

GUIDELINE FOR
MANUFACTURES AND
END-USERS

Transformation of machinery

Substantial modification versus
non-substantial modification



Abbreviations

Abbreviations

DoC	Declaration of Conformity
OEM	Original Equipment Manufacturer
PCM	Partly Completed Machinery

EU directives & regulations

EMC	Electromagnetic Compatibility Directive 2014/30 EU
LVD	Low Voltage Directive 2014/35/EU
MD	Machinery Directive 2006/42/EU
MD-Guide	Guide to the application of the Machinery Directive-edition 2.2
WED	Working Equipment Directive 2009/104/EU



Colophon

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Preface

Modification of existing machines is a frequently occurring issue that is one of the unclear areas of compliance within European regulations.

Practice shows that the consideration of the problems so far is either viewed from the European Machinery Directive or from the end user's perspective, who is mainly confronted with the European Work Equipment Directive. A new perspective is the circular economy that focuses on a sustainable deployment and lifetime extension of the machine or the machine configuration.

A number of parties is involved in this matter, such as machine builders, users of machines and machine engineers maintenance companies, consultants, installation companies, component suppliers and component system suppliers.

The Machinery Directive, where this issue has been frequently raised, focuses in particular on meeting the essential safety requirements when the product is placed on the market or put into service for the first time. The Work Equipment Directive particularly focuses on the end-user and requires a safe work-tool and primarily imposes that responsibility on the employer/user of the machine.

This document is intended for end-users, original equipment manufacturers (OEM) and service support providing companies that become involved in modifications of machinery and/or assembled machinery.

This guideline intends to help end-user, original equipment manufacturer and service support providers with an approach to determine whether or not a substantial modification of machinery applies. This guideline furthermore provides practical tools to determine scope and deliverables. But also in case the modification can be considered as a minor one guidance is provided as even then there are legal obligations for those who are involved.

This guideline also focusses on the responsible parties when modifying machines. The attribution of responsibility and the legal consequences play an important role if something is questioned regarding the final technical safety of substantially modified machinery.

Position papers from other European countries are also taken into consideration as an input for the positioning in the Netherlands, and, on the other hand to strive to a harmonized and workable framework within Europe.

For ease of use of this guideline, texts taken from the Machinery Directive 2006/42/EU are printed in green italic, text taken from the Guide to the application of the Machinery Directive 2006/42/EU version 2.2 are printed in blue italic.

FME-RNCM, Zoetermeer

FME is the Dutch association for the technology sector and represents the interests of its members both national and international.

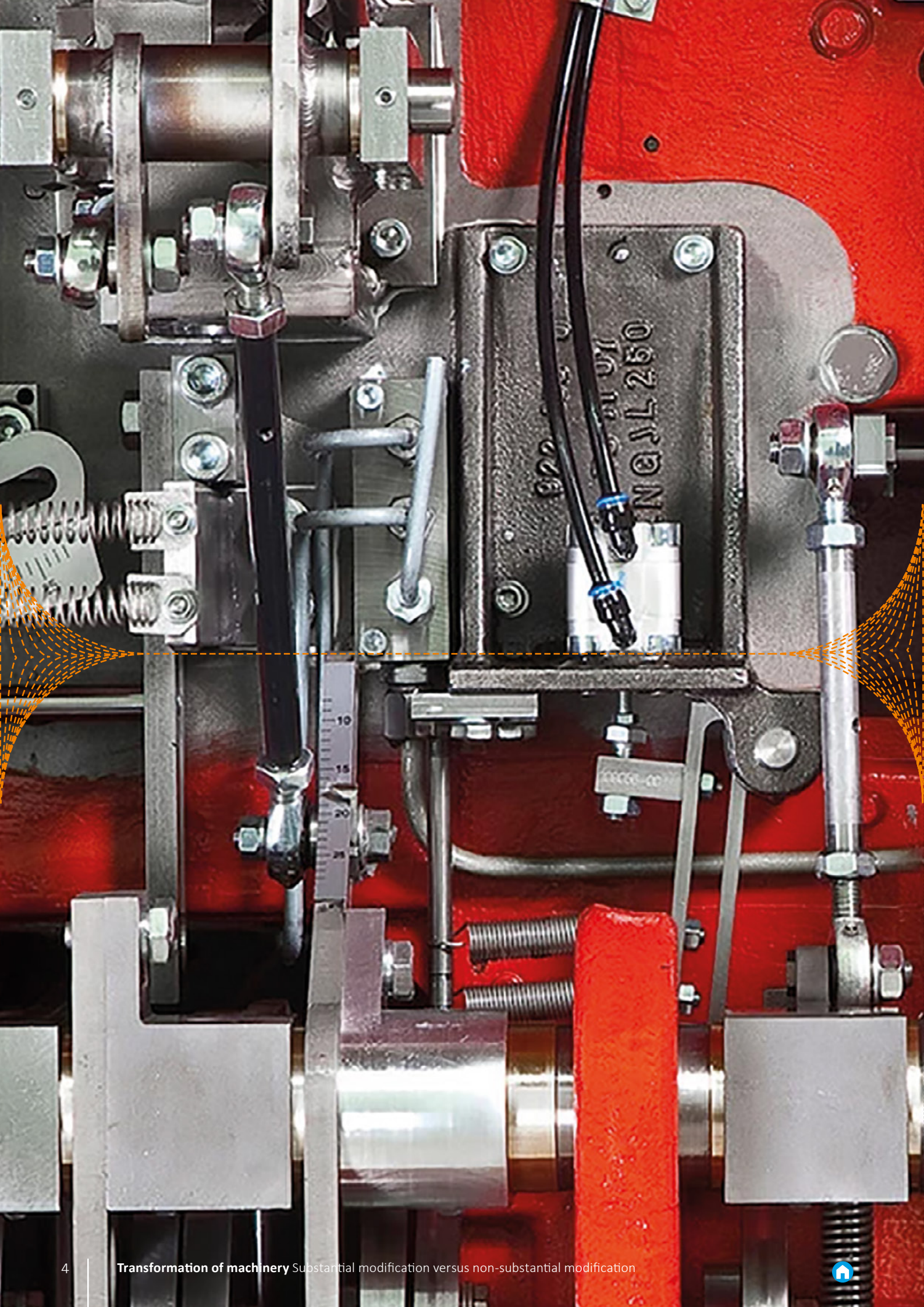
FME-RNCM is FME's core group of machinery manufacturers and represents the interests of the machinery sector in the field of regulation, standardization and certification.





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1 Introduction & scope

Transformations of machines are carried out as the end-user intends to improve the overall performance of the machinery, by renewing vital parts of the machinery and/or to adapt his production process to new demands. Sometimes existing machinery is modified or refurbished to prevent procurement of new machinery (saving costs). Simultaneously one has to observe international & national law to prevent that machinery becomes unsafe or non-compliant due to the modification. Existing machinery that is being transformed, may no longer comply with the essential health & safety requirements of the Directive(s) applicable at the moment of first time placing on the market or putting into service.

In addition it may happen that existing machines are used as a donor to create other machinery that was not in use before or appears on the European market for the first time in that configuration. Both situations require that the machine must be assessed for conformity with the provisions of the applicable and actual European product regulation; in this case mainly Directive 2006/42/EU and other applicable directives.

Legal duties apply to manufacturers (fulfilling the Machinery Directive and other applicable directives), to employers and to owners of machinery in general. Where regulation on machine safety and labour safety are relatively explicit on requirements, the duties to care for machinery for owners is less explicit. Manufacturers have a responsibility towards the end user either a employer or a consumer to provide them with safe machinery, where employers have a duty directly related to health and safety for their employees.

This document gives guidance to determine substantial modification of machinery and per consequence the need for re-affirmation of the conformity of the product. It will also give guidance to determine the responsibilities between parties involved in the process. Machinery for use at home (“do-it-yourself”) for consumers is not covered in this document, nevertheless good practice can also be applied in case such machinery is being transformed.

This document aims at transformation of professional machinery related to the Machinery Directive. Specific applications related to specific directives have not been taken into consideration, e.g.:

- Machinery for use in explosive atmospheres (ATEX 114/Directive 2014/34/EC)
- Machinery having integrated telecom devices (Radio Equipment Directive (RED) - 2014/53/EC)
- Machinery with integrated measuring devices (Measuring Instruments Directive (MID) - 2014/32/EC)
- ROHS and REACH
- Food contact materials (EU 2004/1935)

Nevertheless a modification of a machine can also affect the other specific applicable directives that should be taken into consideration.

2 Present EU machinery regulation

2.1 The scope of the Machinery Directive 2006/42/EG

The Machinery Directive 2006/42/EU only refers to machinery being placed on the market and/or put into operation **for the first time** (Machinery Directive 2006/42/EC, article 2 - h). The MD does **not refer to existing machinery being transformed (modified)**.

Definitions

For the purposes of this Directive, 'machinery' designates the products listed in Article 1(1)(a) to (f).

The following definitions shall apply:

...

(h) 'placing on the market' means making available for the first time in the Community machinery or partly completed machinery with a view to distribution or use, whether for reward or free of charge;

...

Figure 1 -Machinery Directive 2006/42/EC, article 2-h

2.2 The Guide to the application of the Machinery Directive

2.2.1 The Guide and modification of Machinery

The *Guide to the application of the Machinery Directive 2006/42/EU (EU-October 2019-ed.2.2)*. explains that transformation of machinery may affect the conformity of the concerned machinery. **In paragraph 72** where it refers it is stated that such transformation may lead to new machinery.

Paragraph.72.

Machinery is considered as placed on the market when it is made available in the EU for the first time. The Machinery Directive therefore applies to all new machinery placed on the market or put into service in the EU, whether such machinery is manufactured in the EU or outside the EU.

In general, the Machinery Directive does not apply to the placing on the market of used or second-hand machinery. In some Member States, the placing on the market of used or second-hand machinery is subject to specific national regulations. Otherwise the putting into service and use of second-hand machinery for professional use is subject to the national regulations on the use of work equipment implementing the provisions of Directive 2009/104/EU – see §140: comments on Article 15.

There is one exception to this general rule. The Machinery Directive applies to used or second-hand machinery that was first made available with a view to distribution or use outside the EU **when it is subsequently placed on the market or put into service for the first time in the EU**. The person responsible for placing on the market or putting into service such used machinery for the first time in the EU, whether he is the manufacturer of the machinery, an importer, a distributor or the user himself, must fulfil all the obligations set out in Article 5 of the Directive.

The question arises as to when a transformation of machinery is considered as construction of new machinery subject to the Machinery Directive. It is not possible to give precise criteria for answering this question in each particular case. In doubt, it is therefore advisable for the person placing such rebuilt machinery on the market or putting it into service to consult the relevant national authorities.

Figure 2-Guide to the application of the Machinery Directive 2006/42/EC, edition 2.1, paragraph 72

2.2.2 Modification on request of the customer before putting into service

Paragraph 82 of the Guide describes that **new machinery substantially modified** not by the OEM and not foreseen by the OEM before putting into service requires a renewal of the declaration by the party that modifies.



Paragraph 82

In some cases, machinery is sold to an importer or a distributor who then modifies the machinery at the request of a customer before the machinery is put into service for the first time. If the modifications were foreseen or agreed by the manufacturer and covered by the manufacturer's risk assessment, technical documentation and EU Declaration of Conformity, the original manufacturer's CE marking remains valid. *On the other hand, if the modification is substantial (for example, a change of function and/or performance of the machinery) and not foreseen or agreed by the manufacturer, the original manufacturer's CE-marking becomes invalid and has to be renewed – see §72: comments on Article 2 (h). The modifier is then considered as the manufacturer and must fulfil all the obligations set out in Article 5 (1).*

Figure 3-Guide to the application of the Machinery Directive 2006/42/EC, edition 2.1, paragraph 82

2.2.3 Existing machinery with extensive / substantial modification put into service

Paragraph 86 of the Guide explains that in case of substantial modification the manufacturer (that carries out such extensive modification) shall act as if new machinery is placed on the market or put into service.

Paragraph 86

The Machinery Directive applies to machinery when it is placed on the market and/or put into service. Machinery that is placed on the market in the EU is put into service when it is used in the EU for the first time. This applies to new machines that are completed and tested at the users site (may be referred to as 'in-situ' manufacturing), including both machines the user has built himself or have been built for him by another. Existing machinery originally first put into service outside the EU and moved by the user to his own site in the EU is also subject to the Machinery Directive as it is now being put into service for the first time in the EU. *However, 'putting into service' does not apply to existing machinery (which was originally been put into service or placed on the market in the EU) that has had modifications carried out, unless they are so extensive that the machine is considered as new – see §72: comments on Article 2*

(h). In such cases, the obligations of the manufacturer with respect to the placing on the market and the putting into service of the machinery are the same.

Figure 4-Guide to the application of the Machinery Directive 2006/42/EC, edition 2.1, paragraph 86

2.2.4 Assemblies of machinery and modifications

Paragraph 39 of the Guide provides guidance concerning modifications of parts of the machine assembly.

Paragraph 39

The Machinery Directive applies to machinery when it is first placed on the market and put into service in the EU. This is, in general, new machinery – see §72: comments on Article 2 (h). Consequently, the assemblies of machinery referred to in the fourth indent of Article 2 (a) are often new assemblies of new machinery. For machinery in service (used at work), the employer must ensure that the conformity and safety of the machinery is maintained throughout its working life, according to the national regulations implementing Directive 2009/104/EU – see §140: comments on Article 15 and following the manufacturer's instructions – see §272, comments on section 1.7.4.2 (r) of Annex I.

- **Where, one or more of the constituent units of existing assemblies of machinery may be replaced by new units, or new units may be added to an existing assembly of machinery, the question arises as to whether an assembly of machinery comprising new and existing units is, as a whole, subject to the Machinery Directive. It is not possible to give precise criteria for answering this question in each particular case.** In doubt, it is therefore advisable for the person constituting such an assembly of machinery to consult the relevant national authorities. However, the following general guidance can be given:
- **If the risk assessment¹³ shows that the replacement or the addition of a constituent unit in an existing assembly of machinery does not add a new hazard, nor increase an existing risk, no action is required according to the Machinery Directive for the parts of the assembly that are not affected by the modification.**

The same applies where there is a new hazard, or an increase in an existing risk, but the existing protective measures present on the assembly before the modification are still sufficient so that the assembly can still be considered safe after modification. However, for those parts of the assembly that are affected by the replacement or the addition of a constituent unit, action under the Machinery Directive will be required. The employer remains responsible for the safety of the whole assembly according to the national provisions implementing Directive 2009/104/EU – see §140: comments on Article 15.

- If the risk assessment¹⁴ for the new unit shows it does not have any safety implications (e.g. by requiring modifications) on the existing assembly and it is a complete machinery that could also operate independently, that bears the CE-marking and is accompanied by an EU Declaration of Conformity, then the addition of this new unit (as a complete machinery) into the existing assembly is to be considered as the installation of the new unit (machinery) and this does not give rise to a new conformity assessment, CE marking or EU Declaration of Conformity for either the new unit (machinery) or the assembly to which is added.
- However, if the new unit to be added to the assembly comprises partly completed machinery (PCM) as defined by Art. 2 (g), which must be accompanied by a Declaration of Incorporation and assembly instructions, the person incorporating the PCM into the assembly is to be considered as the manufacturer of the new unit (as by incorporating the PCM in the assembly, 'new' machinery is being put into service). He must therefore assess any risks arising from the interface between the PCM, other equipment and the assembly of machinery, fulfil any relevant EHSRs that have not been applied by the manufacturer of the PCM, apply the assembly instructions, draw up an EU Declaration of conformity, compile the technical file for the modified parts of the assembly (essentially how the PCM has been put into service, including any changes to the existing assembly) and affix the CE marking to the new unit as assembled. For example, if a new

automatic reel change unit, which is a partly completed machinery, is added to the end of a paper making line which will not affect the main parts of the line, then only the interface design and any modifications to the control system or to the existing assembly will need to be assessed for the purposes of CE marking the unit, as fitted.

- 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 must be applied. In that case, the whole assembly, including all its constituent units, must comply with the provisions of the Machinery Directive. This may also be required if a new assembly of machinery is constituted from new and second-hand units.

Figure 5- Guide to the application of the machinery directive 2006/42/EC, edition 2.1, paragraph 39

2.3 The Blue Guide and modification of machinery

The EU Blue Guide (2016/C 272/01) gives under 2.1 guidance on what should be considered as a New product on the EC market:

- A product, which has been subject to important changes or overhaul **aiming to modify its original performance, purpose or type** after it has been put into service, **having a significant impact on its compliance with Union harmonisation legislation, must be considered as a new product.** This has to be assessed on a case-by-case basis and, in particular, in view of the objective of the legislation and the type of products covered by the legislation in question. **Where a rebuilt or modified product is considered as a new product, it must comply with the provisions of the applicable legislation when it is made available or put into service.** This has to be verified by applying the appropriate conformity assessment procedure laid down by the legislation in question. **In particular, if the risk**

assessment leads to the conclusion that the nature of the hazard has changed or the level of risk has increased, then the modified product has to be considered as a new product, i.e. compliance of the modified product with the applicable essential requirements has to be reassessed and the person carrying out the modification has to fulfil the same requirements as an original manufacturer, for example preparation of the technical documentation, drawing up a EU declaration of conformity and affixing the CE marking on the product.

- **In any case, a modified product sold under the name or trademark of a natural or legal person different from the original manufacturer, should be considered as new and subject to Union harmonisation legislation. The person who carries out important changes to the product carries the responsibility for verifying whether or not it should be considered as a new product in relation to the relevant Union harmonisation legislation.** If the product is to be considered as new, this person becomes the manufacturer with the corresponding obligations. Furthermore, in the case the conclusion is that it is a new product, the product has to undergo a full conformity assessment before it is made available on the market. However, the technical documentation has to be updated in as much as the modification has an impact on the requirements of the applicable legislation. **It is not necessary to repeat tests and produce new documentation in relation to aspects not impacted by the modification, as long as the manufacturer has copies (or access to copies) of the original test reports for the unchanged aspects. It is up to the natural or legal person who carries out changes or has changes carried out to the product to demonstrate that not all elements of the technical documentation need to be updated.**
- **Products which have been repaired or exchanged (for example following a defect), without changing the original performance, purpose or type, are not to be considered as new products according to Union harmonisation legislation.** Thus, such products do not need to undergo conformity assessment again, whether or not the original product was placed on the market before or after the legislation

entered into force. This applies even if the product has been temporarily exported to a third country for the repair operations. Such repair operations are often carried out by replacing a defective or worn item by a spare part, which is either identical, or at least similar, to the original part (for example modifications may have taken place due to technical progress, or discontinued production of the old part), by exchanging cards, components, sub-assemblies or even entire identical units. If the original performance of a product is modified (within the intended use, range of performance and maintenance originally conceived at the design stage) because the spare-parts used for its repair perform better due to technical progress, this product is not to be considered as new according to Union harmonisation legislation. Thus, maintenance operations are basically excluded from the scope of the Union harmonisation legislation. However, at the design stage of the product the intended use and maintenance must be taken into account.

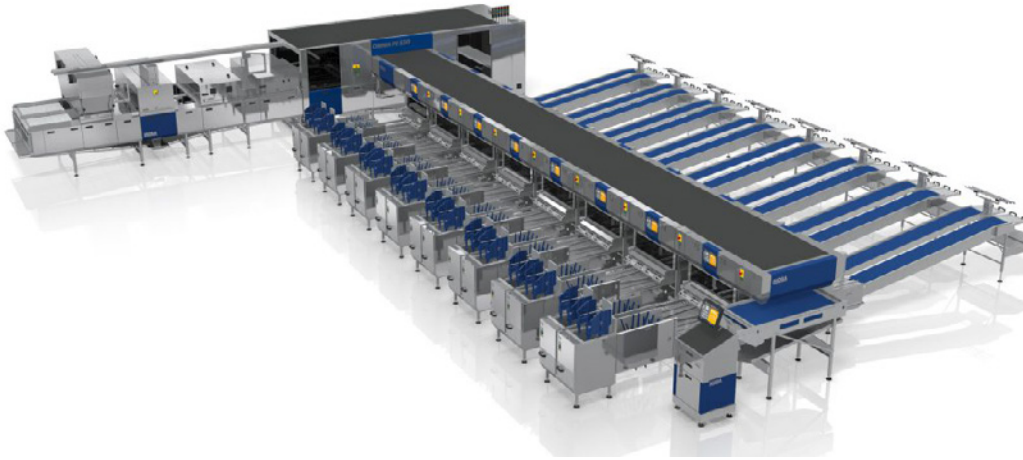
- Software updates or repairs could be assimilated to maintenance operations provided that they do not modify a product already placed on the market in such a way that compliance with the applicable requirements may be affected.

Figure 6-Blue Guide (2016/C 272/01) section 2.1 – Product coverage

The Blue Guide clearly states that products like machinery (or other products) are considered as substantially modified if the:

- Original performance has changed;
- Original purpose has changed;
- Machinery becomes a different type or technology
- Risk assessment demonstrates increased hazard resulting in a new risk;
- Machinery/assembly of machinery is sold under a new name;
- Software update affects compliance with the applicable directives (e.g. leading to an increased risk).
- Modification has a significant impact on the compliance with the set of applicable directives (not only the MD but also other directives applicable).

3 Substantial modification



3.1 A substantial modification

In case of a **substantial/extensive** modification this could lead to the conclusion that a new machine is created. In that case the product must be identified as new machinery hence a conformity assessment shall be conducted taking into consideration **all the actual directives and regulations** applicable to that machinery.

Based on the answers on the questions above, one can determine whether the machinery is to be considered as substantially modified and, as a consequence, should be treated like new machinery. Unfortunately, the Guide to the application of the machinery directive, **does not give precise criteria when to consider a transformation of machinery as a reason for undertaking a conformity assessment**. Instead of this the Guide refers to the judgement of national authorities (i.e. from Member states of the European Union).

3.2 To determine a substantial/extensive modification

The examples from the *Guide to the application of the Machinery directive 2006/42/EC, edition 2.2*, show that one of the most important elements is **the risk assessment of the transformed machinery**.

The main questions are:

- Does the **modification add additional risk(s) going beyond the original specifications** and tolerances of the original machinery specifications?
- Does the **risk level increase above the original design limitations** of the existing machinery?
- Do already available/existing safety measures in the machinery mitigate risk within the original design specifications and tolerances of the machinery?
- Can these additional risks be effectively reduced by additional “basic measures”?



4 Identifying a modification

This section gives guidance for employers and manufacturers/modifiers and other stakeholders in case machinery is transformed.

4.1 Principle of risk based approach- the substantial modification

There is consensus that risk assessment is the basis to determine whether one should consider the transformation as a substantial modification or not. Substantial modification requires a conformity assessment within all the applicable directives/regulations. Combining the available national or institutional approaches is comprised in the following flowchart

4.2 The flowchart and decision tree explained

Choices in the flowchart are explained as following. For each type of choice examples are given;

These examples cannot be considered as an exhaustive list, but cover the major type of transformations.

1. Changing in function, capacity, use

Any transformation that is intended to transform beyond the original specifications of the machinery given by the OEM:

- A. Change of functionality,
- B. Increase of capacity
- C. Change the intended use

Examples of such a possible changes are (not limited):

A. Change of functionality (e.g.):

- possibility to run backwards (for example conveyor belts)
- second control station/remote operation
- additional new manufacturing step

B. Change in capacity resulting in more volume (beyond manufacturer's specification) (e.g.):

- Higher throughput
- Higher speed (rpm)
- Faster acceleration/deceleration
- Increased pressure

C. Change in use (e.g.):

- Products beyond specification (e.g. products and materials larger/smaller, heavier/lighter, different shape)
- Substances or materials beyond specification
- Unintended use
- Change in environment (temperature, humidity, dust, explosive atmosphere)

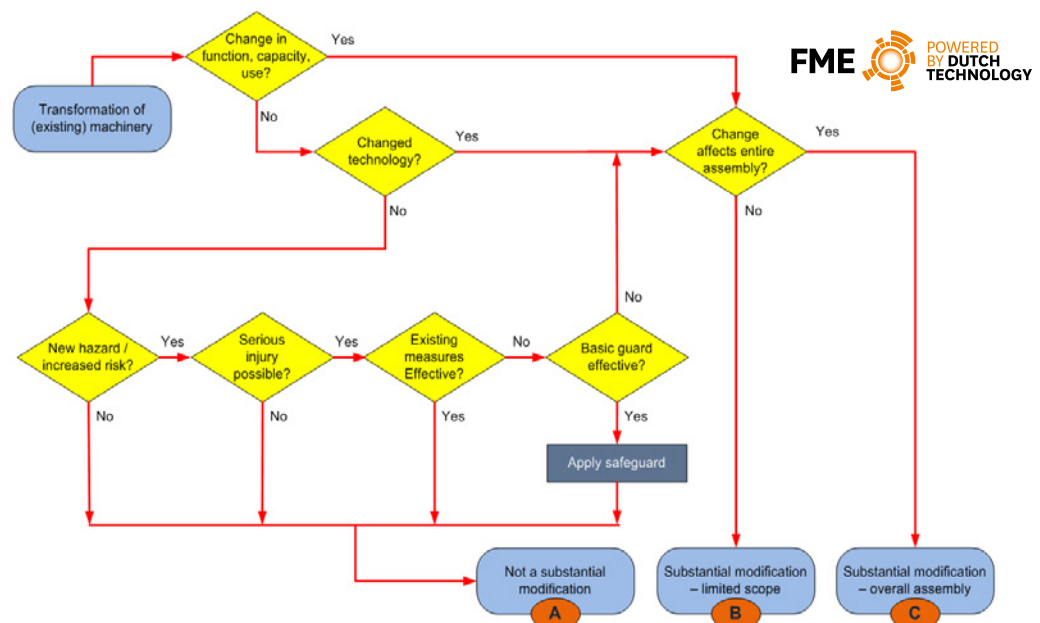


Figure 7; flowchart on machine transformation-decision tree

2. Change affects entire assembly (Scope of the change)

If the change affects the overall assembly then the overall machinery shall be considered as a total **new assembly** and be treated as such. If the change affects only a limited part of the overall assembly of machinery and in such case **the scope can be limited to a segment** between discrete boundaries.

A Large **assembly of machinery with a common functionality** (see the definition in the Machinery Directive art 2 lid a) may not always cause a need to consider the whole as one large assembly of machinery.

If risk is not transferred between the constituent units, an individual unit (machine, pcm, or assembly of machinery) may be substantially modified without affecting the risk at other units. This situation will result in evaluating a limited segment e.g. one production cell or production unit, but not the entire production line.

To document that there is no transfer of risk and/or no new risk to other sections of a production line one shall conduct a risk analyses and documenting this.

This risk assessment shall include the risk of the not-modified parts of a production line to verify that the limitation of scope to the segment is justified. Some examples of a limited scope within an assembly:

- One conveyor belt line being modified as part of a huge material handling system
- A manufacturing line whereby one production cell is substantially modified

Splitting the electrotechnical and mechanical part

Instead of a limited scope within an assembly by defining a boundary between linked machinery, one can also divide the electrical part of a machine and the mechanical part.

This boundary can only be applied if the transformation of the first part does not affect the other parts (to be verified in detail and documented).

Some examples of machine transformation with such scope limitation are:

- Lathe/ milling machine with new computer numerical controls + electrical feeding system
- Overhead crane with new control system + electrical feeding system

3. Changed technology

If a machine is transformed and technology has changed, such modifications are substantial in case of

- **Technology type change** (e.g. hydraulic drive is replaced by an electric drive or vice versa)
- **Modified safety function e.g.:**
 - A mechanical level indicator that is replaced by an acoustic one
 - Fencing replaced by a safety camera system
 - Replacing a relays operated control system by a PLC
- **Modification of a load bearing part**

Transformations related to changed technology often have a limited effect on large complex machinery or machinery assembly as the changed technology often applies to e.g. one step in an integrated manufacturing system or a piece of machinery where improved technology has become available.

4. New hazard or new risk

A. No new hazard: If there is no new or increased risk or hazard the modification can be considered as not-substantial.

NOTE: Also when the modification can be considered as not-substantial the risk analyses shall be completed as the existing machinery shall in any situation comply with the requirements of the Working Equipment Directive/national implementation measure. In such case a new conformity assessment and CE marking are not necessary.

B. New hazard and/or an increased risk: (effect/ exposure/likelihood)- one shall assess the risk of such hazard and mitigate this risk. (see EN-ISO 12100:2010 for possible hazards/hazardous situations)

Examples of a new hazard/new risk:

- New configuration of existing machines/ partly completed machines whereby certain parts are now allocated at a greater height (i.e. not permanently accessible for service/recovery)
- Creation of a new platform at which previously inaccessible hazardous points have become accessible.
- Mounting of a heavier replacement part (e.g. 35 kg motor to replace a 22 kg one)
- New parts causing exposure to new hazardous substances (e.g. nano particles, fumes & dust with heavy metals, bacteria or an explosive atmosphere)





- Reduction of human presence; missing signals that indicate hazardous situation or increase in human presence; more exposure to a certain hazard increasing the risk

5. Serious injury possible

A new hazard or a new risk can possibly cause a serious injury. An injury is considered serious if any of the following effects can occur:

- Fatality
- Irreversible injury like amputation, cancer, whiplash, head trauma
- Hospitalisation (stay)
- Surgery
- Lost time Injury of 3 working days or more.

In case of forces that apply on the body but with uncertain outcome one can make use of one of the following documents to determine if the forces are not excessive (i.e. causing serious injuries):

- ISO/TS 15066:2015 (Robots and robotic devices — Collaborative robots)
- EN 415-10:2014 (Safety of packaging machines - Part 10: General Requirements)

6. Existing measures effective

In case there is an increased risk/new hazard but the existing safety measures will effectively reduce the risk there is no need for considering such transformation as substantial.

Examples of such situations are

- A new nip-point but within an existing enclosure
- Additional transfer but safeguarded within existing safeguarded area (or increased area)

7. Effective Basic guard

In case the existing measures are not effective but an additional basic guard would effectively reduce the risk there is no need to consider the modification as substantial provided that the guard is added as part of the modification job. In that case the safety measures to reduce the risk are included in the modification and for this reason the modification is not substantial.



Figure 8; Milking robots

Basic Guard

A basic guard is a fixed guard that physically protects by preventing contact and based on the principles of the following standards:

- EN-ISO 13857:2019 (Safety of machinery – Safety distances to prevent hazard zones being reached by upper and lower limbs);
- EN-ISO 14120:2015 (Safety of machinery – Guards – General requirements for the design and construction of fixed and movable guards).

Examples of basic guards are:

- Fencing (e.g. around a hazardous machine);
- Cover (e.g. to prevent access to transmission parts);
- Nip guard (e.g. to prevent drawing-in of fingers).

Crushing hazard

Where crushing hazard applies and one can move one of the parts to reduce the crushing effect to values that meet *EN-ISO 13854:2019 (Safety of machinery - Minimum gaps to avoid crushing of parts of the human body)* such measure can be considered as sufficient.

NOTE. Interlocked guards depend on safety related parts of control systems which makes the design more complex; therefore these guards are not considered as basic guard.

Example:

A machine already equipped with perimeter fencing may internally have a new hazard that can cause an irreversible injury but if the access door is equipped with an interlock the risk during operation and service is effectively reduced (some risk may apply in case the machinery can be operated inside the safe guarded area by e.g. a teach pendant).

NOTE. In addition, the annexes to this document show use cases to illustrate the decision process



5 Roles and responsibilities

Following the flow chart (as per figure 7), three possible situations apply. Any of those three situations has different deliverables for different duty-owners:

Scenario A; Not a substantial modification:

From a legal point of view all duties are with the employer/owner of the machine.

An employer needs to:

- Perform a risk assessment to identify hazards/risk/mitigation measures.
- Verify the safety of the existing machinery (working equipment).
- Update the machinery documentation being actual again.
- Create a technical file (modification file).

Scenario B; Substantial modification – limited scope:

This scenario is the mixed scenario; hence there are duties as well for the employer and for the modifier.

The employer needs to:

- Perform a risk assessment to identify hazards/risk/mitigation measures.
- Verify the safety of the existing machinery (working equipment).
- Update the machinery documentation being actual again.
- Create a technical file (modification file + declarations of new/substantially modified equipment).

The modifier (party that realises substantially modified machinery) needs to (in order of the owner):

- Perform a risk assessment for his limited scope to identify hazards/risk/mitigation measures.
- Verify compliancy of substantially modified machinery (or product).
- Create new machine documentation (O&M manual) in accordance with requirements of the machinery directive (2006/42/EC).
- Create a technical file for the substantially modified machinery (or product).
- Apply the CE mark on the machinery (product).
- Draw up the declaration of conformity (new & substantially modified product).

Scenario C; Substantial modification:

From a legal point of view all duties lay with the manufacturer of the substantially modified product (modifying party). The manufacturer/modifying party needs to:

- Perform a risk assessment to identify hazards/risk/mitigation measures.
- Verify compliancy of the (substantially) modified machinery (or product).
- Create new machine documentation (O&M manual) in accordance with requirements of the machinery directive (2006/42/EC).
- Create a technical file for the substantially modified machinery (or product).
- Apply the CE mark on the machinery (product).
- Draw up the declaration of conformity (new & substantially modified product).



6 Revision of machinery documentation

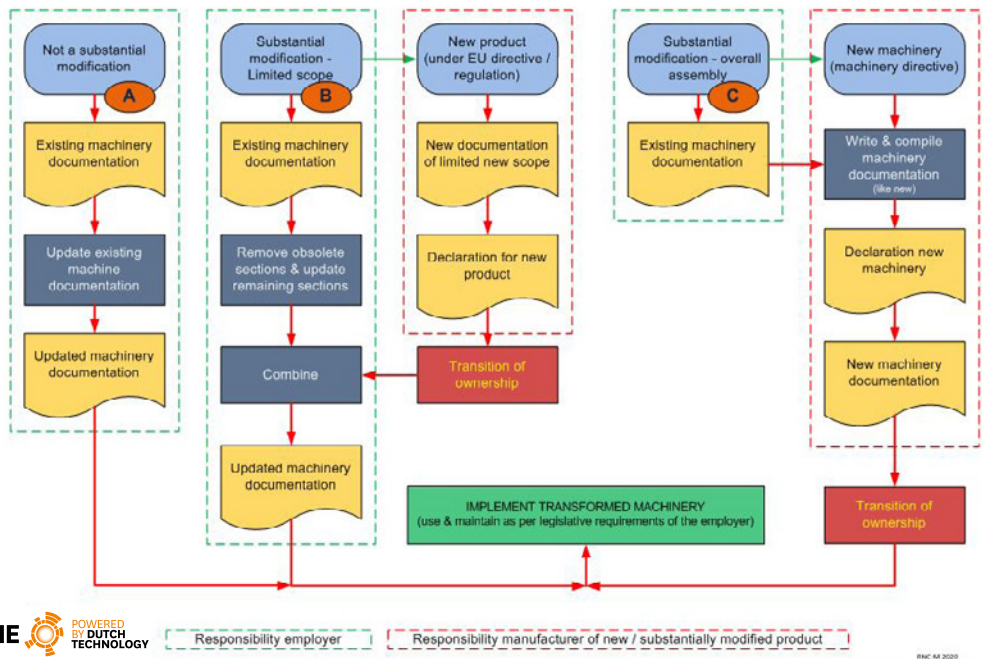


Figure 9; Machinery documentation

6.1 General principles for responsibility

For each option below a different route in obtaining an actual and compliant set of machinery documentation applies, see figure 9 for a graphical representation of the three main routes.

A. Not a substantial modification

In case the transformation concerns a “not a substantial modification” the only requirement to machinery documentation is that the **not substantial but modified equipment is accompanied by adequate information** and where appropriate by actual instructions. This is the responsibility of the owner /employer.

Explanation

Modifications must be documented (to justify it is not substantial).The machinery documentation must be consistent with the machinery as it actually is. Especially conflicting information shall be corrected. Where parts of assembled machinery have been removed, the machine documentation (O&M manual) shall be updated accordingly.

B. Substantial modification – limited scope

In case there is a substantial modification – limited scope - both manufacturer and owner/ employer have a duty to **verify the machinery documentation is correct and complete** as this scenario implies that there is also a part of the machinery that is not substantially modified (hence is not considered as a new product).

Duties for the manufacturer of the substantial modified part of the machinery:

For the new supplied part and substantial modified part the requirements are identical as for new products placed on the EU market (Conformity assessment/declaration of conformity + CE marking an documentation).

Duties for the owner/employer:

As the transformation does not substantially affect the remaining part of the machinery, that remaining part does not get new documentation. The employer owns that part of the documentation (probably already for several years) and remains therefore responsible for that part.

The employer can request the manufacturer of the new added limited scope to rework the overall machinery documentation in the scope of works. For the part that concerns reworking for the original documentation this work must be contracted as a service and not as an implicit agreement to upgrade the entire machinery to actual legislative/normative requirements.

Note: A good dialogue and detailed contractual agreement will help to prevent false expectations and disputes later.

Explanation

- It is likely that the original documentation was once delivered by the manufacturer of the original machinery (or assembly) but as other modifications may have been applied the machine documentation may have been already updated before.
- Based on a private agreement (contract) the employer can request the manufacturer of the original product to /actualize the overall machinery documentation (as a service - outsourced).
- Reworking the *documentation* as a service to the owner, should not be considered as an agreement to upgrade the entire machinery to comply with actual legislative/normative requirements.

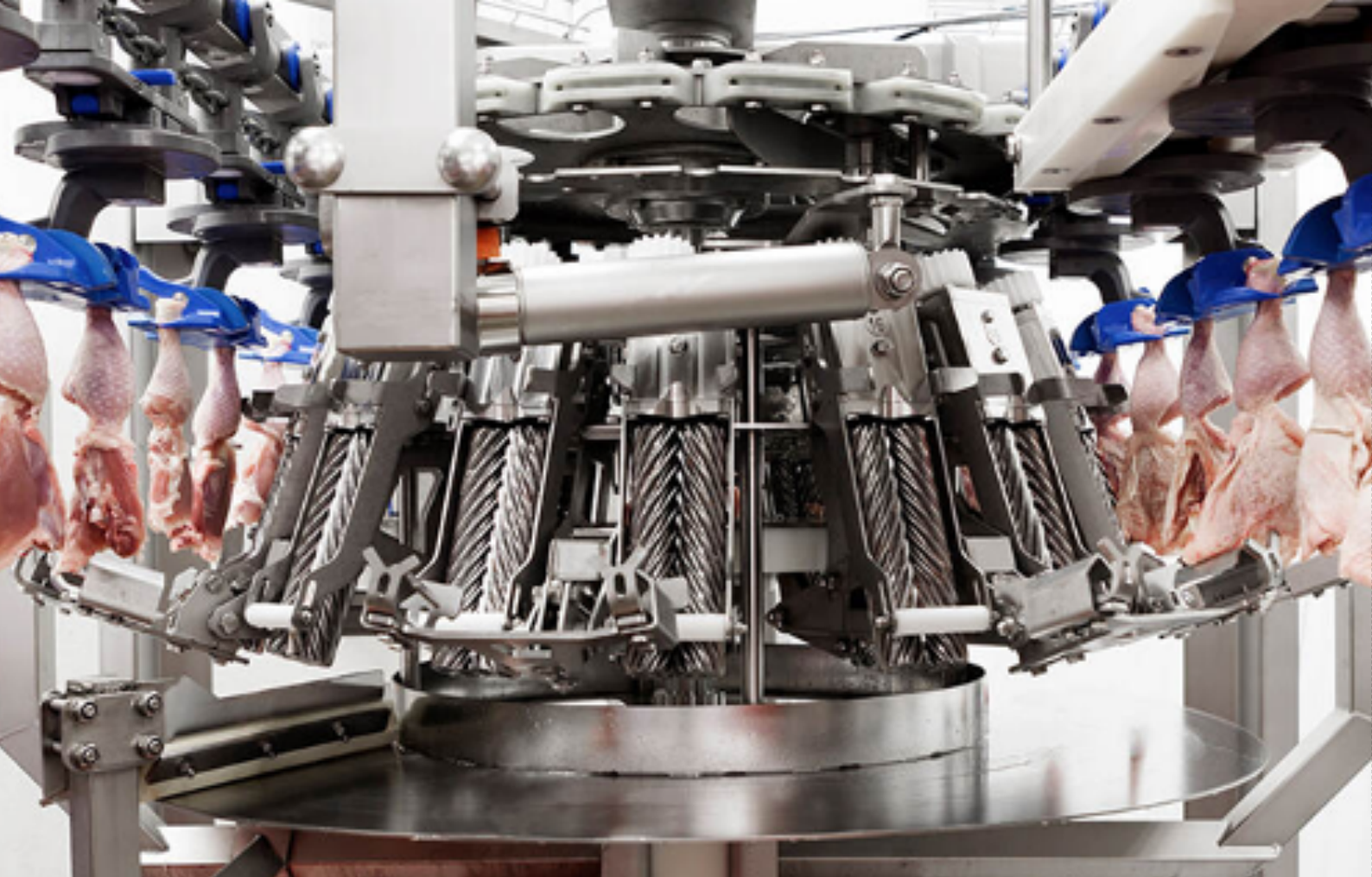
C. Substantial modification – overall assembly

In case of a substantial modification for a complete machinery assembly, -the documentation is the responsibility of the owner/employer or this could be contracted with the modifying party (modifying party could also be the OEM). That also implies that the actual Machinery Directive as a whole applies also to the machinery documentation (see annex I, section 1.7.4.2. Contents of the instructions).

6.2 Drafting principles for machine documentation:

Manufacturers shall apply harmonised standard (EN-ISO 20607:2019 (Safety of machinery - Instruction handbook -General drafting principles as a guidance for writing a complete manual) for new documentation. The principles of this standard can also be applied on existing documentation but that is not mandatory.





6.3 Technical file

In case of a substantial modified product, being considered as a new product the manufacturer shall have a complete technical construction file based on the actual Machinery directive and other actual applicable directives. For machinery the requirements for a technical file are given in annex VII of the Machinery Directive 2006/42/EC.

6.3.1 Update of the technical file – substantially modified machinery

In case of substantially modified machinery, the technical file is equal to new machinery. The technical file shall therefore include the following documents:

- Risk assessment (documented)
- Updated bill of material/parts list (full details in case of a safety component)
- Updated assembly drawings
- Updated electric/pneumatic/hydraulic schemes
- Design verification (calculation, simulation, emulation)
- Specification of parts and their origin
- Test results (visual inspection, measurements, functional tests, special test)
- Updated O&M manual

6.3.2 Update of the technical file – combined machinery and not substantially modified machinery

In case of combined and not-substantially modification of machinery, each modification shall be documented in a so called modification file that includes:

- All of documents as listed in section 6.4
- The decision on whether the modification is assessed as substantial, limited substantial or, non-substantial
- Details on safety measures on the not-substantial modified machinery/parts.

The modification file shall be available with the machinery i.e. the employer/owner shall be capable of providing these to a reasoned request by a supervising authority. If it concerns a substantial modification for the machine as a whole or for the limited scope the owner /employer (or the modifying party based on private concluded contract with the owner /employer) shall issue a declaration of conformity and consequently compile the technical file as laid down in the Machinery Directive.



7 Market surveillance

7.1 Market surveillance requirements for new machinery & substantial modified machinery

In case of an incident or accident whereby the supervisory authority has reasons to presume that the machine played a role in the event leading to that incident or accident the manufacturer (or authorised representative) must provide a copy of the technical file at a reasoned request. With the technical file the authority verifies if the machinery fulfils the essential health & safety requirements of the Machinery Directive. The owner/employer is in such a situation not obliged to provide any documentation except for the declaration of conformity that belongs to the machinery as having such declaration is a necessity as a consequence of Directive 2009/104/EU article 4.

In case of substantial modified existing machinery carried out by the owner /employer or outsourced by the modifying party the owner /employer/modifying party needs to have a technical file of the modified part or the entire substantial modified assembly of machinery, whatever is applicable.

7.2 Market surveillance requirements not substantially modified machinery

In case of non-substantial modified machinery the owner/employer needs to have an actual technical file of the modified part of machinery.

In case that some not-substantial modification is made to any part of the machinery this needs justification why it is not substantial and a clarification on what has been modified exactly. Part of the technical file is the original machinery documentation (the original O&M manual) and the updated (and translated) version (also to enable the supervisory authority to review the process that was followed and how design decisions were made).

7.3 Putting modified machinery back into operation

After the modification of the machinery putting into operation of the machinery requires operators to be instructed/informed about how the transformed machinery works, how it should be operated and how it should be maintained; this is the sole responsibility of the owner/employer. The owner/employer can choose to procure services to assist him with the follow-up but he remains responsible.

The following list of points (non-exhaustive) may require action by the employer:

- Operator instructions (note; machinery documentation ≠ instructions)
- Operator training program
- Workplace risk assessment/plan of approach on risk mitigation
- Maintenance regime
- Inspection program

What of the above items mentioned are applicable shall be determined by the owner/ employer depending of the type of transformation.

8 Importing and leasing

8.1 Importing from outside the EU

When the product is manufactured outside the EU, the responsibilities of the manufacturer can be transferred to an authorised representative in the EU. Machinery from outside the EU is also subject to requirements of the Machinery Directive, also when the machinery is second hand.

8.3 Good practice at any modification

Any work performed on machinery shall be carried out using good engineering practices. Where parts are disassembled/replaced a verification that all parts are re-assembled as intended is necessary as else in case that safety is at stake. If a checklist is available, a filled out checklist, signed by the responsible engineer is recommended.

8.2 Leasing and rental of machinery

If machinery in operation is not owned by the employer it is still the employer who is responsible that working equipment for employees meets the requirements of the European Working equipment Directive 2009/104/EC. Hence in case of leased/hired working equipment the employer needs to verify that working equipment is safe to use. Employers should oblige the rental company to fulfil the legal requirements.



9 Contracting and responsibilities

9.1 Responsibility & scope

Where the transformation of complex machinery involves multiple parties, each with a different role, scope and perhaps expectations, it must be made contractually crisp and clear who is responsible for what part of the work/delivery.

The Machinery Directive attributes duties automatically to a specific party, for example the manufacturer. Where the work is not subject to the Machinery Directive or alike the work shall be described in more detail. Especially the following points requires explicit description:

- **Which party is finally responsible for the overall machine assembly (acts as a principle contractor/integrator)?**
- **For what part of the machinery work is each individual stakeholder responsible and to what extent ?**

For large & complex machinery, it is recommended to create a layout plan that marks respectively the original machinery, not-substantial-modified machinery, removed machinery, substantial-modified machinery and completely new manufactured machinery.

9.2 Contractual information

It is recommended to take the following aspects for consideration:

- Who shall provide information concerning the existing machinery/parts?
- In what format the information shall be made available (pdf or hand written text/ drawings/notes may cause additional rework and makes editing a demanding job)
- How to act where translations are needed (e.g. old machinery not provided with a manual in the required language but the new assembly shall have such)?
- What to do if information is not available (existing parts)?
- Duties of involved parties to assist to complete the works/deliveries.
- Clarify who is the project owner and who "owns" unforeseen situations.

9.3 Availability of existing documentation and data

In case of substantial modification and/or supply of new machinery (or other scope under a product directive) there is a duty to complete the technical file of that machinery before the declaration of conformity or the PCM declaration can be undersigned. For new machinery (completed/partly completed) this is relatively easy to fulfil but where already existing parts become part of the new machinery this is not so easy anymore as the party doing the modification does not always have access to the technical file of the OEM

Machinery older than 10 years may not have a technical file anymore as there is no legal obligation for the OEM to keep the necessary documentation after that period. Other problems may arise whereas the OEM cannot be obliged to hand over the technical file to the owner /employer or a modifying party. This could be a costly hurdle if a complete conformity assessment has to be conducted to create the complete technical file of existing machinery by the modifying party. For this reason this should be contractually described and agreed between parties. Solutions in such a case might be:

- Procure the technical file from the OEM (OEM will probably require a non-disclosure agreement i.e. that the provided information cannot be used for other use than agreed).
- Subcontract certain sections of the work/ supply to the OEM (that include deliverance of e.g. declaration of conformity or a PCM declaration).
- Apply principles of reversed engineering (often done in verification of suitability of steelwork for modified dead load bearing machinery).
- Testing/measuring to determine characteristics/load bearing capacities.

It may therefore be convenient to involve the OEM in the work to prevent extreme efforts to gather the necessary information.

10. Annex I – Use cases



Case 1: Extension of pallet conveyor system + replacement of existing control system

Situation

An existing material handling system for pallets – existing of roller conveyors, chain conveyors and transfers is extended with a new sub-system. That new sub-system will be supplied in accordance with the essential health and safety requirements of the Machinery Directive 2006/42/EC.

Modification

The existing system was built according to the predecessor 98/37/EC; fixed guards are incomplete and do not have captive fixation. To match the new demands, the existing system will run faster (new 24 m/min, existing speed was 18 m/min hence 33% speed increase). According to the OEM this increase in speed is within specification and not increasing the risk level. The existing system will also be foreseen equipped with new wiring (to replace the existing wiring) and a new control system (working on voltage 400V/230/24 V).



Question	Answer
What kind of modification(s) applies to this project?	This project incorporates two transformations (beside the new sub-system): [1] <i>Increase in speed</i> : This modification is a non-substantial modification as the increase in speed is within original specification of the concerned machinery (as confirmed by the original equipment manufacturer). The extension does not affect the existing system. [2] <i>Replaced wiring and control system</i> : The supply of the new control cabinet is to be seen as a limited substantial modification as this concerns the control system only without affecting any other part (this has to be verified by the party executing the modification).
Scope & regulation	
New equipment	The new supplied sub-system requires a Declaration of Conformity in accordance with the Machinery Directive 2006/42/EC.
Substantially modification – overall machinery	Not applicable
Substantial modification -limited scope	Not applicable.
Substantial modification	The existing material handling system that remains (with increased transport speed) is not substantially modified (as the increase in speed is within specification).
Responsibility	
Risk analysis – related to work equipment?	The employer of the system, shall have a risk analysis completed for the total assembly.
Risk analysis – related to machinery?	The manufacturer of the new subsystem shall conduct a risk analysis (as part of the conformity assessment).
Documentation	
Existing part	The operator and maintenance manual requires an update so the existing system corresponds with the system as it is after the transformation. This update includes an update of all schemes, specifications, bill of material, instructions for use, instructions for repair.
New part	The new supplied sub-system shall be supplied with a manual that fulfils the requirements of the actual machinery directive.
What to incorporate in the modification file?	The risk analysis of the overall system/Analysis of the transformation/ Declaration of conformity of existing MHS and new sub-system and new supplied control cabinet/specifications of wiring materials/Updated electrical diagrams/Updated layout (including one showing what falls under what declaration).
Additional advice	
Review of existing guards (risk assessment existing)	Where existing guards are not appropriate/missing i.e. where persons can access hazardous parts during operation additional guarding is required (the risk analysis would probably already indicate such necessity).



Case 2 Installation of a new by-pass line to an existing sorter system

Situation

An existing sorter (material handling system) for parcels.

Modification

Parcel sorter machine is extended with a new by-pass conveyor line. The new by-pass conveyors will be supplied in accordance with the essential health and safety requirements of the Machinery Directive 2006/42/EU but the existing sorter was built according to Directive 98/37/EC. The sorter does not require further modification except for the configuration of an extra output.

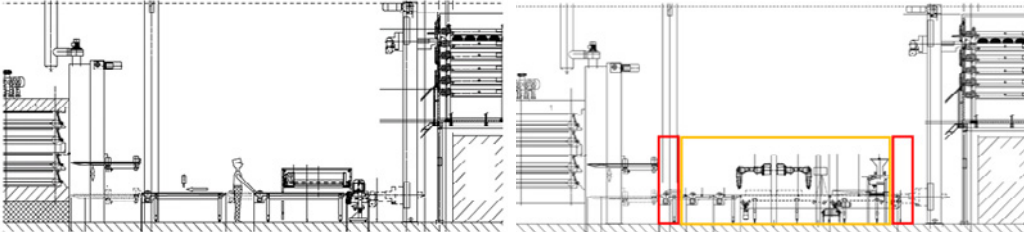


Question	Answer
What kind of modification(s) applies to this project?	The modification is non-substantial modification as the new by-pass conveyor line does not affect the capacity, function of the sorter. The sorter is capable of being reconfigured to accommodate new outputs.
Scope & regulation	
New equipment	The new supplied conveyors + controls require a Declaration of Conformity according to the Machinery Directive as the by-pass can be considered as a sub-system. The new interface is part of the scope of supply.
Substantially modification – overall machinery	Not applicable.
Substantial modification -limited scope	Not applicable.
Substantial modification	The existing material handling system/sorter are not substantially modified i.e. they will accommodate the new line but there is no increased risk to the existing system.
Responsibility	
Risk analysis – related to work equipment?	The employer of the system, shall have a risk analysis completed for the total assembly.
Risk analysis – related to machinery?	The manufacturer of the subsystem shall conduct a risk analysis on the subsystem (as part of the conformity assessment).
Documentation	
Existing part	Where appropriate conflicting information in the O&M will have to be updated; as there is only one extra output the update is limited but may incorporate schemes.
New part	The new supplied by-pass (line) shall be supplied with a manual that fulfils the requirements of the actual machinery directive.
What to incorporate in the modification file?	The risk analysis of the overall system/Analysis of the transformation/ Declaration of conformity of existing MHS and new by-pass/Updated layout (including one showing what falls under which declaration).
Additional advice	
Review of existing guards (risk assessment existing)	If the sorter was not safeguarded (e.g. by fencing/height) but risk of contact with moving elements seems plausible the risk analysis may conclude that the existing sorter should be additionally safeguarded. Such electronic fencing (and where appropriate interlocked access gates) shall comply with the actual standards/Machinery Directive. In such case the fence can be considered as “independently placed on the market” hence such electronic fencing or interlock would require a Declaration of Conformity for its overall assembly.

Existing situation



New situation



Case 3: Installing a robot in an existing integrated manufacturing system (ims)

Situation

Automated bread proofing facility, a manual workstation and a second automated oven area.

Modification

A robot will replace a manual workstation in an integrated manufacturing system (IMS) which a bakery line. The robot – replacing the manual workstation will be safeguarded by additional fencing that incorporates two conveyors. The infeed & process conveyor is new, the outfeed conveyor is shortened and links the new system again with the existing second automated oven area. Both conveyors are allocated within the new additional fencing.



Question	Answer
What kind of modification(s) applies to this project?	The total replacement of the manual workstation by the robot above the line and the conveyors (to be considered as new) can be considered as a limited substantial modification. The automated bread proofing and the second automated oven area are not affected and can be considered as independent systems despite the fact that they are physically working together. The conveyor that is shortened is in itself not substantially modified.
Scope & regulation	
New equipment	The new supplied robot and conveyors sub-system requires a Declaration of Conformity in accordance with the Machinery Directive 2006/42/EC.
Substantially modification – overall machinery	Not applicable.
Substantial modification -limited scope	Yes, new machinery.
Substantial modification	Outfeed conveyor that was reduced in length (no new hazard/no increase in risk).
Responsibility	
Risk analysis – related to work equipment?	The employer of the system, shall have a risk analysis completed for the total assembly.
Risk analysis – related to machinery?	The manufacturer of the subsystem shall conduct a risk analysis on the subsystem (as part of the conformity assessment).
Documentation	
Existing part	The operator- and maintenance annual requires an update. This update is in essence removal of the removed operator position including its associated equipment and a reference to the equipment that has taken over this function (if appropriate; identification numbers can change). The update includes an update of all schemes, specifications, bill of material, instructions for use, instructions for repair.
New part	The new supplied robot/conveyors shall be supplied with a manual that fulfils the requirements of the actual machinery directive.
What to incorporate in the modification file?	The risk Analysis of the transformation/Declaration of conformity of existing system(s) and new robot/ conveyors/Updated layout (including one showing what falls under what declaration).
Additional advice	
Review of existing guards (risk assessment existing)	The risk assessment of the overall system shall include hazards related to installation in-between existing systems, maintenance, cleaning of the robot/conveyors and supply of consumables (e.g. knives for the robot – depending on process) whereby access is restricted as a result of the surrounding systems.



Case 4: Re-location and re-wiring of a complex system

Situation

14 year old assembly of machinery (large complex system).

Modification

An employer requests a manufacturer to move the entire system from one country within the EU to a new location within the EU. As electric cables are old and damaged the end-user wants the manufacturer to replace all cables. The employer also requests the manufacturer to issue a new Declaration of Conformity for the overall assembly.



Question	Answer
What kind of modification(s) applies to this project?	The moving of the system within the EU to a new location and re-assembling the system does not change anything to the existing machinery; the machinery is to be considered as “used” and relocating within the EU without any other modification does not create any ground for considering this assembly as a new assembly under the Machinery Directive. The replacement of electric cables just for machinery*) does not change that situation (the replacement of the cables is necessary to undo wear/tear and for safety so not for a ‘structure’ or building). Consequently the manufacturer /contractor? executing the work shall not issue a Declaration of Conformity for the overall assembly as that manufacturer does not place a new product on the market, neither a new product is put into use.
Scope & regulation	
New equipment	Not applicable.
Substantially modification – overall machinery	Not applicable.
Substantial modification – limited scope	Not applicable.
Substantial modification	The assembly of the existing machinery (large complex system).
Responsibility	
Risk analysis – related to work equipment?	The employer.
Risk analysis – related to machinery?	Not applicable, but the party that re-assembles the assembly of machinery on the new location shall conduct a task risk analysis for the works.
Documentation	
Existing part	As there is no new product the existing documentation should be appropriate (assumed that there is adequate machine documentation). However; the machinery directive states that translations are to be requested (by the end-user) to translate the machine documentation to the official Community language or languages understood by the operators (see 2006/42/ec, annex I, section 1.7.1.); in case of relocating machinery to a different area this calls for a translation of the machinery documentation. In this case obtaining a translation is the responsibility of the end-user.
New part	Not applicable.
What to incorporate in the modification file?	It is recommended to keep records on test reports/inspection reports that relate to the re-assembling works (commissioning of the new assembles assembly).
Additional advice	
Review of existing guards (risk assessment existing)	The risk assessment of the overall system and the investment in re-assembling may give rise to addressing risks of the current assembly. Especially where current directives/standards deviate one shall look for opportunities to incorporate risk mitigation measures as the relocation probably justifies investment. If the employer wants a up to date Declaration of Conformity, the employer can combine the relocation with other modifications in order to create a “new” product. When offering to deliver a new Declaration of Conformity, be aware of modifications on the equipment that could be made after the first installation by the employer on his own behave. To find out all details applicable to the new risk analyses, this could potential consume considerable time/costs to finalise.



Case 5: Replacement of the control cabinet on an existing machine including renewal of all wiring

Situation

A 12 year old machine for which the control cabinet is replaced.

Modification

An employer requests a manufacturer of to replace the control cabinet (same design/specification)) and replace the entire wiring of that machine. With the new control cabinet also the PLC will be upgraded to a newer type as the previous type is no longer supported. The power supply to the machine is 400 VAc.



Question	Answer
What kind of modification(s) applies to this project?	The exchange of the control cabinet does not change function (if no functionality is added), nor capacity nor use of the machine. The technology is also not changed as one plc control system is replaced by another one. As no new hazard/risk is added so the transformation is not a substantial modification. The replacement of cables does not change that situation (the replacement of the cables is necessary to undo wear/tear)and safety.
Scope & regulation	
New equipment	The control cabinet + electrical wiring are new. For the control cabinet/ internal electrical system a Declaration of Conformity is applicable if the manufacturer has designed and built the cabinet in accordance to the Low Voltage Directive (2014/35/EU).
Substantially modification – overall machinery	Not applicable.
Substantial modification – limited scope	Not applicable.
Substantial modification	Not a substantial modification
Responsibility	
Risk analysis – related to work equipment?	The employer of the system, shall have a risk analysis completed for the total assembly.
Risk analysis – related to machinery?	Not applicable (no new machinery).
Documentation	
Existing part	The documentation shall be updated i.e. electrical scheme's, parts list (including new safety components).
New part	See previous (documentation of related to the new control cabinet is to be integrated into the existing documentation).
What to incorporate in the modification file?	It is recommended to keep records on test reports/inspection reports that relate to commissioning works (putting into operation of the new control system).
Additional advice	
Review of existing guards (risk assessment existing)	If the safety related part of the control system (SRP-CS) is being rebuild it is recommended to do this in accordance with EN-ISO 13849-1:2015.



Case 6: Principal manufacturer with modifications by subsidiary

Situation

A manufacturer designs and builds a production line for a customer within the EU. This manufacturer has a subsidiary in another EU country; that subsidiary delivers parts of the overall assembly.

Modification

Several years later that subsidiary in the EU replaces a substantial part of the overall assembly (i.e. several (partly) completed machines of the assembly are replaced by other (partly) completed machines).

Unfortunately, several years later an incident happens and the conformity of the overall assembly is questioned. Several questions arise:

- Whether or not functions, capacity, use, type of technology are affected by the latest transformation is unknown. Documentation is not updated.
- The legal position of the subsidiary (OEM not sure if the subsidiary is either an authorised representative or manufacturer or else).

Is the incident related to the modification and/or the new installed equipment and has the owner/employer breached the Working Equipment Directive (2009/104/EU by use of working equipment not correct CE-marked (the existing OEM Declaration of Conformity does not cover the latest equipment and may have become irrelevant if the overall system is considered substantially modified).



Question	Answer
What kind of modification(s) applies to this project?	A subsidiary of the OEM replaces a section within the machinery assembly.
Scope & regulation	
New equipment	In case part of a complex system is being replaced by a new sections (i.e. machinery) this could be interpreted is a limited scope. Complete new machinery sections will always require a CE declaration. Modification of existing sections can be subject to substantial modification. In case the overall assembly is affected due to new risks affecting also the existing machinery sections a new CE marking of the overall machinery assembly requires a new DoC in accordance with the Machinery Directive (2006/42/EC). New equipment (realised by the subsidiary) should be provided with a declaration (or declarations) as prescribed in annex II of the Machinery Directive 2006/42/EC. The subsidiary is responsible for the CE marking of the new sections introduced. The employer is responsible for the evaluation of the machinery assembly and the CE marking for the whole assembly of machinery, Depending on the legal relationship of the OEM and its subsidiary. Can the OEM be held the responsible modifying party.
Substantially modification – overall machinery	If no additional risk was introduced due to the new section, no substantial modification
Substantial modification – limited scope	If risk were added compared to the original machinery section this should be evaluated in the risk analysis of the new machinery section. This may lead to substantial modification.
Substantial modification	Substantial modification of limited scope
Responsibility	
Risk analysis – related to work equipment?	The employer of the system, shall have a risk analysis completed for the total assembly. Depending on the additional risk created by the modification for the total assembly the employer is responsible for a CE marking for the assembly.
Risk analysis – related to machinery?	The manufacturer of the new section machinery (i.e. the responsible party, the OEM subsidiary) shall conduct a risk analysis (as part of the conformity assessment).
Documentation	
Existing part	The risk analysis documentation shall be updated i.e. electrical scheme's, parts list (including new safety components).
New part	Supply of machine documentation in accordance with the Machinery Directive.
What to incorporate in the modification file?	Risk analysis
Additional advice	
Relation manufacturer - subsidiary	If subsidiaries can act as independent manufacturer they should be organised in such a way that they have competency to design & realise in conformity with the applicable directives/regulations; the subsidiary shall than also issue the declaration as a legal person as they are the actual manufacturer. Such subsidiary is often officially authorised to represent the manufacturer (authorised representative) with all duties under the machinery directive (2006/42/EC). If subsidiaries are not allowed to act as independent manufacturer the holding shall supervise their activities and assess the conformity and issue the declaration(s) themselves.



Case 7: Extension to a non-ce marked assembly of machinery

Situation

material handling equipment

Modification

An employer requests a manufacturer to design/supply an extension to the existing assembly.

The manufacturer recognises that the existing assembly has been modified on multiple occasions by different parties.

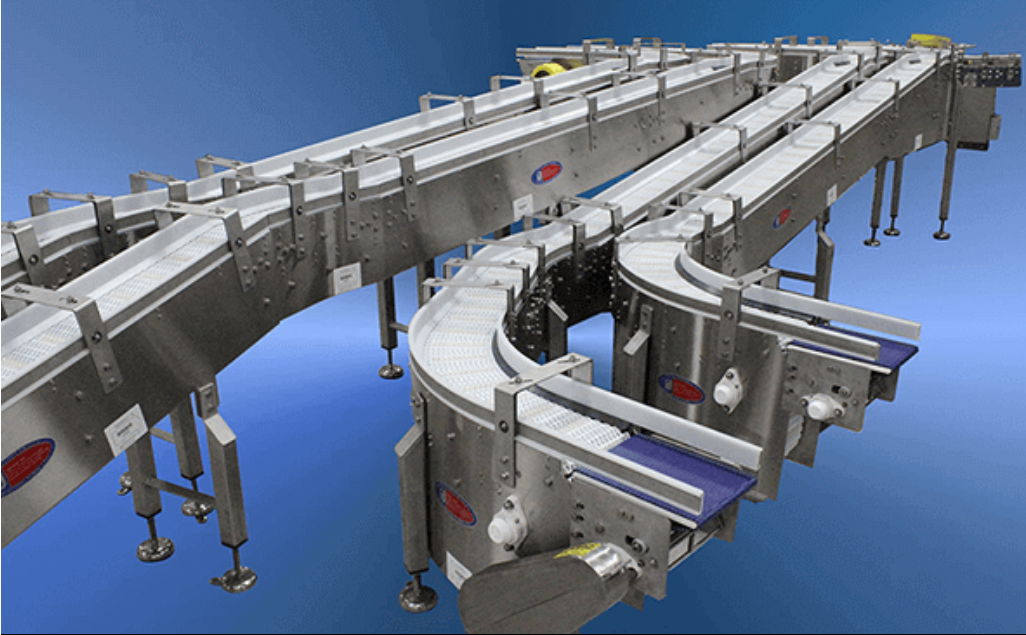
The manufacturer does not want to become responsible for the overall assembly and considers to exclude the responsibility in a contractual way.

Notes:

- [1] The manufacturer of a product under one or more of the community directives/regulations is bound to assess the conformity of that product when placed on the market/put into operation for the first time. Contracts cannot overrule legislative requirements; a clause in the contract that would be contradicting the applicable law would not hold in court.
- [2] If the scope is limited to an extension and given the fact that the system currently functions without, it is likely that there are no consequences for the existing system in terms of hazard/risk (use the risk assessment to verify). If so, the existing system is not substantially modified if the extension works independently.



Question	Answer
What kind of modification(s) applies to this project?	The extension has probably no impact on the current system (to be assessed via the risk assessment) so there is no modification of the existing system.
Scope & regulation	
New equipment	New machinery will always require a Declaration of Conformity when placed on the market/first put into operation.
Substantially modification – overall machinery	Not applicable.
Substantial modification – limited scope	Not applicable.
Substantial modification	Connection with new system may require a minor modification of the system e.g. adaption of side-panels. No substantial modification.
Responsibility	
Risk analysis – related to work equipment?	The employer of the system, shall have a risk analysis completed for the total assembly.
Risk analysis – related to machinery?	The manufacturer of the extension shall conduct a risk analysis on the subsystem (as part of the conformity assessment).
Documentation	
Existing part	Insufficient information but probably limited adaptation needed.
New part	Supply of machine documentation in accordance with the Machinery Directive.
What to incorporate in the modification file?	The risk analysis of the overall system/Analysis of the decision why this situation does not incorporate transformation of existing machinery/ Declaration of conformity of existing MHS/Updated layout (including one showing what falls under which declaration)/new declaration of conformity (i.e. of the extension).
Additional advice	
Review of existing guards (risk assessment existing)	The employer is responsible for assuring that the existing system meets the requirements of Directive 2009/104/EU (safety of working equipment for use by workers).



Case 8: Additional conveyors to extend length of an existing line of 3 conveyors

Situation

An employer wants to extend the length of a conveyor line; the line currently exists out of 3 conveyors that have been individually CE-marked as they have been procured at different moments from different suppliers. All these conveyors have independent controls that allow them to run at a chosen speed. They can be started individually or all at together from a central control system by an input signal on these controls.

Modification

Extra conveyors are necessary to cover the required distance. These conveyor shall have a similar functioning control system. The employer contacts a manufacturer. The employer is not sure however if the additional conveyors can be added without a problem. An emergency stop cord at both sides at the end of the line has been installed.

Note:

The higher level control system that delivers a start command is not necessarily to be seen as reason to speak of one system if that signal would not result in a start unless the local control system and the emergency stop system will prevent the conveyor from starting.



Question	Answer
What kind of modification(s) applies to this project?	The existing assembly of three conveyors is transformed as non-substantial modification as no new function nor other use nor new technology applies. There is however a new risk as there could be drawing-in by an existing conveyor as there is a new transfer point. That hazard can be simply mitigated by either an existing guard on the (if present), else a simple guard can be installed that keeps persons away from the nip point of the conveyor.
Scope & regulation	
New equipment	The additional conveyors are new; A declaration of conformity is required.
Substantially modification – overall machinery	Not applicable.
Substantial modification – limited scope	Not applicable.
Substantial modification	The existing conveyors that have an interface with the new conveyors may be adapted to accommodate the new conveyors, as long as this does not affect the safe-guarding of the existing conveyors it concerns a not-substantial modification.
Responsibility	
Risk analysis – related to work equipment?	The employer of the system, shall have a risk analysis completed for the total assembly.
Risk analysis – related to machinery?	The manufacturer of the new conveyors shall conduct a risk analysis (as part of the conformity assessment).
Documentation	
Existing part	Each conveyor can have its own O&M manual as each can be used individually.
New part	The new conveyor requires a new declaration of conformity and an O&M manual in accordance with the Machinery Directive. Installation manual depends on installation requirements of the manufacturer.
What to incorporate in the modification file?	The risk analysis of the overall configuration, the individual Declarations of Conformity, the various manuals, specification of additional safety measures.
Additional advice	
Review of existing guards (risk assessment existing)	Attention to the emergency stop system is recommended; each conveyor can be equipped with its own emergency stop but signal exchange to realise one span of control is recommended. Alternatively all conveyors have their own emergency stop with limited span of control; in that case the end-user shall inform employees about the limited span of control of each conveyor.



Case 9: Installing an emergency stop on an older machine

Situation

Machine originally equipped with a motor that brakes automatically after loss of power (i.e. category 0).

Modification

An employer wants to install an extra emergency stop to a machine

Note:

As emergency stops can be category 0 or 1 some consideration is necessary what category to build. That choice must correspond with the way the machinery needs to be stopped in case of emergency.



Question	Answer
What kind of modification(s) applies to this project?	The existing machine is transformed as a non-substantial modification as no new motor function nor other use nor new technology applies. The extra emergency stop does not add any hazard/risk to the machinery so no other measures are necessary.
Scope & regulation	
New equipment	Emergency stop including the logic and output (safety relay).
Substantially modification – overall machinery	Not applicable.
Substantial modification – limited scope	Not applicable.
Substantial modification	The original machine as the new function only adds safety; there is no additional hazard created. No substantial modification
Responsibility	
Risk analysis – related to work equipment?	The employer of the system, shall have a risk analysis completed for the workshop/assembly.
Risk analysis – related to machinery?	Not applicable.
Documentation	
Existing part	The operator and maintenance manual requires an update. This update includes an update the electrical schemes, specifications of additional material, instructions for use, instructions for repair.
New part	Not applicable.
What to incorporate in the modification file?	Analysis of the decision why this situation does not incorporate transformation of existing machinery/Declaration of conformity of existing machinery/Updated electrical scheme (including bill of material)/Declaration of conformity for safety component(s)/Performance level calculation of emergency stop/Test report.
Additional advice	
Design of drive system	Attention necessary for the way the machinery is stopped; if e.g. motor would not have an integrated brake an emergency stop may be useless.



Case 10: Installing a second processing line

Situation

Cheese processing line.

Modification

An employer wants to install a second processing line next to an existing one in similar design. The second line will deliver its output on the existing conveyor line that connects the first line to a palletizing area. The palletizing area is not modified but processes twice as much products due to the two lines being able to run simultaneously. The connections is a relative simple conveyor connection whereby the last conveyor of line 2 deposits products sideways onto the existing conveyor.

Note:

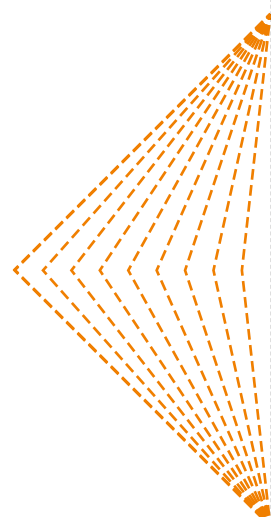
The palletizing area handles the extra volume without modification; the increase in capacity is therefore considered to be within the design specifications of the line (determined by the OEM). If changes are made to increase the capacity e.g. by increasing speed, torque, dimensions etc. that would label that main line to the palletizer to be considered as a substantially modified assembly of machinery.



Question	Answer
What kind of modification(s) applies to this project?	The only modification to the existing system is the induct point where the new line deposits its output onto the existing line. The second processing line itself concerns a new assembled machine.
Scope & regulation	
New equipment	Second processing line (assembly of machinery).
Substantially modification – overall machinery	Not applicable; the process lines and the palletizing line can be considered as separate sections performing their own function.
Substantial modification – limited scope	Not applicable.
Substantial modification	The existing machinery (line 1 and the line to the palletizing area) + adoption for line 2. Not substantial modification
Responsibility	
Risk analysis – related to work equipment?	The employer of the system, shall have a risk analysis completed for the whole plant.
Risk analysis – related to machinery?	The manufacturer of line 2 needs to conduct a risk analysis (as part of the conformity assessment).
Documentation	
Existing part	Integration of the new induct point (connection of discharge of line 2).
New part	Line 2 requires full machine documentation (as required in the machinery directive).
What to incorporate in the modification file?	Updated machinery documentation of main line 1 + original Declaration of Conformity and Declaration of Conformity for the 2th process line.
Additional advice	
Review of existing guards (risk assessment existing)	Possibly the point of connecting the output of line 2 may require additional safe-guarding (to be determined as part of line 2).
Consultation	Consultation with the manufacturer of the original line towards the palletizing area (OEM) shows that the capacity is in specification to handle the extra volume. If the line towards the palletizing area would have to increase speed to process the higher volume of products could result in a substantial modification. It can be advantageous to have this verified by the OEM.

11 Annex II - Definitions

Assembled machinery	Machinery linked together to fulfil a certain function and controlled by one control system (for a full definition, see directive 2006/42/EC).
Authorised representative	A person (legal/natural) situated in the European Community that has been authorised by the manufacturer to represent him and that owns the legal duties otherwise hold by the manufacturer (as the manufacturer is allocated outside the EC).
Basic guard	A physical guard (cover/fencing) that protects by preventing contact and that is constructed from non-complex shapes without need for the control system to e.g. monitor access or monitor state.
Change	Transformation whereby something is being replaced (substitution).
Employer	Any person (legal/natural) that has authority to put others to work (not being relatives).
End-user	Any person (legal/natural) that makes beneficial use of the product (machinery). Often the end-user lets other persons (employees) work with the product/ machinery; in such case the end-user is the employer.
IMS	Integrated Manufacturing System; group of machines working together in a coordinated manner, linked by a material-handling system, interconnected by controls, for the purpose of manufacturing, treatment, movement or packaging of discrete parts or assemblies (see EN-ISO 11161:2007 + A1:2010)
Large complex machinery	Machinery (often assembly of machinery) that due to its size and number of different parts is installed by professionals in a dedicated area for stationary use. See also directive 2011/65/EU article 3 (ROHS II). This implies that large complex machinery is physically bigger than a 40' container.
Load bearing structure	Part of the machinery that is subject to a substantial force e.g. gravity.
Machinery	Assembly of linked parts of which at least one moves and which is powered by external power or by manual/animal power if used to lift/hoist (for a full definition, see directive 2006/42/EC).
Manufacturer	Any person (legal/natural) that designs and realises a product with the intention for placing it on the market and/or putting it into operation.
Modifier	Any person (legal/natural) that modifies a product. Where a modifier modifies the product substantially the modifier becomes the manufacturer of the newly created product.
OEM	Original Equipment Manufacturer; the person (legal/natural) that has designed/ manufactured the original product. The OEM often owns the legal duties under the EU directives unless this manufacturer is situated outside the EU (in which case an authorised representative owns the duties as he was the OEM).
Owner	Any person (legal/natural) that has a machine or machinery lawfully in his possession.
PCM	Partially Complete Machinery; assembly as under machinery but intended to be incorporated into another assembly of machinery whereby the conformity will be assured by the party doing the incorporation/integration.
Safety function (of a control system)	A function of the control system of which failure would immediately (cause – effect) raise the risk level of the persons involved (see also ISO 12100:2010). A safety function
Substantial modification	A transformation that is fundamental (important) i.e. it changes relevant characteristics of the earlier product/machinery.
Structure	Part of the machinery that is intended to keep parts at a certain position, often working against gravity. Structures are often made out of steel/aluminium/wood but can be made from various materials.
Transformation (of machinery)	A change of the machinery that typically is made intentionally with the purpose of making that machinery better and/or more suitable for its purpose.



12 Annex III - Standards

EN 415-10:2014	Safety of packaging machines - Part 10: General Requirements)
EN-ISO 11161:2007+ A1:2010	Safety of machinery — Integrated manufacturing systems — Basic requirements.
EN-ISO 12100:2010	Safety of machinery — General principles for design — Risk assessment and risk reduction.
EN-ISO 13849-1:2015	Safety of machinery — Safety-related parts of control systems — Part 1: General principles for design
EN- ISO 13854:2019	Safety of machinery - Minimum gaps to avoid crushing of parts of the human body).
EN-ISO 13857:2019	Safety of machinery - Safety distances to prevent hazard zones being reached by upper and lower limbs);
EN-ISO 14120:2015	Safety of machinery — Guards — General requirements for the design and construction of fixed and movable guards
ISO/TR 15066:2016-	Robots and robotic devices — Collaborative robots. construction of fixed and movable guards).

13 Annex IV – Reference list

The following documents have been taken into consideration for this document:

13.1 Netherlands

Document: **Zo past u uw machine veilig aan** [LINK](#)
Issued by: Inspectie SZW; Ministerie van Sociale zaken en Werkgelegenheid
Date: April 2017

Content characteristics

- 2 page documentation
- Limited number of examples substantial modification
- Substantial modification requires manufacturers role and responsibilities
- Responsibility between employer /owner and modifying party.

13.2 Germany

Document: **Interpretation paper of the Federal Ministry of Labour and Social Affairs and the Länder on the subject of “substantial modification to machinery”** ([Bundesarbeitsblatt IIIb5-39607-3](#) and [Bundesarbeitsblatt IIIb5-39607-3 EN version](#))
Issued by: Federal Ministry of Labour and Social Affairs (BMAS)
Partners: BAuA/DGUV/VDMA/VGB PowerTech
Date: 9th of April 2015

Content characteristics:

- Party modifying the machine is responsible
- Transformations judged by a risk based approach, only risk increasing situations that cannot be reduced by simple means are considered as substantial modification
- Substantial modified machinery shall comply to the latest regulation
- Replacement parts with identical function and level of safety are not considered as a substantial modification
- Risk assessment always required
- Machine documentation needs to be updated
- Technical file in case of substantial modification (requirements of the MD), otherwise a risk analyses + description of the modification + specification of the measures.

The approach has a strong focus on the risk and technical aspects which correspond to regulation that puts the modification manufacturing party in the centre.



13.3 France

Document:	Guide technique du 9 septembre 2019 relatif aux opérations de modification des machines en service; Guide Technique Relatif aux opérations de modification des machines en service.
Issued by:	Ministère du travail, de l'emploi, de la formation professionnelle et du dialogue social
Partners:	Ministère de l'agriculture, de l'agroalimentaire et de la forêt/INRS/COCT#3rs:
Date:	9 septembre 2019

Content characteristics:

- Employer that employs the machine is responsible
- Explicit description of various possible modifications, many resulting in need to consider the transformation as a substantial modification
- Different substances in process of the machinery ("use") is also considered as a substantial modification
- Substantial modified machinery to comply with regulation in force at the moment of putting machinery into operation/placing on the market (i.e. not necessarily the actual regulation)
- Use of non-genuine replacement parts is often (also involuntary) considered as a substantial modification
- Machine documentation to be updated
- Modification file is always obliged

The approach has a strong focus on the responsibility of the employer.

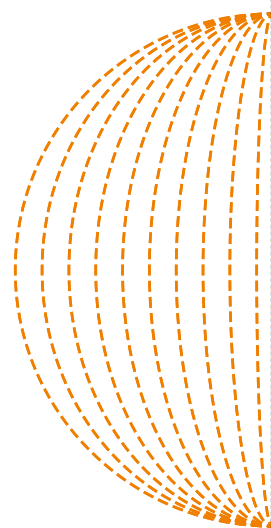
13.4 Switzerland

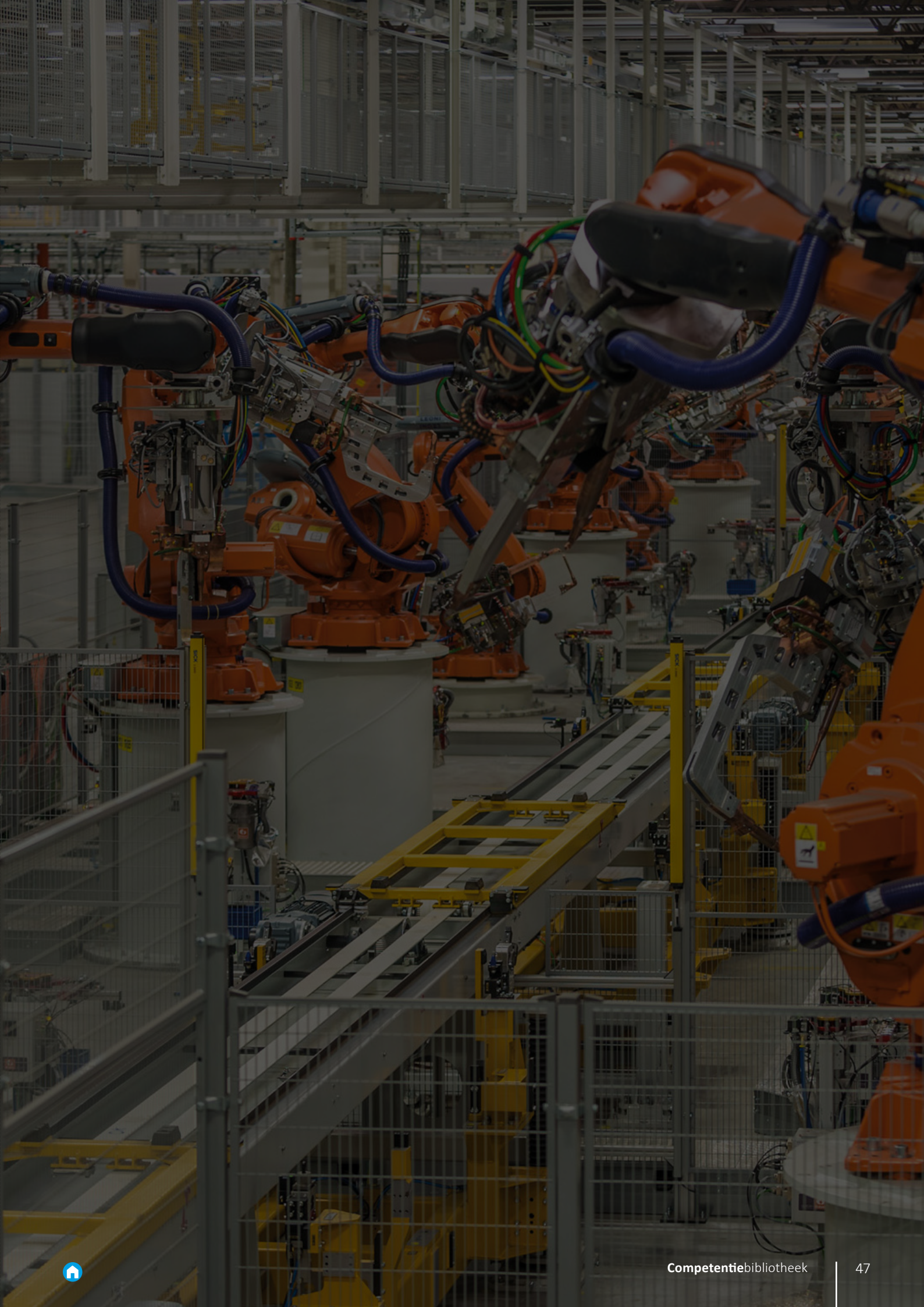
Document:	Ändern von gebrauchten Maschinen LINK
Issued by:	SUVA
Date:	JUNI 2020

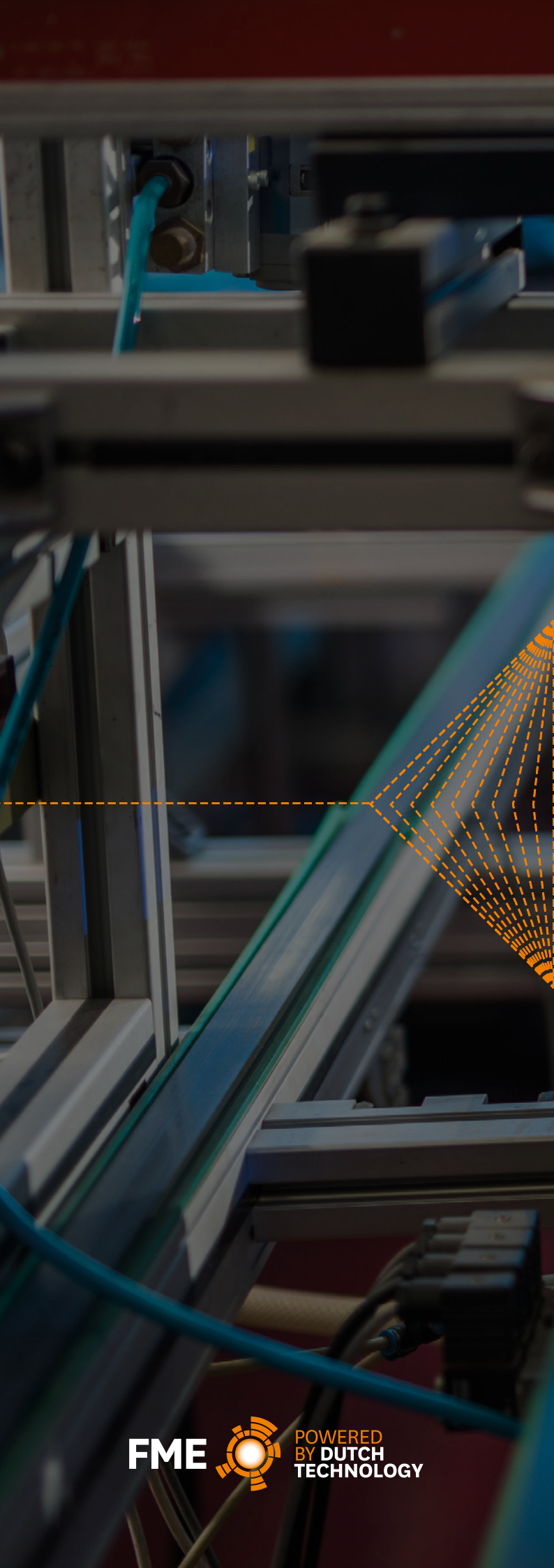
Content characteristics:

- Employer/owner of the machine is responsible
- Transformations judged by a risk based approach, only risk increasing situations that cannot be reduced by simple means are considered as substantial modification
- Different substances in process of the machinery ("use") is also considered as a substantial modification
- Substantial modified machinery shall comply to the latest regulation, otherwise and repair maintain the machine in compliance with the regulation in force at the time of first use
- Replacement parts with identical function and level of safety are not considered as a substantial modification
- Risk assessment always required
- Machine documentation to be updated
- Technical file in case of substantial modification (requirements of the MD), otherwise risk analyses + description of the modification + specification of the measures

The approach has a strong focus on the risk and holds the employer responsible for the modification unless a third party takes over this responsibility.







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