

Assemblies of machinery comprising new and existing machinery:

The Machinery Directive 2006/42/EC applies to machinery when it is first placed on the market and put into service in Switzerland, the EU, or the EEA. This is, in general, new machinery. For assemblies of machinery that comprise both new and already operational machinery, the employer must ensure that the conformity and safety of the machinery is maintained throughout its working life in accordance with the Ordinance on the Prevention of Accidents and Occupational Diseases (VUV, Articles 24 and 32).

In some cases, one or more of the constituent units of existing assemblies of machinery may be replaced with new units, or new units may be added to an existing assembly of machinery. This gives rise to the question as to whether an assembly of machinery comprising new and existing units is, as a whole, subject to the Machinery Directive 2006/42/EC. It is impossible to specify exact criteria that would be capable of answering this question in each particular case.

The following can serve as general guidelines, however:

1. If the replacement or the addition of a constituent unit in an existing assembly of machinery does not significantly affect the operation or the safety of the rest of the assembly, in that case, no further action is required. The employer in question remains responsible for the safety of the whole assembly according to the VUV (Articles 24 and 32).

If a partly completed machine is incorporated into an existing constituent unit of an assembly of machinery, the modified unit must fulfil the regulations of Machinery Directive 2006/42/EC.

2. If the replacement or the addition of new constituent units in an existing assembly of machinery has a substantial impact on the operation or the safety of the assembly as a whole or involves substantial modifications of the assembly, it may be considered that the modification amounts to the constitution of a new assembly of machinery to which the Machinery Directive 2006/42/EC must be applied. In such cases, the entire assembly, including all its constituent units, must comply with the provisions of Machinery Directive 2006/42/EC.

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Assemblies of Machinery – Key Aspects in Brief

Information on the implementation of the Machinery Directive

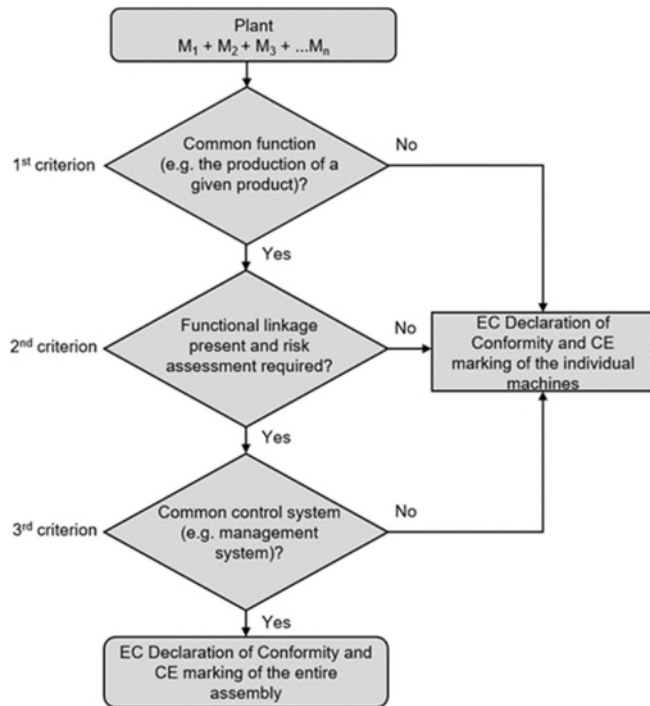
In the realm of industry, machinery (including partly completed machinery) from a variety of manufacturers is frequently purchased and operated as a collective system. According to the regulations of Machinery Directive 2006/42/EC, such arrangements of CE-marked machinery (and partly completed machines) can constitute what is referred to as an “assembly of machinery”. An assembly of machinery is subject to the same CE marking requirements as an individual machine.

This publication seeks to provide an overview on determining what constitutes an assembly of machinery and what to keep in mind in the process.

Definition of an assembly of machinery pursuant to Article 2 (a), indent 4 of Machinery Directive 2006/42/EC:

A collection of individual CE-marked machinery and partly completed machinery constitutes an assembly of machinery when it fulfils the following three criteria:

1. The constituent units are assembled in order to carry out a common function (for example, the production of a given product)
2. The constituent units are functionally linked in such a way that the operation of each unit directly affects the operation of other units or of the assembly as a whole, so that a risk assessment is necessary for the whole assembly,
3. The constituent units have a common control system (a management system, for instance))

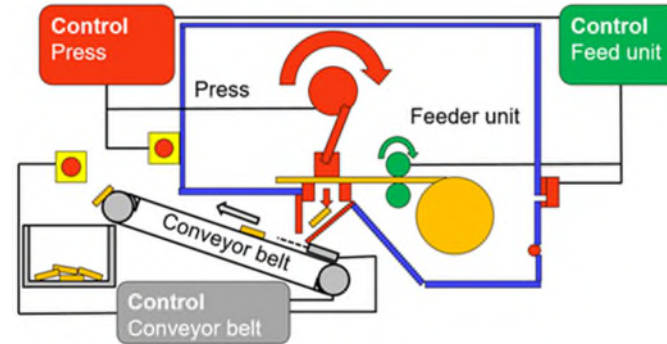


Source of fig. 1: Guide to application of the Machinery Directive 2006/42/EC, § 38, “Assemblies of Machinery”, Edition 2.2, Oct. 2019

The definition of assemblies of machinery does not necessarily cover a complete industrial plant consisting of a considerable number of machines and partly completed machinery from different manufacturers. However, for the application of the Machinery Directive 2006/42/EC, such large installations can usually be divided into sections which may be considered as assemblies of machinery.

An assembly of machinery comprising new machinery and new, partly completed machinery

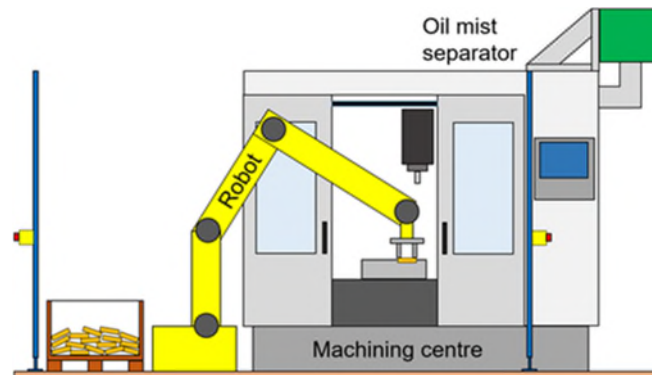
Example 1: Press, feeder unit, and conveyor belt:



Three criteria:	Feeder unit	Press	Conveyor belt
1. Common function (e.g. production of a given product)	√	√	√
2. Functional linkage present, risk assessment required	√	√	-
3. Common control system (e.g. management system)	√	√	-

The press and the feeder unit meet all three criteria and must thus be considered an assembly of machinery. A joint EC declaration of conformity is required for the press and the feeder unit. For the conveyor belt, the EC declaration of conformity provided by the manufacturer is sufficient.

Example 2: Machining centre, robot, and oil mist separator:



Three criteria:	Robot	Machining centre	Oil mist separator
1. Common function (e.g. production of a given product)	√	√	-
2. Functional linkage present, risk assessment required	√	√	-
3. Common control system (e.g. management system)	√	√	√

The machining centre and the robot meet all three criteria and must thus be considered an assembly of machinery. A joint EC declaration of conformity is required for the machining centre and the robot. For the oil mist separator, the EC declaration of conformity provided by the manufacturer is sufficient.

When an EC declaration of conformity needs to be issued for a given assembly of machinery, the entity that constructed (or commissioned the construction of) said assembly from individual constituent parts or partly completed machinery is considered the manufacturer. This entity can be the manufacturer of the individual machines or partly completed machinery, or the operator of the resulting assembly of machinery. This point should be clarified in a corresponding contract; otherwise, the operator in question is considered the manufacturer. The entity functioning as the manufacturer of a given assembly of machinery is responsible for ensuring that the entire assembly fulfils the health and safety requirements of Machinery Directive 2006/42/EC.

Manufacturer obligations with regard to assemblies of machinery:

- Creating the technical file in accordance with Machinery Directive 2006/42/EC, annex VII
 - Carrying out the process of risk assessment and risk reduction with a particular focus on the interfaces that connect the machinery at hand
 - Creating instructions for the assembly (part of which should include instructions and maintenance instructions for the individual machines)
- Performing the procedure required for the conformity assessment of assemblies of machinery in accordance with Machinery Directive 2006/42/EC, Article 12 and annexes VIII-X
- Creating and signing an EC declaration of conformity for the assembly of machinery in accordance with annex II of Machinery Directive 2006/42/EC
- Applying a separate nameplate with the specified information and CE marking to the assembly of machinery in accordance with annex III of Machinery Directive 2006/42/EC
- Adding the EC declarations of conformity and instructions for the complete machines in question (along with the declarations of incorporation and assembly instructions for partly completed machinery that have been incorporated into the assembly) to the technical file on the assembly of machinery, and detailing any modifications made to the individual units in said documentation of the assembly of machinery that were performed during incorporation in the assembly.