

“MODIFICATION” VERSUS CONCEPT OF “SUBSTANTIAL MODIFICATION”

Background

Since a few years, the concept of “substantial modification” is being debated in the machinery sector among various stakeholders even though the terminology has no legal background and only appears in some parts of the Guide to application of the Machinery Directive (MDG)¹ and in the Blue Guide.

A very careful reading of the MDG highlights the fact that the term “substantial modification” is used to describe two different situations:

- a substantial modification of a new machinery not yet put into service, and
- a substantial modification of a machinery after it has been put into service.

In addition, it shall be noted that this term is sometimes used in the MDG as a synonym of « transformation », which can be understood as rebuilding of a used machinery in order to provide a brand-new machinery (see § 72 of MDG²). The term “transformation” is the original term used in the 1st version of the guide (related to 98/37/EC Machinery Directive), in a dedicated annex written by lawyers.

Today, the fact that there is no reference to the term “substantial modification” in any European legal act and only a vague description in the Blue Guide, leaves room for interpretation while current discussions usually omit the existence of the term « modification » referred to in the legal framework of UWED³.

About “modifications” of machinery in service

It has to be noted that:

- This term has a legal background (it is explicitly used in the UWED although there is no definition) and it applies to machinery already in service.
- UWED is a legal act stating clearly some employers’ obligations such as providing to workers compliant machinery for use at the places of work, general risk assessment obligation, obligation to consider the development of technology and last but not least, obligation to remain during the whole machinery lifetime in conformity with the regulations applicable to the machine at the time it was put into service; Those obligations apply, especially in case of modification.
- Without a clear definition of the term “modification”, the boundary of responsibilities between original equipment manufacturers (OEM) and users, today described in the regulations cited above (MD and UWED), may appear confusing
- This confusion has practical implications in the context of “substantial modification” and it already creates damages on the market: in some cases, customers have requested the OEMs to conduct retrofitting operations on their used machinery/assembly of machinery and to provide a new CE mark and a new

¹ Guide to application of the Machinery Directive 2006/42/EC, ed.2.2, (§82, §39, 2th para. §72, 4th para. and §.140, 6th para. ref. to §.72, 4th para.)

² Guide to application of the Machinery Directive 2006/42/EC, § 72 New and used machinery

Machinery is considered as placed on the market when it is made available in the EU for the first time. The Machinery Directive therefore applies to all new machinery placed on the market or put into service in the EU, whether such machinery is manufactured in the EU or outside the EU.

In general, the Machinery Directive does not apply to the placing on the market of used or second-hand machinery. In some Member States, the placing on the market of used or second-hand machinery is subject to specific national regulations. Otherwise the putting into service and use of second-hand machinery for professional use is subject to the national regulations on the use of work equipment implementing the provisions of Directive 2009/104/EC – see §140: comments on Article 15.

There is one exception to this general rule. The Machinery Directive applies to used or second-hand machinery that was first made available with a view to distribution or use outside the EU when it is subsequently placed on the market or put into service for the first time in the EU.³¹ The person responsible for placing on the market or putting into service such used machinery for the first time in the EU, whether he is the manufacturer of the machinery, an importer, a distributor or the user himself, must fulfil all the obligations set out in Article 5 of the Directive.

The question arises as to when a transformation of machinery is considered as construction of new machinery subject to the Machinery Directive. It is not possible to give precise criteria for answering this question in each particular case. In doubt, it is therefore advisable for the person placing such rebuilt machinery on the market or putting it into service to consult the relevant national authorities.

³ Directive 2009/104/EC of the European Parliament and of the Council of 16 September 2009 concerning the minimum safety and health requirements for the use of work equipment by workers at work (second individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)

declaration of conformity, simply because they think they could shift their responsibility onto the manufacturer

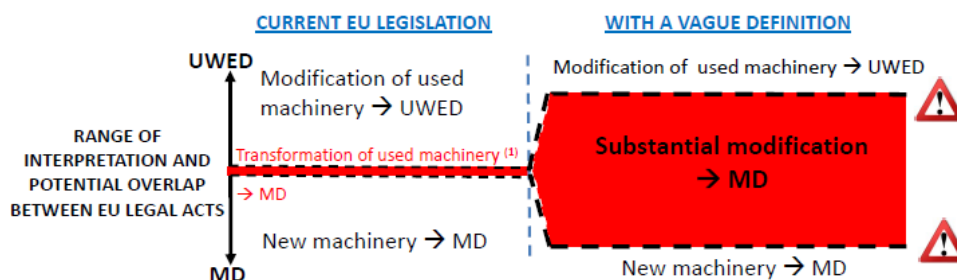
- Modification of used machinery (i.e. any change made on a machinery in service and not foreseen by the OEM) made without neither getting the consent nor even informing OEM can lead to incorrect modifications (i.e. machinery no more compliant with its original state of conformity) that soon or later will generate accidents
- Those incorrect modifications constitute a real and concrete safety issue for employees but also a responsibility issue for companies; both aspects should be clarified in the framework of existing user’s legislation
- At last, this is also an issue for market surveillance authorities because there is no traceability tool to identify a modification

From a pragmatic point of view, modifications of machinery exist since a very long time and will continue to exist in the future. For all the above-mentioned reasons, it would make sense to define at European level what a « modification » is, in the sense of UWED , having in mind that such definition should be broad enough in order to keep the legal responsibility of modifications in the remit of users and shall also be compatible with the existing business practices (e.g. refurbishment, remanufacturing).

About the introduction of the concept of “substantial modification” in the Machinery Directive

It has to be noted that:

- This term has no legal background and is used in the MDG to describe very different situations
- A definition with no objective criterion would open the door to multiple interpretations, the risk being to create a situation where almost any modification in the sense of UWED would be considered as a “substantial” one. Concretely, this would extend the scope of the Machinery Directive to used machinery creating de facto a legal issue between the two legal acts, MD and UWED.



(1) in the sense of §39, 2th para. §72, 4th para. and §.140, 6th para. ref. to §.72, 4th para. of MDG (1)

Figure 1 – Range of interpretation and potential overlap between EU legal acts

- Considering that a “substantially modified used machinery” would need to be CE-remarked, this legal issue would also result in a loss of credibility for CE marking: Indeed, considering that a third party is not able to fulfil all legal obligations at the design stage (because of a lack of skill and knowledge), it is to be expected that modified second-hand machinery with a new CE mark will emerge on the EU market alongside new machinery with the same CE mark. This will destroy the reputation of CE marking and create a competition distortion between OEM and modifiers.
- The application of the concept of “substantial modification” (i.e. fulfilment of all obligations of the MD at the date the substantial modification is realised), is unrealistic from a technical point of view: compliance with the principle of safety integration by design for the **entire machinery** (and not only the modified part), is impossible, especially for old machinery that would require a complete redesign and remanufacture, processes that would be technically difficult and economically unrealistic.
- With a broad meaning of the term « substantial modification », almost all modifications and operations such as retrofitting, remanufacturing, refurbishment made by OEM on used machinery would be considered

as substantial modifications. Considering the costs related to the application of the legislation in force at the date of the operation and the corresponding latest versions of European harmonised standards, such operations would have a huge economic impact both for OEM and users.

- As stated above, the concept of substantial modification is not used in either the NLF or the MD for the simple reason that their respective scopes stop at the 1st putting into service of a product. Introducing the concept of substantial modification in the MD will generate infinite discussions at European level without solving the responsibility issue nor the safety issue related to incorrect modifications of used machinery

Position: For the above-mentioned reasons, EVOLIS is of the opinion that introducing the concept of substantial modification in the Machinery Directive would not only be of no benefits to either OEM or users, but would also create confusion and thus dilute the distribution of responsibilities among the various economic operators in case of incorrect modifications.

All current concerns about modified machinery are based on the notion of “incorrect modification” and not “substantial modification”. In France, accidents linked to incorrect modifications of machinery have led to the drafting of a guide published in 2014 by the French Ministry of Labour and Ministry of Agriculture⁴.

⁴ “Technical Guide dated 18 November 2014 Relative to Modifications to Machinery in Service”, presenting the notion of “modification” as applied to machinery in service, and the rules that employers shall take into consideration when performing such an operation. It also indicates the prevention principles and procedures recommended in order to preserve or improve the safety of machinery.