

## POSITION PAPER

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# Orgalim Contribution to the Guide of Interpretation to the Machinery Directive 2006/42/Ec

## Provision of instructions by the manufacturer of a machine

### Background

The current Machinery Directive 2006/42/EC, Annex I, section 1.7.4. does not specify whether the instructions should be made available in paper or electronic format however, the Guide of Interpretation to the Machinery Directive (edition July 2017) states that the economic operator has the possibility to provide them in electronic file, but without giving further clarification.

In this paper, Orgalim would like to suggest some clarifications to the explanations provided in the guide of interpretation, give practical examples on the different formats in which the instructions can be provided and justify the benefits of each of the alternative means of providing instructions. Finally, we would like to submit a new text to be taken on board in the next revision of the guide.

In line with the opinion expressed by other stakeholders at the last meeting of the Machinery Working group, Orgalim believes that economic operators need a flexible approach on this issue as a one size fits all solution does not work and the possibility to deliver instructions in digital formats besides the paper form offers many opportunities in terms of usability for all parties involved.

### Introduction

When placing machines on the market, the information and in particular the instructions provided by the economic operator on the safe use of machines can take various forms. Indeed, in most cases, the machinery is delivered to an end customer or an employer- who puts the machine into service and uses it themselves or alternatively, makes the machine available to their employees to perform their work.

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One important point is that flexibility should be offered to the economic operator to decide together with the next person in the value chain, which form of the instructions would suit their needs best. This flexibility should be extended along the whole value chain.

### **Legal obligation of the manufacturer**

The availability of the instructions is one of the Essential Health and Safety requirements set out in Annex I of the Machinery. All the requirements laid down in this Annex I are formulated in a technology-free manner, and this is also valid for the form of instructions. The only requisite is that these Essential Health and Safety requirements must be fulfilled by the manufacturer by choosing the technology that represents the State of the Art.

Therefore, based on the provisions of the Machinery Directive, the manufacturer is also free to choose the most suitable technology to provide the information on the safe use of machines, as long as the requirements are met and that whatever format is chosen by the economic operator in the value chain, the instructions will remain available to the user.

### **Requirements in relation to the provision of information for users.**

According to Article 5(1) of the Machinery Directive, the manufacturer must provide all the necessary information, in particular the instructions. As set out in the Essential Health and Safety requirements of Annex I, no 1.7.4., the following requirement must be met:

“All machinery must be accompanied by instructions in the official Community language or languages of the Member State in which it is placed on the market and/or put into service”.

The objective of this provision is to ensure that the instructions accompany the machine until it reaches the next economic operator in the value chain. The sole responsibility of the manufacturer is to supply the instructions to the next economic operator (user/customer/employer). After that, the manufacturer will not have any further responsibility (and does not have any further ability) to continue guaranteeing that the instructions will remain with the machine.

As the machine travels through the value chain, from the first placing on the market to the final economic operator, the risk that paper instructions become separated from the equipment grows.

Electronic instructions under various formats would enable manufacturers to meet the requirements of this provision, linked to the State of the Art and promote the use of digital means of information.

Below are some examples of how instructions can be communicated in practice, so that this information is also made available for the use of the machinery.

1. The manufacturer places the machinery on the market along with instructions in paper form. The instructions are contained in the machine’s packaging.

2. The instructions are integrated in the operator interface of the machine's control system. They can be downloaded by the user to use them on other devices. For most of the activities on and with the machinery, the information relating to such activities is available to the user in the instructions integrated in the machine's control system. For standard activities (foreseen by the manufacturer) for which the operator interface of the machine's control system is not available to the operator, the manufacturer provides instructions containing additional information which is not covered by the instructions integrated in the control system. The additional instructions can always be provided in either paper or electronic form.
3. The customer wishing to use the machine or allow it to be used, requests that the instructions are communicated in electronic form. The electronic instructions are made available to the customer's employees on devices. The customer provides their employees with the devices for reading the instructions.
4. The customer takes delivery, as described in no 3, of not just one item of a specific type of machine but a number of items of that type. All the other elements are identical to case 3.
5. The manufacturer delivers the machinery to a distributor and provides them with the instructions in the official languages of the EU in electronic format (or in paper format upon request). In turn, the distributor delivers the machinery with the instructions to the next economic operator in the required language version, either in electronic format or in paper format.
6. The machinery is accompanied by a quick start guide in paper form which contains the most important safety instructions and information on starting/operating/stopping the machine, derived from the original instructions which are available online free of charge.
7. In some cases, the customer, who is an employer, requests a copy (either paper or electronic format) of the instructions from the manufacturer of the machinery before the machinery is delivered in order to fulfil their responsibilities as an employer ahead of the arrival of the new machines. In this case the instructions are communicated in paper form or in electric form. If communicated in electronic form, they are supplied on an electronic data carrier or as a download from a website address made known to the customer. The customer undertakes, on the basis of contracts under private law, to make the information available to their employees in the required form. The instructions do not accompany the machinery, but all the provisions of the Machinery Directive with respect to the provision of the instructions are nevertheless fulfilled.

### General consideration in relation with the compilation and the provision of the instructions

- The objective of the provision of the Machinery Directive is that the instructions are delivered with the machine to the user. This is valid for all economic operator in the value chain.
- The manufacturer sells the machine to a distributor who in turn, sells the machine to a customer in a different Member State of the European Union. The distributor takes delivery of the machinery and of the instructions in electronic form in all the required official languages of the European Union. The distributor supplies their customer with the machinery together with the instruction in the require language version in paper format.
- The choice of technology for the establishment and delivery of the instructions is responsibility of the various economic operators along the value chain: manufacturer, importer, distributor, customer. Each economic operator who is responsible for the delivery of the machine to the next user in the value chain will decide together with the next user on the most practical format in which to receive the information.

- In relation to the choice of technology for the delivering of information to the first economic operator, the manufacturer must fulfil all the requirements of the Machinery Directive.

## Conclusion

The examples above have been provided to show that in daily business, it is important that the flexibility offered by the Machinery Directive is available to all economic operators.

To this end, Orgalim would request an amendment of paragraph 255 in the guide of interpretation to the Machinery Directive 2006/42/EC

## New § 255 The form of the instructions

The form of the instructions is not specified in accordance with the provisions of point 1.7.4., since the Essential Health and Safety requirements of Annex I are formulated in a technology-free manner. The requirements for the instructions are an integral part of these Essential Health and Safety requirements.

When carrying out the conformity assessment procedure, the manufacturer must determine which form of the instructions is best for the next economic operator in the value chain. This also applies to cases in which the machinery is delivered directly to the user or the machinery is put into service at the user's premises. The manufacturer must also take into account whether the contents of the instructions are accessible and usable by the economic operator or the user. They shall also take into account the technical requirements which are usually met by the next economic operator in the supply chain or by the user. In the case of electronic formats of the instructions, the manufacturer must ensure that the selected data format or formats are legible by the next economic operator to whom they are delivered. If the instructions are made available as a download, the accessibility of the website or the data source during the expected service life of the machinery must be ensured.

The operating instructions can be provided in the following forms:

- Instructions in paper form
- Instructions in electronic form on a data carrier
- Instructions in electronic form as download from a website or similar sources
- Instructions in a combination of paper form and electronic form
- Instructions in a combination of a Quick-Start Guide and instructions in paper or electronic form
- Instructions integrated into the control system of the machinery
- Combinations of the cases described above.

## Description of the Quick-Start Guide

The Quick Start Guide is a document in paper format that accompanies the machine when placed on the market, which provides information allowing the user to operate the machine in a safe manner . It is to be

used in combination with the full instruction manual, which is to be made available by other means, e.g. digitally, on paper by request.

The minimum content of the Quick Start Guide is to cover:

- Product identification
- Sources of information (via e.g. QR code)
- Contents of the package delivered to the user (if applicable)
- Applicable safety warnings
- Instructions for the final assembly of the product (if applicable)
- Instructions for operating the product

The information included in the Quick Start Guide must by no means contradict the content of the full instructions. Consequently, it is fundamental that information used in the Quick Start Guide is identical to that used in the full instructions. The Quick Start Guide will provide the contact information for accessing the full instructions, for example QR codes.

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