1.8 DESIGNING PROCESS OF A NEW SAFE MACHINE TOOL

Machine tools which are placed on the market in EU countries must be in accordance with all relevant legal rules. The machine manufacturer as well as subsuppliers of particular components are responsible for this accordance and their responsibility depends on their role which they have in the supplier chain. All information provided by the manufacturer must be correct, complete and in accordance with all relevant EU regulations.

Another necessary field of knowledge which the designer needs to develop machine tools successfully is a set of techniques and methods, which must be applied in a suitable way to reach the adequate protection level of public interests at a new machine. For this purpose, harmonization legal regulations are issued in the European Union. These regulations determine the essential requirements specifying the level of this protection and they formulate the requirements as the results which shall be obtained at the development of the particular machine. If the essential requirements cannot be used or if it is not suitable to use them, the particular EU harmonization legal regulations can determine detailed specifications with the aim to provide proper consumers' protection, protection of public health and environment or of another public interest. Harmonized standards are adopted to the EU harmonization legal regulations and they formulate requirements on the protection of public interests by means of technical terms. Together with other harmonized standards related to the developed machine, they establish the prerequisite for the accordance with these requirements and at the same time they allow the possibility to obtain the proper protection level of public interests also in another way. Before a machine tool is placed on the market, it must be in accordance with all relevant legal regulations of the European Union, i. e. it must comply with all requirements put on the protection level of public interests following from the harmonization legal regulations. Public administration bodies then perform market supervision, i. e. activities and measures which shall provide that the products are in accordance with the requirements set by the relevant harmonization legal regulations of the EU.

EU harmonization legal regulations

The standard decision-making process followed by the EU bodies during elaboration of legal regulations, is called joint decision-making. This consists in the principle that the directly elected members of the European Parliament approve the suggested regulations together with the Council (i. e. representatives of all EU member states).

A suggestion of a legal regulation is prepared by the commission specified for this purpose. Before this commission submits the suggestion of a legal regulation to other institutions, it is necessary to assess its potential economic, social and environmental impact. The commission prepares for this purpose assessments of impacts, which summarize possible advantages and disadvantages of the suggested measures. The commission also takes counsel with concerned subjects (non-governmental organizations, local self-government bodies, representatives of industrial branches and civil associations). Specialized groups of experts help the commission with special aspects. Thus, the commission ensures that the legislative suggestions comply with needs of the most involved groups of population and that no unnecessary administration costs shall arise, if the suggestion is accepted. Citizens and representatives of various enterprises and organizations can participate in this process within public consultations having their own web site.

The European Parliament and the Council have the task to assess the regulations suggested by the Commission and to submit possible changes. If the standpoint of the European Parliament differs from the standpoint of the Council, the second reading will follow. Various changes can be again suggested during this stage. If no agreement is reached, the Parliament can block the suggestion. In the other case the suggested legal regulation can be accepted. If the standpoints differ from each other, the negotiating committee will be created and this committee shall find the solution. During this last reading the submitted suggestion can be blocked by the European Parliament as well as by the Council. The European Union accomplishes the set targets by means of the following legal regulation types:

- **Regulation** is legally binding. It is valid in its complete scope in the whole European Union.
- **Directive** is the legal act setting the target which must be accomplished by all EU countries. However, each country can decide in what way this will be performed.
- **Decision** is binding for the particular subject which it is specified for (e. g. the particular EU country or the particular corporation) and it can be used directly.
- **Recommendation** is not binding. Using a recommendation, the EU bodies can manifest their opinion and to suggest some certain steps, without drawing the legal obligation for the particular subject which it is specified for.
- **Standpoint** is a legal act, by means of which the EU bodies can express their opinion to a certain issue in the non-binding way, i. e. without establishing the legal obligation for the particular subject which it is specified for.

The following harmonization EU regulations deal with the designing process of a new safe machine tool directly or indirectly:

EU regulation No. 765/2008

The Regulation of the European Parliament and the Council No. 765/2008 of 9th July 2008 determines the requirements on accreditation and market supervision related to introducing of products to the market. This regulation determines the frame for market supervision with products and its aim is to provide that these products shall accomplish requirements put on the high protection level of public interests, like health and safety in general, health protection and safety of work on the working site, consumers' protection, environment protection and safety. Moreover, this regulation determines rules for organization and performance of accreditation at subjects for conformity assessment as well as it determines the frame for the check of products made in the third countries and general principles specified for the CE marking [7].

According to this regulation, the market supervision shall provide removing such products from the market, which the EU harmonization legal regulations are

related to and which, if they are used for intended purposes or under the reasonably predictable conditions and if they have been properly installed and maintained, can endanger health or safety of their users, or which are not otherwise in accordance with relevant requirements set by the EU harmonization legal regulations. The market supervision shall also provide prohibition or limitation of deliveries of such products to the market (supply of products to be distributed, consumed or used on the EC market within the commercial activity, against the payment or free of charge) and it shall inform general public, the Commission and other member states about this fact in a suitable way.

The bodies performing the market supervision have the right to require from economic operators (manufacturers, importers, distributors or authorized representatives) to give them documents and information available, if they consider this to be necessary to perform their work and – if this is necessary and justified – they have the right to enter premises of the involved economic operators and to take the necessary samples of products. They can destroy such products or disable products that present a serious risk, shall they consider it necessary. If the economic operators provide records about tests or certificates confirming the conformity issued by a subject authorized to assess conformity, the bodies performing the market supervision will take these records and certificates properly into account.

The decision whether the product represents serious risk follows from the proper risk assessment which takes into consideration the risk character and the probability that this risk occurs. A possible higher level of safety or availability of other products representing a lower risk degree is not the reason to consider this product to be the one which represents serious risk.

The member states determine sanctions to economic operators for breach of this regulation, including punitive sanctions for serious breach, and they take all measures which are necessary to realize them. The determined sanctions must be effective, adequate and discouraging and it is possible to increase them, if the relevant economic operator broke this regulation in a similar way previously.

Decision No. 768/2008/EC

The Decision of the European Parliament and the Council No. 768/2008/EC of 9th July 2008 about the common frame for product introducing to the market determines the common frame with general principles and reference regulations for elaboration of EU legal rules which harmonize the conditions for product introducing to the market. Besides other things, it mentions the following general principles [10]:

1) The products placed on the EU market must be in accordance with all relevant legal rules.
2) When introducing the products to the EU market, the economic operators are responsible for the product conformity with the relevant legal rules depending on their role within the supplier chain.
3) The economic operators are responsible for the fact that all information given by these subjects about their products are correct, complete and in accordance with all relevant EC rules.

The decision specifies the following in the sphere of protection of public interests:

1) The EU harmonization legal rules only set the essential requirements determining the level of this protection and they formulate these requirements as the results which shall be obtained.
2) If the EC harmonization legal rules set the essential requirements, they also set the possibility to use harmonized standards formulating these requirements by means of technical terms. The harmonized standards themselves or together with other harmonized standards establish the precondition of conformity with these requirements; however, they retain the possibility to set the protection level in another way.

If the EU harmonization legal rules require the manufacturer's declaration that all requirements related to the product have been fulfilled ("EC Declaration of Conformity"), the legal rules set that only one declaration shall be elaborated for all EC acts related to the particular product. This declaration shall include all information necessary to determine the EC harmonization legal rules related to this declaration and it shall mention references to the issue of corresponding acts.

If the EU harmonization legal rules require the conformity assessment, they can set that this assessment shall be performed by public bodies, manufacturers or notified bodies. If the conformity is assessed by public bodies, the legal rules set that those subjects for the conformity assessment on whose specialized assessment the mentioned public bodies are dependent must comply with the criteria set in this decision for notified bodies.

This decision mentions the following manufacturers' obligations:

1) When placing their products on the market, the manufacturers must provide that these products are designed and manufactured in accordance with the requirements set in the relevant harmonized legal rules.
2) The manufacturers shall draw up the required technical documentation and they perform the appropriate procedure of the conformity assessment or they have this process performed. If the product conformity with the valid requirements is proven by this process, the manufacturers will elaborate the EC Declaration of Conformity and add the conformity designation.
3) The manufacturers keep the technical documentation and the EC Declaration of Conformity for the time period given in the relevant legal rule. This time period is proportional to the product life and to the risk extent.
4) The manufacturers shall provide application of such procedures, thanks to which the series production remains in accordance with requirements. It is necessary to consider properly the changes of the product design or the product parameters and the changes in harmonized standards or technical specifications based on which the product conformity is declared.
5) The manufacturers shall ensure that their products bear a type, batch or serial number or any element enabling their identification, or, in such cases when the product size or the product character does not enable it, the manufacturers shall give the required information on a product package or in a document enclosed to the product.
6) The manufacturers mention their name, their registered commercial company

or their registered trademark and the address where they can be contacted on the product, or if this is impossible, on a product package or in a document enclosed to the product. The address must state the only place where the manufacturers can be contacted.

7) The manufacturers shall provide that operating instructions and safety information are enclosed to the product, in accordance with the decision of the corresponding member state. These operating instructions and safety information must be in such a language which can be understood easily by consumers and other end users.
8) The manufacturer, which assume or which have a reason to assume that the product introduced by them to the market is not in accordance with the relevant EC harmonization legal rules, must take immediately the corrective measures necessary to put the product into accordance or they shall remove the product from the market or from circulation. Moreover, if the product represents risk, the manufacturers shall immediately inform the relevant national authorities in the member states, where the product was supplied to the market, and they shall give details especially about the non-conformity and taken corrective measures.
9) Based on the justified request of the relevant domestic body, the manufacturers shall submit all necessary information and documentation necessary to prove the product conformity in such a language which can be understood easily by this body. They cooperate with this body on its request at the activities having the target to eliminate risks caused by the products placed on the market by them.

It is supposed that the products, which are in compliance with harmonized standards or their parts and which the references were published in the EU Official Bulletin to, are in conformity with the requirements included in these standards or their parts and mentioned in the relevant harmonized legal rules.

The EC Declaration of Conformity is elaborated according to the example given in Annex III to the Decision of the European Parliament and the Council No. 768/2008/EC of 9th July 2008 about the common frame for product introducing to the market. It includes the elements determined in appropriate modules given in Annex II and it is still updated. The declaration is translated to the language or languages required by the member state where the product is introduced or supplied to the market. When the manufacturer elaborates the EC Declaration of Conformity, the manufacturer bears the responsibility for the product conformity with this declaration.

The manufacturer shall add the required conformity designation stated in the legal tool to each and every particular product which is in compliance with the applicable legal tool requirements. Moreover, the manufacturer shall elaborate for the particular product model the written conformity declaration. The manufacturer will keep this declaration together with the technical documentation ten years, after the product was placed on the market, to make it available for domestic bodies. The product which the conformity declaration was elaborated for is stated in the conformity declaration. The copy of the conformity declaration shall be submitted to the appropriate bodies on their request.

The following rules and conditions are valid for addition of the CE conformity:

1) The CE marking is affixed to the product or to its data plate in a visible, legible and undeletable way. If this is not possible or justified due to the nature of the product, the CE marking shall be affixed to the package and accompanying documents, if the relevant legal rules set these documents.
2) The CE marking shall be affixed, before the product is placed on the market. A pictograph or any other sign signifying some special risk or usage can be connected to it.
3) The CE marking is completed by the identification number of the notified body in case of its participation in the check stage of manufacture. The identification number of the notified bodyshall be connected by the subject itself, or it is connected by the manufacturer or its authorized representative according to the instructions given by the notified body.

The technical documentation must enable to assess the product conformity with the relevant requirements and it includes the appropriate risk analysis and assessment. The technical documentation particularizes applicable requirements and it relates to the product design, manufacture and operation to the extent necessary for the assessment. If this is suitable, the technical documentation includes at least these elements:

- general product description;
- conceptual design and manufacturing drawings and diagrams of parts, subgroups, circuits, etc.;
- descriptions and explanations necessary to understand these drawings, diagrams and product functions and operation;
- list of harmonized standards or other corresponding technical specifications, which the references were published in the EU Official Bulletin to and which were completely or partly used, and description of solutions used to fulfil the essential requirements of the legal rule if these harmonized standards were not used; in case that the harmonized standards were used partly, the technical documentation shall mention those parts which were used;
- results of designing calculations, performed checks, etc.;
- records about tests.

This decision specifies eight modules of the conformity assessment procedures A to H (Fig. 1.8.1). The manufacturers of CNC machines can use especially modules A, D1 and H1.

Module A – Internal production control plus supervised product testing is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3, 4 and 5 and ensures and declares on its sole responsibility that the products concerned satisfy the requirements of the legislative instrument that apply to them. The manufacturer shall elaborate the technical documentation which must enable to assess the product conformity with the relevant requirements and it includes the appropriate risk analysis and assessment. The manufacturer then takes all necessary measures so that the manufacturing process and its check can provide conformity of manufactured products with the technical