Does the Machinery Directive apply to your products?

or

How I Learned to Stop Worrying and Love the Machinery Directive!

“Experiences working with the EU Machinery Directive (2006/42/EC)”

John McBain
Product Safety Engineer

What is this presentation about?

A *brief* discussion of:

* Does the Machinery Directive (MD) apply to you?
  (MD = 63 pages, but MD Guide = 465 pages)

* Why does it apply?
  (maybe you make machinery, or maybe not)

* If it applies, what do you do about it?
  (how to *start* your evaluation)

* Can you learn to love the MD too?
  (you did come to this presentation …)

What is this presentation NOT about?

A *future* discussion of:

* The Proposal for a **Regulation** of the European Parliament and of the Council on machinery products

* Why not?
  - **It's still a proposal and does not currently apply.**
  - Proposed changes are generally to
    cover new risks originating from emerging technologies, (such as AI, autonomous robots, SW updates), simplify requirements (such as printed instructions), and most existing definitions and evaluations will continue.

* If proposed changes will apply to me, what should I do?
  - Read the proposal, **then give a PSES presentation!**

PART ONE

Does the Machinery Directive apply to my products?

(I sure hope not!)

Why should I care about the Machinery Directive?

1. I want to ship products to Europe.
2. My products are covered by the Machinery Directive.
3. I want to comply with the EU law.

If all three items apply to you and your products, then you do care about the Machinery Directive.

… Let's assume #1 and #3 and take a look at #2.

Are your products within the scope of the MD?

Article 1

Scope

1. This Directive applies to the following products:

(a) machinery;

(b) interchangeable equipment;

(c) safety components;

(d) lifting accessories;

(e) chains, ropes and webbing;

(f) removable mechanical transmission devices;

(g) partly completed machinery.

Scope of the MD (continued)

Let’s see if we can ignore some of these categories:

Article 2

Definitions

The following definitions shall apply:

(b) ‘interchangeable equipment’ means a device which, after the putting into service of machinery or of a tractor, is assembled with that machinery or tractor by the operator himself in order to change its function or attribute a new function, in so far as this equipment is not a tool;

Scope of the MD (continued)

Is that clear, now? Good! Then how about this one:

(c) 'safety component' means a component:

— which serves to fulfill a safety function,
— which is independently placed on the market,
— the failure and/or malfunction of which endangers the safety of persons, and
— which is not necessary in order for the machinery to function, or for which normal components may be substituted in order for the machinery to function.

So if you make & sell light curtains for safety, you make machines, even if they have no moving parts.

Scope of the MD (continued)

To save time I will limit the scope of this discussion to:

(a) machinery;

~~(b) interchangeable equipment;~~

~~(c) safety components;~~

~~(d) lifting accessories;~~

~~(e) chains, ropes and webbing;~~

~~(f) removable mechanical transmission devices;~~

(g) partly completed machinery.

Excluded from the scope of the MD

But wait! That's not all. We have started to look at what is machinery, but we need to look at what is not machinery.

2. The following are excluded from the scope of this Directive:

- (a) safety components intended to be used as spare parts to replace identical components and supplied by the manufacturer of the original machinery;
- (b) specific equipment for use in fairgrounds and/or amusement parks;
- (c) machinery specially designed or put into service for nuclear purposes which, in the event of failure, may result in an emission of radioactivity;
- (d) weapons, including firearms;
- (e) the following means of transport … with the exclusion of machinery mounted on these means of transport;
- (f) seagoing vessels and mobile offshore units and machinery installed on board such vessels and/or units;
- (g) machinery specially designed and constructed for military or police purposes;
- (h) machinery specially designed and constructed for research purposes for temporary use in laboratories;
- (i) mine winding gear;
- (j) machinery intended to move performers during artistic performances;
- (k) electrical and electronic products falling within the following areas, insofar as they are covered by Council Directive 73/23/EEC [Low Voltage Directive] …: household appliances intended for domestic use, audio and video equipment, information technology equipment, ordinary office machinery, low-voltage switchgear and control gear, **electric motors**;
- (l) the following types of high-voltage electrical equipment: switch gear and control gear, transformers.

Excluded from the scope (continued)

Three of these exclusions could use a bit more consideration:

(a) safety components intended to be used as spare parts to replace identical components and supplied by the manufacturer of the original machinery;

- your spare parts are not considered separate machines

(h) machinery specially designed and constructed for research purposes for temporary use in laboratories;

- this lets research scientists build an apparatus … but not you

(k) electrical and electronic products falling within the following areas, insofar as they are covered by Council Directive 73/23/EEC [Low Voltage Directive] …: household appliances intended for domestic use, audio and video equipment, information technology equipment, ordinary office machinery, low-voltage switchgear and control gear, electric motors;

- if your equipment is *fully* in one of these categories (such as ITE), then no MD for you! (But ITE may be part of a machine.)

Excluded from the scope (continued)

Article 3 of the MD also states that the Machinery Directive does not apply to machines for the risks covered more specifically by other EU Directives.

When other Directives cover all the risks associated with the machines, the machines are entirely excluded from the scope of the Machinery Directive.

- Examples are the Toy Directive and the Medical Devices Directive, but not the Low Voltage Directive.

When the specific Directives only cover some of the risks associated with the machines, the machines are in the scope of the Machinery Directive for the remaining risks.

- An example is the ATEX Directive, which applies - for the explosion hazard - to machinery intended for use in potentially explosive atmospheres. The MD applies for all the other hazards.

Included in the scope of the MD

Getting back to our selected two categories –
there are 5 indents narrowly defining the word “machinery”.

(a) ‘machinery’ means:

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

- without all four characteristics [a to d] – it’s *not* a machine

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

- so with no power cord or air hose – it’s *still* a machine

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

- therefore, if it can’t operate until attached to a vehicle or building - such as a gantry crane - it’s *still* a machine

Included in the scope (continued)

… and the last 2 indents for the narrow definition of “machinery”:

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

- without both characteristics [a & b] – it’s *not* a machine
  - proximity of the parts is not enough to make an assembly

— an assembly of linked parts or components, at least one of which moves and which are joined together, intended for lifting loads and whose only power source is directly applied human effort;

- here is the only exception to the indent 1 exclusion of “directly applied human or animal effort” to operate a machine

---

Note that for both indents 1 and 4 all the points highlighted must be true for a device to be considered a machine.

Included in the scope (continued)

For example, a machine is (per indent 1) -

"an assembly, fitted with or intended to be fitted with a

[a] drive system other than directly applied human or animal effort, consisting of

[b] linked parts or components, at least

[c] one of which moves, and which are

[d] joined together for a specific application"

[a] electric motor
[b] assembled
[c] blades move
[d] application is to provide hot air - so the fan is part of the specific application

Heater with fan is a machine

[a] electric motor
[b] assembled
[c] blades move
[d] application is to provide electricity - so the fan is *not* a direct part of the specific application

Power supply with fan is *not* a machine

Included in the scope (continued)

Time for a riddle –

“When is a machine not a machine?”

Included in the scope (continued)

Answer #1 – When it's a "partly completed machine".

(g) 'partly completed machinery' means an assembly which is [a] almost machinery but which [b] cannot in itself perform a specific application. A drive system is partly completed machinery. Partly completed machinery is [c] only intended to be incorporated into or assembled with other machinery or other partly completed machinery or equipment, thereby forming machinery to which this Directive applies;

- without all three characteristics [a to c] – it's *not* a partly completed machine

---

This distinction is similar to the UL category of "Recognized Component" because partly completed machines have some lack that must be remedied in the final product.

This distinction also is important because the required marking and documentation is different for partly completed machines – for example, they need Declarations of Incorporation (DofI) instead of Declarations of Conformity (DofC).

Scope of the MD – summary

So the MD covers machines, assemblies of machines and partly completed machines (as well as the additional categories we ignored earlier), and it does *not* cover ITE (or the other items we mentioned earlier).

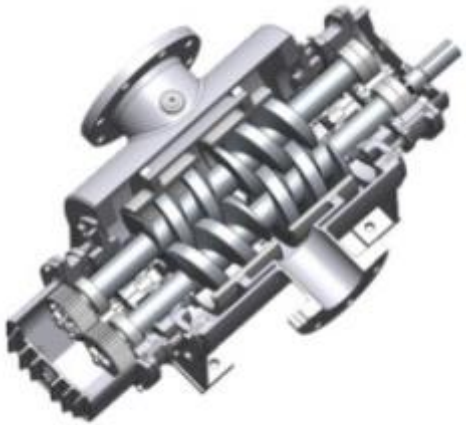
Now you should know if it applies to your products.

- All clear so far?
- Any questions about these 3 categories?

Then let’s take a look at some machines … or are they?

Scope of the MD – included or not?

Centrifugal Pump



Screw Pump

Pump Motor

Water Pump

Scope of the MD (concluded)

A few loose ends to tie up (from the MD Guide):

(1) For machinery to be supplied *without* a drive system:

- the risk assessment must include the drive system
- the instructions must include the specs and installation of the drive system
- assessment must cover the specs and instructions of the drive system
- CE Marking and DofC must cover the specs and instructions for the drive system
- Otherwise, machinery without a fully specified drive system must be considered partly completed machinery, *not* machinery.

(2) Machinery that can in itself perform its specific application but *which only lacks the necessary protective means or safety components* is not to be considered as “partly completed machinery”.

- So machinery without guards is *not* treated the same as item (1) above.

(3) The MD *is applicable* to machinery driven by manual effort which is not applied directly but stored (for example in springs or in pneumatic tanks), so that the machinery can function after the manual effort has ceased.

“Manufacturer” defined by the MD

Now that we’ve figured out what is covered by the MD, we’re ready to go, right? Well … almost!
One more definition to consider: Who is the “Manufacturer”?

> (i) ‘manufacturer’ means any natural or legal person who designs and/or manufactures machinery or partly completed machinery covered by this Directive and is responsible for the conformity of the machinery or the partly completed machinery with this Directive with a view to its being placed on the market, under his own name or trademark or for his own use. In the absence of a manufacturer as defined above, any natural or legal person who places on the market or puts into service machinery or partly completed machinery covered by this Directive shall be considered a manufacturer

That means someone must be responsible, but it need not be the actual builder of the product (machine) or system (assembly of machines). It could be the distributor, installer or end user!

“Manufacturer” per the MD (continued)

Time for a another riddle –

“When is a machine not a machine?”

(that seems familiar, somehow …)

“Manufacturer” per the MD (continued)

Answer #2 – When it’s a “machine” without safety guards.

Here is the problem:

A potential customer wants to buy your machine (or system), but does not want to buy the protective guards or light curtain, perhaps because he already has an enclosure for the machine.

But obviously a machine without required guards …

- is not compliant and cannot have a DofC and CE marking

And remember that machinery without guards also …

- is not a partly completed machine and cannot have a DofI

So how can you ship the product to your customer in Europe?

“Manufacturer” per the MD (concluded)

One answer is to decide who is the Manufacturer.

- Will it be you?

If you are the Manufacturer, then you are responsible for complying with the Machinery Directive, before the product can be either “placed on the market” or “put into service”.

- Will it be your customer?

The product can be included as part of a complete machine by the Manufacturer of the end product, perhaps your customer. Then your customer must comply with all the MD requirements, including writing a DofC and applying the CE Marking!

- But you should decide *before* selling the product.

Required reading

Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery:

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32006L0042

Consolidated text:

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006L0042-20190726

Guide to application of the Machinery Directive 2006/42/EC (Edition 2.2) issued in October 2019:

https://ec.europa.eu/docsroom/documents/38022

Guidance on the application of the essential health and safety requirements on ergonomics set out in section 1.1.6 of Annex I to the Machinery Directive 2006/42/EC:

https://ec.europa.eu/docsroom/documents/9484

List of standards under the MD giving “presumption of conformity”:

https://ec.europa.eu/growth/document/download/b0712b03-0d6e-43f8-87e3-774140ff69c8_en

Proposal for a Regulation of the European Parliament and of the Council on machinery products:

https://ec.europa.eu/docsroom/documents/45508

PART TWO

So what do I have to do to comply with the MD?

(if I can't avoid it)

So what do I do to comply with the MD?

We've figured out (a) your product is a machine (or partly completed machine), and (b) you are the Manufacturer. Now what?

- If the units concerned are placed on the market as complete machinery that could operate independently, they shall bear the CE-marking and must be accompanied by an EC Declaration of Conformity.
- If they are placed on the market as partly completed machinery, they shall *not* bear the CE-marking but must be accompanied by a Declaration of Incorporation *and* assembly instructions.

Let's first look at what goes into the technical files that back up these Declarations.

Documentation required by the MD

From the MD Annex VII - *Technical file for machinery*:

"The technical file must demonstrate that the machinery complies with the requirements of this Directive. It must cover the design, manufacture and operation of the machinery to the extent necessary for this assessment. …"

"1. The technical file shall comprise the following:
(a) a construction file including:
— a general description of the machinery,
— the overall drawing of the machinery and drawings of the control circuits, as well as the pertinent descriptions and explanations necessary for understanding the operation of the machinery,
— full detailed drawings, accompanied by any calculation notes, test results, certificates, etc., required to check the conformity of the machinery with the essential health and safety requirements,"

- **In other words - What does this "complies-with-the-EHSRs" machine really look like and how does it work?**

Documentation (continued)

"— the documentation on risk assessment demonstrating the procedure followed, including:

(i) a list of the essential health and safety requirements which apply to the machinery,

(ii) the description of the protective measures implemented to eliminate identified hazards or to reduce risks and, when appropriate, the indication of the residual risks associated with the machinery,"

- **Now tell us about your hazard identification, risk assessment, risk reduction, and residual risks.**

"— the standards and other technical specifications used, indicating the essential health and safety requirements covered by these standards,

— any technical report giving the results of the tests carried out either by the manufacturer or by a body chosen by the manufacturer or his authorised representative,"

- **Show the standards used & your test results to meet EHSRs. Can you claim "presumption of conformity"?**

Documentation (continued)

"— a copy of the instructions for the machinery,"

- **Include what affects safety – installation, operation, etc.**

"— where appropriate, the declaration of incorporation for included partly completed machinery and the relevant assembly instructions for such machinery,

— where appropriate, copies of the EC declaration of conformity of machinery or other products incorporated into the machinery,"

- **Especially important for "assemblies of machines" that contain several devices, including third-party instruments.**

"— a copy of the EC declaration of conformity;"

- **Or the Declaration of Incorporation for partly completed machinery. More on that shortly ….**

Documentation (continued)

"(b) … internal measures that will be implemented to ensure that the machinery remains in conformity with the provisions of this Directive. … relevant reports and results shall be included in the technical file."

- **How do you know that the next unit you make still will comply with the MD?**

Note that "the technical file does not have to include detailed plans or any other specific information as regards the subassemblies used for the manufacture of the machinery *unless* a knowledge of them is essential for verification of conformity with the essential health and safety requirements."

- **What are the biggest documentation differences if you have only "partly completed machinery"?**

Documentation (continued)

Comments on the technical file for machinery are valid for the technical documentation for partly completed machinery

BUT

the scope of the technical documentation for partly completed machinery is limited to EHSRs that are applied and fulfilled *and* to assembly instructions.

From the MD Annex VII - *Relevant technical documentation for partly completed machinery*:

"The documentation must show which requirements of this Directive are applied and fulfilled. It must cover the design, manufacture and operation of the partly completed machinery to the extent necessary for the assessment of conformity with the essential health and safety requirements applied. …"

- **That is, identify the "EHSR gap" that prevents the partly completed machinery from being machinery.**

Documentation (continued)

"— the risk assessment documentation showing the procedure followed, including:

"(i) a list of the essential health and safety requirements applied and fulfilled,"

- **Partly completed machinery does *not* meet all EHSRs, so the device is *not* compliant with the MD and does *not* qualify for CE Marking or a Declaration of Conformity. (Declarations of Incorporation show the "EHSR gap".)**

"(v) a copy of the assembly instructions for the partly completed machinery;"

- **Assembly instructions show which EHSRs still must be fulfilled in the end product and how to do so. They must accompany the partly completed machinery.**

Documentation (concluded)

What documentation do you need to gather before writing a Declaration of Conformity (or DofI) to send with your product?

1. Risk assessment, showing applicable EHSRs
2. Product description, including critical safety components
3. Construction evaluation and test reports, using applicable standards (If standards are *not* listed under the MD, use the Annex I checklist.)
4. Declarations for the devices that are part of your product
5. Instructions for safe use, including installation
6. Quality control process documentation

And now … the information you've been waiting for …
what are these **Essential Health and Safety Requirements** and where do they come from?

EHSRs in Annex I of the Machinery Directive

Where: Annex I - Essential Health and Safety Requirements relating to the design and construction of machinery

The Key: If you show your product satisfies all the applicable EHSRs in Annex I, then you can apply CE Marking.

Q – Do you need to use only standards listed under the MD?

A – No.

Q – Are you sure?

A – Yes. Those standards give "presumption of conformity" to the MD (when used appropriately), but each EHSR can be shown to be met in other ways (although you may need to meet a higher standard of proof).

EHSRs in Annex I (continued)

What: Essential health and safety requirements stated in Annex I vary from general -

"The materials used to construct machinery or products used or created during its use must not endanger persons' safety or health."

to more specific -

"Internal parts requiring frequent inspection and adjustment, and maintenance areas must be provided with appropriate lighting."

You have to decide which EHSRs apply to your product and how to show your product meets them. The easiest way to do it is to use standards - whether listed under the MD or not. If one standard doesn't cover all the applicable EHSRs, then use other standards to complete your evaluation.

EHSRs in Annex I (continued)

For example – if you want to use **IEC 61010-1** (Safety requirements for electrical equipment for measurement, control, and laboratory use) to evaluate your equipment under …

LVD – This standard gives presumption of conformity – you're done!

MD – This standard does ***not*** give presumption of conformity – you must evaluate the equipment under 61010 **and** complete a checklist for Annex I that shows which EHSRs are met with your 61010-1 evaluation, and which EHSRs are met by using other standards, tests or considerations.

EHSRs in Annex I (checklist example - excerpt)

Conformity Verification Report

MACHINERY DIRECTIVE

DIRECTIVE 2006/42/EC Of The European Parliament and of The Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast).

This report is based on the Essential Health and Safety Requirements identified in Annex I.

Report Reference Number:
Prepared by:
Reviewed by:
Date of issue:
Testing organization:
Type of item tested:
Trademark:
Model and name:
Manufacturer:
Copy of rating plate:

Clause	✓|NA	Comments (compliance demonstrated)
1.1.6 *Ergonomics* Under the intended conditions of use, the discomfort, fatigue and physical and psychological stress faced by the operator must be reduced to the minimum possible, taking into account ergonomic principles such as: — allowing for the variability of the operator's physical dimensions, strength and stamina, — providing enough space for movements of the parts of the operator's body, — avoiding a machine-determined work rate, — avoiding monitoring that requires lengthy concentration, — adapting the man/machinery interface to the foreseeable characteristics of the operators.		
1.1.7 *Operating positions* The operating position must be designed and constructed in such a way as to avoid any risk due to exhaust gases and/or lack of oxygen. If the machinery is intended to be used in a hazardous environment presenting risks to the health and safety of the operator or if the machinery itself gives rise to a hazardous environment, adequate means must be provided to ensure that the operator has good working conditions and is protected against any foreseeable hazards. Where appropriate, the operating position must be fitted with an adequate cabin designed, constructed and/or equipped to fulfil the above requirements. The exit must allow rapid evacuation. Moreover, when applicable, an emergency exit must be provided in a direction which is different from the usual exit.		
1.1.8 *Seating* Where appropriate and where the working conditions so permit, work stations constituting an integral part of the machinery must be designed for the installation of seats. If the operator is intended to sit during operation and the operating position is an integral part of the machinery, the seat must be provided with the machinery. The operator's seat must enable him to maintain a stable position. Furthermore, the seat and its distance from the control devices must be capable of being adapted to the operator. If the machinery is subject to vibrations, the seat must be designed and constructed in such a way as to reduce the vibrations transmitted to the operator to the lowest level that is reasonably possible. The seat mountings must withstand all stresses to which they can be subjected. Where there is no floor beneath the feet of the operator, footrests covered with a slip-resistant material must be provided.		
1.2. **Control Systems**		
1.2.1. *Safety and reliability of control systems* Control systems must be designed and constructed in such a way as to prevent hazardous situations from arising. Above all, they must be designed		

EHSRs in Annex I (concluded)

But even before the checklist -

What's the very first thing stated at the beginning of Annex I?

> **"GENERAL PRINCIPLES**
>
> 1. The manufacturer of machinery or his authorised representative must ensure that a risk assessment is carried out in order to determine the health and safety requirements which apply to the machinery. The machinery must then be designed and constructed taking into account the results of the risk assessment."

Let's take a quick look at Risk Assessment.

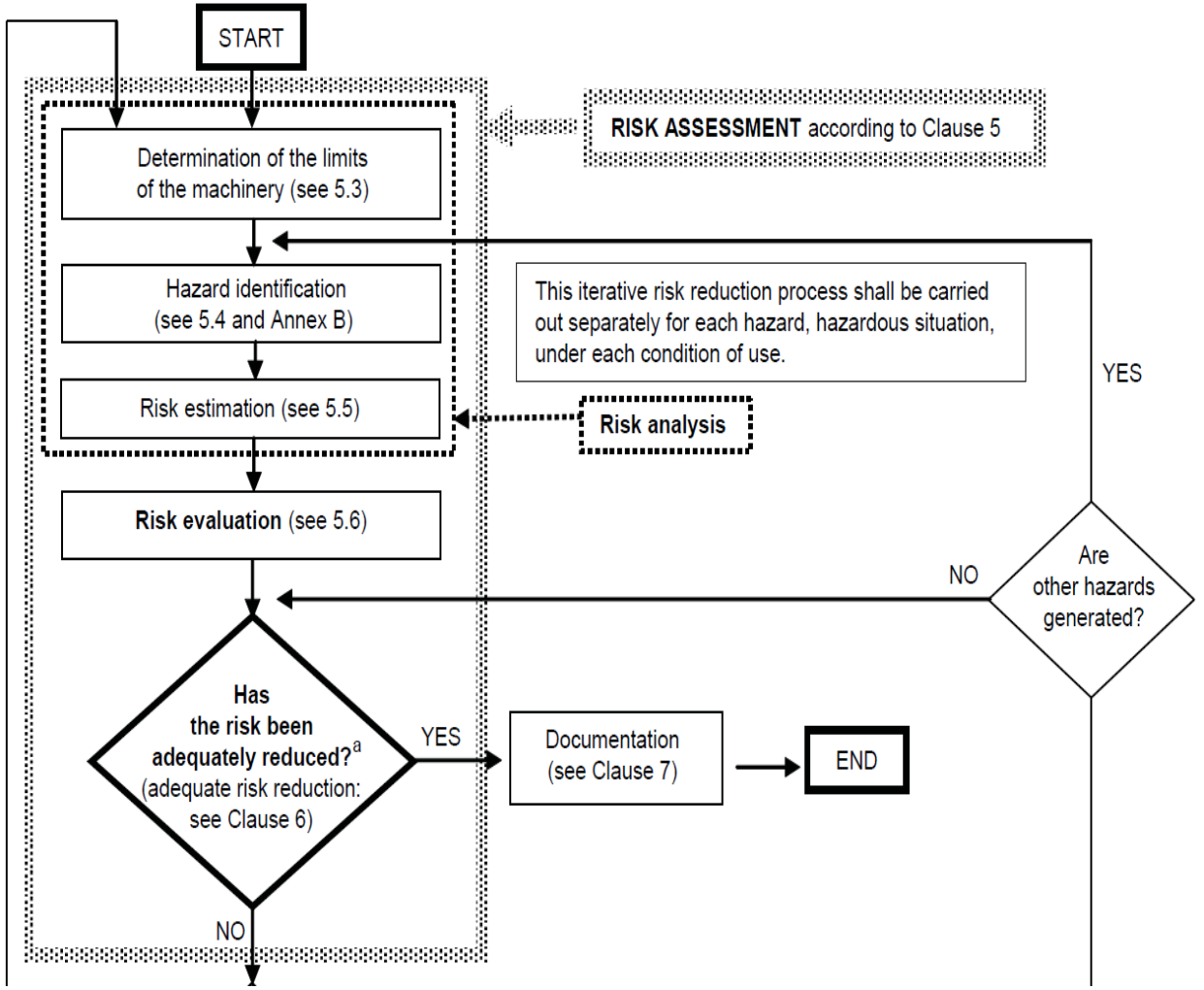
Risk Assessment

There are several standards about risk assessment and reduction.

Recommended:

ISO 12100:2010 Safety of machinery — General principles for design — Risk assessment and risk reduction

The assessment process is repeated during product development as the design changes.

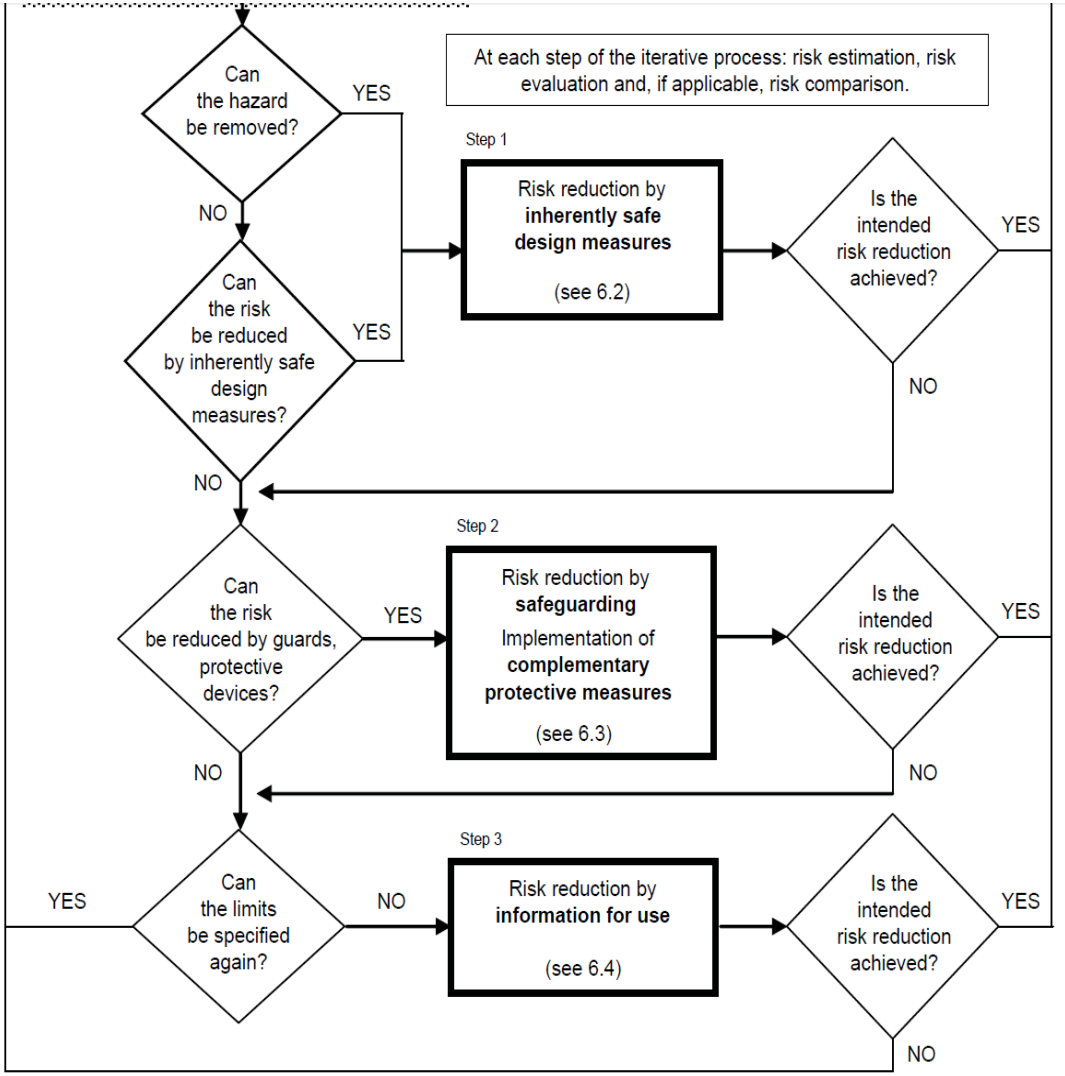


Risk Assessment (continued)

There is a **REQUIRED** hierarchy of design for risk reduction:

- inherently safe design
- safeguards for hazards
- instructions to users

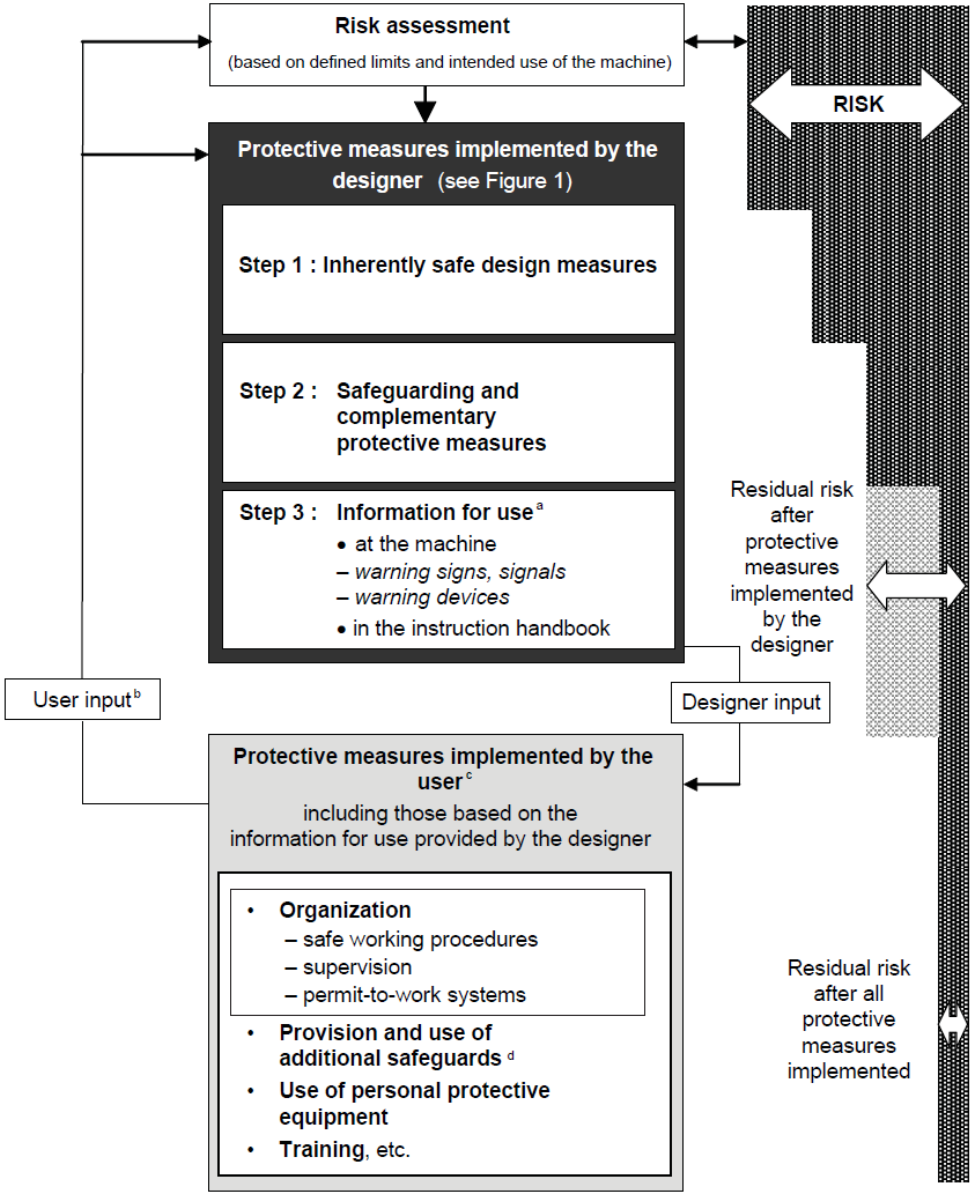
You *must* try for a safe design before adding safeguards.
You *must* add safeguards before relying on instructions or warning labels.



Risk Assessment (continued)

Here's another way to look at risk assessment and risk reduction.

Note that the amount of "residual risk" acceptable must be decided by the Manufacturer, based on the type of product, expected users, "state of the art", and so on.



Risk Assessment (concluded)

On the next two slides is a simple example of an FMEA (Failure Mode and Effects Analysis) table in a format that is useful for completing and documenting the Risk Assessment.

Note that -
“Severity x Occurrence x Detection = Risk Priority Number”.
The actual RPN number limit for acceptable residual risk depends on the assigned scales for each quantity and must be decided by the Manufacturer.

There are many variations on this theme, but I recommend using the least complex approach that will meet your needs.

Risk Assessment (FMEA example - table)

Product: HD 3D Blu-ray DVD Player (Model DMP-BDT310)
Prepared by: John McBain
Date _____

Process Function and Requirements	Potential Failure Mode (Note: A single origin of a hazard can have several potential consequences.)	Potential Effects of Failure (Note: For each type of hazard or group of hazards, some potential consequences can be related to several origins of hazard.)	SEV	Potential Cause(s)/Mechanism(s) of Failure	OCC	Detection Method	DET	RPN
Mechanical hazards	approach of a moving element to a fixed part (drawer closing)	drawing in or trapping / pinch hazard	1	user attempts to remove or adjust diskette while door closes	7	visually see drawer closing and drawer stops if there is a blockage	3	21
		same	1	user accidentally engages closing mechanism by pushing against drawer while loading diskette	5	visually see drawer closing and drawer stops if there is a blockage	3	15
		same	1	second user operates remote control to close drawer while first user is loading diskette	5	visually see drawer closing and drawer stops if there is a blockage	3	15
		same	1	motion sensor activates drawer closing unexpectedly	7	visually see drawer closing and drawer stops if there is a blockage	3	21
	moving elements (drawer opening)	impact	1	second user operates remote control to open drawer while first user is loading diskette	3	visually see drawer closing and drawer stops if there is a blockage	3	9
		same	1	motion sensor activates drawer opening unexpectedly	5	visually see drawer closing and drawer stops if there is a blockage	3	15
	rotating elements (diskette turning)	entanglement	1	long hair or other dangling object such as a necklace could be caught in the mechanism when the diskette starts to turn	1	see item (hair, necklace) caught in door and diskette will not turn if there is an obstruction	3	3
	sharp edges (edge of diskette)	cutting	3	sharp edge of diskette could cut finger when removing or inserting it	1	see diskette edges are sharp and handle carefully	5	15

Risk Assessment (FMEA example - definitions)

Potential Failure Mode	Potential failure mode is defined as the manner in which the process could potentially fail to meet the process requirements and/or design intent. It can be a cause of a failure in a subsequent (downstream) operation.
Potential Effect(s) of the Failure	Defined as the effects of the failure mode on the customer or subsequent operations. Describe in terms of product or system performance or in terms of process/operation performance if a subsequent process/operation is affected.
Potential Cause(s)/Mechanism(s) of Failure	How the failure could occur in terms that describe how the failure could be corrected or controlled such that remedial efforts can be implemented. Use a separate row for each potential cause/mechanism. Note that experiments may be required to determine the principal root cause(s).
RPN (Risk Priority Number)	The product of the Severity, Occurrence, and Detection rankings. This value should be used to rank order the process concerns. Note that where severity is "high", special attention should be given to the process regardless of RPN value.
SEV (Severity)	An assessment of the seriousness of the effect to a customer or subsequent process/operation. What are the possible consequences of the hazard to the End User - on a scale of 1 to 10 where: 1 = no injury, small amounts of smoke may be emitted from the product 3 = minor injury, first aid required, minor cuts, bruises or 1st degree burns 5 = moderate injury, medical treatment required by a physician, normal healing removes all signs of injury 7 = severe Injury, permanent disability or illness, loss of body function, part, or permanent disfigurement 10 = catastrophic injury, death, blindness, paralysis, loss of multiple limbs)
OCC (Occurrence)	How frequently is the specific failure that expresses the hazard (the cause) projected to occur - on a scale of 1 to 10 where: 1 = Very unlikely, no more than once in ten years 3 = Rare, more than once in ten years, but no more than once in five years 5 = Possible, more than once in five years, but no more than once in one year 7 = Likely, more than once in one year, but no more than 5 times per year 10 = Frequently, more than 5 times per year
DET (Detection)	An assessment of the likelihood that the controls in the previous column will detect the process weakness or detect the failure before the part or component leaves the manufacturing operation or assembly location. How likely is it that the process weakness or failure will be discovered before the hazard harms someone - on a scale of 1 to 10 where: 1 = almost certain that controls will detect or prevent the failure, no need for visual observation 3 = very likely, some visual observation needed to identify defect 5 = moderate likelihood, visual observation needed to identify defect 7 = unlikely, diligent visual observation needed to identify defect 10 = almost impossible to detect failure mode using controls or visual observation

Finally, a look a Declarations of Conformity and Incorporation.

Declarations of Conformity and Incorporation

Some excerpts from the MD Annex II A –

EC DECLARATION OF CONFORMITY OF THE MACHINERY [and additional comments]

"This declaration and translations thereof must be … typewritten or handwritten in capital letters." [*and* translated into the applicable EU language *and* marked "Translation" *and* accompanied by an "Original", if no verified Original is available in that EU language *and* shipped with the product rather than separately.]

"This declaration relates exclusively to the machinery in the state in which it was placed on the market, and excludes components which are added and/or operations carried out subsequently by the final user.

The EC declaration of conformity must contain the following particulars:" [shown in the example on the next page – but here is one peculiarity]

"4. a sentence expressly declaring that the machinery fulfils all the relevant provisions of this Directive and where appropriate, a similar sentence declaring the conformity with other Directives and/or relevant provisions with which the machinery complies." [but **NOT** the LVD if compliant with the MD!]

Declarations (continued)

This Declaration is for a custom system (assembly of machines), so specific details of the equipment and the layout for the system are included as part of the DofC.

The other required elements also are included.

Note that no mention is made of the Low Voltage Directive, although the system does comply with it as well as with the MD and the EMCD.

DECLARATION OF CONFORMITY
According to EN ISO/IEC 17050-1:2004

CE

Manufacturer's Name:

Manufacturer's Address:

Declares under sole responsibility that the product as originally delivered

Product Name & Function: Robot Workstation System
Model & Part Numbers: Model
Product Options: As described in Attachments A and B
Serial Number

complies with the essential requirements of the following applicable European Directives, and carries the CE marking accordingly:

EMC Directive 2004/108/EC
Machinery Directive 2006/42/EC

and conforms with the following product standards:

EMC: IEC 61326-1:2005 / EN 61326-1:2006
Safety: IEC 61010-1:2001 / EN 61010-1:2001
IEC 61010-2-081:2001 / EN 61010-2-081:2002

Supplementary Information:
The products were tested in a typical configuration
See Attachments A and B for details of system content and configuration.

This DoC applies to above-listed products placed on the EU market after:

Date Location Quality Manager

Contact established in the Community authorized to compile the technical file or the relevant technical documents:

(address in the EU)

Declarations (continued)

From the MD Annex II B – DECLARATION OF INCORPORATION OF PARTLY COMPLETED MACHINERY

"This declaration and translations thereof must be ..." [similar to the DofC]

The declaration of incorporation must contain the following particulars:" [shown in the example on the next page – but here are two differences]

"4. a sentence declaring which essential requirements of this Directive are applied and fulfilled and that the relevant technical documentation is compiled in accordance with part B of Annex VII, and, where appropriate, a sentence declaring the conformity of the partly completed machinery with other relevant Directives."

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

Declarations (concluded)

This template includes the required elements and leaves blanks for specific characteristics (applicable Essential Health and Safety Requirements) with which the partly completed machine does not comply.

Not being able to perform a specific application - one of the requirements to be a complete machine – also may be included.

No CE marking is described and no mention is made of the LVD, although the product may comply with it as well as with the EMCD.

DECLARATION OF INCORPORATION
According to Directive 2006/42/EC, Annex II, part B

Manufacturer's Name:

Manufacturer's Address:

Declares under sole responsibility that the product as originally delivered

Product Name & Function: _____
Model & Part Numbers: _____
Product Options: _____
Serial Number: _____

is incomplete machinery and must not be put into service until the machinery into which it is to be incorporated has been declared in conformity with the provisions of Machinery Directive 2006/42/EC. This equipment complies with all applicable EHSRs in Annex I, except clauses _____, and _____, (but cannot in itself perform a specific application) and is required to be installed and used only as part of a complete system.

(The Company) **also hereby declares** that these models comply with the essential requirements of the following European Directives:

EMC Directive 2004/108/EC

and conform with the following product standards:

EMC: IEC 61326-1:2005 / EN 61326-1:2006
Safety: IEC 61010-1:2001 / EN 61010-1:2001

Relevant technical documentation is compiled in accordance with part B of Annex VII of the Machinery Directive. undertakes to transmit, via email, relevant information on the partly completed machinery in response to a reasoned request by national authorities.

Contact established in the Community authorized to compile the technical file or the relevant technical documents:

(address in the EU)

Supplementary Information:

The products were tested in a typical configuration

This Declaration of Incorporation applies to above-listed products placed on the EU market after:

Date _____ Location _____ <Name> <Title> _____

Conclusion

So the steps to compliance with the Machinery Directive are:

- Decide if your product falls under the MD.
- Decide if you will be the Manufacturer.
- Create a Risk Assessment and reiterate as necessary.
- Document the safety evaluation and testing.
- Compile other required documentation, including instructions.
- Create the Declaration of Conformity (or Incorporation).
- Ensure documents are translated and sent as required.
- Stop worrying … and love the Machinery Directive?

Required reading (again)

Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery:

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32006L0042

Consolidated text:

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006L0042-20190726

Guide to application of the Machinery Directive 2006/42/EC (Edition 2.2) issued in October 2019:

https://ec.europa.eu/docsroom/documents/38022

Guidance on the application of the essential health and safety requirements on ergonomics set out in section 1.1.6 of Annex I to the Machinery Directive 2006/42/EC:

https://ec.europa.eu/docsroom/documents/9484

List of standards under the MD giving “presumption of conformity”:

https://ec.europa.eu/growth/document/download/b0712b03-0d6e-43f8-87e3-774140ff69c8_en

Proposal for a Regulation of the European Parliament and of the Council on machinery products:

https://ec.europa.eu/docsroom/documents/45508

And finally …

Any questions?

Supplemental slides

Requirements for Components:

AVAILABLE COMPONENT INFORMATION	COMPONENT IS USED AS:		
	FUNCTIONAL COMPONENT	SAFETY RELATED COMPONENT	SAFETY COMPONENT (not covered by Annex IV)
	Failure of the component does not decrease the safety level	Failure of the component causes a limited decrease of safety	Failure leads to unacceptable decrease of safety
Manufacturer's specifications No conformity mark and no reference to compliance with standards	Y	N	N
Manufacturer's specifications with reference to a standard No conformity mark No declaration of Conformity	Y	Y(1)	N
Manufacturer's specifications +Declaration of Conformity	Y	Y	Y
Voluntary conformity marks	Y	Y	Y(2)
	EXAMPLES Plugs and sockets(3) Cables Push-buttons Pilot lights Switches/contactors/timers El. Magnetic valves Temp. controls Motor start capacitor	See below (A)	See below (B)

In all cases it is assumed that components operate within their specified limits
Y= The notified body may accept the component with the information certificate provided
N= The notified body shall not accept the component as such other types of certificate or additional testing are needed

(1) if manufacturer states in writing that he has followed the standard
(2) only if test report shows that the safety functions have been checked as well
(3) strictly speaking plugs and sockets outlets for domestic use are not under the low voltage directive.

(A): EXAMPLES Transformers. Temp. limiters. Position Switches without positive opening operation. Motor protectors. Overload protectors. Main power switches. Power supply units. Fuses
(B): EXAMPLES: see Machinery Directive Annex V (Note: some of the safety components listed in Annex V are also listed in Annex IV)

Machinery Directive: Revision of Directive 2006/42/EC *(17-09-2021)*

The Machinery Directive establishes a regulatory framework for mechanical engineering industry products. It regulates the harmonisation of essential health and safety requirements for machinery in order to ensure the free movement of machinery products within the internal market on the one hand, and a high level of protection for machinery users on the other.

The European Commission's Regulatory Fitness and Performance Programme (REFIT) evaluation of 2018 concluded that the directive has generally remained relevant and effective. However, it pointed at certain shortcomings in the enforcement of the directive (mainly related to market surveillance, a Member State responsibility), and found that despite its technology-neutral design, the directive might not sufficiently cover new risks stemming from emerging technologies (in particular robots using artificial intelligence technologies). Furthermore, it identified the potential for administrative simplification.

The Commission issued its new proposal for a regulation on machinery products (COM(2021) 202) on 21 April 2021, as part of the 'artificial intelligence package'. In particular, the change of instrument (regulation instead of a directive) aims at ensuring a uniform implementation in the Member States.

Machinery Directive: Revision of Directive 2006/42/EC *(17-09-2021)*

The proposal expects to tackle the following problems:

Problem 1: The MD does not sufficiently cover new risks originating from emerging technologies.

Problem 2: (i) Legal uncertainty due to a lack of clarity on the scope and definitions; and (ii) possible safety gaps in traditional technologies.

Problem 3: Insufficient provisions for high risk machines.

Problem 4: Monetary and environmental costs due to extensive paper-based documentation.

Problem 5: Inconsistencies with other pieces of Union product safety legislation.

Problem 6: Divergences in interpretation due to transposition.