



## PRISE DE POSITION

# Regulatory framework for the modification of machineries

Courbevoie, the 27<sup>th</sup> of February 2018

### Context

During their lifespan, machineries placed on the market by manufacturers are often modified by third parties, in the following cases:

- A. Modification between the placing on the market and the first putting into service in the EU
- B. Modification after the first putting into service in the EU

For instance, these modifications can be performed by a distributor (case A) or by a third party on behalf of the user of the machinery (case B) and may have an impact on the conformity of the machinery.

On the field, we have identified several issues regarding the applicable legal framework when it comes to the modification of machinery. In particular, it appears that (case A) some distributors modify machineries without affixing a new CE mark, although the modification has an impact on the conformity of the product and (case B) some users consider that the modification of a machinery after it has been put into service implies a new CE mark.

In addition, the guidance provided by the « Blue Guide on the implementation of EU product rules (2016)<sup>1</sup> » (Blue Guide) or by the « Guide to application of the Machinery Directive 2006/42/EC<sup>2</sup> » (MD Guidelines) does not seem to be sufficient to provide clear answers to stakeholders. For instance, the concept of « substantial modification » given in the Blue Guide (chapter 2.1) is misleading.

The purpose of this position paper is to clarify, in the BtoB context, the implementation of the existing regulatory framework when a machinery is modified.

### Regulatory framework for the modification of machineries

The current European legislation provides two distinct legal frameworks, one for the placing on the market of machinery (Directive 2006/42/EC or MD<sup>3</sup>) and one for the use of work equipment (Directive 2009/104 /EC or UWED<sup>4</sup>). In this context, the applicability of MD concerns new machinery while the applicability of UWED concerns machinery after their putting into service, i.e. used machinery (see annex).

Any modification done to a machinery before its first put into service in the EU falls into the remit of the MD because it can still be considered as a new machinery. If the conformity of the machinery to the MD is not valid anymore, the MD must be applied once again by the person in charge of the modification. He is then considered as a manufacturer. This will lead to a new conformity assessment and a new CE mark under his own name/trademark.

Any modification done to a machinery after its first putting into service in the EU falls into the remit of the UWED. This Directive sets requirements that the employer must fulfill, concerning the minimum safety and health requirements for the use of work equipment by workers at work. In particular, article 4.2 states that the employer must ensure that the conformity and safety of the machinery is maintained at a level such that it complies with the provisions that were applicable when it was first put into service in the undertaking or establishment. This directive does not require to CE mark. In addition, provided the modified machinery

<sup>1</sup> [Blue Guide](#)

<sup>2</sup> [Machinery Directive Guidelines](#)

<sup>3</sup> [Machinery Directive](#)

<sup>4</sup> [Use of Work Equipment Directive](#)

is not new, the employer or any other economic operator would not be allowed to affix a new CE-mark (deceitful practice).

One specific case has to be highlighted. If an economic operator intends to design a new machinery and chooses to manufacture this machinery with parts from a used one (Re-build), then this shall not be considered as a modification. The economic operator is *de jure* a manufacturer, who has to perform a conformity assessment and affix the CE mark for this new machinery.

As a conclusion:

- In case a machinery is modified
  - Between the placing on the market and the first putting into service in the EU, provided the conformity and safety of the machinery has not been maintained at a level such that it complies with the provisions that were applicable when it was first made available by the manufacturer, the economic operator who has made the modification has to fulfill the MD requirements, i.e. a new conformity assessment and a new CE mark under his own name/trademark
  - After the first putting into service, the employer has to fulfil the UWED requirements, i.e. the conformity and safety of the machinery shall be maintained at a level such that it complies with the provisions that were applicable when it was first made available in the undertaking or establishment. No new CE mark is required.
- In case a new machinery is designed and manufactured with parts of a used machinery and new parts, then the manufacturer has to fulfil the requirements of MD and affix a CE mark on this new machinery.

In addition, it appears that the available guidance (Blue guide and MD guidelines) does not clearly capture the legal situation highlighted above, especially when it comes to the borderline between MD and UWED.

For instance, the Blue Guide (Paragraph 3.1) and the MD Guidelines (paragraphs 39, 82 and 140) introduce the concept of « substantial Modification », which is misleading because it is not legally defined, either in MD or in UWED.

These documents have to be clarified.

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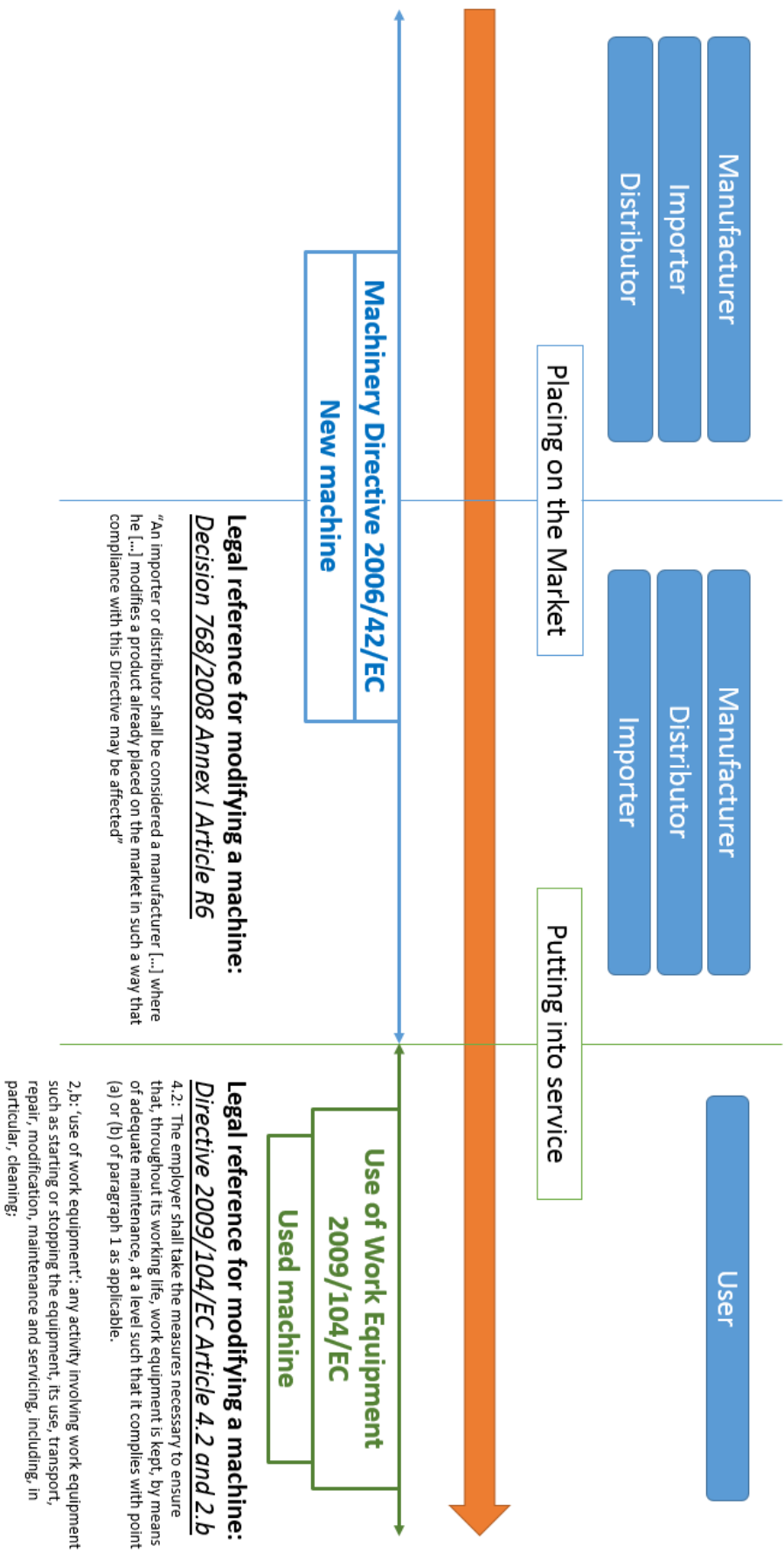
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Annex: Machinery modification: scope of the “MD” and the “UWED”



See also MD Guidelines §82

See also MD Guidelines §140 & §72