentation for machinery and partially completed machinery, printed with this Rulebook and its integral part, is available;
- 3) provide, in particular, the necessary information (such as instructions) on machinery;
- 4) carry out the appropriate procedures for assessing conformity in accordance with Article 8 of this Rulebook;

5) draw up the Declaration of Conformity in accordance with Annex 2, Chapter A – Declaration of Conformity of machinery and Declaration of Incorporation of partly completed machinery, pointed with this Rulebook and its integral part and ensure that it accompanies the machinery;

6) affix the conformity mark on machinery in accordance with Article 12 of this Rulebook.

Obligations under Paragraph 1, Points (2), (3), (5) and (6) the manufacturer may transfer to its authorised representative.

Machinery with conformity mark being affixed to it and accompanied by Declaration of Conformity is considered to comply with the provisions of this Rulebook.

Where machinery is also the subject to other regulations governing other aspects and providing for the affixing of the conformity mark, the conformity mark shall indicate that the machinery also complies with the provisions of those other regulations.

Information on regulations referred to in Paragraph 4 of this Article shall be stated in the Declaration of Conformity.

Before placing partly completed machinery on the market, the manufacturer or his authorised representative shall draw up documentation and other documents referred to in Article 9 of this Rulebook.

Free movement

Article 6

Machinery that complies with provisions and conditions of this Rulebook shall be placed on the market and/or put into service freely, without any restrictions.

Partly completed machinery shall be placed on the market without restrictions where the manufacturer or his authorised representative draws up and issues a Declaration of Incorporation referred to in Annex 2, Chapter B. This Declaration shall state that partly completed machinery is intended for incorporation into machinery or assembly with other partly completed machinery in order to form machinery.

Machinery or partly completed machinery which does not conform to provisions and conditions under this Rulebook may be showed at trade fairs, exhibitions, demonstrations, and such like, provided that a visible sign clearly indicates that it does not conform to provisions under this Rulebook and that it will not be placed on the market and /or put into service until it has been brought into conformity.

During demonstrations of machinery or partly completed machinery referred to in Paragraph 3 of this Article, adequate safety measures shall be taken to ensure the protection of people.

III PRESUMPTION OF CONFORMITY

Serbian standards transposing harmonised standards

Article 7

Machinery shall be presumed to comply with the essential health and safety requirements set out in Annex 1, if it is constructed in accordance with Serbian standards relating to machinery which transposed relevant harmonised standards, the list of which (hereinafter referred to as: List of standards) is made and published in accordance with the law governing technical requirements for products and conformity assessment and the regulation adopted on the basis of that law.

IV CONFORMITY ASSESSMENT PROCEDURES

Procedures for assessing the conformity of machinery

Article 8

The manufacturer or his authorised representative shall, in order to certify the conformity of machinery with provisions of this Rulebook, apply one of the conformity assessment procedures described in Paragraphs 2, 3 and 4 of this Article.

Where the machinery is not referred to in Annex 4 – Type of machinery to which conformity assessment in the manner described in Article 8 (3) and (4) is applicable, printed with this Rulebook and its integral part, the manufacturer shall apply the procedure for conformity assessment - internal production control under Annex 8 – Conformity assessment procedure carried out by the manufacturer (internal production control), printed with this Rulebook as its integral part.

Where the machinery is specified in Annex 4 and manufactured in accordance with the Serbian standards referred to in Article 7 of this Rulebook, and provided that those standards cover all of the relevant health and safety requirements, the manufacturer shall apply one of the following procedures:

- 1) Conformity assessment procedure applying internal production control as per Annex 8;
- 2) Type-examination procedure provided for in Annex 9 – Type examination, printed with this Rulebook as its integral part, and internal production control as per Annex 8, Point 3;
- 3) Full quality assurance procedure provided for in Annex 10 – Full quality assurance procedure, printed with this Rulebook as its integral part.

Where the machinery is specified in Annex 4 and has not been manufactured in accordance with the harmonised standards under Article 7 of this Rulebook, or only partly in accordance with such standards or if the standards do not cover all the relevant essential health and safety requirements or if there is no standards applicable to machinery concerned, the manufacturer shall apply one of the following procedures:

- 1) Type-examination procedure provided for in Annex 9 and internal production control of the machinery provided for in Annex 8, Point 3;
- 2) Full quality assurance procedure referred to in Annex 10.

Procedure for assessing the conformity of partly completed machinery

Article 9

The manufacturer of partly completed machinery or his authorised representative, prior to placing it on the market shall:

- 1) prepare relevant technical documentation referred to in Annex 7, Chapter B;
- 2) prepare assembly instructions referred to in Annex 6 – Assembly instructions for partly completed machinery, printed with this Rulebook as its integral part;
- 3) draw up a Declaration of Incorporation of partly completed machinery referred to in Annex 2, Chapter B.

The assembly instructions and the Declaration of Incorporation of partly completed machinery shall accompany the partly completed machinery until it is incorporated into machinery, and then shall form integral part of the technical documentation for that machinery.

V NOTIFIED BODIES FOR ASSESSING THE CONFORMITY OF MACHINERY

Notified Body

Article 10

Conformity assessment body may carry out the conformity assessment of machinery referred to in Article 8 (3) and (4) of this Rulebook, if it fulfils the requirements for conformity assessment set out in Annex 11 - Requirement that shall be met by conformity assessment body to be notified for conformity assessment, printed with this Rulebook as its integral part, and if such body (hereinafter referred to as: Notified Body) is notified in accordance with the law governing technical requirements for products and conformity assessment and the regulation adopted on the basis of such law.

The Notified Body shall carry out the assessment of conformity of machinery in a manner described in Annexes 9 and 10.

Confirmation of conformity

Article 11

The manufacturer or his authorised representative or importer if the manufacturer or his authorised representative is not established in the Republic of Serbia, prior to placing on the market machinery to which this Rulebook applies and for which conformity assessment procedure was applied as per Annex 6, as: electric-powered lifts for vertical transport of freight with the cabin inaccessible for people; chains and constituent elements of chains; steel ropes intended for general use and portable tools with electric motors

of nominal alternating voltage up to 250 V for domestic use and alike, shall communicate to the Notified Body, a original copy of Declaration of Conformity of that machinery or certified copy with accompanying technical documentation with a view of certifying the conformity of the machinery with the requirements under this Rulebook.

If the Notified Body, on the basis of documents referred to in Paragraph 1 of this Article, establishes conformity of the machinery, it shall issue a Confirmation of conformity with the essential requirements stipulated in Annex 1.

Confirmation of conformity of machinery shall contain, in particular: business name or name of the manufacturer; the title of this Rulebook and number of the Official Gazette where this Rulebook was published; type of machinery and designation of the type of machinery which is the subject of conformity assessment.

Confirmation of conformity referred to in Paragraph 2 of this Article shall be valid for the same type or type of machinery of the same manufacturer for the period of three years from the date of issue of this confirmation.

The Notified Body shall keep a record on issued confirmations referred to in Paragraph 2 of this Article, and shall issue an excerpt from the record upon request by the manufacturer or his authorised representative or importer; the excerpt shall contain in particular information on business name of the manufacturer and type of machinery for which confirmation was issued and its validity period.

The Notified Body shall publish the records on issued confirmation on its official website.

Documentation as per Paragraph 1 of this Article does not need to be submitted to the Notified Body for new delivery of machinery of the same manufacturer and the same type for which Confirmation of conformity was issued; and excerpt from the records under Paragraph 5 of this Article shall be regarded as evidence of validity of issued confirmation.

The manufacturer or his authorised representative shall affix the Serbian conformity mark on the basis of the confirmation of conformity or the excerpt from the records issued by the Notified Body.

The Applicant under Paragraph 1 of this Article shall bear costs related to the review of documentation and issuance of the confirmation of conformity.

Amount of costs referred to in Paragraph 9 of this Article shall be determined by the pricelist provided by the Notified Body and it shall be proportional to the scope and complexity of documentation to be reviewed and time required for carrying out such review.

Costs related to issuing of excerpts from the records referred to in Paragraph 5 this Article may be charged up to the amount of costs necessary for issuing the excerpt, which is determined by the price list of the Notified Body.

Submission of documentation and providing the Confirmation of conformity under Paragraphs 2 and 3 of this Article, shall not apply to the manufacturer of machinery manufactured in the Republic of Serbia and where the Notified Body carried out the assessment of conformity.

VI CONFORMITY MARK

Conformity marking

Article 12

The machinery in conformity with the requirements of this Rulebook shall be marked with conformity mark, with its form and contents as stipulated in Annex 3 –Conformity mark, printed with this Rulebook as its integral part.

The manufacturer, or his authorised representative, or importer if the manufacturer of his representative is not established in the Republic of Serbia, shall affix the conformity mark so as to be visible, easily legible and indelible, in accordance with the regulation governing the manner of affixing and use of conformity marks.

Other marks, symbols and designations may be placed on machinery provided that they do not affect visibility, legibility and/or meaning of the conformity mark.

Marks, symbols and designations whose placing on machinery is forbidden by the act governing technical requirements and conformity assessment shall be prohibited to be placed.

Unduly marking

Article 13

Unduly marking shall be considered as placing of marks, symbols and other designations whose placing is forbidden by the act governing technical requirements for products and conformity assessment, as well as:

- 1) affixing conformity mark on machinery or products to which this Rulebook does not apply;
- 2) lack of conformity mark on machinery which is in conformity with requirements under this Rulebook.

Affixing and use of conformity mark, and other marks, symbols and designations referred to in Article 12 of this Rulebook and Paragraph 1 of this Article, shall be provided in accordance with the act governing technical requirements for products and conformity assessment.

VII CONFIDENTIALITY

Data confidentiality

Article 14

Data and information regarding assessment of conformity of machinery available to the Notified Bodies, the competent authorities and other persons whom this Rulebook apply to, shall be treated as confidential.

Confidential data and information referred to in Paragraph 1 of this Article shall be considered, in particular, any business, professional and trade secrets in accordance with this Rulebook and other regulations.

Mutual exchange of confidential data and information referred to in Paragraph 2 of this Article between the competent authorities and the Notified Bodies shall be performed in accordance with the act and other regulations governing the confidentiality of data and information.

Safeguard clause

Article 15

Supply or use of machinery being placed on the market in the Republic of Serbia, which meets requirements under this Rulebook, with conformity mark affixed on, accompanied by the Declaration of Conformity of machinery and used in compliance with prescribed use or in conditions which can be reasonably foreseen, may be restricted or prohibited in accordance with the act governing technical requirements for products and conformity assessment.

Conformity with EU regulations

Article 16

This Rulebook is in compliance with all principles and essential requirements from the European Parliament and Council Directive No. 2006/42/EC regarding machinery of 17 May 2006.

VIII TRANSITIONAL AND FINAL PROVISIONS

Article 17

From the day when the ratified international agreement on conformity assessment and acceptance of industrial products with the EU comes into force (ACAA agreement), in this Rulebook, for machinery to which this Rulebook applies, the term: " Declaration of Conformity " in Articles 1, 5 and 15 of this Rulebook, as well as in Annex 1, Annex 2 and Annex 7 of this Rulebook, shall mean: "EC Declaration of Conformity of machinery"; the term: " conformity mark " in Articles 1 and 5, in the title of Chapters above Article 12 and in Articles 12, 13 and 15 of this Rulebook, as well as in Annex 1 of this Rulebook shall mean: "CE mark "; the term: "Type-examination" in Article 8 of this Rulebook, in Annex 2, Chapter A and Annex 9 of this Rulebook shall mean: "EC Type-examination"; and the term: " Type-examination certificate " in Annex 9 of this Rulebook shall mean: "EC Type-examination certificate ".

If the agreement under Paragraph 1 of this Article shall not be concluded, meanings of terms: "Declaration of Conformity of machinery ", "conformity mark", "type-examination" and "Type-examination certificate " under Paragraph 1 of this Article shall apply as from the day of accession of the Republic of Serbia to the European Union.

Article 18

From the day when this Rulebook enters into force till the ratified international agreement on conformity assessment and acceptance of industrial products with the EU for machinery to which this Rulebook applies, enters into force conformity marking shall be performed by affixing the Serbian conformity mark in accordance with this Rulebook and relevant regulations.

If the agreement under Paragraph 1 of this Article shall not be concluded, conformity marking by affixing the Serbian conformity mark shall be performed till the day of accession of the Republic of Serbia to the European Union.

From the day when the ratified international agreement on conformity assessment and acceptance of industrial products with the EU for machinery to which this Rulebook applies, conformity marking shall be performed by affixing CE mark in accordance with this Rulebook and relevant regulations.

If the agreement under Paragraph 3 of this Article shall not be concluded, conformity marking by affixing the CE mark shall be performed as from the day of accession of the Republic of Serbia to the European Union.

Article 19

Conformity assessment bodies which are accredited or authorised to carry out assessment of conformity as per regulations under Article 21 (1) of this Rulebook shall issue confirmations of conformity referred to in Article 11 of this Rulebook until they get notification in accordance with this Rulebook and relevant regulations.

Article 20

Provisions of Article 11 of this Rulebook shall be repealed as from the day when the ratified international agreement on conformity assessment and acceptance of industrial products with the EU for machinery to which this Rulebook applies, enters into force.

If the agreement under Paragraph 1 of this Article shall not be concluded, provisions of Article 11 of this Rulebook shall cease to have effect as from the day of accession of the Republic of Serbia to the European Union.

Article 21

Following regulations shall cease to have effect as from the day when this Rulebook enters into force:

- 1) Rulebook on technical standards for safety against static electricity ("Official Gazette of SFRY", No. 62/73);
- 2) Rulebook on technical standards for casting industry ("Official Gazette of SFRY", No. 14/79 and 65/91);
- 3) Rulebook on technical standards for application of motor chain saws in forestry ("Official Gazette of SFRY", No. 34/80);
- 4) Rulebook on technical standards for electric powered facade lifts ("Official Gazette of SFRY", No. 19/86);
- 5) Rulebook on technical standards for electric powered suspended scaffolds ("Official Gazette of SFRY", No. 19/86);
- 6) Rulebook on technical standards for plastic processing of non-ferrous metals ("Official Gazette of SFRJ", No. 25/86);
- 7) Rulebook on technical standards for electric powered lifts for vertical transport of freight with the cabin inaccessible to people ("Official Gazette of SFRY", No. 55/87);
- 8) Rulebook on mandatory attestation of electric powered lifts for vertical transport of freight with the cabin inaccessible to people and requirements that shall be met by organisations of associated labour authorised to attest such products ("Official Gazette of SFRY", No. 18/91);
- 9) Rulebook on technical standards for cranes ("Official Gazette of SFRY", No. 65/91);
- 10) Rulebook on technical standards for escalators and moving staircase for transport of people ("Official Gazette of SFRY", No. 83/94);
- 11) Rulebook on technical standards for agricultural machinery ("Official Gazette of SRY", No. 34/95);

12) Rulebook on technical and other requirements for motor-driven car ladders ("Official Gazette of RS", No. 56/09);

13) Order on mandatory attestation of chains and constituent elements ("Official Gazette of SFRY", No. 9/83);

14) Order on mandatory attestation of steel ropes for general purpose ("Official Gazette of SFRY", No. 61/83 and 17/88);

15) Order on mandatory attestation of portable tools with electric motors ("Official Gazette of SFRY", No. 43/88).

Certificate of Conformity issued on the basis of the regulation under Paragraph 1 of this Article shall be repealed as from 1 January 2012.

Article 22

The manufacturer or his authorised representative, or importer, may, not later than 1 January 2012, place on the market and/or put into service machinery or product designed and constructed and for which conformity was assessed in accordance with requirements under the regulation referred to in Article 21 (1) of this Rulebook.

The conformity document issued on the basis of conducted assessment of conformity under Paragraph 1 of this Article or other documents accompanying machinery or product shall state information of regulations with which such machinery or product is in conformity (title of regulation and number of the Official Gazette where that regulation was published).

Article 23

This Rulebook shall enter into force on the eighth day following its publication in the Official Gazette of the Republic of Serbia.

ESSENTIAL HEALTH AND SAFETY REQUIREMENTS RELATING TO THE DESIGN AND CONSTRUCTION OF MACHINERY

GENERAL PRINCIPLES

1. The manufacturer of machinery must ensure that a risk assessment is carried out in order to determine the health and safety requirements which apply to the machinery. The machinery must then be designed and constructed taking into account the results of the risk assessment.

By the iterative process of risk assessment and risk reduction referred to Paragraph 1 of this Point, the manufacturer shall:

1) determine the limits of the machinery including the intended use and any reasonably foreseeable misuse thereof;

2) identify the hazards that can be caused by the machinery and the associated hazardous situations;

3) estimate the risks, taking into account the severity of the possible injury or damage to health and the probability of its occurrence;

4) evaluate the risks, with a view to determining whether risk reduction is required, in accordance with the objectives of this Rulebook;

5) eliminate the hazards or reduce the risks associated with these hazards by application of protective measures, in the order of priority established in Item 1.1.2(b) of this Annex.

2. The obligations laid down by the essential health and safety requirements must be only applied when the corresponding hazard exists for the machinery in question when it is used under the conditions foreseen by the manufacturer in foreseen cases of the misuse. In any event, the principles of safety integration referred to in Item 1.1.2 of this Annex and the obligations concerning marking of machinery and instructions referred to in Items 1.7.3 and 1.7.4 must be applied.

3. The essential health and safety requirements laid down in this Annex must be treated as mandatory. However, taking into account the level of the technique development, it may not be possible to meet the objectives set by this Annex. In that event, the machinery must, to the maximum possible extent, be designed and constructed with the purpose of approaching these objectives.

4. This Annex is organised in several parts. The first one has a general scope and is applicable to all kinds of machinery. The other parts refer to certain kinds of more specific hazards. When machinery is being designed, the requirements of the general part and the requirements of one or more of the other parts shall be taken into account, depending on the results of the risk assessment carried out in accordance with Point 1 of these General Principles.

1. ESSENTIAL HEALTH AND SAFETY REQUIREMENTS

1.1 GENERAL NOTES

1.1.1 Definitions

For the purpose of this Annex, following meanings must be applied:

a) “hazard” means a potential source of injury or damage to health;

b) “danger zone” means any zone within and/or around machinery in which a person is subject to a risk to his health or safety;

v) “exposed person” means any person wholly or partly in a danger zone;

g) “operator” means the person or persons installing, operating, adjusting, connecting, maintaining, cleaning, repairing or moving machinery;

d) “risk” means a combination of the probability and the degree of an injury or damage to health that can arise out in a hazardous situation;

d) “guard” means a part of the machinery used specifically to provide protection by means of a physical barrier;

e) “protective device” means a device (other than a guard) which reduces the risk, either by itself or in conjunction with a guard;

ž) “intended use” means the use of machinery in accordance with the information provided in the instructions for use;

z) “reasonably foreseeable misuse” means the use of machinery in a way not intended in the instructions for use, but which may result from readily predictable human behaviour.

1.1.2 Safety principles

a) Machinery must be designed and constructed so that it is fitted for its function, and can be operated, adjusted and maintained without putting persons at risk when these operations are carried out under the conditions foreseen but also taking into account any reasonably foreseeable misuse thereof.

The aim of measures taken must be to eliminate any risk throughout the foreseeable lifetime of the machinery including the phases of transport, assembly, dismantling, disabling and scrapping.

b) In selecting the most appropriate methods, the manufacturer must apply the following principles, in the order given:

- eliminate or reduce risks to the extent as possible in the phase of design and construction of machinery;

- take the necessary protective measures in relation to risks that cannot be eliminated;

- inform users of the residual risks due to any shortcomings of the protective measures adopted, indicate whether any particular training is required and specify any need to provide personal protective equipment.

v) When designing and constructing machinery and when drafting the instructions, the manufacturer must envisage not only the intended use of the machinery but also any reasonably foreseeable misuse thereof.

The machinery must be designed and constructed in such a way as to prevent abnormal use if such use would engender a risk. Where appropriate, the instructions must draw the user's attention to ways —which experience has shown might occur — in which the machinery should not be used.

g) Machinery must be designed and constructed to take account of the constraints to which the operator is subject as a result of the necessary or foreseeable use of personal protective equipment.

d) Machinery must be delivered with all the special equipment and accessories essential to enable it to be adjusted, maintained and used safely.

1.1.3 Materials and products

The materials used to construct machinery or products applied or created during its use must not endanger persons' safety or health. In particular, where fluids are used, machinery must be designed and constructed to prevent risks due to filling, use, recovery or discharging.

1.1.4 Lighting

Machinery must be delivered with integral lighting suitable for the intended operations where the absence thereof is likely to cause a risk despite ambient lighting of normal intensity.

Machinery must be designed and constructed so that there is no area of shadow likely to cause nuisance, that there is no irritating dazzle and that there are no dangerous stroboscopic effects on moving parts due to the lighting.

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

1.1.5 Design of machinery to facilitate its handling

Machinery or each component part thereof, must:

- be capable of being handled and transported safely,
- be packaged or designed so that it can be stored safely and without damage (for example adequate stability, special supporters etc.).

During the transportation of the machinery and/or its component parts, there must be no possibility of sudden movements or of hazards due to instability as long as the machinery and/or its component parts are handled in accordance with the instructions.

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

- either be fitted with attachments for lifting gear, or
- be designed so 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 moveable, or
- be equipped for lifting and moving safely.

Special arrangements must be made for the handling of tools and/or machinery parts which, even if lightweight, may be hazardous (shape, material and alike).

1.1.6. Ergonomic

Under the intended conditions of use of machinery, the discomfort, fatigue and physical and psychological stress faced by the operator must be reduced to the minimum possible extent, taking into account ergonomic principles such as:

- the operator may be of various physical dimensions, strength and stamina;
- the operator has enough space for movements of the parts of his body,
- avoiding a machine-determined work rate,
- avoiding monitoring that requires lengthy concentration of the operator,
- adapting the man/machinery interface to the foreseeable characteristics of the operators.

1.1.7 Operating positions

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

If the machinery is intended to be used in a hazardous environment presenting risks to the health and safety of the operator or if the machinery itself gives rise to a hazardous environment, adequate means must be provided to ensure that the operator has good working conditions and is protected against any foreseeable hazards.

Where appropriate, the operating position must be fitted with an adequate cabin designed, constructed and/or equipped to fulfil the requirements specified in Paragraph 1 and 2 of this Item. The exit must allow rapid evacuation. Moreover, when applicable, an emergency exit must be provided in a direction which is different from the usual exit.

1.1.8. Seating

Where appropriate and where the working conditions so permit, work stations constituting an integral part of the machinery must be designed for the installation of seats.

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

The operator's seat must enable him to maintain a stable position. Furthermore, the seat and its distance from the control devices must be capable of being adapted to the operator.

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 operator to the lowest level that is reasonably possible. The seat

mountings must withstand all stresses to which they can be subjected. Where there is no floor beneath the feet of the operator, footrests covered with a slip-resistant material must be provided.

1.2 CONTROL SYSTEM

1.2.1 Safety and reliability of control systems

Control systems must be designed and constructed in such a way as to prevent hazardous situations from arising out. Above all, they must be designed and constructed in such a way that:

- they can withstand the intended operating stresses and external influences;
- a fault in the hardware or the software of the control system does not lead to hazardous situations;
- errors in the control system logic do not lead to hazardous situations;
- reasonably foreseeable human error during operation does not lead to hazardous situations.

Particular attention must be given to the following:

- the machinery must not start unexpectedly;
- the parameters of the machinery must not change in an uncontrolled way, where such change may lead to hazardous situations;
- the machinery must not be prevented from stopping if the stop command has already been given;
- no moving part of the machinery or piece held by the machinery must fall or be ejected;
- automatic or manual stopping of the moving parts, whatever they may be, must be unimpeded;
- the protective devices must remain fully effective or give a stop command;
- the safety-related parts of the control system must apply in a coherent way to the whole of an assembly of machinery and/or partly completed machinery.

For cable-less control, an automatic stop must be activated when correct control signals are not received, including loss of communication.

1.2.2 Control devices

Control devices must be:

- clearly visible and identifiable, using adequate pictograms where appropriate;
- positioned in such a way as to be safely operated without hesitation or loss of time and without ambiguity,
 - designed in such a way that the movement of the control device is consistent with its effect;
 - located outside the danger zones, except where necessary for certain control devices such as an emergency stop or a teach pendant;
 - positioned in such a way that their operation cannot cause additional risk;
 - designed or protected in such a way that the desired effect, where a hazard is involved, can only be achieved by a deliberate activation;
 - made in such a way as to withstand foreseeable forces; particular attention must be paid to emergency stop devices liable to be subjected to considerable forces.

Where a control device is designed and constructed to perform several different actions, the action to be performed must be clearly displayed and subject to confirmation, where necessary.

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 fitted with indicators (meters, alarm devices and alike) as required for safe operation. The operator must be able to read them from the control position.

From each control position, the operator must be able to ensure that no one is 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 the operator cannot ensure or if neither of these possibilities referred to in Paragraph 5 of this Item is applicable, before the machinery starts, an acoustic and/or visual warning signal must be given. The exposed persons must have time to leave the danger zone or prevent the machinery starting up.

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

Where there is more than one control position, the control system must be designed in such a way that the use of one of them precludes the use of the others, except for stop controls and emergency stops.

When machinery has 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 hazardous situation.

1.2.3 Starting

It must be possible to start machinery only by deliberately actuation of a control device provided for the purpose.

The same requirement applies:

- when restarting the machinery after a stoppage, whatever the cause,
- when effecting a significant change in the operating conditions (for example speed level, pressure, and alike).

However, the restarting of the machinery or a change in operating conditions may be effected by deliberately actuation of a device other than the control device provided for the purpose, on condition that this does not lead to a hazardous situation.

For machinery functioning in automatic mode, the starting of the machinery, restarting after a stoppage, or a change in operating conditions may be possible without intervention, provided that this does not lead to a hazardous situation.

Where machinery has several starting control devices and the operators can therefore put each other in danger, additional devices must be fitted to rule out such risks. If safety requires that starting and/or stopping must be performed in a specific sequence, there must be devices which ensure that these operations are performed in the correct order.

1.2.4. Stopping

1.2.4.1. *Normal stop*

Machinery must be fitted with a control device whereby the machinery can be brought safely to a complete stop.

Each workstation must be fitted with a control device to stop some or all of the functions of the machinery, depending on the existing hazards, so that the machinery is rendered safe.

The machinery's stop control device must have priority over the start control devices.

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*

Where, for operational reasons, a stop control that does not cut off the energy supply to the actuators is required, the stop condition must be monitored and maintained.

1.2.4.3 *Emergency stop*

Machinery must be fitted with one or more emergency stop devices to enable actual or impending danger to be averted, except for:

- machinery in which an emergency stop device would not reduce the risk, either because it would not reduce the stopping time or because it would not enable the special measures required to deal with the risk to be taken;

- portable hand-held and/or hand-guided machinery.

The stop device must, in case of emergency:

- have clearly identifiable, clearly visible and quickly accessible control devices,
- stop the hazardous process as quickly as possible, without creating additional risks,
- where necessary, trigger or permit the triggering of certain safeguard movements.

Once active operation of the emergency stop device has ceased following a stop command, that command must be sustained by engagement of the emergency stop device until that engagement is specifically overridden. It must not be possible to engage the device without triggering a stop command. It must be possible to disengage the device 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 and operational at all times, regardless of the operating mode.

Emergency stop devices must be a back-up to other safeguarding measures and not a substitute for them.

1.2.4.4 *Assembly of machinery*

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

1.2.5 **Selection of 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 machinery has been designed and constructed to allow its use in several control or operating modes requiring different protective measures and/or work procedures (for example in order to adjust, maintain, inspect and alike), it must be fitted with 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 referred to in Paragraph 2 of this Item may be replaced by another selection method which restricts the use of certain functions of the machinery to certain categories of operator (for example accessible codes for certain numeric control functions etc.).

If, for certain operations, the machinery must be able to operate with a guard displaced or removed and/or a protective device disabled, the control or operating mode selector must simultaneously:

- disable all other control or operating modes;
- permit operation of hazardous functions only by control devices requiring sustained action;
- permit the operation of hazardous functions only in reduced risk conditions while preventing hazards from linked functions,
- prevent any operation of hazardous functions by intentional or accidental action on the machine's sensors.

If the four conditions specified in Paragraph 4 of this Item cannot be fulfilled simultaneously, the control or operating mode selector must activate other protective measures designed and constructed to ensure a safe intervention zone.

In addition, the operator must be able to control operation of the parts he is working on from the adjustment point.

1.2.6 **Failure of the power supply**

The failure, the re-establishment after an interruption or the fluctuation in whatever manner of the power supply to the machinery must not lead to dangerous situations. Particular attention must be given to the following:

- the machinery must not start unexpectedly,
- the parameters of the machinery must not change in an uncontrolled way when such change can lead to hazardous situations,
- the machinery must not be prevented from stopping if the command has already been given,
- no moving part of the machinery or piece held by the machinery must fall or be ejected,

- automatic or manual stopping of the moving parts, whatever they may be, must be unimpeded,
- the protective devices must remain fully effective or give a stop command.

1.3 PROTECTION AGAINST MECHANICAL HAZARDS

1.3.1 Risk of loss of stability

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

If the shape of the machinery itself or its intended installation does not provide sufficient stability, appropriate means of fixing must be incorporated and indicated in the instructions.

1.3.2 Risk of rupture during operation

The various parts of machinery and their linkages must be able to withstand the stresses to which they are subject when used.

The durability of the materials used must be adequate for the nature of the working environment foreseen by the manufacturer or his authorised representative, in particular as regards the phenomena of fatigue, ageing, corrosion and abrasion (wearing).

The instructions must indicate the type and frequency of inspections and maintenance required for safety reasons. They must, where appropriate, indicate the parts subject to wear and the criteria for replacement.

Where a risk of rupture or disintegration (for example in case of grinders) remains despite the measures taken, the parts concerned must be mounted, positioned and/or guarded in such a way that any fragments will be contained, preventing hazardous situations.

Both rigid and flexible tubes carrying fluids, particularly those under high pressure, must be able to withstand the foreseen internal and external stresses and must be firmly attached and/or protected to ensure that no risk is posed by a rupture.

Where the material to be processed is fed to the tool automatically, the following conditions must be fulfilled to avoid risks to persons (for example tool rupture):

- when the workpiece comes into contact with the tool, the tool must have attained its normal working condition;
- when the tool starts and/or stops (intentionally or accidentally), the feed movement and the tool movement must be coordinated.

1.3.3 Risks due to falling or ejected objects

Precautions must be taken to prevent risks from falling or ejected objects.

1.3.4 Risks due to surfaces, edges or angles

Insofar as their purpose allows, accessible parts of the machinery must have no sharp edges, no sharp angles and no rough surfaces likely to cause injury.

1.3.5 Risks related to combined machinery

Where the machinery is intended to carry out several different operations with manual removal of the piece between each operation (combined machinery), it must be designed and constructed in such a way as to enable each element to be used separately without the other elements constituting a risk for exposed persons.

For the purpose referred to in Paragraph 1 of this Item, it must be possible to start and stop separately any elements that are not protected.

1.3.6 Risks related to variations in operating conditions

Where the machinery performs operations under different conditions of use, it must be designed and constructed in such a way that selection and adjustment of these conditions can be carried out safely and reliably.

1.3.7 Risks related to moving parts

The moving parts of machinery must be designed and constructed in such a way as to prevent risks of contact which could lead to accidents or must, where risks persist, be fitted with guards or protective devices.

All necessary steps must be taken to prevent accidental blockage of moving parts involved in the work. In cases where, despite the precautions taken, a blockage is likely to occur, the necessary specific protective devices and tools must be provided to enable the equipment to be safely unblocked.

The instructions and, where possible, a sign on the machinery shall identify specific protective devices under Paragraph 2 of this Item and how they are to be used.

1.3.8 Choice of protection against risks arising from moving parts

Guards or protective devices designed to protect against risks arising from moving parts must be selected on the basis of the type of risk. The following guidelines must be used as help to make the choice:

1.3.8.1 *Moving transmission parts*

Guards designed to protect persons against the hazards generated by moving transmission parts must be:

- either fixed guards as referred to in Item 1.4.2.1, or
- interlocking movable guards as referred to in Item 1.4.2.2.

Interlocking movable guards should be used where frequent access is envisaged.

1.3.8.2 *Moving parts involved in the process*

Guards or protective devices designed to protect persons against the hazards generated by moving parts involved in the process must be:

- either fixed guards as referred to in Item 1.4.2.1, or
- interlocking movable guards as referred to in Item 1.4.2.2, or
- protective devices as referred to in Item 1.4.3, or
- a combination of the all above mentioned solution.

However, when certain moving parts directly involved in the process cannot be made completely inaccessible during operation owing to operations requiring operator intervention, such parts must be fitted with:

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

1.3.9 Risks of uncontrolled movements

When a part of the machinery has been stopped, any drift away from the stopping position, for whatever reason other than action on the control devices, must be prevented or must be such that it does not present a hazard.

1.4 REQUIRED CHARACTERISTICS OF GUARDS AND PROTECTIVE DEVICES

1.4.1 General requirements

Guards and protective devices must:

- be of robust construction;
- be securely fixed;
- not give rise to any additional hazard;
- not be easy to by-pass or render non-operational;
- be located at an adequate distance from the danger zone;
- cause minimum obstruction to the view of the production process;
- enable essential work to be carried out on the installation and/or replacement of tools and for maintenance purposes by restricting access exclusively to the area where the work has to be done, if possible without the guard having to be removed or the protective device having to be disabled.

In addition to the required referred to in Paragraph 1 of this Item, guards must, where possible, be protected against the ejection or falling of materials or objects and against emissions generated by the machinery.

1.4.2 Special requirements for guards

1.4.2.1 *Fixed guards*

Fixed guards must be fixed by systems that can be opened or removed only with tools.

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

Where possible, guards must be incapable of remaining in place if not being fixed.

1.4.2.2 *Interlocking movable guards*

Interlocking movable guards must:

- remain attached to the machinery when open, as far as possible;
- be designed and constructed in such a way that they can be adjusted only by an intentional action.

Interlocking movable guards must be associated with an interlocking device that:

- prevents the start of hazardous machinery functions until they are closed;
- gives a stop command whenever they are no longer locked.

Where it is possible for an operator to reach the danger zone before the risk due to the hazardous machinery functions has ceased, movable guards must be associated with a guard locking device in addition to an interlocking device that:

- prevents the start of hazardous machinery functions until the guard is closed and locked;
- keeps the guard closed and locked until the risk of injury from the hazardous machinery functions has ceased.

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

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, depending on the type of work involved;
- easily adjustable without the use of tools.

1.4.3 *Special requirements for protective devices*

Protective devices must be designed and incorporated into the control system in such a way that:

- moving parts cannot start up while they are within the operator's reach,
- persons cannot reach moving parts while the parts are moving, and
- the absence or failure of one of their components prevents starting or stops the moving parts.

Protective devices must be adjustable only by an intentional action.

1.5 RISKS DUE TO OTHER HAZARDS

1.5.1 Electricity supply

Where machinery is supplied by electricity, it must be designed, constructed and equipped in such a way that all hazards of an electrical nature are or can be prevented.

The safety objectives set out in the regulation governing the electrical machinery intended for use within certain voltage limits shall apply to machinery.

Requirements relating to assessment of conformity of machinery and placing machinery on the market and/or putting into service, with regard to hazards of electrical nature must be governed solely by the regulation referred to in Paragraph 2 of this Item.

1.5.2 Static electricity

Machinery must be designed and constructed to prevent or limit the build-up of potentially dangerous electrostatic charges and/or be fitted with a discharging system.

1.5.3 Energy supply other than electricity

Where machinery is powered by source of energy other than electricity (for example hydraulic, pneumatic or heat), it must be so designed, constructed and equipped as to avoid all potential risks associated with such sources of energy.

1.5.4 Errors of fitting

Errors likely to be made when fitting or refitting certain parts which could be a source of risk must be prevented by the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings. The same information must be given on moving parts and/or their housings where the direction of movement needs to be known in order to avoid a risk.

Where appropriate, the instructions must give further information on the risks under Paragraph 1 of this Item.

Where a faulty connection can be the source of risk, improper connections must be made impossible by design or, failing this, by information given on the elements to be connected and, where appropriate, on the means of connection.

1.5.5 Extreme temperatures

Measures must be taken to eliminate any risk of injury arising from contact with or proximity to machinery parts or materials at high or very low temperatures.

The necessary measures must also be taken to avoid or protect against the risk of hot or very cold material being ejected.

1.5.6 Fire

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

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 by gases, liquids, dust, vapours or other substances produced or used by the machinery.

Machinery must comply, as far as the risk of explosion due to its use in a potentially explosive atmosphere is concerned, with the provisions of the specific regulations.

1.5.8 Noise

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

The level of noise emission may be assessed with reference to comparative emission data for similar machinery.

1.5.9 Vibrations

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

The level of vibration emission may be assessed with reference to comparative emission data for similar machinery.

1.5.10 Radiation

Machinery must be design and constructed in such a way that all undesirable radiation emissions from the machinery are eliminated or reduced to levels that do not have adverse effects on persons.

Any functional ionising radiation emissions must be limited to the lowest level which is sufficient for the proper functioning of the machinery during setting, operation and cleaning. Where a risk exists, the necessary protective measures must be taken.

Any functional non-ionising 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

Where laser equipment is used, the following must be taken into account:

— laser equipment on machinery must be designed and constructed in such a way as to prevent any accidental radiation;

— laser equipment on machinery must be protected in such a way that effective radiation, radiation produced by reflection or diffusion and secondary radiation do not damage health;

— optical equipment for the observation or adjustment of laser equipment on machinery must be such that no health risk is created by laser radiation.

1.5.13 Emissions of hazardous materials and substances

Machinery must be designed and constructed in such a way that risks of inhalation, ingestion, contact with the skin, eyes and mucous membranes and penetration through the skin of hazardous materials and substances which it produces can be avoided.

Where a hazard cannot be eliminated, the machinery must be so equipped that hazardous materials and substances can be contained, removed, precipitated by water spraying, filtered or treated by another equally effective method.

Where the process is not totally enclosed during normal operation of the machinery, the devices for containment and/or evacuation must be situated in such a way as to have the maximum effect.

1.5.14 Risk of being trapped in a machine

Machinery must be designed, constructed or equipped with a means of preventing a person from being enclosed within it or, if that is impossible, with a means of summoning help.

1.5.15 Risk of slipping, tripping or falling

Parts of the machinery where persons are liable to move about or stand must be designed and constructed in such a way as to prevent persons from slipping, tripping or falling on or off these parts.

Where appropriate, the parts specified in Paragraph 1 of this Item must be fitted with handholds that are fixed relative to the user and that enable them to maintain their stability.

1.5.16 Lightning

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

1.6. MAINTENANCE

1.6.1 Machinery maintenance

Adjustment and maintenance points must be located outside danger zones. It must be possible to carry out adjustment, maintenance, repair, cleaning and servicing operations while machinery is at a standstill.

If one or more of the above conditions cannot be satisfied for technical reasons, measures must be taken to ensure that these operations can be carried out safely (see Item 1.2.5).

In the case of automated machinery and, where necessary, other machinery, a connecting device for mounting diagnostic fault-finding equipment must be provided.

Automated machinery components which have to be changed frequently must be capable of being removed and replaced easily and safely. Access to the components must enable these tasks to be carried out with the necessary technical means in accordance with a specified operating method.

1.6.2 Access to operating positions and servicing points

Machinery must be designed and constructed in such a way as to allow access in safety to all areas where intervention is necessary during operation, adjustment and maintenance of the machinery.

1.6.3 Isolation of energy sources

Machinery must be fitted with means to isolate it from all energy sources. Such devices must be clearly identified. They must be capable of being locked if reconnection could endanger persons.

Devices specified in Paragraph 1 of this Item must also be capable of being locked where an operator is unable, from any of the points to which he has access, to check that the energy is still cut off.

In the case of machinery capable of being plugged into an electricity supply, removal of the plug is sufficient, provided that the operator can check from any of the points to which he has access that the plug remains removed.

After the energy is cut off, it must be possible to dissipate normally any energy remaining or stored in the circuits of the machinery without risk to persons.

As an exception to the requirement laid down in Paragraphs 1 to 4 of this Item, certain circuits may remain connected to their energy sources in order, for example, to hold parts, to protect information, to light interiors, etc. In this case, special steps must be taken to ensure operator safety.

Intervention by Operator

Machinery must be so designed, constructed and equipped that the need for operator intervention is limited. If operator intervention cannot be avoided, it must be possible to carry it out easily and safely.

Cleaning of internal parts

The machinery must be designed and constructed in such a way that it is possible to clean internal parts which contained dangerous substances or preparations without entering them. Any necessary unblocking must also be possible from the outside. If it is impossible to avoid entering the machinery, it must be designed and constructed in such a way as to allow cleaning to take place safely.

1.7. INFORMATION

1.7.1 Information and warnings on the machinery

Information and warnings on the machinery should preferably be provided in the form of readily understandable symbols or pictograms. Any written or verbal information and warnings must be expressed in Serbian language regarding the machinery to be placed on the market and/or put into service in the Republic of Serbia.

1.7.1.1 Information and information devices

The information required to control machinery must be provided in a form that is unambiguous and easily understood. It must not be excessive to the extent of overloading the operator.

Visual display units or any other interactive means of communication between the operator and the machine must be easily understood and easy to use.

1.7.1.2 Warning devices

Where the health and safety of persons may be endangered by a fault in the operation of unsupervised machinery, the machinery must be equipped in such a way as to give an appropriate acoustic or light signal as a warning.

Where machinery is equipped with warning devices these must be unambiguous and easily perceived. The operator must have facilities to check the operation of such warning devices at all times.

Warning devices must be complied with requirements of the specific regulations regulating colours and safety signals.

1.7.2 Warning of residual risks

Where risks remain despite the inherent safe design measures, safeguarding and complementary protective measures adopted, the necessary warnings, including warning devices, must be provided.

1.7.3 Marking of machinery

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

— The business name, or name and full address of the manufacturer and, where applicable, his authorised representative,

— Designation of the machinery;

— Conformity mark;

— Designation of series or type;

— Serial number, if any;

— the year of construction (i.e. the year in which the manufacturing process is completed).

Machinery designed and constructed for use in a potentially explosive atmosphere must be marked accordingly.

Machinery must also bear all information relevant to its type and essential for safe use.

The information under Paragraph 3 of this Item is subject to the requirements set out in Item 1.7.1 of this Annex.

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

1.7.4 Instructions

All machinery being placed on the market and/or putting into service in the Republic of Serbia must be accompanied by original instructions by manufacturer or his authorised representative in Serbian language or a translation of such instructions into Serbian language accompanied by the original instructions

in the language of the manufacturer of his authorised representative if the machinery is intended to be imported in the Republic of Serbia.

The instructions referred to in Paragraph 1 of this Item, must be made by the manufacturer or his authorised representative or importer.

Exceptionally, the maintenance instructions intended for use by specialised personnel who are foreign citizens and employed by the manufacturer or his authorised representative may be provided in one of the European Community languages which the specialised personnel understand.

The instructions referred to in Paragraph 1 to 3 must be drafted in accordance with the principles set out in Items 1.7.4.1, 1.7.4.2 and 1.7.4.3 of this Annex.

1.7.4.1 *General principles for the drafting of instructions*

(a) The instructions for machinery being placed on the market and/or put into service in the Republic of Serbia must be drafted in accordance with Item 1.7.4 of this Annex.

(b) The instructions for machinery being exported from the Republic of Serbia to the market of the Member States of the European Community or other states must be drafted in one or more official languages of the state where the machinery is to be placed on the market and/or put into service.

The wording 'Original instructions' must appear in the same language as it is instructions made in by the manufacturer or his authorised representative.

(v) If the original instructions for machinery being exported from the Republic of Serbia are made in Serbian language, such instructions must be accompanied by a translations into official language of the state where the machinery is to be placed on the market and/or put into service or into other language acceptable for that state. The translations must bear the wording 'Translation of the original instructions'.

Translation of instructions referred to in Paragraph 1 of this Item must be provided by the manufacturer or his authorised representative or a person importing such machinery from the Republic of Serbia.

(g) The contents of the instructions must cover not only the intended use of the machinery but also take into account any reasonably foreseeable misuse thereof.

(d) In the case of machinery intended for use by non-professional operators, the wording and layout of the instructions for use must take into account the level of general education and acumen that can reasonably be expected from such operators.

1.7.4.2 *Contents of the instructions*

Each instruction manual must include, where applicable, in particular the following information:

- a) The business name or name and full address of the manufacturer and his authorised representative;
- b) The designation of the machinery as marked on the machinery itself, except for the serial number (see Item 1.7.3);
- c) The Declaration of Conformity, or a document setting out the contents of the Declaration of Conformity, showing the characteristics of the machinery, excluding the serial number and the signature of person drawn up that Declaration;
- d) General description of the machinery;
- e) Drawings, diagrams, descriptions and explanations necessary for the use, maintenance and repair of the machinery and for checking its correct functioning;
- f) Description of the workstation(s) likely to be occupied by operators;
- g) Description of the intended use of the machinery;
- h) Warnings concerning ways in which the machinery must not be used that experience has shown might occur;
- i) Assembly, installation and connection instructions, including drawings, diagrams and the means of fixing and the designation of the base or installation on which the machinery is to be mounted;
- j) Instructions relating to installation and assembly for reducing noise or vibration;
- k) Instructions for the putting into service and use of the machinery and, if necessary, instructions for the training of operators;

l) Information about the residual risks that remain despite the inherent safe design measures, safeguarding and complementary protective measures adopted;

m) Instructions on the safety measures to be taken by the user, including, where appropriate, the personal protective equipment to be provided;

n) The essential characteristics of tools which may be fitted to the machinery;

o) The conditions in which the machinery meets the requirement of stability during use, transportation, assembly, dismantling when out of service, testing or foreseeable breakdowns;

p) Instructions with a view to ensuring that transport, handling and storage operations can be made safely, giving the mass of the machinery and of its various parts where these are regularly to be transported separately;

q) The operating method to be followed in the event of accident, malfunction or breakdown, in the event of blockage, as well as the operating method to be followed so as to enable the equipment to be safely unblocked;

r) The description of the adjustment and maintenance operations that should be carried out by the user and the preventive maintenance measures that should be observed;

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) Specifications of the spare parts to be used, when these affect the health and safety of operators;

u) The following information on airborne noise emissions:

— the A-weighted emission sound pressure level at workstations, where this exceeds 70 dB(A); where this level does not exceed 70 dB(A), this fact must be indicated;

— the peak C-weighted instantaneous sound pressure value at workstations, where this exceeds 63 Pa (130 dB in relation to 20 µPa);

— the A-weighted sound power level emitted by the machinery, where the A-weighted emission sound pressure level at workstations exceeds 80 dB(A).

These values must be either those actually measured for the machinery in question or those established on the basis of measurements taken for technically comparable machinery which is representative of the machinery to be produced.

In the case of very large machinery, instead of the A-weighted sound power level, the A-weighted emission sound pressure levels at specified positions around the machinery may be indicated.

Where the corresponding Serbian standards under Article 7 of this Rulebook are not applied, sound levels must be measured using the most appropriate method for the machinery. Whenever sound emission values are indicated the uncertainties surrounding these values must be specified. The operating conditions of the machinery during measurement and the measuring methods used must be described.

Where the workstation(s) is (are) undefined or cannot be defined, A-weighted sound pressure levels must be measured at a distance of 1 metre from the surface of the machinery and at a height of 1,6 metres from the floor or access platform. The position and value of the maximum sound pressure must be indicated.

Where specific regulation lays down other requirements for the measurement of sound pressure levels or sound power levels, such regulations must be applied not the corresponding provisions of this Item;

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

1.7.4.3 *Sales literature*

Sales literature describing the machinery must not contradict the instructions as regards health and safety aspects. Sales literature describing the performance characteristics of machinery must contain the same information on emissions as is contained in the instructions.

2. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR CERTAIN CATEGORIES OF MACHINERY

Foodstuffs machinery, machinery for cosmetics or pharmaceutical products, hand-held and/or hand-guided machinery, portable fixing and other impact machinery, machinery for wood processing and material with similar physical characteristics must meet all the essential health and safety requirements described in this Point (see General Principles, Point 4).

2.1 FOODSTUFFS MACHINERY AND MACHINERY FOR COSMETICS AND PHARMACEUTICAL PRODUCTS

2.1.1 General

Machinery intended for use with foodstuffs or with cosmetics or pharmaceutical products must be designed and constructed in such a way as to avoid any risk of infection, sickness or contagion.

The following requirements must be satisfied:

(a) Materials in contact with, or intended to come into contact with, foodstuffs or cosmetics or pharmaceutical products must satisfy the conditions set down in the relevant regulations. The machinery must be designed and constructed in such a way that these materials can be cleaned before each use. Where this is not possible disposable parts must be used;

(b) All surfaces, including their connections, in contact with foodstuffs or cosmetics or pharmaceutical products, other than surfaces of disposable parts, must:

- be smooth and have no ridges, crevices or cracks which could harbour organic materials.
- be designed and constructed in such a way as to reduce the projections, edges and recesses of assemblies to a minimum,
- be easily cleaned and disinfected, where necessary after removing easily dismantled parts. The inside surfaces must have curves with a radius sufficient to allow thorough cleaning.

(c) It must be possible for liquids, gases and aerosols deriving from foodstuffs, cosmetics or pharmaceutical products as well as from cleaning, disinfecting and rinsing fluids to be completely discharged from the machinery (if possible, in a ‘cleaning’ position);

(d) Machinery must be designed and constructed in such a way as to prevent any substances or living creatures, in particular insects, from entering, or any organic matter from accumulating in, areas that cannot 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 continuing compliance with this requirement can be checked.

2.1.2 Instructions

The instructions for foodstuffs machinery and machinery for use with cosmetics or pharmaceutical products must indicate recommended products and methods for cleaning, disinfecting and rinsing, not only for easily accessible areas but also for areas to which access is impossible or inadvisable.

2.2 PORTABLE HAND-HELD AND/OR HAND-GUIDED MACHINERY

2.2.1 General

Portable hand-held and/or hand-guided machinery must:

- depending on the type of machinery, have a supporting surface of sufficient size and have a sufficient number of handles and supports of an appropriate size, arranged in such a way as to ensure the stability of the machinery under the intended operating conditions;

— except where technically impossible, or where there is an independent control device, in the case of handles which cannot be released in complete safety, be fitted with manual start and stop control devices arranged in such a way that the operator can operate them without releasing the handles;

— be designed, constructed and equipped in such a way to present no risks of accidental starting and/or continued operation after the operator has released the handles. Equivalent steps must be taken if this requirement is not technically feasible,

— be designed and constructed in such a way to permit, where necessary, visual observation of the danger zone and of the action of the tool with the material is being processed.

The handles of portable machinery must be designed and constructed in such a way as to make starting and stopping straightforward.

2.2.1.1 Instructions

The instructions must give the following information concerning vibrations transmitted by portable handheld and hand-guided machinery:

— The total vibration value to which the hand-arm system is subjected, if it exceeds 2,5 m/s². Where this value does not exceed 2,5 m/s², this must be indicated,

— The uncertainty of measurement.

These values must be either those actually measured for the machinery in question or those established on the basis of measurements taken for technically comparable machinery which is representative of the machinery to be produced.

If the corresponding Serbian standards under Article 7 are not applied, the vibration data must be measured using the most appropriate measurement method for the machinery.

The operating conditions during measurement and the methods used for measurement, or the reference of the corresponding Serbian standards applied under Article 7 of this Rulebook, must be specified.

2.2.2 Portable fixing and other impact machinery

2.2.2.1 General

Portable fixing and other impact machinery must be designed and constructed in such a way that:

— energy is transmitted to the impacted element by the intermediary component that does not leave the device;

— an enabling device prevents impact unless the machinery is positioned correctly with adequate pressure on the base material;

— accidentally triggering is prevented. Where necessary, an appropriate sequence of actions on the enabling device and the control device must be required to trigger an impact;

— accidental triggering is prevented during handling or in case of shock;

— loading and unloading operations can be carried out easily and safely.

Where necessary, it must be possible to fit the device with splinter guard(s) and the appropriate guard(s) must be provided by the manufacturer of the machinery.

2.2.2.2 Instructions

The instructions must give the necessary information regarding:

— the accessories and interchangeable equipment that can be used with the machinery,

— the suitable fixing or other impacted elements to be used with the machinery,

— where appropriate, the suitable cartridges to be used.

2.3 MACHINERY FOR PROCESSING OF WOOD AND MATERIALS WITH SIMILAR PHYSICAL PROPERTIES

Machinery for processing of wood and materials with similar physical properties must comply with the following requirements:

(a) the machinery must be designed, constructed or equipped in such a way that the piece being processed can be placed and guided in safety. Where the piece is hand-held on a work-bench, it should be sufficiently stable during the work and must not impede the movement of the piece;

(b) where the machinery is likely to be used in conditions involving the risk of ejection of workpieces or parts of them, it must be designed, constructed, or 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/or exposed persons;

(c) the machinery must be equipped with an automatic brake that stops the tool in a sufficiently short time if there is a risk of contact with the tool whilst it runs down;

(d) where the tool is incorporated into a non-fully automated machine, such tool must be designed and constructed in such a way as to eliminate or reduce the risk of accidental injury.

3. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS TO OFFSET HAZARDS DUE TO THE MOBILITY OF MACHINERY

Machinery presenting hazards due to its mobility must meet all the essential health and safety requirements described in this Chapter (see General Principles, Point 4).

3.1 GENERAL

3.1.1 Definitions

a) “Machinery presenting hazards due to its mobility” must mean:

— machinery where its operation requires either mobility while working, or continuous or semi-continuous movement between a succession of fixed working positions, or

— machinery which is operated without being moved, but which may be equipped in such a way as to enable it to be moved more easily from one place to another.

(b) “Driver” must mean an operator responsible for the movement of a machine. The driver may be transported by the machinery or may be on foot, accompanying the machinery, or may guide the machinery by remote control.

3.2 WORK POSITIONS

3.2.1 Driving positions

Visibility from the driving position must be such that the driver can, in complete safety for himself and the exposed persons, operate the machinery and its tools in their foreseeable conditions of use. Where necessary, appropriate devices must be provided to remedy hazards due to inadequate direct vision.

Machinery on which the driver is transported must be designed and constructed in such a way that, from the driving positions, there is no risk to the driver from inadvertent contact with the wheels and tracks.

The driving position of ride-on drivers must be designed and constructed in such a way that a driver's cab may be fitted, provided this does not increase the risk and there is space for it. The cab must incorporate a place for the instructions needed for the driver.

3.2.2 Seating

Where there is a risk that operators or other persons transported by the machinery may be crushed between parts of the machinery and the ground, where there is a risk of the machinery to roll or tip over, in particular for machinery equipped with a protective structure referred to in Item 3.4.3 or 3.4.4, seats of operators and other persons being transported by the machinery must be designed or equipped with a restraint system so as to keep the persons in their seats, without restricting movements necessary for operations or movements relative to the structure caused by the suspension of the seats. Such restraint systems should not be fitted if they increase the risk.

3.2.3 Positions for other persons

If the conditions of use provide that persons other than the driver may occasionally or regularly be transported by the machinery or work on it, appropriate positions must be provided which enable them to be transported or to work on it without risk.

Paragraphs 2 and 3 of Item 3.2.1 must apply to the places provided for persons other than the driver.

3.3 CONTROL SYSTEM

If necessary, steps must be taken to prevent unauthorised use of controls.

In the case of remote controls, each control unit must clearly identify the machinery to be controlled from that unit.

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

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

3.3.1 Control devices

The driver must be able to actuate all control devices required to operate the machinery from the driving position, except for functions which can be safely actuated only by using 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 driving position in order to control them safely.

Where there are pedals, they must be so designed, constructed and fitted as to allow safe operation by the driver with the minimum risk of incorrect operation. They must have a slip-resistant surface and be easy to clean.

Where use of pedals can lead to hazards, and in particular, notably dangerous movements, the control devices, except for those with preset positions, must return to the neutral position as soon as they are released by the operator.

In the case of wheeled machinery, the steering system must be designed and constructed in such a way as to reduce the force of sudden movements of the steering wheel or the steering lever caused by shocks to the guide wheels.

Any control that locks the differential must be so designed and arranged that it allows the differential to be unlocked when the machinery is moving.

Paragraph 6 of Item 1.2.2, concerning acoustic and/or visual warning signals, applies only in the case of reversing.

3.3.2 Starting/moving

All movements of self-propelled machinery with a ride-on driver must be possible only if the driver is at the controls.

Where, for operating purposes, machinery is fitted with devices which exceed its normal clearance zone (e.g. stabilisers, jib, etc.), the driver must be provided with the means of checking easily, before moving the machinery, that such devices are in a particular position which allows safe movement.

The provision of Paragraph 2 of this Item must also apply to all other parts which, to allow safe movement, have to be in particular positions, locked if necessary.

Where it does not give rise to other risks, movement of the machinery must depend on safe positioning of the parts referred to in Paragraph 3 of this Item.

It must not be possible for unintentional movement of the machinery to occur while the engine is being started.

3.3.3 Travelling function

Without prejudice to road traffic regulations, self-propelled machinery and its trailers must meet the requirements for slowing down, stopping, braking and immobilisation so as to ensure safety under all the operating, load, speed, ground and gradient conditions allowed for.

The driver must have the option to slow down or stop self-propelled machinery by means of central device. Where safety so requires, in case of failure of the central device or failure of power supply for starting the central device, a control device fitted with totally independent and easily accessible commands for slowing down or stopping the machinery must be provided for the case of hazard.

Where safety so requires, a parking device must be provided to render stationary machinery immobile. This device may be combined with one of the devices referred to in Paragraph 2, provided that it is purely mechanical.

Remote-controlled machinery must be equipped with devices for stopping operation automatically and immediately and for preventing potentially dangerous operation in the following situations:

- if the driver loses control,
- if it receives a stop signal,
- if a fault is detected in a safety-related part of the system,
- if no validation signal is detected within a specified time.

Provisions of Item 1.2.4 does not apply to the travelling function.

3.3.4 Movement of pedestrian-controlled machinery

Movement of pedestrian-controlled self-propelled machinery must be possible only through sustained action on the relevant control device by the driver. In particular, it must not be possible for movement to occur while the engine is being started.

The control systems for pedestrian-controlled machinery must be designed in such a way as to minimise the risks arising from inadvertent movement of the machine towards the driver, in particular:

- crushing;
- injury from rotating tools.

The speed of travel of the machinery must be compatible with the pace of a driver on foot.

In the case of machinery on which a rotary tool may be fitted, it must not be possible to actuate the tool when the reverse control is engaged, except where the movement of the machinery results from movement of the tool. In that case, the reversing speed must be such that it does not endanger the driver-pedestrian.

3.3.5 Control circuit failure

A failure in the power supply to the power-assisted steering, where fitted, must not prevent machinery from being steered during the time required to stop it.

3.4 PROTECTION AGAINST MECHANICAL HAZARDS

3.4.1 Uncontrolled movements

Machinery must be designed, constructed and where appropriate placed on its mobile support in such a way as to ensure that, when moved, uncontrolled oscillations of its centre of gravity do not affect its stability or exert excessive strain on its structure.

3.4.2 Moving transmission parts

By way of exception to Item 1.3.8.1, in the case of engines, moveable guards preventing access to the moving parts in the engine compartment need not have interlocking devices if they have to be opened either by the use of a tool or key or by a control located in the driving position, providing the latter is in a fully enclosed cab with a lock to prevent unauthorised access.

3.4.3 Roll-over and tip-over

Where, in the case of self-propelled machinery with a ride-on driver, operator(s) or other person(s), there is a risk of rolling or tipping over, the machinery must be fitted with an appropriate protective structure, unless this increases the risk.

Protective structure referred to in Paragraph 1 of this Item must be such that in the event of rolling or tipping over it affords the ride-on person(s) an adequate deflection-limiting volume.

In order to verify that the structure complies with the requirement laid down in Paragraph 2 of this Item, the manufacturer or his authorised representative must, for each type of structure concerned, perform appropriate tests or have such tests performed.

3.4.4 Falling objects

Where, in the case of self-propelled machinery with a ride-on driver, operator(s) or other person(s), there is a risk due to falling objects or material, the machinery must be designed and constructed in such a way as to take account of this risk and fitted, if its size allows, with an appropriate protective structure.

The structure referred to in Paragraph 1 of this Item must be such that, in the event of falling objects or material, it guarantees the ride-on person(s) an adequate deflection-limiting volume.

In order to verify that the structure under Paragraph 1 of this Item complies with the requirement laid down in Paragraph 2 of this Item, the manufacturer or his authorised representative must, for each type of structure concerned, perform appropriate tests or have such tests performed.

3.4.5 Means of access

Handholds and stair treads must be designed, constructed and arranged in such a way that the operators use them instinctively and do not use the control devices to assist access.

3.4.6 Towing devices

All machinery used to tow or to be towed must be fitted with towing or coupling devices designed, constructed and arranged in such a way as to ensure easy and secure connection and disconnection and to prevent accidental disconnection during use.

Insofar as the tow bar load so requires, the machinery referred to in Paragraph 1 of this Item must be equipped with a support with a bearing surface suited to the load and the ground.

3.4.7 Transmission of power between self-propelled machinery (or tractor) and recipient machinery

Removable mechanical transmission devices linking self-propelled machinery (or a tractor) to the first fixed bearing of recipient machinery must be designed and constructed in such a way that any part that moves during operation is protected over its whole length.

On the side of the self-propelled machinery (or tractor), the power take-off to which the removable mechanical transmission device is attached must be protected either by a guard fixed and linked to the self-propelled machinery (or tractor) or by any other device offering equivalent protection.

It must be possible to open this guard for access to the removable transmission device. Once it is in place, there must be enough room to prevent the drive shaft damaging the guard when the machinery (or the tractor) is moving.

On the recipient machinery side, the input shaft must be enclosed in a protective casing fixed to the machinery.

Torque limiters or freewheels may be fitted to universal joint transmissions only on the side adjoining the driven machinery.

The removable mechanical transmission device must be marked accordingly.

All recipient machinery, the operation of which requires a removable mechanical transmission device to connect it to self-propelled machinery (or a tractor), must have a system for attaching the removable mechanical transmission device so that, when the machinery is uncoupled, the removable mechanical transmission device and its guard are not damaged by contact with the ground or part of the machinery.

The outside parts of the guard must be so designed, constructed and arranged that they cannot turn with the removable mechanical transmission device. The guard must cover the transmission to the ends of

the inner jaws in the case of simple universal joints and at least to the centre of the outer joint or joints in the case of wide-angle universal joints.

If means of access to working positions are provided near to the removable mechanical transmission device, they must be designed and constructed in such a way that the shaft guards cannot be used as steps, unless designed and constructed for that purpose.

3.5 PROTECTION AGAINST OTHER HAZARDS

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 in the event of rollover or tip over and to avoid the accumulation of vapours in places occupied by operators.

Machinery must be designed and constructed in such a way that the battery can be disconnected with the aid of an easily accessible device provided for that purpose.

3.5.2 Fire

Depending on the hazards anticipated by the manufacturer, machinery must, where its size permits:

- either allow easily accessible fire extinguishers to be fitted, or
- be provided with built-in extinguisher systems.

3.5.3 Emissions of hazardous substances

Provisions of Paragraphs 2 and 3 of Item 1.5.13 do not apply where the main function of the machinery is the spraying of products. However, the operator must be protected against the risk of exposure to such hazardous emissions.

3.6 INFORMATION AND INDICATIONS

3.6.1 Signs, signals and warnings

All machinery must have signs and/or instruction plates concerning use, adjustment and maintenance, wherever necessary, so as to ensure the health and safety of persons. They must be chosen, designed and constructed in such a way as to be clearly visible and indelible.

Without prejudice to the provisions of road traffic regulations, machinery with a ride-on driver must have the following equipment:

- an acoustic warning device;
- a system of light signals relevant to the intended conditions of use. This requirement does not apply to machinery intended solely for underground working and having no electrical power,
- where necessary, there must be an appropriate connection between a trailer and the machinery for the operation of signals.

Remote-controlled machinery which, under normal conditions of use, exposes persons to the risk of impact or crushing must be fitted with appropriate means to signal its movements or with means to protect persons against such risks. The same applies to machinery which involves, when in use, the constant repetition of a forward and backward movement on a single axis where the area to the rear of the machine is not directly visible to the driver.

Machinery must be constructed in such a way that the warning and signalling devices cannot be disabled unintentionally. Where it is essential for safety, such devices must be provided with the means to check that they are in good working order and their failure must be made apparent to the operator.

Where the movement of machinery or its tools is particularly hazardous, signs on the machinery must be provided to warn against approaching the machinery while it is working. These signs must be legible at a sufficient distance to ensure the safety of persons who have to be in the vicinity.

3.6.2 Marking

The following must be shown legibly and indelibly on all machinery:

- nominal power expressed in kilowatts (kW),
 - mass of the most usual configuration, in kilograms (kg);
- and, where appropriate:
- maximum drawbar pull provided for at the coupling hook, in Newton (N),
 - maximum vertical load provided for on the coupling hook, in Newton (N).

3.6.3 Instructions

3.6.3.1 Vibrations

The instructions must give the following information concerning vibrations transmitted by the machinery to the hand-arm system or to the whole body:

- The total vibration value to which the hand-arm system is subjected, if it exceeds 2,5 m/s². Where this value does not exceed 2,5 m/s², this must be indicated;
- The highest root mean square value of weighted acceleration to which the whole body is subjected, if it exceeds 0,5 m/s². Where this value does not exceed 0,5 m/s², this must be indicated;
- The uncertainty of measurement.

The values referred to in Paragraph 1 of this Item must be either those actually measured for the machinery in question or those established on the basis of measurements taken for technically comparable machinery which is representative of the machinery to be produced.

Where Serbian standards under Article 7 of this Rulebook are not applied, the vibration must be measured using the most appropriate measurement method for the machinery concerned.

The operating conditions during measurement and the measurement methods used must be described.

3.6.3.2 Multiple uses

The instructions for machinery allowing several uses depending on the equipment used and the instructions for the interchangeable equipment must contain the information necessary for safe assembly and use of the basic machinery and the interchangeable equipment that can be fitted.

4. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS TO OFFSET HAZARDS DUE TO LIFTING OPERATIONS

Machinery presenting hazards due to lifting operations (for example hazards due to falling of load or crushing, or due to rolling over caused by lifting and alike) must meet all the relevant essential health and safety requirements described in this Chapter (see General Principles, Point 4).

4.1 GENERAL

4.1.1 Definitions

a) “Lifting operation” must mean a movement of unit loads consisting of goods and/or persons necessitating, at a given moment, a change of level;

b) “Guided load” must mean a load where the total movement is made along rigid or flexible guides whose position is determined by fixed points;

c) “Working coefficient” must mean the arithmetic ratio between the load guaranteed by the manufacturer or his authorised representative up to which a component is able to hold it and the maximum working load marked on the component;

d) “Test coefficient” must mean the arithmetic ratio between the load used to carry out the static or dynamic tests on lifting machinery or a lifting accessory and the maximum working load marked on the lifting machinery or lifting accessory;

e) “Static test” must mean the test during which lifting machinery or a lifting accessory is first inspected and subjected to a force corresponding to the maximum working load multiplied by the appropriate static test coefficient and then re-inspected once the said load has been released to ensure that no damage has occurred;

f) “Dynamic test” must mean the test during which lifting machinery is operated in all its possible configurations at the maximum working load multiplied by the appropriate dynamic test coefficient with account being taken of the dynamic behaviour of the lifting machinery in order to check that it functions properly;

g) “Carrier” must mean a part of the machinery on or in which persons and/or goods are supported in order to be lifted.

4.1.2 Protection against mechanical hazards

4.1.2.1. Risks due to lack of stability

Machinery must be designed and constructed in such a way that the stability required by Item 1.3.1 is maintained both in service and out of service, including all stages of transportation, assembly and dismantling, during foreseeable component failures and also during the tests carried out in accordance with the instruction handbook. To that end, the manufacturer or his authorised representative must use the appropriate verification methods.

4.1.2.2 Machinery running on guide rails and rail tracks

Machinery must be provided with devices which act on the guide rails or tracks to prevent derailment.

If, despite such devices mentioned in Paragraph 1 of this Item, there is a risk of derailment or of failure of a rail or of a running component, devices must be provided which prevent the equipment, 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 withstanding the stresses to which they are subjected, both in and, where applicable, out of use, under the installation and operating conditions provided for and in all relevant configurations, with due regard, where appropriate, to the effects of atmospheric factors and forces exerted by persons. This requirement must also be met during transport, assembly and dismantling.

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

The materials used must be chosen on the basis of the intended working environments, with particular regard to corrosion, abrasion, impacts, extreme temperatures, fatigue, brittleness and ageing.

Machinery and lifting accessories must be designed and constructed in such a way as to withstand the overload in the static tests without permanent deformation or patent defect. Strength calculations must take account of the value of the static test coefficient chosen to guarantee an adequate level of safety. That coefficient has, as a general rule, 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 as to undergo, 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: the coefficient is, as a general rule, equal to 1,1. As a general rule, the tests will be performed at the nominal speeds provided for. Should the control circuit of the machinery allow for a number of simultaneous movements, the tests must be carried out under the least favourable conditions, as a general rule by 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 can be fitted.

Drums and wheels must be designed, constructed and installed in such a way that the ropes or chains with which they are equipped can be wound without coming off.

Ropes used directly for lifting or supporting the load must not include any splicing other than at their ends. Splicings are, however, tolerated in installations which are intended by design to be modified regularly according to needs of use.

Complete ropes and their endings must have a working coefficient chosen in such a way as to guarantee an adequate level of safety. As a general rule, this coefficient is equal to 5.

Lifting chains must have a working coefficient chosen in such a way as to guarantee an adequate level of safety. As a general rule, this coefficient is equal to 4.

In order to verify that an adequate working coefficient has been attained, the manufacturer or his authorised representative must, for each type of chain and rope used directly for lifting the load and for the rope ends, perform the appropriate tests or have such tests performed.

4.1.2.5 *Lifting accessories and their components*

Lifting accessories and their components must be sized with due regard to fatigue and ageing processes for a number of operating cycles consistent with their expected life-span as specified in the operating conditions for a given application.

Moreover:

a) The working coefficient of wire-rope and rope-end combination must be chosen in such a way as to guarantee an adequate level of safety. This coefficient is, as a general rule, equal to 5. Ropes must not comprise any splices or loops other than at their ends;

b) Where chains with welded links are used, they must be of the short-link type. The working coefficient of chains must be chosen in such a way as to guarantee an adequate level of safety. This coefficient is, as a general rule, equal to 4;

c) The working coefficient for textile ropes or slings is dependent on the material, method of manufacture, dimensions and use. This coefficient must be chosen in such a way as to guarantee an adequate level of safety. This coefficient is, as a general rule, equal to 7, provided the materials used are shown to be of very good quality and the method of manufacture is appropriate to the intended use. Should this not be the case, the coefficient is, as a general rule, set at a higher level in order to secure an equivalent level of safety. Textile ropes and slings must not include any knots, connections or splicing other than at the ends of the sling, except in the case of an endless sling;

d) All metallic components making up, or used with, a sling must have a working coefficient chosen in such a way as to guarantee an adequate level of safety; this coefficient is, as a general rule, equal to 4;

e) The maximum working load of a multilegged sling is determined on the basis of the working coefficient of the weakest leg, the number of legs and a reduction factor which depends on the slinging configuration;

f) In order to verify that an adequate working coefficient has been attained, the manufacturer or his authorised representative must, for each type of component referred to in Points a), b), c) and d), perform the appropriate tests or have such tests performed.

4.1.2.6 *Control of movements*

Devices for controlling movements must act in such a way that the machinery on which they are installed is kept safe.

a) Machinery must be designed and constructed or fitted with devices in such a way that the amplitude of movement of its components is kept within the specified limits. The operation of such devices must, where appropriate, be preceded by a warning.

b) Where several fixed or rail-mounted machines can be manoeuvred simultaneously in the same place, with risks of collision, such machinery must be designed and constructed in such a way as to make it possible to fit systems enabling these risks to be avoided.

c) Machinery must be designed and constructed in such a way that the loads cannot creep dangerously or fall freely and unexpectedly, even in the event of partial or total failure of the power supply or when the operator stops operating the machine.

d) It must not be possible, under normal operating conditions, to lower the load solely by friction brake, except in the case of machinery whose function requires it to operate in that 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*

The operating position of machinery must be located in such a way as to ensure the widest possible view of trajectories of the moving parts, in order to avoid possible collisions with persons, equipment or other machinery which might be manoeuvring at the same time and liable to constitute a hazard.

Machinery with guided loads must be designed and constructed in such a way as to prevent persons from being injured by movement of the load, the carrier or the counterweights, if any.

4.1.2.8 *Machinery serving fixed landings*

4.1.2.8.1 *Movements of the carrier*

The movement of the carrier of machinery serving fixed landings must be rigidly guided to and at the landings. Scissor systems are also regarded as rigid guidance.

4.1.2.8.2 *Access to the carrier*

Where persons have access to the carrier, the machinery must be designed and constructed in such a way as to ensure that the carrier remains stationary during access, in particular while it is being loaded or unloaded.

The machinery must be designed and constructed in such a way as to ensure that the difference in level between the carrier and the landing being served does not create a risk of tripping.

4.1.2.8.3 *Risks due to contact with the moving carrier*

Where necessary in order to fulfil the requirement expressed in Paragraph 2 of Item 4.1.2.7, the travel zone must be rendered inaccessible during normal operation.

When, during inspection or maintenance, there is a risk that persons situated under or above the carrier may be crushed between the carrier and any fixed parts, sufficient free space must be provided either by means of physical buffers or by means of mechanical devices blocking the movement of the carrier.

4.1.2.8.4 *Risk due to the load falling off the carrier*

Where there is a risk due to the load falling off the carrier, the machinery must be designed and constructed in such a way as to prevent this risk.

4.1.2.8.5 *Landings*

Risks due to contact of persons at landings with the moving carrier or other moving parts must be prevented.

Where there is a risk due to persons falling into the travel zone when the carrier is not present at the landings, guards must be fitted in order to prevent this risk. Such guards must not open in the direction of the travel zone. They must be fitted with an interlocking device controlled by the position of the carrier that prevents:

- hazardous movements of the carrier until the guards are closed and locked;
- hazardous opening of a guard until the carrier has stopped at the corresponding landing.

4.1.3 **Fitness for purpose**

When lifting machinery or lifting accessories are placed on the market or are first time put into service, the manufacturer or his authorised representative must ensure, by taking appropriate measures or having them taken, that the machinery or the lifting accessories which are ready for use — whether manually or power-operated — can fulfil their specified functions safely.

The static and dynamic tests referred to in Item 4.1.2.3 must be performed on all lifting machinery ready to be put into operation.

Where the machinery cannot be assembled in the manufacturer's premises or in the premises of his authorised representative, the appropriate measures must be taken at the place of use.

4.2 REQUIREMENTS FOR MACHINERY WHOSE POWER SOURCE IS OTHER THAN MANUAL EFFORT

4.2.1 Control of movements

Hold-to-run control devices must be used to control the movements of the machinery or its equipment.

However, for partial or complete movements in which there is no risk of the load or the machinery colliding, the devices under Paragraph 1 of this Item, may be replaced by control devices authorising automatic stops at pre-selected positions without the operator holding a hold-to-run control device.

4.2.2 Loading control

Machinery with a maximum working load of not less than 1 000 kilograms or an overturning moment of not less than 40 000 Nm must be fitted with devices to warn the driver and prevent dangerous movements in the event of overloading, either as a result of the maximum working load or the maximum working moment due to the load being exceeded, or of the overturning moment being exceeded.

4.2.3 Installations guided by ropes

Rope carriers, tractors or tractor carriers must be held by counterweights or by a device allowing permanent control of the tension.

4.3 INFORMATION AND MARKINGS

4.3.1 Chains, ropes and webbing

Each length of lifting chain, rope or webbing not forming part of an assembly must bear a mark or, where this is not possible, a plate or irremovable ring bearing the name and address of the manufacturer or his authorised representative and the identifying reference of the relevant certificate.

The certificate mentioned in Paragraph 1 of this item must contain the following information, in particular:

- a) The business name or name and address of the manufacturer and, if appropriate, his authorised representative;
- b) Description of the chain or rope which includes:
 - its nominal size,
 - its production method,
 - the material from which it is made, and
 - any special metallurgical treatment applied to the material;
- c) The test method used;
- d) The maximum load to which the chain or rope should be subjected in service. A range of values may be given on the basis of the intended applications.

4.3.2 Lifting accessories

Lifting accessories must show the following:

- identification of the material where this information is needed for safe use,
- the maximum working load.

In the case of lifting accessories on which marking is physically impossible, the particulars referred to in Paragraph 1 of this item must be displayed on a plate or other equivalent means and securely affixed to the accessory.

The information referred to in Paragraphs 1 and 2 of this Item must be legible and located in a place where they are not liable to disappear as a result of wear or jeopardise the strength of the accessory.

4.3.3 Lifting machinery

The maximum working load must be prominently marked on the machinery. This marking must be legible, indelible and in an un-coded form.

Where the maximum working load depends on the configuration of the machinery, each operating position must be provided with a load plate indicating, preferably in diagrammatic form or by means of tables, the working load permitted for each configuration.

Machinery intended for lifting goods only, equipped with a carrier 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.

4.4 INSTRUCTIONS

4.4.1 Lifting accessories

Each lifting accessory or each commercially indivisible batch of lifting accessories must be accompanied by instructions containing the following in particular:

- (a) The intended use;
- (b) The limits of use (particularly for lifting accessories such as magnetic or vacuum pads which do not fully comply with Item 4.1.2.6(e));
- (c) Instructions for assembly, use and maintenance;
- (d) The static test coefficient used.

4.4.2 Lifting machinery

Lifting machinery must be accompanied by instructions containing information on:

- a) The technical characteristics of the machinery, and in particular:
 - the maximum working load and, where appropriate, a copy of the load plate or load table described in paragraph 2 of section 4.3.3,
 - the reactions at the supports or bearings and, where appropriate, characteristics of the tracks,
 - where appropriate, the definition and the means of installation of the ballast;
- b) The contents of the logbook, if it is not delivered with the machinery;
- c) Advice for use, particularly to offset the lack of direct vision of the load by the operator;
- d) Where appropriate, a test report detailing the static and dynamic tests carried out by or for the manufacturer or his authorised representative;
- (e) For machinery which is not assembled on the premises of the manufacturer in the form in which it is to be used, the necessary instructions for performing the measures referred to in Item 4.1.3 before it is put into service.

5. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR MACHINERY INTENDED FOR UNDERGROUND WORK

Machinery intended for underground work must meet all the essential health and safety requirements described in this Chapter (see General Principles, Point 4).

5.1 RISKS DUE TO LACK OF STABILITY

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 come under load and after the load has been removed. They must be equipped with anchorages for the top plates of the individual hydraulic props.

5.2 MOVEMENT

Powered roof supports must allow for unhindered movement of persons.

5.3 CONTROL DEVICES

The accelerator and brake controls for movement of machinery running on rails must be hand-operated. However, enabling devices may be foot-operated.

The control devices of powered roof supports must be designed and positioned in such a way that, during displacement operations, operators are sheltered by a support in place. The control devices must be protected against any accidental release.

5.4. STOPPING

Self-propelled machinery running on rails for use in underground work must be equipped with an enabling device acting on the circuit controlling the movement of the machinery such that movement is stopped if the driver is no longer in control of the movement.

5.5 FIRE

Indent 2 of Item 3.5.2 of this Annex is mandatory in respect of machinery which comprises highly flammable parts.

The braking system of machinery intended for use in underground workings must be designed and constructed in such a way that it does not produce sparks or cause fires.

Machinery with internal combustion engines for use in underground workings must be fitted only with engines using fuel with a low vaporising pressure and which exclude any spark of electrical origin.

5.6 EXHAUST EMISSIONS

Exhaust emissions from internal combustion engines must not be discharged upwards.

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

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

6.1 GENERAL

6.1.1 **Mechanical strength**

The carrier, including any automatic doors, must be designed and constructed in such a way as to offer the space and strength corresponding to the maximum number of persons permitted on the carrier and the maximum working load.

The working coefficients for components set out in Items 4.1.2.4 and 4.1.2.5 are inadequate for machinery intended for the lifting of persons and must, as a general rule, be doubled. Machinery intended for lifting persons or persons and goods must be fitted with a suspension or supporting system for the carrier designed and constructed in such a way as to ensure an adequate overall level of safety and to prevent the risk of the carrier falling.

If ropes or chains are used to suspend the carrier, as a general rule, at least two independent ropes or chains are required, each with its own fixing point.

6.1.2 Loading control for machinery moved by power other than human strength

The requirements of Item 4.2.2 of this Annex must apply regardless of the maximum working load and overturning moment, unless the manufacturer can demonstrate that there is no risk of overloading or overturning.

6.2 CONTROL DEVICES

Where safety requirements do not impose other solutions, the carrier must, as a general rule, be designed and constructed in such a way that persons in the carrier have means of controlling upward and downward movements and, if appropriate, other movements of the carrier.

In operation, the control devices referred to in Paragraph 1 of this Item must override any other devices controlling the same movement with the exception of emergency stop devices.

The control devices for the movements referred to in Paragraph 1 of this Item must be of the hold-to-run type except where the carrier itself is completely enclosed.

6.3 RISKS TO PERSONS ON THE CARRIER

6.3.1 Risks due to movements of the carrier

Machinery for lifting persons must be designed, constructed or equipped in such a way that the acceleration or deceleration of the carrier does not engender risks for persons.

6.3.2 Risk of persons falling from the carrier

The carrier must not tilt to an extent which creates a risk of the occupants falling, including when the machinery and carrier are moving.

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

If the measures referred to in Item 1.5.15 are not adequate, carriers must be fitted with a sufficient number of suitable fixing points for the number of persons permitted on the carrier. The fixing points must be strong enough for the use of personal protective equipment against falls from a height.

Any automatic doors in floors or ceilings or side doors must be designed and constructed in such a way as to prevent inadvertent opening and must open in a direction that obviates any risk of falling, should they open unexpectedly.

6.3.3 Risk due to objects falling on the carrier

Where there is a risk of objects falling on the carrier and endangering persons, the carrier must be equipped with a protective roof.

6.4 MACHINERY SERVING FIXED LANDINGS

6.4.1 Risks to persons in or on the carrier.

The carrier must be designed and constructed in such a way as to prevent risks due to contact between persons and/or objects in or on the carrier with any fixed or moving elements. Where necessary in order to fulfil 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 closed. The doors must remain closed if the carrier stops between landings where there is a risk of falling from the carrier.

The machinery must be designed, constructed and, where necessary, equipped with devices in such a way as to prevent uncontrolled upward or downward movement of the carrier. These devices must be able to stop the carrier at its maximum working load and at the foreseeable maximum speed.

The stopping action must not cause deceleration harmful to the occupants, whatever the load conditions.

6.4.2 Controls at landings

Controls, other than those for emergency use, at landings must not initiate movements of the carrier when the control devices in the carrier are being operated and/or the carrier is not at a landing.

6.4.3 Access to the carrier

The guards at the landings and on the carrier must be designed and constructed in such a way as to ensure safe transfer to and from the carrier, taking into consideration the foreseeable range of goods and persons to be lifted.

6.5 MARKINGS

The carrier must bear the information necessary to ensure safety including the number of persons permitted on the carrier and the maximum working load.

DECLARATION OF CONFORMITY OF MACHINERY AND DECLARATION OF INCORPORATION OF PARTLY COMPLETED MACHINERY

1. CONTENT

A. DECLARATION OF CONFORMITY OF MACHINERY

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

The Declaration referred to in Paragraph 1 of this Chapter relates exclusively to the machinery in the state in which it was placed on the market, and excludes components which are added and/or operations carried out subsequently by the final user.

The Declaration of conformity must contain the following information:

1) Business name, or name and full address of the manufacturer and, where appropriate, his authorised representative;

2) Name and address of the person authorised to compile the technical documentation,

3) Description and designation of the machinery, including generic denomination, function, model, type, serial number and commercial name;

4) Explicitly stating that the machinery conforms to all relevant provisions of this Rulebook and where appropriate, a stating about conformity with other regulations and/or relevant provisions to which the machinery conforms. Such stating must include a reference to the regulation applied and number of the Official Gazette where such regulation was published;

5) Where appropriate, the business name, or name and address and identification number of the Notified Body from the relevant Registry in accordance with specific regulation or the relevant identification number of the Notified Body which carried out the EC type-examination referred to in Annex 9, if the machinery being imported in the Republic of Serbia, and the number of the EC type-examination certificate;

6) Where appropriate, the business name, or name, address and identification number of the Notified Body referred to in Point 5 of this Chapter which approved the full quality assurance system referred to in Annex X;

7) Where appropriate, a reference to the Serbian standards used, as referred to in Article 7 of this Rulebook;

8) Where appropriate, the reference to other technical standards and specifications used;

9) The place and date of the issuing of Declaration;

10) The identity and signature of the person empowered to draw up the declaration on behalf of the manufacturer or his authorised representative.

B. Declaration of incorporation of partly completed machinery

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

The declaration of incorporation must contain the following particulars:

1) Business name, or name and address of the manufacturer of the partly completed machinery and, where appropriate, his authorised representative;

2) Name and address of the person authorised to compile the relevant technical documentation;

3) Description and designation of the partly completed machinery including generic denomination, function, model, type, serial number and commercial name;

4) Statement on essential requirements under this Rulebook which were applied and met, and that the technical documentation is conformity with Annex 7, Chapter B and, where appropriate, a statement on conformity of partly completed machinery with other relevant regulations if were applied. These statements must include a reference to the regulation applied and number of the Official Gazette of the Republic of Serbia where that regulation was published;

5) Statement about undertaking obligations relating to submission of relevant information on partly completed machinery in response to a request by the competent inspector. This statement shall include a method of submission; this submission is mandatory and must be without prejudice to the intellectual property rights of the manufacturer of the partly completed machinery;

6) Statement that the partly completed machinery must not be put into service until the final machinery into which it is to be incorporated, has been established that it is conformity with the provisions of this Rulebook;

7) The place and date of the issuing of Declaration of Incorporation of partly completed machinery;

8) The identity and signature of the person empowered to draw up the Declaration on behalf of the manufacturer or his authorised representative.

2. CUSTODY

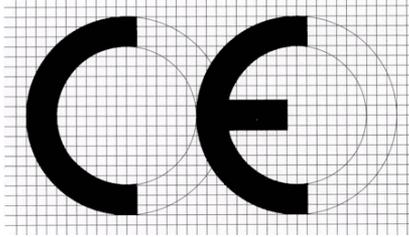
The manufacturer of machinery or his authorised representative shall keep the original Declaration of Conformity for a period of at least 10 years from the last date of manufacture of the machinery.

The manufacturer of partly completed machinery or his authorised representative shall keep the original Declaration of Incorporation for a period of at least 10 years from the last date of manufacture of the partly completed machinery.

CONFORMITY MARK

1. CE MARKING

The CE conformity marking shall consist of the initials ‘CE’ taking the following form:



If the CE mark is reduced or enlarged the proportions shown in the above drawing must be respected.

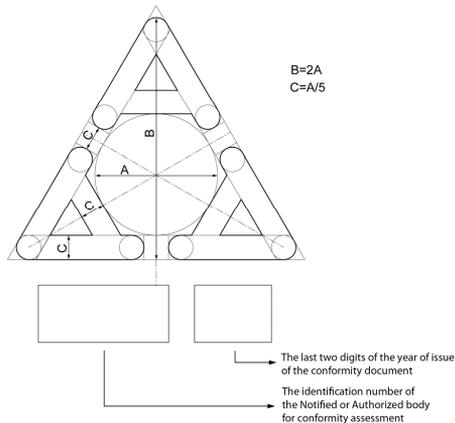
The various components of the CE mark must have substantially the same vertical dimension, which may not be less than 5 mm. The minimum dimension may be waived for small-scale machinery.

The CE mark must be affixed in the immediate vicinity of the name of the manufacturer or his authorised representative, using the same technique.

Where the full quality assurance procedure referred to in Article 8(3)(3) and 8(4)(2) of this Rulebook has been applied, the CE marks must be followed by the identification number of the Notified Body from the relevant Registry in accordance with relevant regulation, or the identification number of the Notified Body if it refers to machinery being imported into the Republic of Serbia.

2. SERBIAN CONFORMITY MARK

The Serbian conformance mark consists of three capital letters “A” interconnected in the shape of an equilateral triangle (3A), of appearance and contents as in the figure below:



Size of the mark shall be determined by the height B of the mark which may only have values of standard numbers rounded up, to the order of magnitude R10 expressed in millimetres (mm), as per Serbian standard – Standard numbers, numerical values and definitions – SRPS A.A0.001.

The height B of the mark shall be, as a rule, at least 5 millimetres.

The identification number of the Notified, or Authorized body from the Registry of notified or authorized bodies for conformity assessment, and the last two digits of the year of issue of the conformity document, if this body performed, or participated in, conformity assessment, must be placed next to the Serbian mark.

**CATEGORIES OF MACHINERY TO WHICH ONE OF THE CONFORMITY
ASSESSMENT PROCEDURES REFERRED TO IN ARTICLE 8 (3) AND (4) OF THIS
RULEBOOK MUST BE APPLIED**

1. Circular saws (single- or multi-blade) for wood processing and materials with similar physical properties or for working with meat and material with similar physical properties, of the following types:

1.1. Sawing machinery with fixed blade(s) during cutting, having a fixed bed or support with manual feed of the workpiece or with a demountable power feed;

1.2. Sawing machinery with fixed blade(s) during cutting, having a manually operated reciprocating saw-bench or carriage;

1.3. Sawing machinery with fixed blade(s) during cutting, having a built-in mechanical feed device for the workpieces, with manual loading and/or unloading;

1.4. Sawing machinery with movable blade(s) during cutting, having mechanical movement of the blade, with manual loading and/or unloading.

2. Hand-fed surface levelling machinery for woodworking.

3. Thicknesser (planer) for one-side dressing having a built-in mechanical feed device, with manual loading and/or unloading for woodworking.

4. Band-saws with manual loading and/or unloading for working with wood and material with similar physical characteristics or for working with meat and material with similar physical characteristics, of the following types:

4.1. Sawing machinery with fixed blade(s) during cutting, having a fixed or reciprocating-movement bed or support for the workpiece;

4.2. Sawing machinery with blade(s) assembled on a carriage with reciprocating motion.

5. Combined machinery of the types referred to in Points 1 to 4 and in Point 7 of this Annex for working with wood and material with similar physical characteristics.

6. Hand-fed tenoning machinery with several tool holders for woodworking.

7. Hand-fed vertical spindle moulding machinery for working with wood and material with similar physical characteristics.

8. Portable chainsaws for woodworking.

9. Presses, including press-brakes, for the cold working of metals, with manual loading and/or unloading, whose movable working parts may have a travel exceeding 6 mm and a speed exceeding 30 mm/s.

10. Injection or compression plastics-moulding machinery with manual loading or unloading.

11. Injection or compression rubber-moulding machinery with manual loading or unloading.

12. Machinery for underground working of the following types:

12.1. locomotives and brake-vans;

12.2. hydraulic-powered roof supports.

13. Manually loaded trucks for the collection of household refuse incorporating a compression mechanism.

14. Removable mechanical transmission devices including their guards.

15. Guards for devices specified in Point 14 of this Annex.

16. Vehicle servicing lifts.

17. Devices for the lifting of persons or of persons and goods involving a hazard of falling from a vertical height of more than three metres.

18. Portable cartridge-operated fixing and other impact machinery.

19. Protective devices designed to detect the presence of persons.

20. Power-operated interlocking movable guards designed to be used as safeguards in machinery referred to in Points 9, 10 and 11.
21. Logic units to ensure safety functions.
22. Roll-over protective structures (ROPS).
23. Falling-object protective structures (FOPS).

LIST OF THE SAFETY COMPONENTS

1. Protective devices designed to detect the presence of persons.
2. Power-operated interlocking movable guards designed to be used as safeguards in machinery referred to in Points 9, 10 and 11 of Annex 4.
3. Logic units to ensure safety functions.
4. Valves with additional means for failure detection intended for the control of dangerous movements on machinery.
5. Extraction systems for machinery emissions.
6. Guards and protective devices designed to protect persons against moving parts involved in the process on the machinery.
7. Monitoring devices for loading and movement control in lifting machinery.
8. Restraint systems to keep persons on their seats.
9. Emergency stop devices.
10. Discharging systems to prevent the build-up of potentially dangerous electrostatic charges.
11. Energy limiters and relief devices referred to in Items 1.5.7, 3.4.7 and 4.1.2.6 of Annex 1.
12. Systems and devices to reduce the emission of noise and vibrations.
13. Roll-over protective structures (ROPS).
14. Falling-object protective structures (FOPS).
15. Two-hand control devices.
16. Components for machinery designed for lifting and/or lowering persons between different landings and included in the following list:
 - a) devices for locking landing doors;
 - b) devices to prevent the load-carrying unit from falling or unchecked upwards movement;
 - c) overspeed limitation devices;
 - d) energy-accumulating shock absorbers,
 - non-linear, or
 - with damping of the return movement;
 - e) energy-dissipating shock absorbers;
 - f) safety devices fitted to jacks of hydraulic power circuits where these are used as devices to prevent falls;
 - g) electric safety devices in the form of safety switches containing electronic components.
17. Guards for removable mechanical transmission devices.

ASSEMBLY INSTRUCTIONS FOR PARTLY COMPLETED MACHINERY

The assembly instructions for partly completed machinery must contain a description of the conditions which must be met with a view to correct incorporation in the machinery, so as not to compromise safety and health of people.

The original assembly instructions for partly completed machinery must be written in Serbian language.

Where partly completed machinery is to be imported in the Republic of Serbia to be assembled or incorporation, the instructions must be also provided in Serbian language.

Where partly completed machinery is to be exported from the Republic of Serbia, the assembly instructions must be written in one of the official languages of the Member States of the EU or the official language of other state acceptable for the manufacturer of the machinery in which the partly completed machinery will be assembled, or to his authorised representative.

TECHNICAL FILE FOR MACHINERY AND PARTLY COMPLETED MACHINERY

A. TECHNICAL DOCUMENTATION FOR MACHINERY

This part describes the procedure for compiling a technical documentation.

The technical file must demonstrate that the machinery complies with the requirements of this Rulebook.

It must cover the design, manufacture and operation of the machinery to the extent necessary for this assessment.

The technical file must be drawn up in Serbian language, or one of the official languages of the EU, with adequate translation into Serbian language as per provisions of Annex 1, Item 1.7.4.1.

1. The technical file shall comprise the following:

a) construction documentation including:

general description of the machinery;

the overall drawing of the machinery and drawings of the control circuits, as well as the relevant descriptions and explanations necessary for understanding the operation of the machinery;

full detailed drawings, accompanied by any calculation notes, test results, certificates, etc., required to check the conformity of the machinery with the essential health and safety requirements;

the documentation on risk assessment demonstrating the procedure followed, including:

(i) a list of the essential health and safety requirements which apply to the machinery,

(ii) the description of the protective measures implemented to eliminate identified hazards or to reduce risks and, when appropriate, the indication of the residual risks associated with the machinery,

the standards and other technical specifications used, indicating the essential health and safety requirements covered by these standards and specifications;

all technical report giving the results of the tests carried out either by the manufacturer or by a Notified Body chosen by the manufacturer or his authorised representative;

a copy of the instructions for the machinery;

where appropriate, the Declaration of Incorporation of partly completed machinery and the relevant assembly instructions for such machinery;

where appropriate, copies of the Declaration of Conformity of machinery or other products incorporated into the machinery;

a copy of the Declaration of Conformity;

(b) for series manufacture, the internal measures that will be implemented to ensure that the machinery remains in conformity with the provisions of this Rulebook.

The manufacturer must carry out necessary research and tests on components, fittings or the completed machinery to determine whether by its design or construction it is capable of being assembled and put into service safely. The relevant reports and results shall be included in the technical documentation.

2. The technical file referred to in Point 1 must be made available to the competent authorities for at least 10 years following the date of manufacture of the machinery or, in the case of series manufacture, of the last unit produced.

The technical file does not have to be kept in the territory of the Republic of Serbia, nor does it have to be permanently available in material form.

Person designated in the Declaration of Conformity of machinery must be capable to draw up technical file and make it available at the request of the competent inspector.

The technical file does not have to include detailed plans or any other specific information as regards the subassemblies used for the manufacture of the machinery unless knowledge of them is essential for verification of conformity with the essential health and safety requirements.

3. Failure to present the technical file in response to a duly reasoned request by the competent inspector may constitute sufficient grounds for doubting the conformity of the machinery in question with the essential health and safety requirements.

B. TECHNICAL DOCUMENTATION FOR PARTLY COMPLETED MACHINERY

This part describes the procedure for compiling relevant technical documentation.

The documentation referred to in Paragraph 1 must confirm that partly completed machinery meets requirements under this Rulebook.

Technical documentation for partly completed machinery must cover the design, manufacture and operation of the partly completed machinery to the extent necessary for the assessment of conformity with the essential health and safety requirements applied.

The technical documentation referred to in Paragraph 3 of this Section must be compiled in Serbian language or a translation thereof must be provided into one of the official languages of the Member States of the EU or other language acceptable for the manufacturer.

Technical documentation for partly completed machinery shall comprise the following:

a) construction documentation including:

(1) the overall drawing of the partly completed machinery and drawings of the control circuits,

(2) full detailed drawings, accompanied by any calculation notes, test results, certificates, etc., required to check the conformity of the partly completed machinery with the applied essential health and safety requirements,

(3) the risk assessment documentation showing the procedure followed, including:

- list of the essential health and safety requirements applied and fulfilled;

- the description of the protective measures implemented to eliminate identified hazards or to reduce risks and, where appropriate, the indication of the residual risks;

- the standards and other technical specifications used, indicating the essential health and safety requirements covered by these standards and specifications;

- all technical report giving the results of the tests carried out either by the manufacturer or by a Notified Body chosen by the manufacturer or his authorised representative,

- a copy of the assembly instructions for the partly completed machinery

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

The manufacturer must carry out necessary research and tests on components, fittings or the partly completed machinery to determine whether by its design or construction it is capable of being assembled and used safely. The relevant reports and results shall be included in the technical documentation.

The relevant technical documentation must be available for at least 10 years following the date of manufacture of the partly completed machinery or, in the case of series manufacture, of the last unit produced, and on request presented to the competent authorities.

The technical documentation does not have to be kept in the territory of the Republic of Serbia, nor does it have to be permanently available in material form.

Person designated in the Declaration of Incorporation of partly completed machinery must be capable to draw up technical documentation and make it available at the request of the competent inspector.

Failure to present the relevant technical documentation in response to a duly reasoned request by the competent national authorities may constitute sufficient grounds for doubting the conformity of the partly completed machinery with the essential health and safety requirements applied and attested.

**CONFORMITY ASSESMENT PROCEDURE CARRIED OUT BY THE
MANUFACTURER**

(INTERNAL PRODUCTION CONTROL)

This Annex describes the procedure by which the manufacturer, who carries out the obligations laid down in Points 2 and 3, ensures and declares that the machinery concerned satisfies the relevant requirements of this Rulebook.

2. For each representative type of the series in question, the manufacturer shall draw up the technical file referred to in Annex VII, Section A.
3. The manufacturer must take all measures necessary in order that the manufacturing process ensures compliance of the manufactured machinery with the technical file referred to in Annex VII, Section A, and with the requirements of this Rulebook.

TYPE-EXAMINATION

Type-examination is the procedure whereby the Notified Body ascertains and certifies that a representative model of machinery referred to in Annex IV (hereafter referred to as: type) satisfies the provisions of this Rulebook.

1. The manufacturer or his authorised representative must, for each type, draw up the technical file referred to in Annex VII, Section A.

2. For each type, the application for an type-examination shall be submitted by the manufacturer or his authorised representative to the Notified Body of his choice.

The application for type-examination shall include:

Business name, or name and address of the manufacturer and, where appropriate, his authorised representative;

a written statement that the application has not been submitted to another notified body;
the technical documentation.

Moreover, the Applicant shall place at the disposal of the Notified Body a sample of the type.

The Notified Body may ask for further samples if the test programme so requires.

The Notified Body shall:

3.1. examine the technical documentation, check that the type was manufactured in accordance with it and establish which elements have been designed in accordance with the relevant provisions of the standards under Article 7 of this Rulebook, and those elements whose design is not based on the relevant provisions of those standards;

3.2. carry out or provide appropriate inspections, measurements and tests to ascertain whether the solutions adopted comply with the essential health and safety requirements of this Rulebook, where the standards under Article 7 were not applied;

3.3. where standards under Article 7 of this Rulebook were applied, carry out or provide appropriate inspections, measurements and tests to verify that those standards were actually applied;

3.4. agree with the Applicant as to the place where the verification that the type was manufactured in accordance with the examined technical file and the necessary inspections, measurements and tests will be carried out.

4. If the type complies the provisions of this Rulebook, the Notified Body shall issue the Applicant with a type-examination certificate. The certificate shall include the business name, or name and address of the manufacturer and his authorised representative, the data necessary for identifying the approved type, the conclusions of the examination and the conditions to which its issue may be subject.

The manufacturer and the Notified Body shall retain a copy of this certificate, the technical file and all relevant documents for a period of 15 years from the date of issue of the certificate.

5. If the type fails to meet the provisions of this Rulebook, the Notified body shall refuse to issue the Applicant with a type-examination certificate, giving detailed reasons for its refusal. It shall inform the Applicant and the other Notified Bodies which notified it.

6. The Applicant shall inform the Notified Body which retains the technical file relating to the type-examination certificate of all modifications to the approved type.

The Notified Body referred to in Paragraph 1 of this Point shall examine these modifications and shall then either confirm the validity of the existing type-examination certificate or issue a new one if the modifications are liable to compromise conformity with the essential health and safety requirements or the intended working conditions of the type.

7. The Notified Bodies issued type-examination certificate must deliver the copy of it to the competent authority or other Notified Body on request.

The Notified Body issued type-examination certificate and which keeps the associated technical documentations and test results must deliver the copy of the technical documentation and test results to the competent authority on request.

8. Documentation and correspondence referring to the type-examination procedures shall be written in the Serbian language or in any other official language of the state where the Notified Body is established accompanied with adequate translation into Serbian language.

9. Validity of the type-examination certificate

9.1. The Notified Body has the ongoing responsibility of ensuring that the type-examination certificate remains valid.

The manufacturer shall inform the Notified Body about all changes of approved type which would have an implication on the validity of the certificate, and if the Notified Body issues a new type-examination certificate, the previously issued certificate is no longer valid.

9.2. The manufacturer of the machinery concerned has the ongoing responsibility of ensuring that the said machinery meets the corresponding state of the technique.

9.3. The manufacturer shall request from the Notified Body the review of the validity of the type-examination certificate every five years.

If the Notified Body established that the certificate remains valid, taking into account the state of the technique, it shall renew the certificate for a further five years.

The manufacturer and the Notified Body shall retain a copy of this certificate, of the technical file and of all the relevant documents for a period of 15 years from the date of issue of the certificate.

9.4. In the event that the validity of the type examination certificate is not renewed, the manufacturer shall cease the placing on the market of the machinery concerned.

FULLY QUALITY ASSURANCE

This Annex describes the conformity assessment of machinery referred to in Annex 4, manufactured using a full quality assurance system, and the procedure whereby a Notified Body assesses and approves the quality system and monitors its application.

1. The manufacturer must apply an approved quality system for design, manufacture, final inspection and testing, as specified in Point 2 of this Annex, and shall provide the verification of approved quality system to the Notified Body in accordance with Point 3 of this Annex.

2. Quality system

2.1 The manufacturer or his authorised representative shall submit an application for assessment of his quality system to a Notified Body of his choice.

The application shall contain:

- Business name, or name and address of the manufacturer and, where appropriate, his authorised representative,
- Places of design, manufacture, inspection, testing and storage of the machinery,
- Technical file described in Annex 7, Section A, for one model of each category of machinery referred to in Annex 4 which he intends to manufacture,
- Documentation on the quality system,
- A written statement that the application has not been submitted to another notified body.

2.2. The quality system must ensure conformity of the machinery with the provisions of this Rulebook. All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner, in the form of measures, procedures and written instructions. The documentation on the quality system must permit a uniform interpretation of the procedural and quality measures, such as quality programmes, plans, manuals and records.

It must contain, in particular, an adequate description of:

- the quality objectives, the organisational structure, and the responsibilities and powers of the management with regard to the design and quality of the machinery;
- Technical design specifications, including standards that will be applied and, where the standards referred to in Article 7 of this Rulebook are not applied in full, the means that will be used to ensure that the essential health and safety requirements of this Rulebook are fulfilled;
- Design inspection and design verification techniques, processes and systematic actions that will be used when designing machinery covered by this Rulebook;
- The corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;
- Inspections and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;
- Quality records, such as inspection reports and test data, calibration data, and reports on the qualifications of the personnel concerned;
- The means of monitoring the achievement of the required design and quality of the machinery, as well as the effective operation of the quality system.

2.3 The Notified Body shall assess the quality system to determine whether it satisfies the requirements of Point 2.2 of this Annex.

The elements of the quality system which conform to the relevant standard regarding quality system shall be presumed to conform to the corresponding requirements referred to in Point 2.2 of this Annex.

The team of auditors must have at least one member who is experienced in the assessment of the technology of the machinery. The assessment procedure shall include an inspection to be carried out at the manufacturer's premises. During the assessment, the team of auditors shall carry out a review of the

technical file referred to in Point 2.1, second paragraph, third indent to ensure their compliance with the relevant health and safety requirements.

The manufacturer or his authorised representative shall be notified of the decision referred to in Paragraph 3 of this Point. The notification shall contain the conclusions of the examination and the reasoned assessment decision including legal remedies and complaint shall be decided on by a body of the Notified body, in accordance with its Act on Internal Organisation.

2.4. The manufacturer shall undertake to fulfil the ongoing obligations arising from the quality system as approved and to ensure that it remains appropriate and effective.

The manufacturer or his authorised representative shall inform the Notified Body which approved the quality system of any planned change to it.

The Notified Body shall evaluate the proposed changes and decide whether the modified quality assurance system will continue to satisfy the requirements referred to in Point 2.2 of this Annex, or whether a re-assessment is necessary.

The Notified Body shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

3. Verification of approved quality system by the Notified Body

3.1. The purpose of verification is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

3.2. The manufacturer shall, for inspection purposes, allow the Notified Body access to the places of design, manufacture, inspection, testing and storage, and shall provide it with all necessary information, such as:

- the documentation concerning the quality system;
- the quality records provided for in that part of the quality system concerned with design (results of analyses, calculations, tests, etc.) ;
- the quality records provided for in that part of the quality system concerned with manufacture (inspection reports and test data, calibration data, reports on the qualifications of the personnel concerned, etc).

3.3. The Notified Body shall conduct periodic audits to make sure that the manufacturer is maintaining and applying the quality system; it shall provide the manufacturer with an audit report. The frequency of the periodic audits shall be such that a full reassessment is carried out every three years.

3.4. Moreover, the Notified Body may pay the manufacturer unannounced visits except periodic audits referred to in Paragraph 3.3 of this Annex . The need for these additional visits and their frequency will be determined on the basis of a visit monitoring system managed by the Notified Body. In particular, the following factors will be taken into account in the visits monitoring system:

- Results of previous surveillance visits,
- Need to monitor remedial measures,
- Where appropriate, special conditions attaching to approval of the system,
- Significant modifications in the organisation of the manufacturing process, measures or techniques.

On the occasion of such visits, the Notified Body may, if necessary, carry out tests or provide them out in order to verify the proper functioning of the quality system. It shall provide the manufacturer with a visit report and, if a test was carried out, with a test report.

4. The manufacturer or his authorised representative shall keep available, for the national authorities, for a period of 10 years from the last date of manufacture:

- the documentation referred to in Point 2.1,
- the decisions and reports of the Notified Body referred to in Paragraph 4 of Point 2.4, and Points 3.3 and 3.4 of this Annex.

**CRITERIA TO BE TAKEN INTO ACCOUNT FOR THE NOTIFICATION OF BODIES
FOR ASSESSMENT OF CONFORMITY**

1. The conformity assessment body, its director, the members of managing board of directors or members of managing board of that body, as well as employees and other involved persons (hereinafter referred to as: staff) responsible for carrying out the procedures for assessing conformity in accordance with this Rulebook shall not be the designer, manufacturer, supplier or installer of machines which they inspect, nor the authorised representative of any of these parties. They shall not become involved, either directly or as authorised representatives, in the design, construction, marketing or maintenance of the machines. This does not preclude the possibility of exchanges of technical information between the manufacturer and the body.

2. The body referred to in point 1 of this Annex and its staff shall carry out the assessment of conformity with the highest degree of professional integrity and technical competence and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of the inspection, especially from persons or groups of persons with an interest in the result of assessments.

3. For each category of machinery for which it is notified, as well as for each conformity assessment procedure, the body must, prior to and after the notification, possess personnel with technical knowledge and sufficient and appropriate experience to perform a conformity assessment.

The staff responsible for carrying out conformity assessment shall have:
appropriate experience, and authorisation to perform conformity assessment activities,
qualification and independency in drawing up reports on conducted assessment and perform checks stipulated under this Rulebook

4. Conformity assessment body shall have adequate facilities depending on the requirements laid down in Serbian standards in the List of standards under Article 7 of this Rulebook on type of machinery which is a subject of conformity assessment, or relevant requirements and aspects to be assessed.

5. The impartiality of staff conducting conformity assessment shall be guaranteed. Their remuneration shall not depend on the number of tests carried out or on the results of such tests.

6. The conformity assessment body shall possess adequate general act governing basic procedures with regard to conducting conformity assessment activities including decision-making procedure on complaints on the performance of the body and made decisions.

7. The conformity assessment body shall have damage liability insurance.

8. The staff of the body shall be bound to observe professional secrecy with regard to all information obtained in carrying out conformity assessment activities in accordance with its general act on professional secrecy, this Rulebook and other regulations.