



# CECIMO position paper on the EC Proposal for a new Machinery Directive

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## 1 Introduction

CECIMO, the European Committee for Co-operation of the Machine Tool Industries, regroups 15 national associations representing about 1400 companies.

The machine tool sector is a supplier of high technology manufacturing equipment to the European manufacturing industries, including the automotive, aerospace and the supply chain industries.

This document contains the comments from CECIMO on the proposal for a new machinery directive issued by the EC on January 2001 (document COM(2000) 899 final). Some of the comments are similar to the comments made in the position paper issued by ORGALIME. CECIMO endorsed the principals of the ORGALIME position paper, but nevertheless wishes to express its specific concerns regarding some particular issues.

## 2 Comments

### Article 1, point 2: Exclusions

#### Item (a): spare parts

In order to have a clear distinction between components "provided by the manufacturer of the original machinery" and components that have been placed on the market independently, CECIMO proposes the following:

Delete from item (a): "or by a third party in accordance with the manufacturer's instructions".

This will assure that safety components (e.g. polycarbonate vision panels) that are independently placed on the market have to comply with the machinery directive. It will avoid discussion and confusion about whether the parts are included in the directive through article 2 (d) (v) or excluded based on article 1 point 2 (a).

### Article 2: Definitions

#### Item (i) "partly completed machinery"

Herewith CECIMO wishes to stress the fact the limitation of "partly completed machinery" to machines that cannot themselves perform a specific application is not practicable.

Example: It happens regularly that customers of machine tools want to buy this machine without protection guards and install these by themselves. In this case, the manufacturer of the machine tool cannot affix a CE-mark (because the machine is not yet in line with the directive). But he also cannot issue a declaration of incorporation (Annex IIB-declaration) because the machine tool can already perform a specific function, but this however in an unsafe way. As a consequence, the free circulation of goods in the EU-market is not ensured.

CECIMO therefore proposes to modify the definition of partly completed machinery as follows:

"partly completed machinery" means an assembly, fitted or intended to be fitted with a drive system, of linked parts or mechanical components ~~which are almost a machine but~~ which cannot safely perform a specific application or which cannot perform a specific application at all. Partly completed machinery is intended to be incorporated into or assembled with one or more machines or other partly completed machinery, or completed by the addition of one or more safety components, thereby forming a ~~single~~ machine which complies with this directive.

(Note: a machine is by definition a single machine)

Furthermore, CECIMO would like to see an explicit mentioning of the fact that partly completed machinery is not to bear the CE-marking. (To be added in the definition or possibly in article 13)

## **Article 8 in combination with article 22 (competence of the "Machinery Committee)**

CECIMO proposes to keep the present structure under the existing Directive with the Standing Committee (and the related working group). This approach has proven to work since all the stakeholders were represented and thus, all the interests of the concerned parties have been taken into consideration before decisions have been made.

## **Article 9: Specific measures to deal with categories of potentially hazardous machinery**

Article 9 of the directive proposal enables a Member State to restrict or even to prohibit the placing on the market of specific categories of machinery. In combination with the already mentioned article 8(1)e it would thereby even be possible to completely ban a specific machinery category for the European Union.

CECIMO is of the opinion that article 9 must be deleted, since it is in contradiction with the purpose of the directive, which is to ensure the free movement of machinery.

## **Article 12: Procedures for conformity assessment of machinery**

### Approval of the technical file according to Annex IX

Article 12 (4) of the directive proposal foresees the following conformity assessment procedures for Annex IV machines that are produced according to "complete" harmonised standards (i. e. standards that cover all of the relevant risks):

- Approval of technical file according to Annex IX,
- EC type examination according to Annex X and
- Full quality assurance according to Annex XI.

The first option does not offer (in contrast with the existing directive) the possibility to lodge the technical file with a notified body, which takes receipt without examining the notified body. This possibility has proven to be valuable during the application of the existing directive. The *approval* of the technical file according to Annex IX would significantly reduce the added value of the existing and future harmonised standards.

Therefore, CECIMO is of the opinion that in the case of annex IV machines manufactured in accordance with harmonised standards an option should be established where the technical file should not be sent to a notified body (i.e. the Annex VII option providing assessment of conformity with internal checks on the manufacture).

### Full quality assurance according to Annex XI

CECIMO is of the opinion that the practical meaning of this option is not well described. The current annex XI of the proposal raises questions concerning the practical implementation of such quality assurance system, in particular regarding the evaluation of it by a notified body. How will existing ISO schemes (ISO 9000...) be applied? Companies that already apply e.g. ISO/EN 9000 should not be subject to an additional certification audit. As it reads now, annex XI will lead to a duplication of certification procedures. The Annex XI procedure only makes economic sense if it will be integrated into existing certification schemes. (ISO 9000...)

Annex XI does furthermore raise questions about how the competence of the notified bodies in this area would be guaranteed.

## Annex I

### Clause 1.1.2.: Principles of safety integration

CECIMO believes that the differentiation between:

- Qualified and instructed operators with sense of responsibility and capabilities of self-protection based on technical knowledge
- Auxiliary personnel (unskilled workers)

has to be expressed more accurately.

In the working groups of CEN TC 143, C-standards are being elaborated, which are considered by many manufacturers as taking insufficiently into account the own sense of responsibility and capabilities of self-protection of qualified operators.

Since the machinery directive is the starting point for the elaboration of C-standards, the text of the machinery directive should open the way to an appropriate consideration of practical aspects in the C-standards.

CECIMO therefore proposed to modify clause 1.2.1 "principals of safety integration" point c) as follows:

"When designing and constructing machinery, and when drafting the instructions, the manufacturer or his authorized representative must envisage not only the normal use of the machinery but also uses of which could reasonably be expected when used by trained operators. "

CECIMO is of the opinion that this modification is correctly taking into account the user's responsibility as laid down in the directive on the safety of work equipment 89/655/EEC.

### Clause 1.10.1.: Instructions

Many customers prefer the availability of the instructions in a language other than their own language. Furthermore, the cost of providing translations is very important and could increase dramatically, certainly taking into account the enlargement process of the European Union.

Therefore, CECIMO is of the opinion that the following should be introduced into the revised directive:

"The instructions have to be provided in one of the official Community languages. A translation of the instructions into the language of the user country is not necessary, if the user requires instructions in a different language and his operators are able to understand this language or are educated in it."

## Annex II

### Part A, point 5

CECIMO believes that it should be clarified that ONE declaration of conformity is sufficient. The present wording could lead to the interpretation that there is a need for further declarations, e.g. for EMC- or LVD-aspects.

CECIMO therefore supports the ORGALIME suggestion to merge articles 4 and 5 of Annex II:

*"a declaration of conformity with the present directive and, where appropriate, with other European directives and/or relevant provisions with which the machine complies".*

### Part A, point 2

This paragraph says that the name and address of the person who is authorised to compile the technical file must be indicated.

Considering point 12 of the same annex, CECIMO believes that point 2 of Annex IIA is a redundant bureaucratic burden, which does not add value to the directive and therefore should be deleted.

## Part B, point 4

Paragraph (4) says "...This shall include the method of transmission..."

CECIMO believes this requirement is unclear and ambiguous.

## Other comments

The proposal for a new directive does not include the previous Article 8.7. anymore. This could lead to a gap in this new legislation, especially when neither the manufacturer nor his authorised representative fulfil their obligations regarding conformity assessment.

CECIMO proposes to include the wording of article 8.7. of the present directive 98/37, because it provides a clear sequence of responsible persons.