

## INDUSTRY CONCERNS ABOUT THE INTRODUCTION OF “SUBSTANTIAL MODIFICATION” IN THE DRAFT OF THE FUTURE MACHINERY PRODUCT REGULATION

### ABOUT EVOLIS SYMOP

EVOLIS SYMOP is the French organisation representing the manufacturers of equipment goods.

EVOLIS and SYMOP joined forces on January 1 to form a single large organization of manufacturers of machinery and technological equipment for the entire industry. We represent 600 companies, 82,000 employees, and a turnover of €19 billion, 65% of which comes from exports. We are members of the European committees CECE, FEM, CECIMO, PNEUROP, EUROPUMP and CEIR and of the "Industry of the Future Solutions" strategic contract. Thanks to our technological innovations, we contribute to the competitiveness of all our client industries.

### EXECUTIVE SUMMARY

The concept of “substantial modification” recently introduced in the future **machinery product regulation (MPR)** is raising a lot of misunderstanding and significant concerns vis a vis its intention, its scope and all related consequences this will create for the relevant stakeholders (manufacturers, users,...) and in the same time, strangely enough, some past discussions and recommendations are today omitted in this theoretical debate. In any case, this matter cannot be separated from the notion of “modification” in the sense of user’s legislation.

### “MODIFICATION” OF MACHINERY IN SERVICE IN THE SENSE OF THE EUROPEAN USER’S LEGISLATION

Modifications of machinery in service is a proven practice since a very long time and will still remain a strong one for the next decades. Consequently, for all the reasons given in annex, **our organisation fully supports the improvement proposal highlighted in the last evaluation of the Use of work equipment directive (UWED) <sup>(1)</sup> and it’s interplay with related Directives consisting in publishing a guide on modifications of machinery in service <sup>(2)</sup> in the framework of this user’s legislation** (as already done by some member states), **keeping in mind that the legal responsibility of modifications shall be in the remit of users and also be compatible with the existing business practices (e.g. refurbishment, remanufacturing) and the objectives of a circular economy.**

### INTRODUCTION OF “SUBSTANTIAL MODIFICATION” IN FUTURE MACHINERY PRODUCT REGULATION

In order to avoid a lot of confusion and to dilute the responsibilities among the various stakeholders (manufacturers, users,...) and for all the reasons listed in annex, **our association is of the opinion that introducing the concept of “substantial modification” in the future MPR shall be absolutely framed according to the boundaries of the New Legislation Framework (NLF) and the European legislations currently enforced**, meaning that:

- **Either**, all modifications done after the putting into service should fall under the scope of UWED <sup>(1)</sup> as it is the case today, which then implies to **keep the concept of substantial modification only for machinery modified before its putting into service**
- **or**, if the legislator’s intention is to address “substantial modification” of used machinery in the future MPR, **this concept shall assimilate the substantial modification to a transformation i.e., defined by the criterion of a “change of the specific application”**, in the original spirit of the lawyers who drafted the annex to the guide of Directive 98/37/EC and that of the last interpretation guide of Directive 2006/42/EC

<sup>(1)</sup> 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 (UWED)

<sup>(2)</sup> page 4 of Evaluation of 2009/104/EC Work Equipment Directive and it’s interplay with related Directives, adopted by 68th SLIC Plenary in Riga

## Annex

### Background

Since a few years, the concept of “substantial modification” is being debated in the machinery sector. A careful reading of the guide for application of Machinery Directive (MDG) <sup>(3)</sup> 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.

To refer to this second case the MDG also uses the term “transformation”, which can be understood as rebuilding of a used machinery in order to provide a brand-new machinery (see MDG, § 72 *New and used machinery*).

The topic is not new and many discussions were held already over the last decades: Indeed, « transformation » is the term originally used in the 1<sup>st</sup> version of the guide related to 98/37/EC Machinery Directive, in a dedicated annex which insisted on the predominance of user legislation and equated a “transformation” of a machine with a redesign/rebuilding.

Besides, the last evaluation of UWED <sup>(2)</sup> published in 2017 highlighted an improvement proposal consisting in publishing a guide on modifications of machinery in service, in the framework of this user’s legislation.

Strangely enough, those past discussions and recommendations are today omitted in this theoretical debate.

### Current practice around the notion of “modifications” of machinery in service

- **This term has a legal background** (although there is no definition, it is explicitly used in the UWED <sup>(1)</sup> and it applies to machinery already in service
- UWED <sup>(1)</sup> 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**
- Despite this existing legal framework, **we acknowledge some confusion with some practices/operations coming from the field (confusion actually reinforced with the current debate):**
  - Some 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 declaration of conformity, to shift their responsibility onto the manufacturer.
  - Modification of used machinery made without neither getting the consent nor even informing the OEM can lead to incorrect modifications, i.e. the machinery is no more compliant with its original state of conformity, that soon or later will generate accidents. Those **incorrect modifications** (forbidden by law), constitute a real safety issue for employees but also a responsibility issue for companies;

**In both cases, those aspects should be clarified in the framework of existing user’s legislation.**

- At last, this ambiguity in the legal text is also an **issue for market surveillance authorities** because there is no traceability to identify a modification
- It has also to be reminded that the last evaluation of UWED and it’s interplay with related Directives <sup>(2)</sup> highlighted an improvement proposal consisting in **publishing a guide on modifications of machinery in service** in the framework of this user’s legislation, as already done by some member states <sup>(4)</sup>.

<sup>(3)</sup> 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.)

<sup>(4)</sup> 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.

## About the introduction of “substantial modification” concept in future Machinery Regulation

- In its legislative proposal of 21<sup>st</sup> April 2021 the European Commission gives the following definition:  
*“(16) ‘substantial modification’ means a modification of a machinery product, by physical or digital means after that machinery product has been placed on the market or put into service, which is not foreseen by the manufacturer and as a result of which the compliance of the machinery product with the relevant essential health and safety requirements may be affected”.*

Since then, this definition has been amended at several occasions by both the Council and the European Parliament and yet, still no objective criteria have been identified for determining whether a modification is substantial or not.

- Failing in defining properly what a “substantial modification” is will open the door to multiple interpretations, the risk being to create a situation where almost any modification in the sense of UWED<sup>(1)</sup> would be considered as a “substantial” one. Concretely, this would extend the scope of the Machinery Legislation to used machinery creating de facto a legal issue between the two legal acts MPR and UWED<sup>(1)</sup> (see fig. 1).

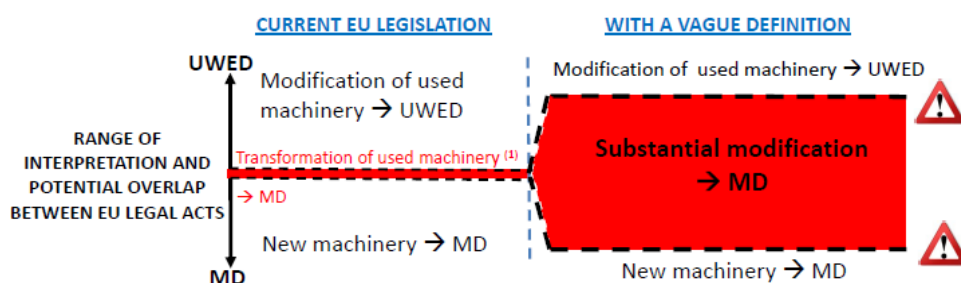


Fig. 1 - Range of interpretation and potential overlap between two EU legal acts

- 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, 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**, would be misleading for all economic operators 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 future Machinery Product Regulation (MPR) 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** (even only for the modified part and not the entire machinery), is impossible, especially for old machinery that would require a complete redesign and remanufacture, processes that would be **technically difficult and economically unrealistic**.
- Considering the costs related to the application of the legislation in force at the date of the modification together with the corresponding latest versions of European harmonised standards, **such operations would have a huge economic impact** both for OEM and users.
- 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 which is **in total contradiction with the circular economy**.
- We also would like to draw the attention on the difficulty the experts in the ESOs will have to assess all the hazards raising from all potential modification of a used machinery, based also on their foreseeable misuse. Yet, the introduction of such a concept in the MPR will create expectations from users and inevitable gaps in the coverage of relevant essential health and safety requirements. **The legislator should consequently clarify if and how this aspect is supposed to be addressed in harmonised standards**.