Mirko Djapic[1)]
Vladimir Zeljkovic[2)]
Ljubomir Lukic[1)]
Milos Veselinovic[3)]
Zorana Dancuo[2)]

1) University of Kragujevac, Faculty of Mechanical Engineering Kraljevo, Serbia djapic.m@mfkv.kg.ac.rs
2) LOLA Institute Belgrade, Serbia vladazz@yahoo.com
3) NTIM TEHNOLOGI, Beograd, office@ntim.rs

RISK ASSESSMENT AS A BASE FOR PRODUCT SAFETY IMPROVEMNET

Abstract: *European Union has accomplished, through introducing New Approach to technical harmonization and standardization, a breakthrough in the field of technical products safety and in assessing their conformity, in such a manner that it integrated products safety requirements into the process of products development. This is achieved by quantifying risk levels with the aim of determining the scope of the required safety measures and systems. Follow that in the paper are presented concept of the international standardization in the risk management field and concept of integrating risk assessment into the product safety improvement (foodstuff machines example).*
Keywords: *Risk assessment, Safety, Foodstuff machines*

1. INTRODUCTION

European Union through introducing the New Approach to technical harmonization and standardization achieve a breakthrough in the product safety by integrating its safety requirements into the product development process [1, 2]. In the directives for technical products, essential health and safety requirements have been set, which each technical product has to satisfy prior to place in the market. These requirements are defined in general form and the way of their implementation is given in the harmonized standards. In this way, designers and suppliers of technical products have got clear instructions regarding the way to accomplish conformity of these products to the directives' requirements and the way of integrating safety requirements into the phase of developing these products. In this way, fundamental change has been achieved in preventing possible occurrence of accidents. The decision regarding level of safety measures is based on previously conducted risk assessment.

Risk assessment is the methodology through which risk levels are quantified with the objective of determining the scope of required safety measures [2].

The main objective of this paper is to preset way of product safety requirements integration into the product development process which have to be based on previous risk assessment.

In order to fulfill this objective, the text to follow first presents the concept of international standardization in the risk management field after that we present the model of risk assessment integration into the technical product development process and on the end as an example we present foodstuffs machines safety requirements and risk assessment integration into the product development process.

2. STANDARDIZATION IN THE RISK MANAGEMENT

All organizations, regardless of their field of activity and size, are faced, in realizing their objectives, with some form of risk. The objectives may vary and may be related to a strategic initiative, operative realization of a project, product, service and similar.

The importance of individual risks for an organization is determined by numerous factors, both internal ones depending on the organization itself and by external factors set forth by the environment in which the organization operates.

Experience in the business practice in the last fifteen years has shown that the risk management concept has been in the phase of significant changes. This is substantiated by the fact that business associations, international, regional and national standardization body have created several models, standards and operation frameworks.

Presenting the standards, i.e. frameworks presented in the world today surpasses the objectives of this paper. Therefore, we are going to focus further only on standardization in the field of risk conducted by the International Organization for Standardization and some of the most significant national standardization bodies (Table 1).

Table 1. The most influential international and national risk management standards

Publisher	Standards	Publisher	Standards
ISO	**ISO 31000:2009,** *Risk management -- Principles and guidelines*	CSA (Canada)	**CSA Q 850: 1997**, *Risk Management Guidelines for Decision Makers*
ISO/IEC	**ISO/IEC 73:2009**, *Risk management -- Vocabulary*	JSA (Japan)	**JIS Q 2001:2001**, *Guidelines for development and implementation of risk management system*
	ISO/IEC 51:1999, *Safety aspects -- Guidelines for their inclusion in standards*	AS/NZS (Australia / New Zealand)	**AS/NZS 4360:2004**, *Risk Management*
	ISO/IEC 31010:2009, *Risk management -- Risk assessment techniques*	BSI (Great Britain)	**BS 25999-2:2007**, *Business continuity management. Specification*
ISO	**ISO 14121-1:2007**, *Safety of machinery — Risk assessment — Part 1:Principles*		**BS 31100:2011**, *Risk management. Code of practice and guidance for the implementation of BS ISO 31000*
	ISO/TR 14121-2:2007, *Safety of machinery -- Risk assessment -- Part 2: Practical guidance and examples of methods*		**BS 6079-3:2000**, *Project management. Guide to the management of business related project risk*
	ISO 14971:2007, *Medical devices -- Application of risk management to medical devices*	ON (Austria)	**ONR 49000:2010**, *Risk Management for Organizations and Systems - Terms and basics - Implementation of ISO 31000*
ISO/IEC	**ISO/IEC 27005:2011**, *Information technology -- Security techniques -- Information security risk management*		**ONR 49001:2010**, *Risk Management for Organizations and Systems - Risk Management - Implementation of ISO 31000*
ISO	**ISO 14798:2009**, *Lifts (elevators), escalators and moving walks -- Risk assessment and reduction methodology*		**ONR 49002-1:2010**, *Risk Management for Organizations and Systems - Part 1: Guidelines for embedding the risk management in the management system - Implementation of ISO 31000*
	ISO 17776:2000, *Petroleum and natural gas industries -- Offshore production installations -- Guidelines on tools and techniques for hazard identification and risk assessment*		**ONR 49002-2:2010**, *Risk Management for Organizations and Systems - Part 2: Guideline for methodologies in risk assessment - Implementation of ISO 31000*
EN	**EN 1127-1:2011,** *Explosive atmospheres. Explosion prevention and protection. Basic concepts and methodology*		**ONR 49002-3:2010**, *Risk Management for Organizations and Systems - Part 3: Guidelines for emergency, crisis and business continuity management - Implementation of ISO 31000*
	EN 13463-1:2009, *Non-electrical equipment for use in potentially explosive atmospheres. Basic method and requirements*		**ONR 49003:2010**, *Risk Management for Organizations and Systems - Requirements for the qualification of the Risk Manager - Implementation of ISO 31000*

The concept of standardization in the field of risk, implemented by the International Organization for Standardization ISO and European standards bodies (CEN and CENELEC) has got the hierarchical structure of standards, as depicted in Figure 1. The concept starts from the fact that successful implementation of risk management in any organization requires a standards structure which sets up from general standards and through the standards defining terminology to standards in which risk analysis and assessment requirements are set for individual business processes and/or functions, and further on to standards in which there are guidelines directing about how to execute these analyses and assessments, and finally, there are structures defining the tools to be used in the risk analyses and assessments. Figure 1 depicts complete hierarchy structure of international and regional standards in the field of risk management, which are of importance for implementing the NAD directives.

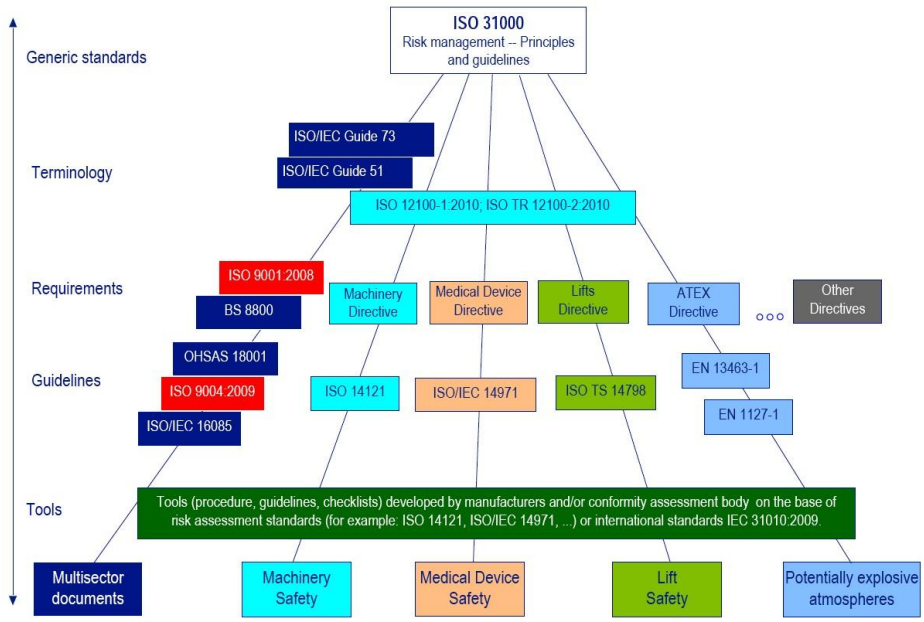


Figure 1. Hierarchy structure of standards in the risk management field, of importance in implementing the EU technical legislation (Adjusted on the basis of [3])

At the highest generic level, there is the standard ISO 31000:2009 which provides for general instructions and principles for developing and implementing risk management in any organization. In the following level, there are the standards and guidelines incorporating the vocabularies of terms. These are ISO/IEC Guide 73:2009 and ISO/IEC Guide 51:1999 standards.

This group of standards defining the terms might also be extended by standard ISO 12100-1:2010, expressing the basic overall methodology to be followed when designing machinery and when producing safety standards for machinery, together with the basic terminology related to the philosophy underlying this work. The requirements for technical products safety are given in the New Approach directives. They are defined in general form so that they cannot not become obsolete so quickly. From the risk point of view, the requirements defined in such a manner

represent the risk management objectives in the process of product development related to safety of the products.

In the course of product development, designers has a dilemma of how to determine if a product is safe or not, i.e. how to execute the risk analysis and assessment and how to improve the design solution on the basis of this. It is difficult to determine in practice the safety of a non-standardized product if there is no adequate reference with respect to which it can be done.

In response to this problem, the European Commission has initiated with CEN the development of generic harmonized standards enabling the systematic approach and providing the guidelines for: (1) identification of hazards; (2) risk assessment due to these dangers, and (3) assessment of acceptability of the selected safety measures.

Thus, a set of generic standards ensued for assessing risks in the NAD, such as: ISO 14121-1:2007 for machines products, EN ISO 14971: 2002 for medical products, ISO TR 14798:2006 for lifts, etc.

From the standpoint of product safety, these standards serve as guidelines on how to conduct the risk analysis and assessment. Thus, as it is depicted in Figure 2, they have got a dual role. On the one hand, they serve as the tool (guidelines) used by designers and engineers in analyzing and assessing the level of safety of design solution in the course of product development process, while on the other hand they are also the tool for the organization's staff and/or conformity assessment body in assessment whether a product satisfies the requirements of directives and/or harmonized standards, i.e. whether they possess satisfactory levels of safety.

At the lowest level of the standards structure hierarchy, there are the tools developed as independent standards, such as, for example, ISO/IEC 31010:2009 which provides large number of techniques that can be applied in risk assessment. In addition to the standards serving as tools, organizations very often also develop specific tools in which the risk assessment methodology given in some of the standards, such as for instance ISO 14121:2007, is adjusted to products and business practice present in that particular organization. These tools are presented in the form of various procedures, instructions or, most often, in the form of checklists.

3. RISK ASSESSMENT AS A BASE FOR PRODUCT SAFETY IMPROVEMENT

3.1 Risk assessment integration into the product development process

Risk assessment of technical products is the constituent part of their design and development process [4, 5]. It is conducted according to the requirements of directives, i.e. of harmonized standards developed and published for that purpose. Thus, the risk assessment of machinery products is done according to standard ISO 14121:2007, and that of medical devices according to standard ISO 14798:2007, etc. If there is no adequate harmonized standard according to which to perform the risk assessment for certain technical products, there remains available to the designers the general structure of the process for managing risks given in standard ISO 31000:2009.

All designers and employees who take decisions in product development process have to be familiar with the general and/or specific processes for risks assessment which is required by NAD (Figure 2).

At the operational level, in the course of product conformity assessment, as shown in Figure 1, various tools are used in the form of checklists in which the risk assessment methodology, given in

harmonized standards, is adjusted to the actual products in question. Each conformity assessment body develops these tools according to its own needs.

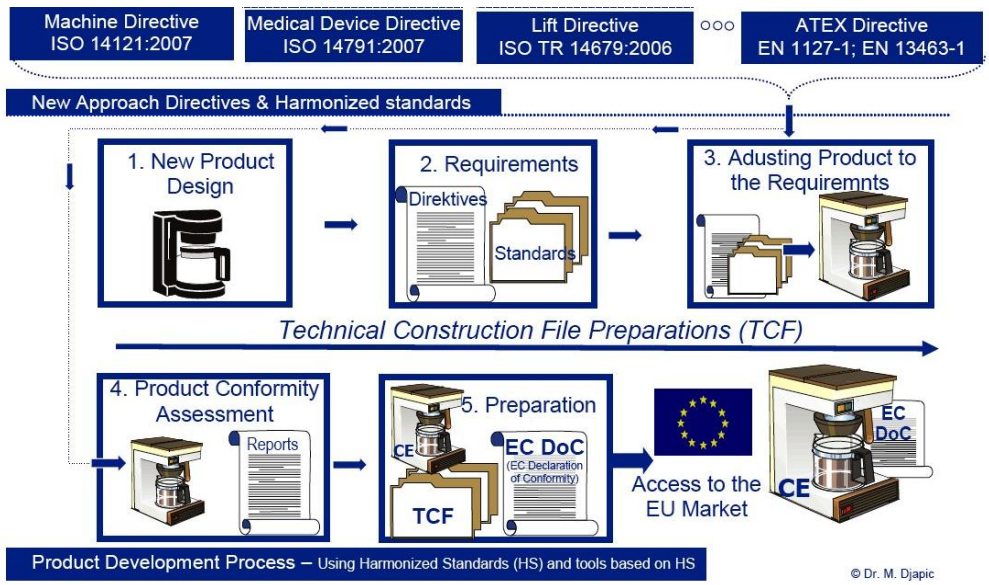


Figure 2. Integrating risk assessment in NAD into the technical product development

3.2 Product safety improvement – foodstuff machines examples

3.2.1 Requirements for foodstuff machines safety

EU requirements for foodstuff machines have to fulfill two groups of regulations:

- Regulations for foods
- Technical regulations for machine which are included in the food processes production.

International and European regulation {Regulation (EC) No 178/2002, Food law etc.[6]} and standards (HACCP, ISO 22000 for food safety management system) for food safety is intended to provide security by ensuring that there are no week links in the food supply chain. By ensuring integrity of food supply chain it helps to minimize the failures in food supply which can be dangerous and cost plenty. Food and feed imported to the EU shall comply with the relevant requirements of food law or conditions recognized by the Community to be at least equivalent with requirements contained therein.

Technical regulations for machine which are included in the processes of production foods also have to fulfill requirement of EU Technical legalization (EU Directives). Machinery Directive (MD) 2006/42/EC [7], is one of them. In its Annex I there are supplementary essential health and safety requirements for ”Foodstuffs machinery”.

Point 2.1 of the Annex I [7] define supplementary requirements for the machinery design for food processing. Some of the requirements are:

- *materials in contact with, or intended to come into contact with, foodstuffs ..must satisfy the condition ... cleaned before each use ... disposable.*
- *all surfaces in contact with foodstuffs must be: smooth, designed to reduce the projections, easily cleaned and*

disinfected, ...

- *it must be possible for liquids, ... deriving from foodstuffs, ...cleaning, ...*
- *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,*
- *machinery must be designed and constructed in such a way that no ancillary substances hazardous to health, including lubricants used, can come into contact with foodstuffs, ...*
- *In the point 2.1.2 state that instruction for foodstuffs must indicate recommended products and methods for cleaning, disinfection etc.*

Also, EU standardization body (CEN) published standard EN 1672-2:2005+A1 *Food processing machinery – Basic concepts – Part 2: Hygiene requirements* to cover the MD requirements and to give guides to risk assessments and verification foodstuffs machinery.

3.2.2 Risk assessment - Example of foodstuff machines SOLARIS 1

As an example of foodstuff machine we present Solar Electric Energy Dryers - SOLARIS 1 which is developed by NTIM Technology company. ”SOLARIS 1” is intended for drying fruits, vegetable, medical herbs, spices and mushrooms. It is fully automated and capable of performing all drying processes according to programmed parameters, giving possibilities of on-site control or over internet and GSM module, allowing to control the drying processes from any place in the world. This means that, with this innovative technology, the buyer of dried products gets a guaranteed quality and an insight into a full drying process, as well as the possibility to review all drying processes during the last couple of years, unlike other standard types of dryers.

This advanced dryer, powered by solar energy, is a product unique in the world. It is patented in Serbia and as well by international patents P-2007/0441 and WO/2009/061229. It is important to mention that in ”SOLARIS 1” (Figure 3) have been implemented nine new designs solution and completely new technical solutions. The dryer is mobile, with installed wheels, and can be handled according to the client’s needs.

Figure 3. Solar Electric Energy Dryers "NTIM TEHNOLOGI"

The process in the dryer is controlled by a microprocessor including 50 different programs and allows an automatic transfer from solar to electric energy and vice versa. Microprocessor chooses the source of energy itself, which means that it uses daylight (sun) as source of energy until it is possible, otherwise it uses electric energy.

The control system gives the possibility of setting parameters for 50 different drying modes. The parts of the plant which contain material to be dried, as well as the components for air distribution, are made entirely of stainless steel conforming to HACCP and ISO food industry production standards.

In the aim of ”SOLARIS 1” export to the EU and USA markets it was necessary

improvement of design solution i.e. to conform that solution to requirements of EU directives and appropriate harmonized standards.

First step was carry on risk assessment and on the that base it is necessary to improve design solution. Risk assessment carried out in regards to directive requirements (MD 2006/42/EC , Annex I, 2.) and appropriate harmonized standards (EN 12100-1:2010 and EN 14121:2007).

In continue we present some of results of the risk assessment procedure (Table 2.) from the harmonized standards EN ISO 14121 and EN ISO 12100.

According to the Standard EN 1672-2:2005+A1, the Supplementary essential health and safety requirements (MD 2006/42/EC , Annex I, 2.) "Foodstuffs machinery" (MD 2006/42/EC, Annex I, 2.1), are listed in Table 3.

Table 2. Risk assessment, hazards grouped, measure, verification (EN 12100-1; EN 14121)

No.	Type or group	Hazards	Analysis/ Standard(s)	Verification	Note
1	Mechanical hazards	Kinetic energy, ..., Stability, Sharp edges	√	Drawing, Inspection	
2	Electrical hazards	Arc, Live parts, Short-circuit, ...	√	Measurement EN 60204-1	Report
3	Thermal hazards	Objective or materials with a high or low temperature, ...	√	Instruction manual	
4	Noise hazards	Cavitations, moving parts, ...	√	Measurement EN 11202-1	Report
8	Ergonomic hazards	Access, ...	√		
9	Hazards associated with environment in which the machine is used	Surface, Dust and fog, EMC, Lathing, Pollution, Temperature, Water, Wind, ...	√	Instruction manual	
10	Combination of hazards	Repetitive activity + Effort + high , ...	√		
Supplementary requirements					
No.	Type or group	Hazards	Analysis/ Standard(s)	Verification	Note
	Foodstuffs machinery (MD 2006/42, Annex I,2.1)	Hygiene risk	√ EN 1672-2:2005+A1	Drawing, Inspection	4.2 Supplementary EHS requirements (2006/42/EC Annex I, 2.)

On the base of risk assessment the dryer "SOLARIS 1" design solution improvement carried out.

The improved technical solution are:

- draying space is reconstructed – shelf lean on, verification of material and surface in regard to appropriate standards (improved solution is represented on Figure 4a)
- Control system is reconstructed with precise draying parameters control (compartment temperature, humidity and process diagram) (Figure 4b)
- Monitoring improvement of safety

values (air pressure, safety connections etc.)

Table 3. Risk assessment, hazards grouped, measure, verification (EN 1672-2:2005+A1)

Reference subclauses	Requirement	Verification	Status
5.1	Hygiene risk assessment	Documentary evidence	√
5.2.1	Durable	Material specification (food, process and cleaning) and/or practical or functional test	√
5.2.1 5.3.1.1 5.3.1.3 5.3.1.5 5.3.1.6 5.3.1.7 5.3.1.9 5.3.2 5.3.3	Cleanable and/or capable of being disinfected	Visual inspection (of technical drawing and/or machinery) and/or practical test, micro biological test or functional test	√
5.2.2 5.3.3	Corrosion resistant	Material specification (food, process and cleaning) and/or practical or functional test	√
5.2.2	Non toxic	Material specification or practical test for materials intended to come into contact with food	√
5.2.2	Non absorbent	Material specification or practical test for materials intended to come into contact with food	√
5.2.2	Not transfer undesirable odors, colors or taint to the food	Material specification or practical test for materials intended to come into contact with food	√
5.2.2 5.3.3	Not contribute either to the contamination of food or have any adverse influence on the food	Material specification or practical test for materials intended to come into contact with food	√
5.3.1.1	Surface design	Visual inspection (of technical drawing and/or machinery)	√
5.3.1.1 5.3.2	Surface finish	Measuring e.g. according to EN ISO 4288	√
5.3.1.2.1	Permanent joints	Visual inspection	√
5.3.1.2.2	Dismountable joints	Visual inspection	√
5.3.1.3	Fasteners	Visual inspection	√
5.3.1.4 5.3.1.6 5.3.3	Drainage	Visual inspection (of technical drawing and/or machinery) and practical test	√
5.3.1.5 5.3.2	Internal angles and corners	Measurements	√
5.3.1.6	Dead spaces	Visual inspection	√

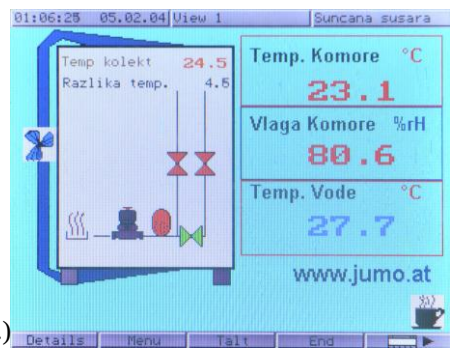
Table 2. - Continue

Reference subclauses	Requirement	Verification	Status
5.3.1.7	Bearings and shaft entry points	Visual inspection	√
5.3.1.9	Panels, covers, doors	Visual inspection	√
5.3.1.10	Control devices	Visual inspection	√
5.3.2	Splash area	Compliance with Reference subclouses	√
5.3.3	Non-food area	Compliance with Reference subclouses	√
5.3.4	Services	Compliance with Reference subclouses	√

a.)

b.)

b.)



b.)

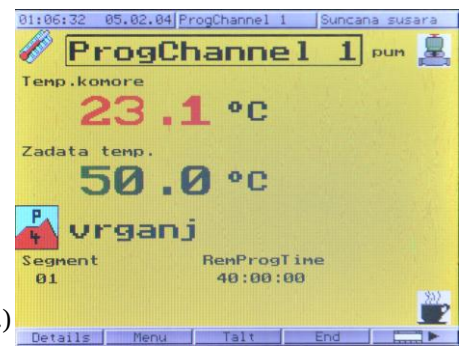


Figure 4. Reconstructed: a) draying space b) control system with precise draying parameters control

5. CONCLUSION

European Union has accomplished, through introducing New Approach to technical harmonization and standardization a breakthrough in the field of technical products safety and in assessing their conformity in such a manner that it integrated products safety requirements into the process of products design and development. This is achieved by quantifying risk levels, in the course of the designing process, with the aim of determining the scope of the required

safety systems, where the safety requirements are preventively considered during the designing process.

Follow that in the paper are presented concept of the international standardization in the risk management field

Through the example of foodstuff machine ”SOLARIS 1” we present way of using risk assessment as a base for machine design improvement.

”SOLARIS 1” is intended for drying fruits, vegetable, medical herbs, spices and mushrooms processing.

REFERENCES:

[1] Guide to the Implementation of Directives Based on the New Approach and Global Approach, by the European Commission (Blue Guide), (November 2011) http://ec.europa.eu/ enterprise/.

[2] Djapic, M., Popovic, P., Lukic, Lj., Mitrovic, R., Integrating Risk Assessment in the NAD into the ERM Model, TTEM Journal, Vol. 7, No. 3, 8/9. 2012 (Accepted paper for publishing).

[3] CEN/BT WG 160, Implementation of Risk Assessment in European Standardization, Annex 3, 2005.

[4] Djapic, M., Lukic, Lj., Ivanovic, S., Machine Safety Requirement Integration in the Process Designing – Risk Assessment in the Machinery Directive, Journal of IMK-14 Research and Development, Institute IMK 14. October, Krusevac, Vol. XV, No. (30-31) 1-2/2009, pp. 43- 58, ISSN 0354-6829.

[5] Djapic, M., Zeljkovic, V., Vojinovic, M., Machine Tools Harmonization with EU Technical Legalizations Requirements, International Journal for Quality research, Vol. 2, No. 3, pp 171-177, 2008.

[6] REGULATION (EC) No 178/2002 general principles and requirements of food law, Official Journal of European Communities L 31/1, 1.2.2002.

[7] Directive 2006/42/EC of the European Parliament and Council of 17 May 2006 on machinery, L 157/24 Official Journal of the European Union, 9.6.2006.

[8] ISO EN 12100-1-2 Safety of machinery – Basic concept, general principles for design – Part 1 Basic terminology, methodology, Part 2 – Technical principles, www.iso.org.

[9] ISO EN 14121 -1 Safety of machinery – Risk assesment - Part 1 – Priciples, www.iso.org.

[10] EN 1672-2:2005+A1 Food processing machinery – Basic concepts – Part 2: Hygiene requirements, March 2009, www.cen.org.

[11] ISO 31000:2009 Risk management - Principles and guidelines, International Organization for Standardization, www.iso.org.

[12] ISO/IEC Guide 73 Risk Management - Vocabulary - Guidelines for use in standards, International Organization for Standardization, www.iso.org.

[13] Standards Australia & Standards New Zealand Committee OB/7 on Risk Management, Risk management, AS/NZS 4360:2004, www.saiglobal.com.

[14] IEC 31010:2009, Risk management — Risk assessment techniques, International Electrotechnical Commission, www.iec.org.

Acknowledgment: In the paper are presented some of the results from the project No. TR35031 which is partly funded be Serbian ministry of education and sciences.