STIRRING and MIXING

LEGAL STATUS OF AGITATORS: PARTLY COMPLETED MACHINES (PCM) OR MACHINES?

GUIDE TO APPLICATION OF THE "MACHINERY SAFETY" LEGISLATION

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FOREWORD

Standardisation is, in general, a vector of our companies' strategy, in particular as a support for the conformity assessment of capital equipment in the field of machinery safety. Investment in standardisation is also an indicator of the health of our economy and our companies.

EVOLIS is a major player in the drafting of texts that govern the life of products (especially in the design-manufacturing phase) and actively participates in many programmes in this field.

With regard to the conformity assessment of capital equipment, our professional organisation has been working for many years on several aspects in parallel.

One of the main areas of work is to determine the legal status of certain machinery products under the European legislation on the safety of machinery (Machinery Directive 2006/42/EC). One of the most frequently asked questions is whether certain product is to be considered as machine or partly completed machinery, with the understanding that the legal obligations arising from the answer are quite different. This subject is a permanent line of work within EVOLIS, which this time has resulted in the publication of a new guide in the field of fluidic equipment, focusing on agitation-mixing equipment. It takes into account the typologies of equipment and the different cases related to the scope of supply of this equipment.

By providing this specific insight into the legal status of mixing equipment in relation to machinery safety legislation, we hope to contribute to a better understanding of the legal concepts and obligations and to better communication between the various economic operators and authorities.

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GUIDE TO APPLICATION OF THE « MACHINERY SAFETY" LEGISLATION

I. INTRODUCTION

The Machinery Directive 2006/42/EC was published on 9 June 2006 and entered into force on 29 December 2009, repealing Directive 98/37/EC.

It aims to harmonise the health and safety requirements for machinery on the basis of a high level of protection, in order to improve the safety of machinery placed on the market and to ensure its free circulation within the EU. It applies in particular to machinery and partly completed machinery.

This document is intended to indicate the legal status of agitators and mixers under the Machinery Directive 2006/42/EC and the corresponding obligations for manufacturers and integrators.

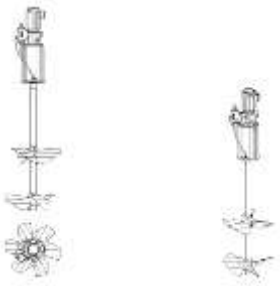
This guide does not deal with submersible mixers as defined in ISO 21630.

II. DÉFINITIONS

Agitator

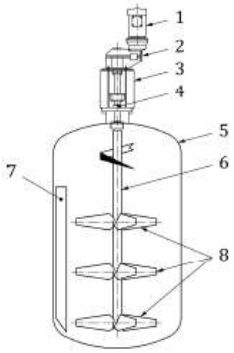
equipment for moving at least one liquid contained in a delimited tank [NF E 44-601].

Note: the word "agitator" is used in this document, in this context, it can be considered as a synonymous of "mixer"



Mixing unit

unit consisting of an agitator and a tank including fittings providing the mixing of liquid, paste or powder into the liquid continuous phase [NF E 44-601].



Key

1 motor
2 gear reducer
3 guiding lantern
4 seal
5 tank
6 shaft
7 baffle
8 impeller

Portable agitator

agitator designed to work with different tanks, the installation and removal of which on each tank is part of the foreseeable use described in the instruction manual.

Floating agitator

agitator that floats on the liquid in motion, during the operating phase.

Machine

- an assembly, fitted with or intended to be fitted with a **drive system other than directly applied human or animal effort**, consisting of linked parts or components, **at least one of which moves, and which are joined together for a specific application,**

- an assembly referred to in the first indent, missing only the components to connect it on site or to sources of energy and motion

- an assembly referred to in the first and second indents**, ready to be installed** and able to function as it stands only if **mounted on a means of transport, or installed in a building or a structure,**

- assemblies of machinery referred to in the first, second and third indents or partly completed machinery referred to in point (g) which, in order to achieve the same end, **are arranged and controlled so that they function as an integral whole**

[Extract from Article 2 (a), Machinery Directive 2006/42/CE]

Partly Completed Machinery (=PCM)

assembly which is almost machinery **but which cannot in itself perform a specific application**. A drive system is partly completed machinery.

Partly completed machinery is **only intended to be incorporated into or assembled with other machinery** or other partly completed machinery or equipment, thereby forming machinery to which this Directive applies;

[Article 2 (g), Machinery Directive 2006/42/CE]

Control system

System that responds to input signals from machine parts, operators, external control equipment or any combination of these and generates output signals that cause the machine to perform an expected behaviour.

NOTE 1: The machine control system may use any technology or combination of different technologies (e.g. electrical/programmable electronic, hydraulic, pneumatic, mechanical).

NOTE 2: Operating controls (push-buttons, levers, switches, handles, cursors, joystick, steering wheels, pedals, keyboards, touch screens) located on the machine itself or at a certain distance (connected by wires, radio signals, etc.) are external control equipment that are part of the control system.

[EN-ISO 12100]

III. INTERPRETATIONS AND EXAMPLE

Strictly reading the definition of a machine in the directive does not allow one to determine simply whether or not an agitator is a machine, especially given the different types of such equipment or their applications. To help determine this on a case-by-case basis, additional criteria must be used.

A. INTERPRÉTATIONS

Generally speaking, the use of an agitator requires one or more additional integrations. Indeed, the agitator cannot perform its function without :

- being integrated into a tank or fixed to the edge of the tank in the case of portable agitators
- and being connected to a control system (automated or not).

1. SUPPLY OF AN AGITATOR INTENDED TO BE INTEGRATED INTO A TANK

In many cases, for economic reasons, the integrator prefers to supply the tank separately from the agitator.

The manufacturer of the agitator is not responsible for the choice of material imposed by the customer. The integrator provides the dimensional characteristics of the tank, certain physical properties of the fluid to be mixed, or the materials of the mixing unit, and the manufacturer is responsible for sizing and manufacturing the device for moving the fluid, according to the specifications provided by the integrator.

The tank is neither a support (even if it can participate in the support function), nor a structure, but an essential component of the machine. The tank that holds the fluid to be mixed is intimately linked to the agitator. It is therefore an integral part of the machine (i.e. the mixing unit), whose specific application is to mix fluids.

The tank can also be fitted with devices for cooling or heating the agitated liquid, gas supply devices when the process needs to disperse gas to cause/sustain a reaction. It incorporates baffles necessary for a good agitation, in some cases, and the required devices for draining (or transfer to the next vessel). In a number of applications, the container also incorporates process monitoring devices.

In the case of an **agitator supplied alone** and manufactured according to the specifications provided by the integrator (depending on the tank in which it is to be integrated), this agitator is a **partly completed machinery** (Art.2 (g)).

WHAT ARE THE MANUFACTURER'S OBLIGATIONS?

The **manufacturer of the agitator alone** (without the tank) shall establish:

+ a relevant **technical documentation** which he keeps (see Annex 3)

+ a **declaration of incorporation** that accompanies the partly completed machinery (see Annex 3)

+ an **assembly instructions** accompanying the partly completed machinery (see annex 3).

As a reminder, for partly completed machinery, these are procedural and informative obligations and not a conformity assessment procedure, but the "essential requirements applied and fulfilled" of annex I of the Machinery Directive shall be declared.

The **integrator** as manufacturer of the machine shall **carry out a risk assessment, compile a technical file** that will include the declaration of incorporation and the assembly instructions provided by the manufacturer of the partly completed machinery and shall:

+ draw up and sign an **EC declaration of conformity**

+ affix the **CE marking** to the machine and

+ draw up an **instruction manual** dealing in particular with the residual risks associated with the various phases of use of the machine (transport, assembly/installation, maintenance, use, etc).

Assembly instructions are necessary for machinery or partly completed machinery which are **not delivered to the user ready for use**, e.g. where parts have been dismantled for packaging and transport purposes.

In the case of **machinery or partly completed machinery delivered without a drive system**, the instruction manual or the assembly instructions must provide all the specifications of the drive system to be installed, such as type, power and means of connection, and include precise assembly instructions for the drive system.

Installation instructions are also required for machines that are to be installed and/or fixed on particular supports, structures or buildings, on foundations or on the ground, to ensure safe operation and stability. The instructions must specify the required dimensions and load-bearing capacity of the supports and the means to be used to secure the machine to its supports.

The **connection instructions** must describe the measures to be taken to ensure the safe connection of the machinery to the power supplies, fluids, etc. The relevant characteristics of these supplies such as voltage, power, pressure or temperature must be specified.

The person who assumes legal responsibility for the conformity of the machinery with a view to placing it on the market under his own name or trademark shall ensure that he has sufficient control over the work carried out by his suppliers and subcontractors and that he is in possession of sufficient information to fulfil all his obligations under the Machinery Directive, as listed in Article 5.

2. WHETHER OR NOT TO PROVIDE A CONTROL SYSTEM

It is common for the manufacturer of the agitator to supply the equipment without a control system. In fact, the integrator or user generally prefers to define or program the control system himself, in order to

have a comprehensive safety system designed for his installations. He alone knows the type of premises, the manufacturing process of his plant and its operation, and the potential presence of operators in the vicinity during the various phases of the lifecycle (operating conditions, maintenance, etc.). He carries out a risk analysis (HAZOP for example) taking into account the recommendations of the manufacturer of the agitator.

In the case of the supply of an agitator and its tank without a control system, this assembly "agitator + tank" cannot alone be considered as a machine because it simply does not meet the definition of a machine (see definition of Machinery): "*an assembly fitted with or intended to be fitted with a drive system other than directly applied human or animal power, consisting of linked parts or components, at least one of which moves, and* ***which are joined together*** *for a specific application*.".

It is not enough that the agitator and the tank are mechanically joined to make them integral for mixing fluids. It is also necessary that the control system has been designed in a coherent way so that the "agitator + tank" assembly performs the specific application safely, taking into account all the phases in the life cycle of the mixing unit, including the maintenance phase. The control system may include control devices (on/off switch, emergency stop) and safety functions (parts of the control system related to the safety of the machine) that will automatically act on the control system of the machine to control moving parts (e.g. slow down/stop).

The design and construction of the control system and control devices to ensure safe and reliable operation of the machine are key factors in ensuring the safety of the machine as a whole. If the manufacturer of the agitator + tank assembly is not directly involved in the design of the control system, he cannot be responsible for the related risk assessment.

In this case, the "agitator + tank" assembly should be treated as a partly completed machinery.

On the other hand, when the equipment manufacturer controls the entire assembly (agitator + tank + control system), he can carry out a coherent and exhaustive risk assessment for the machine as a whole (mixing unit), based on the essential requirements of the Machinery Directive.

In this case, **the "agitator + tank + control system" assembly is a machine whose specific application** is the setting in motion of at least one fluid, for a precise purpose and in a context described by user specifications.

WHAT ARE THE OBLIGATIONS?

The **manufacturer of the "agitator + tank" assembly** shall establish:

+ a relevant **technical documentation** which he keeps (see Annex 3)

+ a **declaration of incorporation** to accompany the partly completed machinery (see Annex 3)

+ the **assembly instructions** that accompanies the partly completed machinery (see annex 3)

The integrator or designer of the assembly "agitator + tank + control system", as manufacturer of the machine, shall **carry out a risk assessment**, **compile a technical file** that will include the declaration of incorporation and the assembly instructions supplied by the manufacturer of the partly completed machinery and shall:

+ draw up and sign an **EC declaration of conformity**

+ affix the **CE marking** to the machine and

+ draw up an **instruction manual**

Note: Delivering equipment without its cables or components allowing it to be connected to its energy source **does not allow the conclusion that it is not a machine** (cf. 2nd indent of Article 2a of the Machinery Directive and Annex 1: §36 of the application guide).

3. CASE OF PORTABLE AGITATORS

Unlike the agitators described above, portable agitators are not intended to be integrated into a tank, but rather to be attached to the edge of the tank. Although they are ready to be installed, they can only function once they have been mounted on a structure (tank or basin. These agitators are standard equipment whose design and construction are not linked to the tank. They can be delivered with or without their lifting means.

They therefore meet the definition of a machine and in particular indent 3 of article 2 "assembly referred to in the 1st and 2nd indents, **ready to be installed** and able to **function as it stands only if mounted on a means of transport or installed in a building or a structure**", if they are fitted with their control system guaranteeing their safe operation in all phases of the equipment's life cycle.

Portable agitators delivered with their control systems are therefore **machines whose specific application is fluid agitation.**

B. SUMMARY TABLE

The table below identifies and classifies different types of agitators:

Type	Supply	Key notions	Illustration annex I	Classification	Provider's Obligations	Customer's Obligations
Portable agitator	Agitator provided with its control system	Machine by definition	Figures 2-4, 2-5, 2-6	Machine	CE Marking – DoC (*)	
	Agitator provided without control system	Are not joined together to fulfil a specific application Comprehensive risk assessment Impossible	Figure 1-5	Partly completed machinery	DoI (*) – Assembly instructions	CE Marking - DoC of the assembly constituted (*)
Agitator permanently fixed on a tank	Agitator + container, but without control system	Are not joined together to fulfil a specific application Comprehensive risk assessment Impossible	Figure 1-4	Partly completed machinery	DoI (*)– Assembly instructions	CE Marking – DoC of the assembly constituted (mixing unit) (*)
	Agitator + control system + tank	Machine by definition	Figures 2-1, 2-2, 2-3	Mixing fluid machine (= mixing unit)	CE Marking – DoC (*)	
	Agitator + control system but without the associated tank	Comprehensive risk assessment impossible if the design of the agitator depends on the characteristics of the container	Figure 1-2	Partly completed machinery	DoI (*) – Assembly instructions	CE Marking – DoC of the assembly constituted (mixing unit) (*)
	Agitator alone	Cannot fulfil its function. Comprehensive risk assessment Impossible	Figures 1-1 1-2, 1-3	Partly completed machinery	DoI (*) – Assembly instructions	CE Marking – DoC of the assembly constituted (mixing unit) (*)
Floating Agitator	Agitator with its control system	Machine by definition		Machine	CE Marking – DoC (*)	
	Agitator without control system	Cannot fulfil its function. Comprehensive risk assessment impossible	Figure 1-6	Partly completed machinery	DoI (*) – Assembly instructions	CE Marking – DoC of the assembly constituted (mixing unit) (*)

DoC : declaration of conformity

DoI : declaration of incorporation

Annex I Illustrations of the different cases and possible supplies

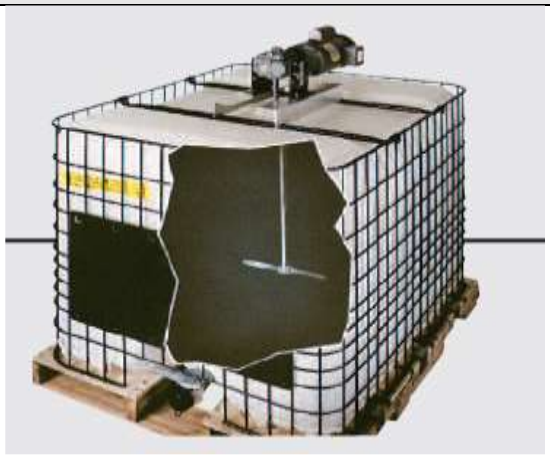
1. EXAMPLES OF PARTLY COMPLETED MACHINERY

Pendulum agitators	
Figure 1-1 : examples of pendulum agitators Agitator to be integrated in a tank and associated with a control system, not constituting a machine	
Figure 1-2 : pendulum agitators with a control system Agitator to be integrated in a tank, not constituting a machine	
Horizontal and lateral agitators	
Figure 1-3 : horizontal agitator to be integrated in a tank Agitator to be integrated in a tank, not constituting a machine	

Figure 1-4 : horizontal agitator fixed to a tank Agitator fixed to a tank. Without the control system, it does not constitute a machine	
Portable agitator	
Figure 1-5 : agitator to be controlled by lifting means Agitator that is intended to operate in a slave mode with a “up and down” mast (lifting means) The agitator supplied alone, without a “up and down” mast, or without its control system, is a **Partly completed machinery**	
Floating agitator	
Figure 1-6 Floating agitator Agitator to be installed in a lagoon. Usually the control system is not delivered: it is a **Partly completed machinery**	 

2. MIXING UNITS AND AGITATORS AS MACHINES

Mixing unit with pendulum agitators	
Figure 2-1 : mixing unit Supplied equipment : the agitator integrated into a tank and the control system. The assembly is fully equipped to perform its function, it is indeed a **machine**. Note: depending on frequency and maintenance needs, permanent means of access may be provided.	
Figure 2-2 : pendulum agitator after integration in its tank Agitator for chemistry, installed by the integrator on an open tank. The equipment cannot perform its agitation function without this integration. The manufacturer of the agitator has manufactured it to the customer's specifications so that it can be integrated into an existing tank. The complete assembly, including the tank and the control system, constitutes **a machine** and must fulfil all associated requirements.	
Figure 2-3 : pendulum agitator after integration in an open tank The complete assembly, including the control system, constitutes **a machine** and must fulfil all associated requirements.	

Portable agitators	
Figure 2-4 : portable pendulum agitator on IBC container Agitator whose function, apart from agitation, is to be able to be moved from one tank to another. It is a machine.	
Figure 2-5 : portable agitator positioned at the edge of the tank. A manually operated portable agitator, requiring no integration, this type of agitator is only attached to the edge of the tank to perform its specific application (agitation of fluids). The equipment can also be moved or manipulated by the operator during operation. It is **a machine**.	
Figure 2-6 : agitator controlled by lifting means An agitator to be operated in a servo-controlled manner with a “up and down” mast (lifting means) Supplied as a whole assembly : it is a machine	

Annex II: Extracts of the Guide to application of the Machinery Directive

Article 2 (a) - second indent

. . .

'machinery' means:

. . .

- an assembly referred to in the first indent, missing only the components to connect it on site or to sources of energy and motion,

. . .

§36 Machinery supplied without connection components.

The second indent of the definition of machinery recognizes that the characteristics of the components needed to connect a machine on site to the sources of energy and motion may depend on the site where the machinery is to be used or installed. Machinery may therefore be supplied without these components. In that case, the machinery manufacturer must set out in his instructions all the necessary specifications for the safe means of connection.

Article 2 (a) – fourth indent

. . .

'machinery' means:

. . .

- assemblies of machinery referred to in the first, second and third indents or partly completed machinery referred to in point (g) which, in order to achieve the same end, are arranged and controlled so that they function as an integral whole,

. . .

§38 Assemblies of machinery

The fourth indent deals with assemblies of machinery consisting of two or more machines or partly completed machines assembled together for a specific application. Assemblies of machinery may be constituted by two units such as, for example, a packaging machine and a labelling machine, or by several units assembled together, for example, in a production line.

The definition of assemblies of machinery indicates that assemblies are arranged and controlled so that they function as an integral whole in order to achieve the same end. For a group of units of machinery or partly completed machinery to be considered as an assembly of machinery, all of these criteria must be fulfilled:

- the constituent units are assembled together in order to carry out a common function, for example, the production of a given product;
- 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;
- the constituent units have a common control system – see §184: comments on section 1.2.1, and §203: comments on section 1.2.4.4 of Annex I.

A group of machines that are connected to each other but where each machine functions independently of the others is not considered as an assembly of machinery in the above sense.

Annex III: Documentation to be provided by the manufacturer of partly completed machinery

Assembly instructions for partly completed machinery

[Annex VI of the Machinery Directive 2006/42/EC]

The assembly instructions for partly completed machinery must contain a description of the conditions which must be met with a view to correct incorporation in the final machinery, so as not to compromise safety and health.

The assembly instructions must be written in an official Community language acceptable to the manufacturer of the machinery in which the partly completed machinery will be assembled, or to his authorised representative.

Declaration of incorporation of partly completed machinery

[Annex II.1.B of the Machinery Directive 2006/42/EC]

This declaration and translations thereof must be drawn up under the same conditions as the instructions (see Annex 1, section 1.7.4.1(a) and (b)), and must be typewritten or else handwritten in capital letters.

The declaration of incorporation must contain the following particulars:

1. business name and full address of the manufacturer of the partly completed machinery and, where appropriate, his authorised representative;

2. name and address of the person authorised to compile the relevant technical documentation, who must be established in the Community;

3. description and identification of the partly completed machinery including generic denomination, function, model, type, serial number and commercial name;

4. a sentence declaring which essential requirements of this Directive are applied and fulfilled and that the relevant technical documentation is compiled in accordance with part B of Annex VII, and, where appropriate, a sentence declaring the conformity of the partly completed machinery with other relevant Directives. These references must be those of the texts published in the Official Journal of the European Union;

5. an undertaking to transmit, in response to a reasoned request by the national authorities, relevant information on the partly completed machinery. This shall include the method of transmission and shall be without prejudice to the intellectual property rights of the manufacturer of the partly completed machinery;

6. a statement that the partly completed machinery must not be put into service until the final machinery into which it is to be incorporated has been declared in conformity with the provisions of this Directive, where appropriate;

7. the place and date of the declaration;

8. the identity and signature of the person empowered to draw up the declaration on behalf of the manufacturer or his authorised representative

Relevant technical documentation for partly completed machinery
[Annex VII.B of the Machinery Directive 2006/42/EC]

This part describes the procedure for compiling relevant technical documentation. The documentation must show which requirements of this Directive are applied and fulfilled. It must cover the design, manufacture and operation of the partly completed machinery to the extent necessary for the assessment of conformity with the essential health and safety requirements applied. The documentation must be compiled in one or more official Community languages.

It shall comprise the following:

(a) a construction file including:
- *— the overall drawing of the partly completed machinery and drawings of the control circuits,*
- *— full detailed drawings, accompanied by any calculation notes, test results, certificates, etc., required to check the conformity of the partly completed machinery with the applied essential health and safety requirements,*
- *— the risk assessment documentation showing the procedure followed, including:*
  - *(i) a list of the essential health and safety requirements applied and fulfilled,*
  - *(ii) the description of the protective measures implemented to eliminate identified hazards or to reduce risks and, where appropriate, the indication of the residual risks,*
  - *(iii) the standards and other technical specifications used, indicating the essential health and safety requirements covered by these standards,*
  - *(iv) any technical report giving the results of the tests carried out either by the manufacturer or by a body chosen by the manufacturer or his authorised representative,*
  - *(v) a copy of the assembly instructions for the partly completed machinery;*

(b) for series manufacture, the internal measures that will be implemented to ensure that the partly completed machinery remains in conformity with the essential health and safety requirements applied.

The manufacturer must carry out necessary research and tests on components, fittings or the partly completed machinery to determine whether by its design or construction it is capable of being assembled and used safely. The relevant reports and results shall be included in the technical file.

The relevant technical documentation must be available for at least 10 years following the date of manufacture of the partly completed machinery or, in the case of series manufacture, of the last unit produced, and on request presented to the competent authorities of the Member States. It does not have to be located in the territory of the Community, nor does it have to be permanently available in material form. It must be capable of being assembled and presented to the relevant authority by the person designated in the declaration for incorporation.

Failure to present the relevant technical documentation in response to a duly reasoned request by the competent national authorities may constitute sufficient grounds for doubting the conformity of the partly completed machinery with the essential health and safety requirements applied and attested.