Transformation of machinery

Guideline for manufacturers and end-users of machinery

DECEMBER 2024

FME POWERED BY DUTCH TECHNOLOGY

Transformation of machinery - Substantial modifications vs non-substantial modifications

Guidelines for manufacturers and end-users of machinery

This brochure provides guidance on the transformation of professional machinery to improve performance or adapt to new demands while ensuring compliance with the relevant European regulations. It addresses the need to determine whether modifications constitute substantial changes that require reassessment of conformity. The document also outlines the responsibilities of manufacturers, employers, and owners in maintaining safety and regulatory compliance. It excludes consumer “do-it-yourself” machinery but emphasizes good practices applicable to such scenarios. The brochure underscores the importance of thorough documentation, risk assessment, and adherence to the EU Machinery Regulation 2023/1230 and other directives.

Colophon

Authors
Ing. Chris van der Heijden
Vanderlande - Design Safety Improvement Manager
Chris.van.der.Heijden@vanderlande.com

John van Leeuwen, MSc
Priva - Compliance Advisor
John.van.Leeuwen@priva.com

This is a publication by FME; Federation of enterprises in the technological Industry.
It’s written by experts in de field of product regulation, standardization and conformity assesment.

FME
Postbus 190, 2700 AD Zoetermeer
Zilverstraat 69, 2718 RP Zoetermeer
T: +31 (0)79 353 1100

FME, commitee RNC Machinebouw
FME Belangenbehartiging, belangenbehartiging@fme.nl

More information please contact
belangenbehartiging@fme.nl

Nothing from this publication may be disclosed or reproduced without prior written permission from the publisher, including reproduction by means of printing, offset, photocopying, microfilm, or in any digital, electronic, optical, or other form.

Index

1. Introduction

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/lowering environmental impact). Simultaneously one has to observe international & national law to prevent that machinery becomes unsafe or non-compliant due to the applied modification(s).

Existing machinery that is being transformed, may no longer comply with the essential health & safety requirements of the Directive(s) / Regulation(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 Machinery Regulation (EU) 2023/1230 (or for a short time still Machinery Directive 2006/42/EC) and other applicable Directive(s) / Regulation(s).

Legal duties apply to manufacturers (fulfilling the Machinery Regulation and/or 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 an 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 whether a change on machinery constitutes a substantial modification, resulting in 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 focuses on the transformation of machines intended for professional use in relation to the Machinery Directive / Regulation. Specific applications related to specific directives have not been taken into consideration, e.g.:

- Equipment for potentially explosive atmospheres (ATEX) - Directive 2014/34/EU)
- Radio Equipment Directive (RED) - Directive 2014/53/EU
- Measuring Instruments (MID) - Directive 2014/32/EU
- RoHS 2 (Directive 2011/65/EU) and REACH
- Food Contact Materials (FCMs) - Regulation (EC) 1935/2004

Always be aware that a modification of a machine can also affect other specific applicable directives / regulations that should be taken into consideration.

2. EU Regulation – Legal basis

The Machinery Regulation (EU) 2023/1230 (and before it Machinery Directive 2006/42/EC, which remains effective until January 20th, 2027) defines the legal framework in which any natural or legal person established within the EU can place a piece of machinery onto the market. Not complying with the Machinery Regulation is considered an economic violation, which can be punished by a substantial fine or in exceptional cases jail-time. Also any incident resulting from violations are considered a direct responsibility of the person(s) involved, equally prone to legal repercussions.

The Machinery Regulation mostly refers to machinery being placed on the market and/or put into operation for the first time (Machinery Regulation (EU) 2023/1230, article 3 - 12). The Machinery Regulation also defines the act of modifying a machine (Machinery Regulation (EU) 2023/1230, article 3 - 16).

In both cases, the manufacturer is responsible for making sure that the (resulting) machine that is placed on the market (again) can be used safely. However, a person carrying out a modification should not be required to repeat tests and produce new documentation in relation to machinery or related products that are part of an assembly of machinery, and that are not affected by the modification.

As the current Machinery Directive 2006/42/EC was less specific on several areas of responsibility, the EU published the 'Blue Guide on the implementation of the product rules'. This Guide is meant for a better understanding of EU product rules and facilitation of their uniform application across sectors throughout the Single Market. The Blue Guide is a non-binding instrument, that elaborates on specific features such as distance sales, making products available on the market subject to physical modifications or software updates and the assessment of conformity assessment bodies.

The status of the Blue Guide with respect to the new Machinery Regulation is still unclear, but in case of doubt it is advised to apply the Blue Guide as sound guidance on top of the Machinery Regulation.

2.1 Importing from outside EU

When the product is manufactured outside the EU, some of the responsibilities of the manufacturer can be transferred to an authorized representative in the EU, i.e. the natural or legal person established within the EU who places a piece of machinery onto the market. Machinery from outside the EU is unequivocally subject to the same requirements of the machinery, even when the machinery is second hand.

2.2 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 Use of Work 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. It is recommended for employers to contractually oblige the rental company to fulfil such requirements.

3. Implications of transformation of machinery

3.1 Transformations of machinery

Transformations of machinery come in many different shapes. An existing machine or assembly of machinery itself can be modified but it is also possible that an assembly of machinery changes due to added or removed machinery or partly completed machinery or other parts. It is therefore that the title of this paper reads “transformation” instead of “modification”, we reserve the term “modification” to changes that apply to the existing machinery (or assembly of machinery) since the day of first placing on the market or putting into use in the EU.

3.1.1 Substantial modification

The Machinery Regulation (EU) 2023/1230 gives a precise definition for substantial modification. This definition provides criteria that needs to be fulfilled to consider the transformation as a substantial modification of existing machinery.

- Repair and maintenance work is not considered as creating a substantial modification as long as it does not affect safety (conformity) – see recital 26.
- A substantial modification is either a physical or digital modification – see article 3 sub 16.
- A substantial modification is not foreseen / planned by the original equipment manufacturer – see article 3 sub 16.
- A substantial modification realizes a new hazard or increases existing risk – see article 3 sub 16.

A substantial modification typically requires additional safety measures like:

- Guarding of hazardous parts.
- Measures to assure stability and structural integrity.

The implication of a substantial modification is that de facto a new machine has been created whereby the existing machinery is basically nothing more than a donor of parts. In that case the new product shall undergo a conformity assessment taking into consideration all the actual directives, regulations and harmonized standards that are applicable to that machinery at the time of the conformity assessment. A substantial modification therefore may require more measures than just the safety measures that result from new hazards / increased risk; also measures to deliver conformity with the actual legal and normative framework shall be included due to the need to deliver compliance.

Regulation (EU) 2023/1230 enters into force on the 20th of January 2027. The definition of “substantial modification” can nevertheless already be used as it does not conflict with the current edition of the Machinery Directive (2006/42/EC) due to absence of further clarification.

3.2 Not-substantial modification

Where there is no new product (placed on the market or put into use for the first time in the EU), machinery falls under the regime of working equipment which implies duties for the employer. The Use of Work Equipment Directive 2009/104/EC includes minimum (safety) requirements that always apply where work is done with or on existing machinery.

Directive 2009/104/EC is the European directive on working equipment. This directive lays down requirements for all kinds of work equipment which means it applies to more than just machinery, also climbing materials and hand tools are within the scope of this directive. This directive also applies to machinery that was put into use or placed on the market before the first edition of the Machinery Directive came into effect meaning it also applies to non-CE-marked machinery.

As this directive provides minimum requirements there is a possibility that a member state requires additional safety requirements. Such additional requirements may not result in additional requirements on new machinery (as that would effectively cause barriers to trade). Additional requirements often relate to periodical inspections of equipment to assure safe use. An example of such additional requirement is a 3-monthly inspection by a notified body or an inspection before equipment is being used at another location.

4. Using the flowchart

Figure 1 shows a flow chart that helps to determine what to do for several possible transformation. To ease the use the flow chart is built-up from several blocks with reference to the relevant section of the Machinery Regulation (EU) 2023/1230. The flow chart will be explained per block but first the blocks themselves are explained:

A. New products under EU Community directives / regulations
B. Repair / maintenance
C. Definition substantial modification article 16
D. Requirements digital modification / safety component (new)
E. Scope of the substantial modification
F. Not substantial modification – regulation

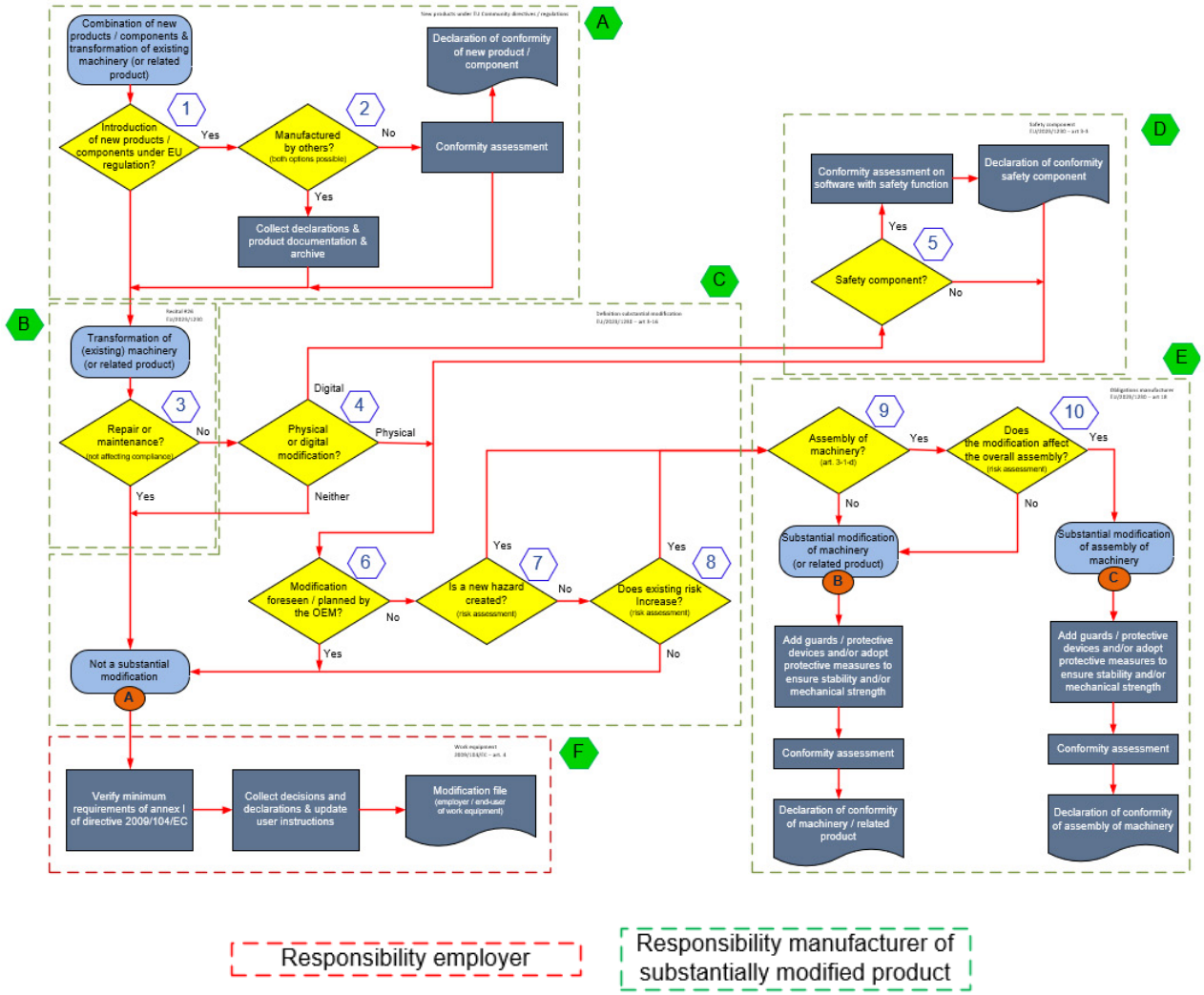


Figure 1; flowchart on machine transformation-decision tree

4.1 New products under EU Community directives / regulations [A]

Often machinery or related products are transformed while simultaneously new products (usually machinery, partly completed machinery, safety components, radio equipment) are added. Transformations whereby a machine or assembly of machinery is enlarged by other products that fall under one of the EU community directives or regulations require that those products are delivered with a declaration of conformity or declaration of incorporation of partly completed machinery (whatever is appropriate), even when the existing machinery / assembly of machinery appears not to undergo a substantial modification itself. After all, the new products are put into use for the first time and that there is another product to which these are fitted doesn't change this.

Removing of machinery / partly completed machinery / parts on existing machinery does usually not result in the creation of new hazards or increase of existing hazards unless safety devices are being removed or changed. In such case new hazards / increase of risk can be avoided by a well-considered new layout based upon a risk assessment.

In case of enlargement of a machinery the issue on new products first put into use is handled by block [A], figure 1-A shows the related decisions.

Block [A] contains two questions:

[1] Introduction of new products / components under EU regulation?
Yes: Situations in which a product is added that falls under one or more EU directives / regulations
No: Situations in which no parts are added that fall under one or more EU directives / regulations

[2] Manufactured by others (or both):
Yes: Others have manufactured the concerned part. In that case that party will have to provide a declaration of conformity.
No: In case manufactured by yourself you need to do a conformity assessment on that particular product (including compilation of the technical file), mark the product as appropriate and underwrite the declaration of conformity.

In case both situations apply both actions shall be followed.

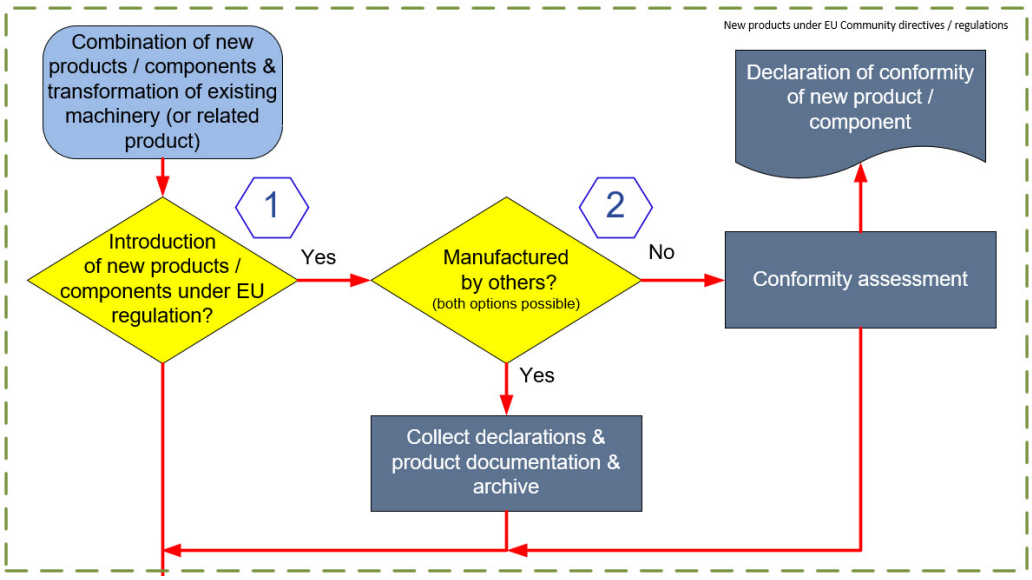


Figure 1-A; block "New product under EU Community directive / regulation"

An example of machinery being enlarged is a conveyor system in a warehouse. Often additional functionality is added due to the need for additional capacity. The additional equipment needs to be physically connected to the existing plant. For the original machinery the transformation means little, often an existing output or input is sacrificed to connect new equipment to the existing system. Most of the new equipment falls under the scope of the Machinery Directive / regulation (and probably also the EMC directive and possibly some directives / regulations more) and as that equipment is put into use for the first time in the EU the new assembly of machinery that is being realized must comply with essential health & safety requirements of the Machinery Directive / regulation. The existing system shall be analyzed separately regarding the question whether it is being substantially modified or not.

Another example is a huge CNC machine on which an automatic tool-exchange is being fitted (as a conversion kit). The automatic tool-exchange is an assembly of parts of which one moves, and it has its own drive motor and control unit. As such the tool-exchange falls under the scope of the Machinery Directive / regulation (and probably also the EMC directive and since the tool-exchange is put into use for the first time in the EU it must comply with the essential health & safety requirements of the Machinery Directive / regulation. The tool-exchange is fitted onto existing CNC machine, thereby it may be necessary to modify some parts of the CNC-machine to accommodate the tool-exchange, it may be necessary to adapt the frame and the housing which fulfils a safeguarding function. The original machinery therefore must be assessed in accordance with the method explained in this document.

4.2 Repair / maintenance [B]

Figure 1-B shows the decision “Repair or maintenance”

[3 Repair or maintenance (not affecting compliance)?
Yes: Any activity only intended to keep the machinery (or related product) in good working order by undoing wear / tear whereby the repair does not affect the compliance of the original product
No: Activity intended to change more than what is required to keep the machinery (or related product) in good working order or any case of repair / maintenance whereby compliance with the EHSR is affected.

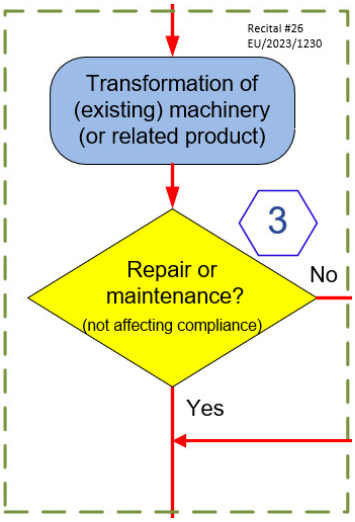


Figure 1-B; block “Recital #26”

Example 1: The housing of a gearbox is cracked and cannot be repaired. The original gearbox manufacturer does no longer exist, a replacement gearbox having nearly the same properties can be fitted by adding a few filling plates underneath. The calculations show that the gearbox can handle the torque. This repair does not affect compliance (safety is not affected) and the gearbox shall come with an EU declaration of incorporation of partly completed machinery. This repair does not affect compliance hence one can choose “yes” in this situation.

Example 2: A hard wired safety function is based on relays; the original spare parts are no longer available. The customer would like to substitute the safety function as the system’s availability due to the old parts is also affected. The substitute function will be based on a safety PLC. This repair however does affect compliance as the substitute control function has never been assessed on conformity. In this situation one shall choose “no” for this decision.

4.3 Substantial modification

The decisions that relate to the definition of substantial modification as laid down in article 3, sub. 16 are shown in figure 1-C

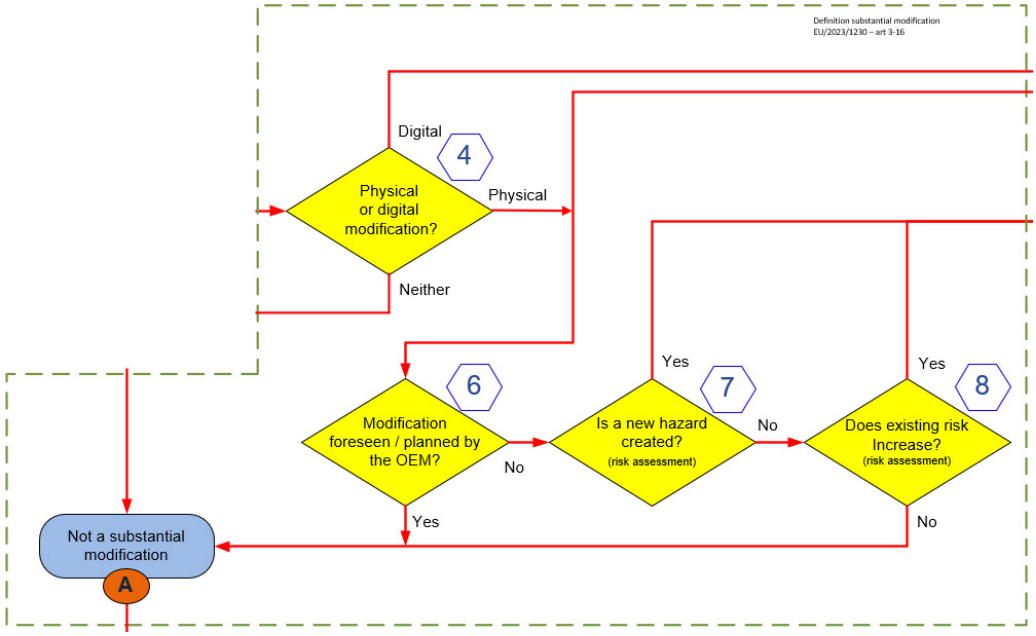


Figure 1-C; block “Definitions article 3 - #16”

[4] Physical or digital modification?
Digital modification; a modification whereby software is being changed (new / changed program).
Physical modification; a modification whereby the geometry and/or mechanical properties of the machinery or related product are changed.
Neither; a change not being digital nor physical

[6] Modification foreseen / planned by the Original Equipment Manufacturer?
Yes; the OEM anticipated already on the modification or even planned this modification. The modification of the machinery / related product will be “easy” due to measures taken in advance.
No; the OEM did not expect this modification. Measures to facilitate the modification are missing or insufficient.

[7] Is a new hazard created?
Yes; the modification introduces a hazard that previously was not present
No; the modification does not introduce a hazard not already applicable

[8] Does existing risk increase?
Yes; one of the existing risks increases due to the modification
No; none of the existing risk increases due to the modification

Note; decisions #7 and #8 shall be analyzed by means of a risk assessment

4.4 Digital modification / safety component

Example 1: A loop-sorter system is being modified to increase the number of outputs by increasing the sorter-length and by adding spiral chutes. The spiral chutes (a curved slide bringing products to a lower level) do not have moving parts and are by themself therefor not subject to any EU product regulation. The loop-sorter can be extended by adding-in additional sections, the loop-sorter is designed in a modular way and can be extended easily by opening of the loop and adding-in of extra parts.
The new spiral chutes shall not be CE marked. The extension of the loop is not repair / maintenance work and is a physical modification. The extension was not planned nor foreseen. There are however no new hazards (all hazards that were present before still apply) and risk does not increase just because the loop of the sorter has been extended.
Having new outputs will require an update of the software so there is also a digital modification. This modification does not necessarily include a safety function and if so this software can be issued without a CE mark / declaration of conformity.
All in all, this modification although physical can be seen as a non-substantial modification.

Example 2: An existing robot palletizer (cell) is being equipped with improved fencing and a light curtain due to a near miss whereby a worker entered the robot cell via the aperture for the conveyor.
Fencing and light curtains are safety components and where these are placed on the EU market separately they will have to be CE marked and come with a declaration of conformity.
The work on the robot cell cannot be seen as repair / maintenance work and there is a physical and digital modification.
The physical modification of the system (fencing and placing of the light curtain) were not foreseen nor planned by the OEM. The improved fencing (if positioned correctly) will not introduce new hazards (mind shearing hazard though) and the light curtain does neither (the LED's emit little energy). None of the existing risks increases due to the modification.
The digital modification incorporates a safety function (the light curtain and the muting thereof) which means the new software shall undergo a conformity assessment as this concerns a safety component. The manufacturer of the new software shall issue a declaration of conformity.

Figure 1-D shows decision in case of a digital modification whereby the digital modification possibly should be considered as a safety component.

[5] Safety component?
Yes; the software includes a safety function
No; the software does not include a safety function

Note: A safety function is a function of a machine whose failure can result in an immediate increase of the risk(s) – source ISO 12100:2010 – section 3.30

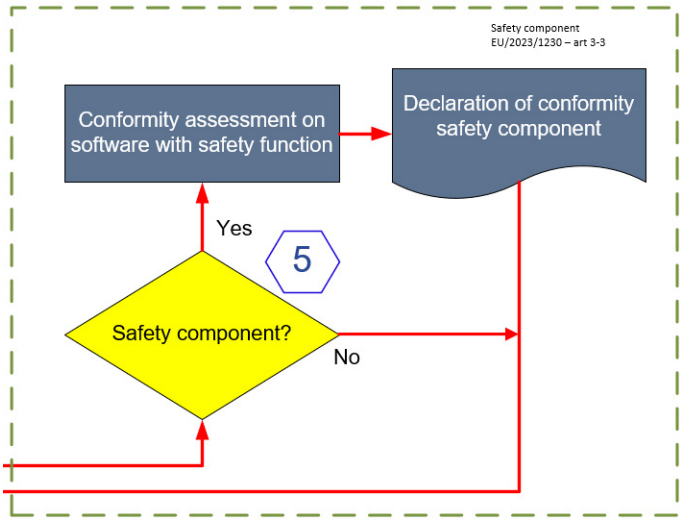


Figure 1-D; block "Safety component"

Example 1: A machine whereby the safety PLC is being replaced requires that the software is adapted to run on the replacement PLC. This replacement is necessary as the old safety PLC is no longer supported by the manufacturer so in essence it is a necessary repair. But as safety is affected (decision #3) and as there is a digital modification (decision #4) we need to consider decision #5. In case the software includes a safety function this software shall be considered as a safety component resulting in the need to assess the conformity of this software. In case the software that includes a safety-function is compliant a declaration of conformity shall be provided for this software.

4.5 Scope

Figure 1-E shows the decisions to determine the scope of a substantial modification. This is done by looking at two decisions. This part is based on article 18 and refers to obligations of the manufacturer regarding what is being placed onto the market or put into use for the first time in the EU.

[9 Assembly of machinery?
Yes; in case of an assembly of machinery the modification may apply to the entire assembly or just a part thereof (next decision)
No; the modified product does not concern an assembly of machinery but a "single" machine

[10] Does the modification affect the overall assembly?
Yes; the entire assembly is affected by the substantial modification
No; the impact of the substantial modification is limited to a section of the assembly (e.g. a single machine or a single line)

In case the entire assembly is affected the overall assembly shall be assessed on conformity against the actual regulation and harmonized standards. Where this is not the case the conformity assessment can be limited to the affected section of the assembly.

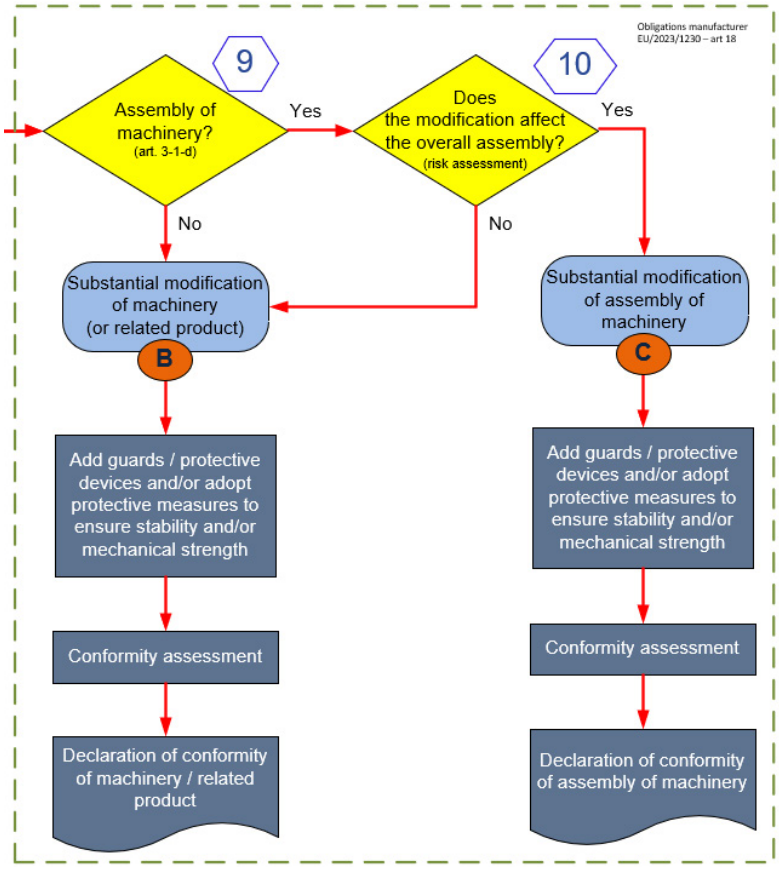


Figure 1-E; block "obligation manufacturer

Example 1: The lead screw of a small scissors lift (capacity 100 kg) is worn and acted too slow anyway, the user requests a manufacturer to revise the scissor lift and replace the lead screw by a pneumatic cylinder that can be fed via the pneumatic network that is installed in the factory.
This work is no ordinary repair, and it obviously concerns a physical modification that was also never foreseen by the OEM. Introducing a pneumatic cylinder in a system that previously did not have pneumatics introduces new hazards like stored energy, unexpected movements and possibility of leaks followed by sagging loads. Consequently, such conversion should be considered as a substantial modification. This scissor lift is not to be considered as an assembly of machinery hence the scissor lift as a product shall be considered equally a new product meaning the party that modifies this scissor lift shall redesign the scissors lift, assess its conformity with the essential health & safety requirements, compile the technical file, mark the product with CE (under that party's name) and issue a declaration of conformity.

Example 2: A foil wrapper that is incorporated in a packaging line for pallets is adapted to make it suitable for bigger rolls of foil, previously the machine allowed 20 kg rolls, after the modification rolls of 60 kg can be used.
As the lifting of 60 kg rolls is an ergonomic hazard, we need to consider this modification as substantial. The wrapper is part of an assembly line but the hazard only applies to the wrapper itself so the substantial modification can be limited to the wrapper itself. The party that executes this modification must do a conformity assessment on the foil wrapper and take the necessary technical measures to bring this machine in conformity with the essential health & safety requirements of the Machinery Regulation. Following the conformity assessment, the manufacturer compiles the technical file and issues a declaration for the foil wrapper which could be an EU declaration of incorporation of partly completed machinery or a declaration of conformity (depending on the scope).

4.6 Work equipment

The final block is shown in figure 1-F below. In case block B or block C result in “not a substantial modification” there is still the need to verify that the minimum health & safety requirements of directive 2009/104/EC are met. This directive is about the use of working equipment by employees. An employer may outsource modification work but remains responsible and therefore the employer shall take the necessary steps to assure that the work equipment after the modification is safe to use.

As there is no manufacturer the working equipment will not undergo a conformity assessment and consequently there will be no new declaration of conformity. This implies that the employer must keep a record of the modification including the justification that the modification is not substantial. Other documents that need to be kept are the risk assessment, declarations of incorporated products, test results, updated scheme’s / drawings and the updated instructions for use.

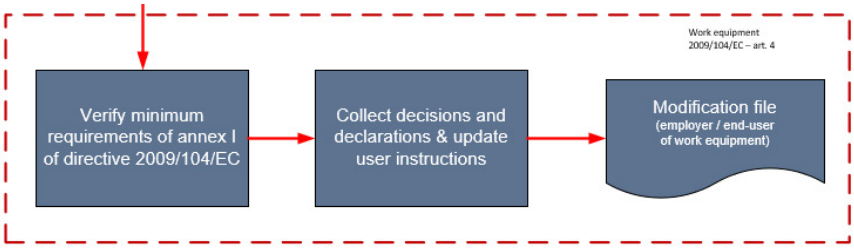


Figure 1-F; block “work equipment”

Example 1: An existing production line is relocated within the EU meaning the entire line is carefully disassembled into transportable sections, transported to another EU member state, and re-assembled just like it was done before. This means that the production line is in fact “second hand” equipment.
The route to being a not-substantial modification runs via decision #3; no (not repair / maintenance) and decision #4; neither (there is no physical nor digital modification) so by definition this cannot be considered as a substantial modification.
Nevertheless, it is important that the entire production line is commissioned equally a new line hence all safety critical points shall be tested, and these test results shall be documented. Where parts are replaced (e.g., cables) the certificates of those products shall be kept too. The risk assessment that supports the way the decision was made including the conclusion that the relocation is seen as a non-substantial modification shall also be added to the modification file.
Due to the relocation, it may be necessary to translate the user manual in case the official EU language of the area where the machine was relocated is different than the language of the earlier manual. If so, the warnings on the machinery (signs / interactive screens) may require a different language too.

5. Roles and responsibilities

5.1 Different roles & responsibilities depending on scope

Following the flow chart (as per figure 1), there are multiple possible situations:
1) Not a substantial modification (outcome A)
2) Substantial modification of machinery (outcome B)
3) Substantial modification of an assembly of machinery whereby:
   i. The modification does not affect the overall assembly (outcome B)
   ii. The modification does affect the overall assembly (outcome C)

Each outcome has different deliverables for different duty-owners.

[1] Outcome A - Not a substantial modification

In case of a not-substantial modification all duties are owned by the end-user (employer) of the work equipment (as there is no new machinery or related product). Therefore, the end-user needs to:
- Perform a risk assessment to identify hazards/risk/mitigation measures.
- Verify the safety of the transformed working equipment.
- Update the instructions for use (of the machinery) so the instructions represent the actual situation.

It is strongly recommended to create a "modification file" in which the following is documented:
- The modification including how it was and what was changed.
- Risk assessment in relation to the modification.
- Rationale for why the modification is not substantial (this can be based upon figure 1).
- Test reports of all safety related functions and provisions to assure they have maintained their functionality.

See chapter 6 for more details on instructions for use.

[2] Outcome B - Substantial modification of machinery

Where there is a substantial modification there is a manufacturer and this manufacturer must assure compliance of the machinery or related product with the Machinery Regulation (EU) 2023/1230 or (until the 20th of January 2024) the Machinery Directive 2006/42/EC.

The end-user receives a new declaration (often a declaration of conformity). The process is equal to the supply of new machinery with an exception that:
- The end-user makes the existing machinery available to the modifying manufacturer.
- The end-user provides the available documentation to the modifying manufacturer like:
  - Instructions for use
  - Declarations and test reports

In case documentation has gone lost the substitution the modifying manufacturer shall create new documentation; this requires to be contractually agreed as this will increase the scope of works by the modifying manufacturer.

[3-i] Outcome B - Substantial modification of machinery – within an assembly of machinery

A substantial modification within an assembly of machinery but where the modification does not affect the overall assembly can be handled as a modification of individual machinery (completed or partly complete – hence equals outcome B). In such case the part of the assembly that is not-substantially modified remains as it was but the original instructions-for-use nevertheless require an update which means rework.

In this situation the ownership of the overall documentation (i.e., the part not supplied as part of the substantially modified individual machinery) remains with the end-user of the machinery. Therefore, it is strongly recommended for the end-user (employer) to create a "modification file" in which the following is documented:

- The transformation of the assembly indicating the following on a layout:
  - Existing situation,
  - Not substantial modified equipment,
  - Substantially modified equipment,
  - Relocated not substantial modified equipment,
  - New equipment.
- Risk assessment in relation to the modification.
- Rationale for why some parts of the assembly are not-substantially modified and why others are (this can be based upon figure 1).
- Test reports of all safety related functions and provisions to assure they have maintained their functionality.

The end-user can outsource this work (or parts thereof) to the involved manufacturer; the work needs to be considered as a service and therefore the end-user needs to be contractually agreed with the manufacturer of the modification. The end-user however remains legally responsible as this part of the work is not covered under the Machinery Regulation.

[3-ii] Outcome C - Substantial modification of the assembly of machinery
A substantial modification whereby the modification also affects other parts / components / assemblies of that assembly (meaning a new hazard is introduced or an increase in risk level applies) the overall assembly is considered as substantially modified. This means that the manufacturer of the overall assembly owns the overall responsibility like the overall assembly is new.

5.2 Responsibility of a manufacturer of a substantial modification

A substantial modification of machinery means that the manufacturer must assure compliancy with the Machinery Regulation (EU) 2023/1230. This includes compiling the technical documentation as prescribed in annex IV of the regulation.

5.3 Recommendation in case of transformation of machinery

In case the contract lacks detail on the scope of works it often happens that the expectation of the end-user differs to that of the party that executes the transformation. It is self-explaining that such situation always results in conflicts concerning work, material, and budget. It is therefore recommended that the end-user and the party that execute the transformation discuss the needs of the end-user and the legal consequences of the transformation.

For complex transformations (often assemblies of machinery) it is recommended that the party that executes the transformation includes in the quotation the following specifics:
- Describes the work and material, preferably with a drawing that shows:
  - Not-substantial modified equipment (original / relocated),
  - Substantial modified equipment,
  - New equipment.
- Describe what declaration(s) will be provided including the applicable directives / regulations.
- What harmonized standards / common specification will be applied.
- Planning on phasing (if applicable).

The end-user in return shall review the quotation in detail to verify it matches the expectations. Where work in relation to a non-substantial modification is contractually agreed the end-user shall inspect the work in detail as it concerns a service for which the end-user has a legal responsibility.

6. Instructions (for use)

Instructions (machine documentation) are mandatory with machinery or related products, but also under the working equipment directive it is a requirement to have instructions although the requirements are less stringent.

Following the previous steps, the situation for documentation can be split-up in three possibilities:

I. Update for a “not-substantial modification” (chapter 5, situation 1)
II. New instructions for a “substantial modification” (chapter 5, situation 2 and 3-ii)
III. Combination of I and II (chapter 5, situation 3-i)

6.1 [I] Instructions in case of “not a substantial modification”

In case the instructions (machine documentation) only require an update to ensure that the instructions match the actual work equipment figure 2-A applies.

The content and the language of the instructions are subject to the strictest requirements of either:

- the national transposition of directive 2009/104/EC (the Use of Work Equipment Directive 2009/104/EC) or;
- The Machinery Directive / Regulation that applied at the time when the machinery was first put into operation / placed on the market.

End-users (employers) may need to obtain translations of instructions in case there are employees that do not master the native language sufficiently to understand the content. This however has no direct relation with transformation of machinery.

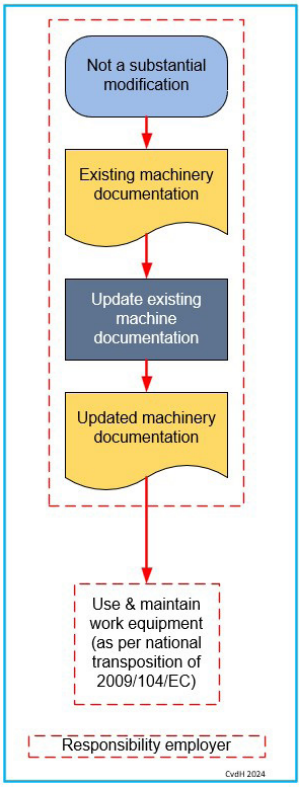


Figure 2-A; instructions – in case of a not-substantial modification

6.2 [II] Instructions in case of a substantial modification

In case of a substantial modification (covering the entire machinery or assembly) figure 2-B applies.

The manufacturer of the transformed machinery has to provide instruction (machine documentation) that totally complies with the essential health & safety requirements of regulation (EU) 2023/1230 (or directive 2006/42/EC if the first placing on the EU market or putting into operation applies before the 20th of January 2027).

A manufacturer of the substantial modified machinery can apply the following (harmonized) standards:

- IEC/IEEE 82079-1:2019, Preparation of information for use (instructions for use) of products — Part 1: Principles and general requirements
- EN ISO 20607:2019, Safety of machinery - Instruction handbook - General drafting principles

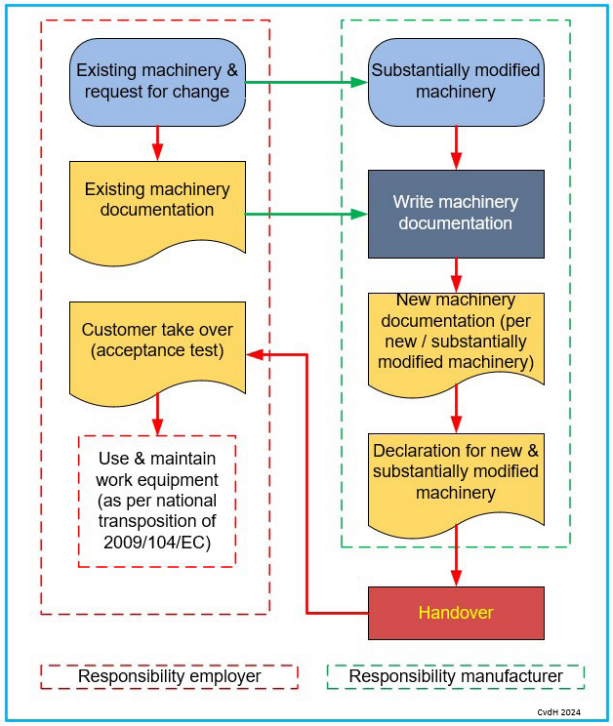


Figure 2-B; instructions – in case of a substantial modification

The work involved to create new instructions can be huge, especially if the existing information is not available, of poor quality or in a non-electronic or non-compatible format. It is recommended therefore for the manufacturer of the modification to investigate the amount of work before handing out the quotation.

6.3 [III] Instructions in case of a combination

In case of a combination of I and II (chapter 5, situation 3-i) figure 2-C applies:

This situation usually results in new instructions being embedded in (an update of) the original version of the instructions. The embedded part is newly created by the manufacturer and this manufacturer shall adhere to the requirements as explained in previous section.

The end-user (employer) holds the responsibility for the overall instructions (machine documentation). This work can be outsourced to the manufacturer of the modification (see chapter 5, [3-i]), if the end-user wishes to do it should be covered under the scope of works of the contract. As the work is hugely depending on the availability, quality and format of instructions the work can be quite demanding in terms of involved hours. Especially when the existing instructions are not available, have a poor quality or are in a non-electronic or non-compatible format.

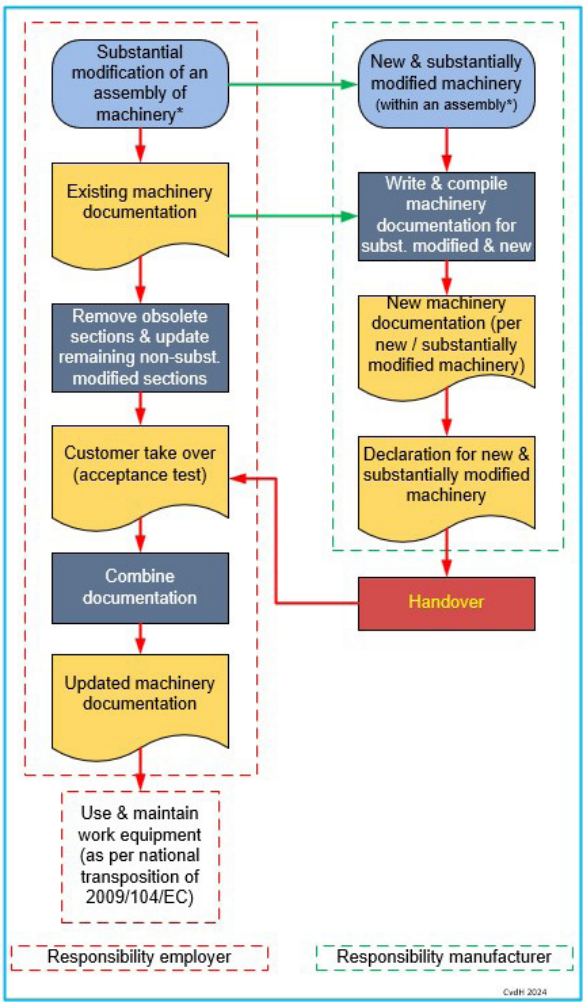


Figure 2-C; instructions – in case of combination of I and II

7. Market surveillance

7.1 Market surveillance on new machinery & substantial modified machinery

In case of a serious accident whereby the supervisory authority has reasons to suspect that the machinery played a role in causing that accident the manufacturer (or authorized representative) must provide a copy of the technical documentation in case of a reasoned request.

The supervising authority will study the technical documentation to verify whether the machinery fulfils the essential health & safety requirements of the Machinery Regulation (EU) 2023/1230 (or Machinery Directive 2006/42/EC for machinery placed on the market / put into use before the 20th of January 2027).

An end-user is obliged to have a declaration for work equipment (in case of e.g. machinery) as laid down in **Directive 2009/104/EC** article 4 (minimum safety and health requirements for the use of work equipment by workers at work) unless the concerned machinery was first placed on the market or put into service before the 1st of January 1995.

Note: If the end-user himself makes a substantial modification he is simultaneously employer and manufacturer meaning the duty to provide the technical documentation after a reasoned request is his.

7.2 Market surveillance on not-substantially modified machinery

In case of not-substantially modified machinery all comes down on the end-user (employer). Therefore the end-user shall have a technical file.

In case a modification is made to any part of the machinery, apart from whether this is a substantial or not even a non-substantial modification this needs justification why it is not substantial and a clarification on what has been modified exactly. Part of the technical file is also 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).

8 Practical issues

8.1 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. Note that under the Machinery Directive / Regulation some duties automatically apply to a specific party, for example the manufacturer. Where the work is not subject to the Machinery Directive / Regulation or alike the work shall be described in more detail. Especially the following points requires explicit description:

- Which party is responsible for the overall machinery (acts as a principle contractor / integrator)?
- And for what part of the machinery / work is each stakeholder responsible?
  - 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.

8.2 Contractual elements

Furthermore, it is recommended to describe the following aspects in each contract that involves modification of machinery (especially if that modification could turn out to be substantial):

- Who provides information concerning the existing machinery / parts?
- In what format is the information available (pdf or handwritten text / drawings / notes)? Especially hand-written information may cause additional rework and makes editing a demanding job).
- How to act in case translations are needed? For instance, where the existing machinery was not provided with a manual in the official EU language manual.
- What to do if information (on existing parts) is not available?
- Duties of involved parties to participate in assistance necessary to complete the works/ deliveries.
- Clarify who is the project owner and who “owns” unforeseen situations.

8.3 Availability of existing documentation / data

In case of substantial modification and/or supply of new machinery (or other scope under a product directive / regulation) there is a duty for the responsible party to complete the technical file of that product 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 the availability of the technical file of the original machinery (or part thereof) at their disposal.

Machinery older than 10 years may not have a technical file anymore as there is no obligation for the OEM to keep the necessary documentation. Note that the OEM cannot be obliged to hand over the technical documentation to a customer, an end-user or another third party..

Ways to constitute the technical documentation of machinery or work around:

- 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 for instance deliverance of a declaration of conformity or a PCM declaration).

- Apply principles of reversed engineering (often done in verification of suitability of steelwork for increased dead-load of machinery).
- Testing and/or measuring to determine characteristics / load bearing capacities.

8.4 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 to ensure safety. If a checklist is available, a filled-out checklist, signed by the responsible engineer is recommended.

8.5 Putting transformed machinery back into operation

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

The following list of attention points (non-exhaustive) requires action by the end-user:
1) Operator instructions (note; machinery documentation ≠ instructions)
2) Operator training program
3) Workplace risk assessment / plan of approach on risk mitigation
4) Maintenance regime
5) Inspection program

Whether or not any of the above is applicable shall be evaluated by the end-user on a case-by-case approach. It is recommended to document each step for future reference.

9. Use cases

9.1 Replacing a safety PLC

An end-user needs to replace a safety PLC because the original one is no longer supported by the manufacturer and the current one has become unreliable.

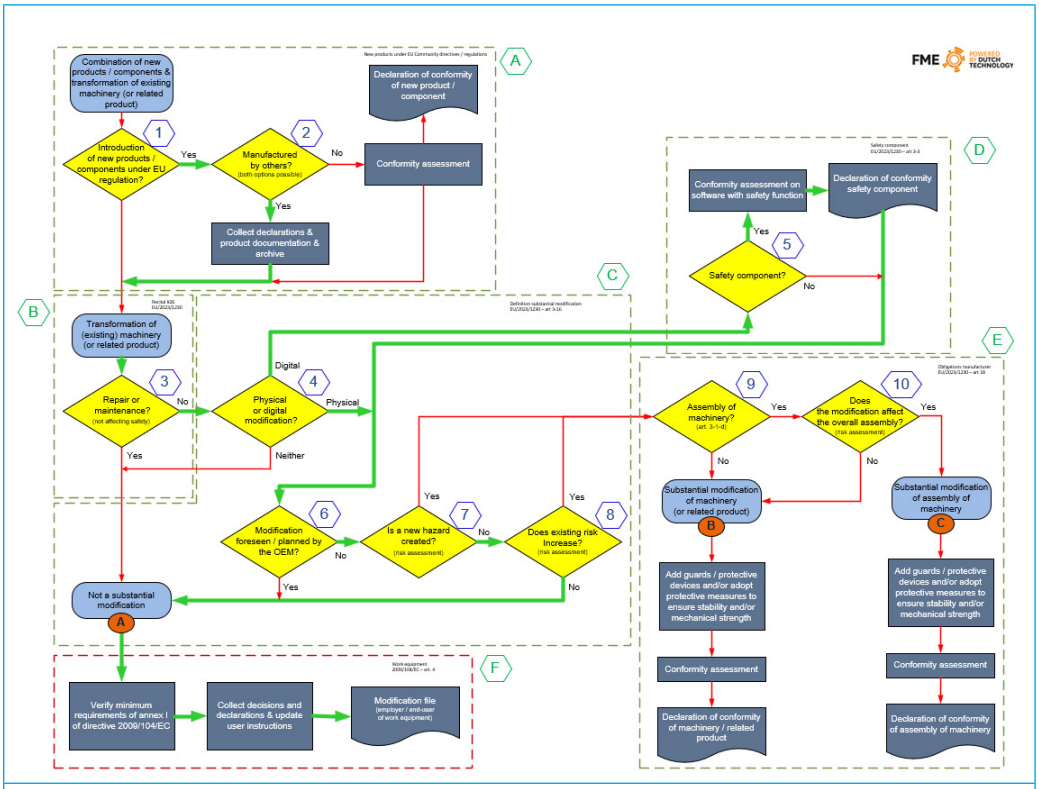
The safety PLC is new [1] and manufactured by a well-known manufacturer of safety components [2]. As this concerns a safety component this safety PLC shall be CE marked and shall be supplied with a declaration of conformity under the Machinery Regulation (or directive if supplied before the 20th of January 2027).

This replacement is done to keep the machinery in operation and is thus an act of repair as shown in figure 1 under [3] as long as the form / fit / function remains identical. However, the replacement does affect safety and some reprogramming is required so further analysis is necessary hence the answer to decision [3] is “no”.

The modification concerns both a physical as well as digital modification [4]. The digital modification concerns a safety component [5] and therefore the new software shall undergo a full conformity assessment against the actual legislative and normative requirements (harmonized standards). Replacement of a safety PLC is typically not foreseen by the OEM [6]. As the replacement follows the form / fit / function rule and because the safety related software is assessed on conformity there is no introduction of a new hazard [7] (the machinery operates like previous). Similar there is no increase in existing risk [9]. Consequently the (physical) change is a non-substantial modification [A].

For the new safety related software, we have a manufacturer and that manufacturer needs to provide a declaration of conformity for this product as it is a safety component. The end-user of the system needs to collect this declaration and the declaration of conformity of the new safety PLC itself. Other than that, there are no new declarations (hereby we assume that wiring is not replaced).

To assure that all safety functions work like they should it is important that all these functions are verified, such tests shall be documented, and these reports shall be added to the modification file that is owned by the end-user (as this is not covered by a declaration of conformity of the manufacturer as there is none).



Use case #1 – figure 1 flow (thick green arrows)

9.2 Increasing the power on a lawn mower

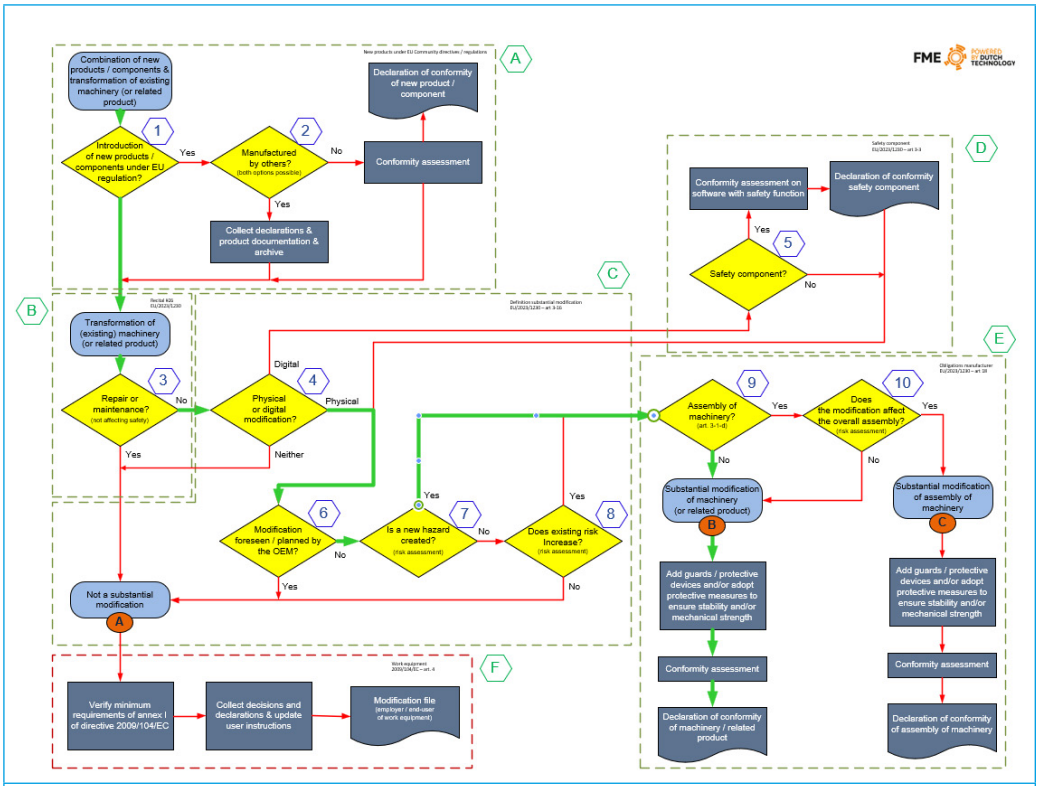
An end-user runs a gardening business and owns several lawn mowers. One of the lawn mowers is used to mow shoulders and therefore demands more torque. The petrol engine (single piston) has seen better days, and stalls frequently due to insufficient torque. The end-user takes a bigger engine (taken from another bigger mower) and installs that one on the existing mower frame. Fitting the bigger engine requires an adaptor-ring to fit the engine onto the frame. Another adaptor is manufactured to mount the cutting blade onto the shaft.

This replacement has nothing to do with repair / maintenance hence the answer to decision [3] is “yes”.

The modification concerns only a physical modification [4]. There is no digital modification so block D is not relevant. The motor replacement does not create a new hazard [7] (the machinery operates like previous). Due to the stronger engine there is an increase of the existing risks [9] like more noise, more stress on the frame and perhaps more force to pull-start the engine. Consequently the (physical) change is a substantial modification hence we need to explore block E.

A lawn mower is not an assembly of machinery [9] and consequently the substantial modification applies to the overall lawn mower as one machine. This means that a conformity assessment shall be done on the entire lawn mower and this assessment shall be against the actual set of legislative (Machinery Regulation, outdoor noise directive, EMC directive) and normative requirements i.e., the harmonized standards under the regulations / directives that would apply to the lawn mower.

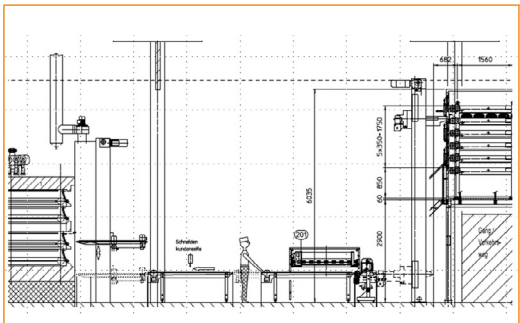
By replacing the engine by a bigger one the end-user has become the manufacturer of the new modified lawn mower and consequently the end-user shall assure all relevant essential health & safety requirements are met. From economic perspective it could turn out cheaper to procure a designed for purpose mower instead but that is another discussion.



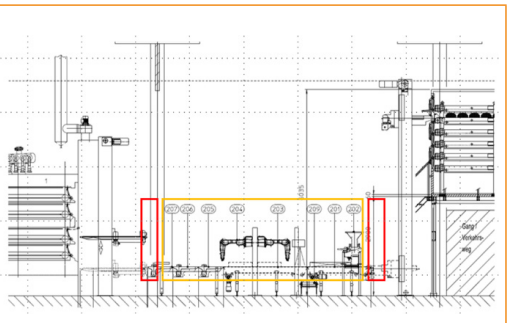
Use case #2 – figure 1 flow (thick green arrows)

9.3 Replacing a manual workstation by a robot in a large manufacturing system

An end-user owns a production line in which a manual workstation is situated. The work exists of picking up semi-finished product and placing that on a cutting and packing unit. Due to poor ergonomics and monotone and a machine determined work rate the end-user wants to get rid of this workstation. Unfortunately, the OEM went broke several years ago so the end-user contacts another manufacturer of similar production lines for the works. An image of the old versus new situation is shown in the figure below. The part in the yellow rectangle is new machinery, the red marked areas are modified so the new equipment fits within the two existing sections. The modification of the existing parts concerns shortening of belt conveyors.



Existing situation (old)



Desired situation (new)

Existing situation (old) versus desired situation (new)

The original production line was taken into operation 15 years ago but is well maintained and still functions to the satisfaction of the end-user. The technical documentation is not available, only a hardcopy of the original declaration and user-manual with some drawings of the overall system and the electrical diagrams exist. The end-user wonders if it is necessary to consider the transformation of the production line (left, center, right) as one new assembly because of the modification. As end-user and manufacturer want to execute this complex job in a good way, they discuss the scope and who owns what responsibility and thereto they use figure 1 of this brochure.

The part that replaces the old manual workstation is new machinery [1] and this machinery is manufactured by the contracted manufacturer [2]. The new machinery requires a declaration of conformity and shall therefore undergo a conformity assessment. As the new equipment (automatic operating arms) typically involve crushing and shearing hazards the deployment of perimeter guarding is practically unavoidable. Such guards are typically based on fencing and as frequent intervention is expected one or multiple interlocked access doors are needed (unless a camera based virtual guard is applied). The safety related part of the control system can be part of the new machinery. The software to run this machinery incorporates multiple safety functions and therefore this software is seen as a safety component that requires its own declaration of conformity except if that software is already uploaded on the machinery (version 1.0). Future updates are separately placed on the market (even in case of service) and consequently meet the definition that way.

This replacement has nothing to do with repair / maintenance hence the answer to decision [3] is “yes”.

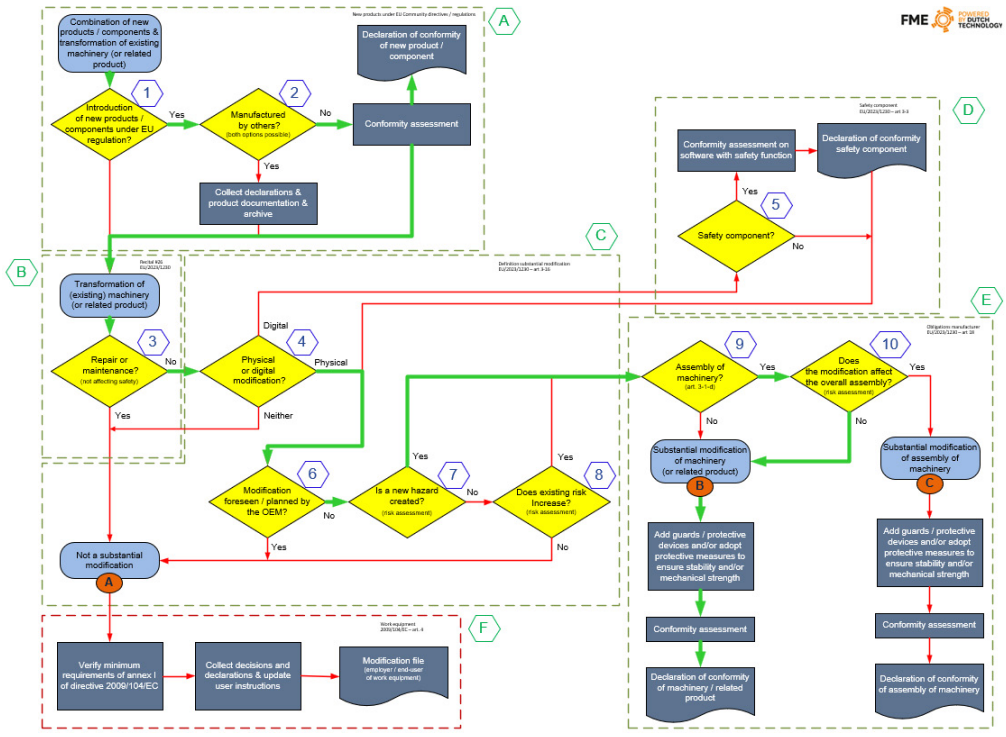
The transformation concerns obviously a physical modification [4]. Replacement of the workstation was not foreseen by the OEM [6]. The installation of new equipment in between existing equipment introduces new hazards like crushing / shearing hazards due to exposure to moving machinery. Also hazards in relation to accessibility to serviceable points and points where intervention can be expected apply (for instance removing jammed products). Due to such new hazards [7] one needs to consider the transformation as a substantial modification. That risk may increase [8] is not relevant anymore but increase of risk (for instance more noise) can simultaneously apply.

If the transformation also requires changes to the existing control system [4] an investigation is necessary whether safety functions are affected [5]. If so, a conformity assessment on that software is required as that software is then considered as a safety component that is substantially modified. For this case we assume that this is not the case (and therefore the lines to/from block D are not marked green.

The new situation is an assembly of machinery as defined in the Machinery Regulation [9]. The modifications however only apply to the new automated part (see figure – yellow frame) and the interface (red frame) and accessibility to the existing parts [10]. Where the existing assembly of machinery is not affected by the transformation a split can be made (basically the part beyond the interface). Note that the interface is not limited to the physical machinery but also access routes and emergency stop system are to be taken in consideration. Nevertheless there remains a huge part of the existing system that is not affected at all and that part can be considered as “not physically modified”[4]. The Machinery Regulation speaks of “avoiding disproportional burden” when doing a substantial modification. The guide to the application of the Machinery Directive 2006/42/EC allows in paragraph 38 the dividing of industrial plants into sections and even into single lines or separate machines if there is no safety relation. The risk assessment shall of course be the instrument to use to investigate whether this is the case.

...
So for the purpose of applying the Machinery Directive, most industrial plants can be divided into different sections, each of which may be a distinct assembly (of machinery) or even an independent machine (e.g. a mixing vessel). Even a single production line may be divided into separate assemblies and/or machines if there is no safety related connection between constituent assemblies or machinery.
...

Guide to the application of the Machinery Directive 2006/42/EC, edition 2.3 paragraph 38



Use case #3 – figure 1 flow (thick green arrows)


63
65
67
69
71
73
75
77
79
PARIS
ETOILE

9.4 Increasing a sorter's capacity but within design specification

An end-user that uses a sorter (sorting conveyor within a material handling system) wants to increase capacity. The OEM that designed the sorter is requested to increase the operating speed to 2,5 m/s. As the end-user initially didn't have a demand for this capacity the operating speed was reduced 1,5 m/s (to save energy and reduce wear). The higher speed does mean an extra linear motor has to be installed (which can be fitted and fed without changing other parts). The sorter was built according to the Machinery Directive 2006/42/EC.

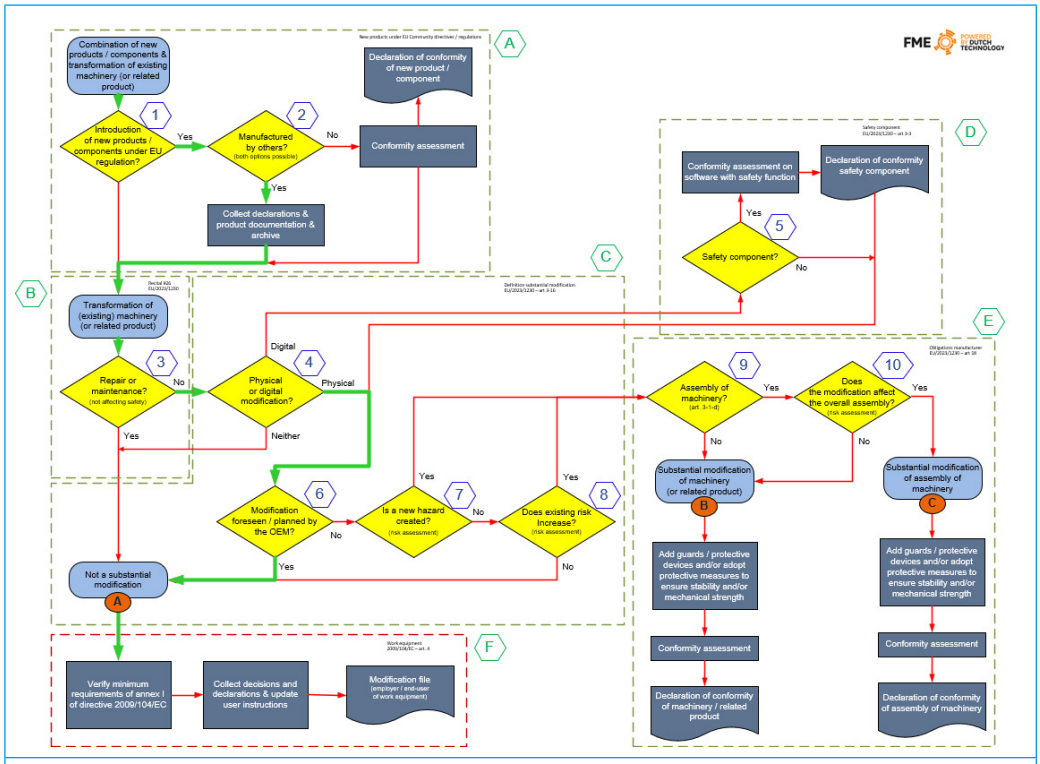
As the business grows the end-user also wants to add five gravity outputs (spiral curves = curved sliding plate without moving parts) to the existing sorter (which is installed on a supporting frame), this does not require any modification to the sorter as the sorter's software can easily be configured to feed those extra outputs. According to the health and safety risk assessment and harmonized standard EN 619:2022 there is no reason to consider the sorting function as a safety related part of the control system as a failure in that function will not result in immediate risk of persons (due to presence of already included safeguarding measures like safety netting to catch mis-sorts).

As there are multiple modifications applying simultaneously, we need to split this case in two:
1. Increasing the speed of the sorter from 1,5 m/s to 2,5 m/s.
2. Adding additional outputs and reconfiguring the software of the sorter.

[1] Increasing the sorter's speed

There are some new parts / components required that are subject to EU regulations [1] and [2]; a linear motor and the electrical parts to feed and control this motor. These parts are manufactured by others and the OEM of the sorter needs to collect the declarations.

The modification is not repair nor maintenance [3]. There is a physical modification [4] due to the additional drive section.



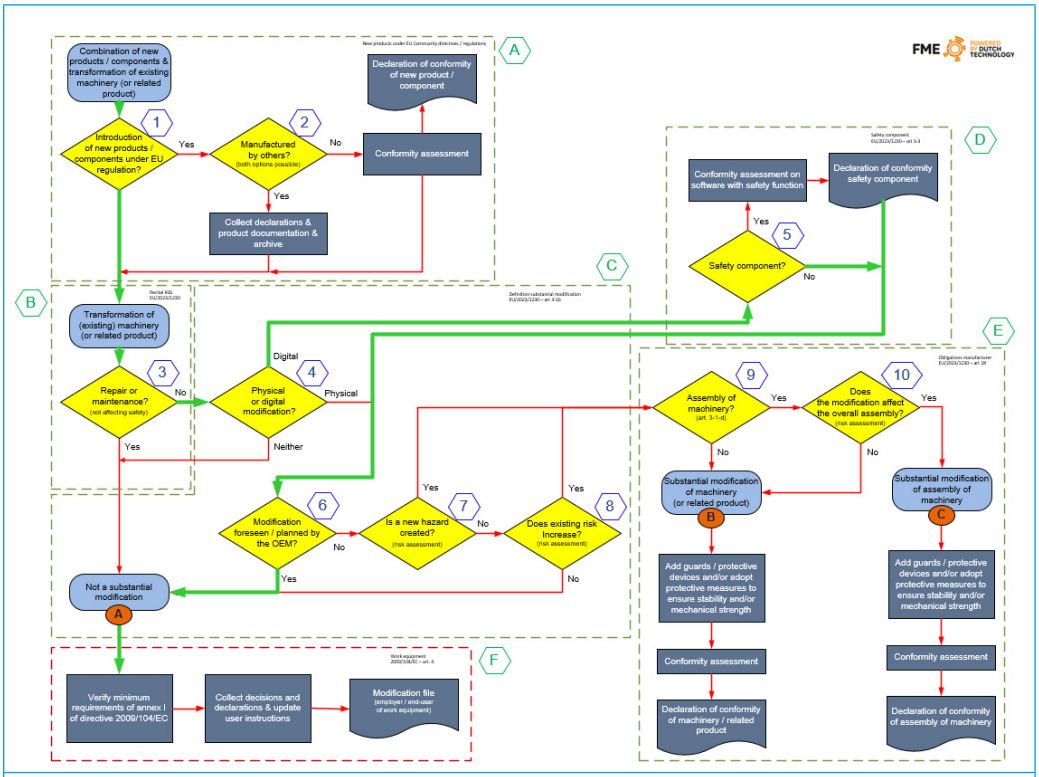
Use case #4a – figure 1 flow (thick green arrows)

The OEM did envisage the higher speed (the speed increase stays within the design specifications of the sorter) and therefore this modification can be considered as foreseen by the OEM [6] as all safety measures are designed for the higher operational speed of 2,5 m/s. This means that the modification of the speed increase can be considered as non-substantial one. The modification file shall be completed with the collected declarations of motor and electrical / control parts and cables and the test reports on electrical safety and proper operation.

[2] Adding additional outputs and reconfiguring the software of the sorter.
The new outputs do not have moving parts and therefore fail to meet the definition of machinery [1]. The outputs are also not covered as related products under the Machinery Regulation (EU) 2023/1230. Other EU regulation are also not applicable, so these outputs come without CE marking / declaration.

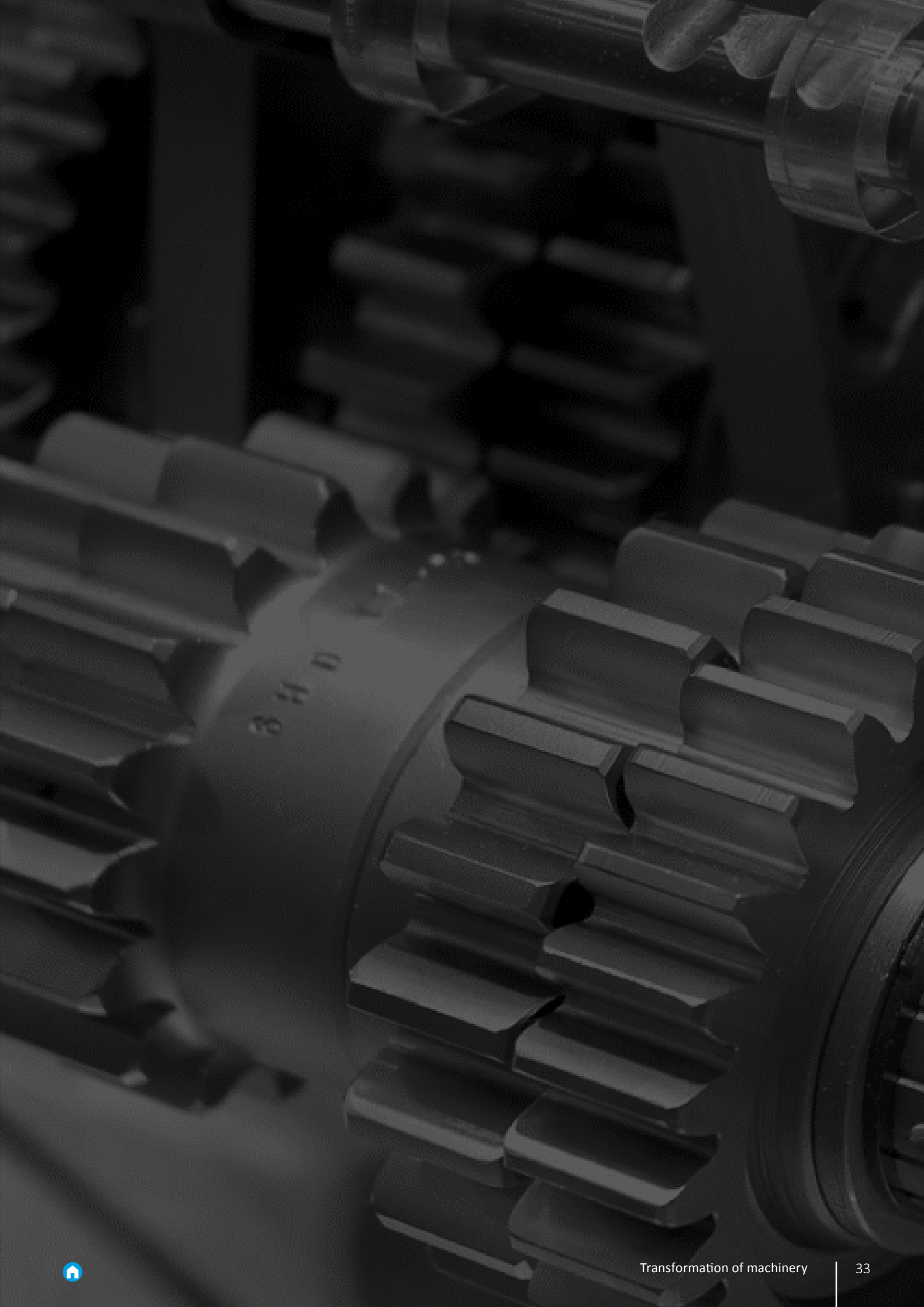
The modification is not repair nor maintenance [3]. There is no physical modification to the sorter itself [4] but there is a digital modification, so we continue in block D. The modified software does not include a safety related function so it's not subject to the Machinery Regulation (EU) 2023/1230 [5].

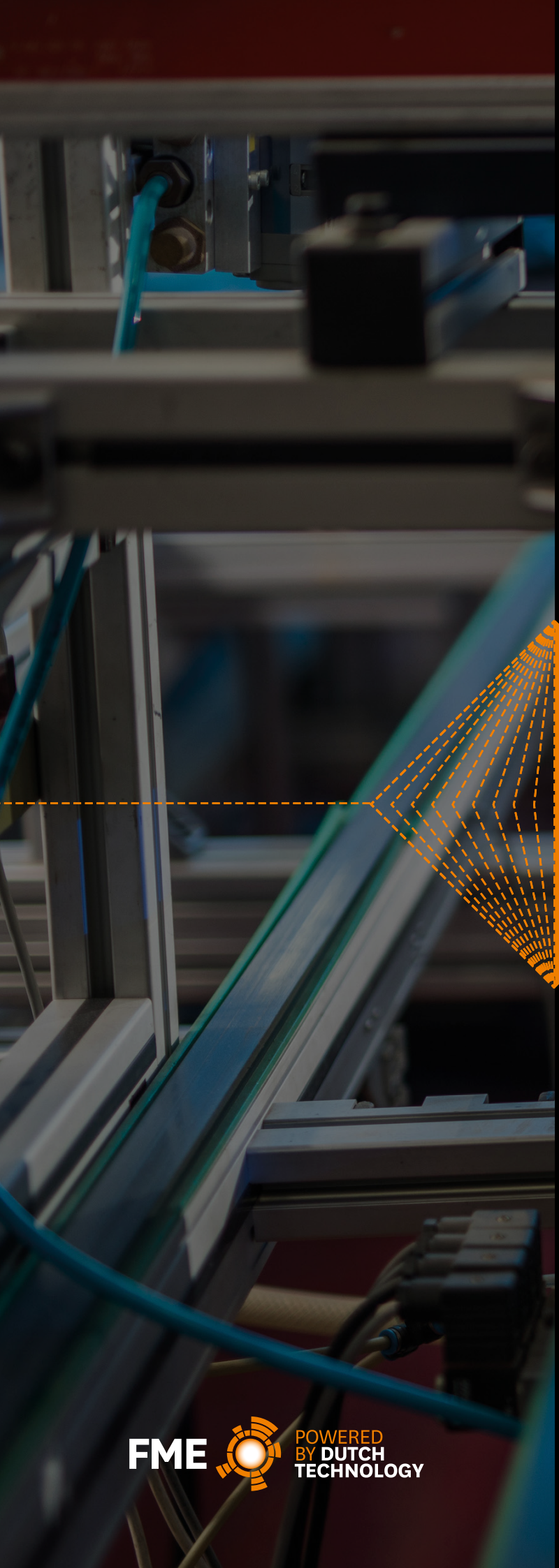
The OEM did design the sorter in such a way that along the sorter's length outputs can be installed (this flexibility is a precious property of the sorter) so again the OEM envisaged that additional outputs can be installed [6].



Use case #4b – figure 1 flow (thick green arrows)

This means that again this modification is not substantial. The test report in which the safety requirements are verified (like robust execution, absence of sharp edges, measures against falling objects etc.) shall be added to the modification file.





FME POWERED BY DUTCH TECHNOLOGY

Postbus 190, 2700 AD Zoetermeer
Zilverstraat 69, 2718 RP Zoetermeer
+31 (0)79 353 11 00
info@fme.nl

fme.nl