



75
1948
2023
VALUES.
CREATE.
FUTURE.

► De toekomst van machineveiligheid: EU-Machineverordening 2027

Peter Eland

PILZ
THE SPIRIT OF SAFETY

► Onze filosofie

Onze visie

the spirit of safety in digital automation

Onze missie

Met onze automatiseringsoplossingen maken we de wereld elke dag digitaler, meer verbonden, flexibeler, efficiënter, veiliger en meer secure.

THE SPIRIT OF SAFETY



Susanne Kunschert
Beherend vennoot

Thomas Pilz
Beherend vennoot

We
automate.

Safely.

- ▶ Pilz is een **wereldwijde leverancier van producten, systemen en diensten** voor alles wat met automatisering te maken heeft.
- ▶ **Klantgerichte, innovatieve en allesomvattende** automatiseringsoplossingen volgens geldende normen en wetgeving
- ▶ **Compromisloze veiligheid** voor mens, machine en milieu, wereldwijd



► De toekomst van machineveiligheid

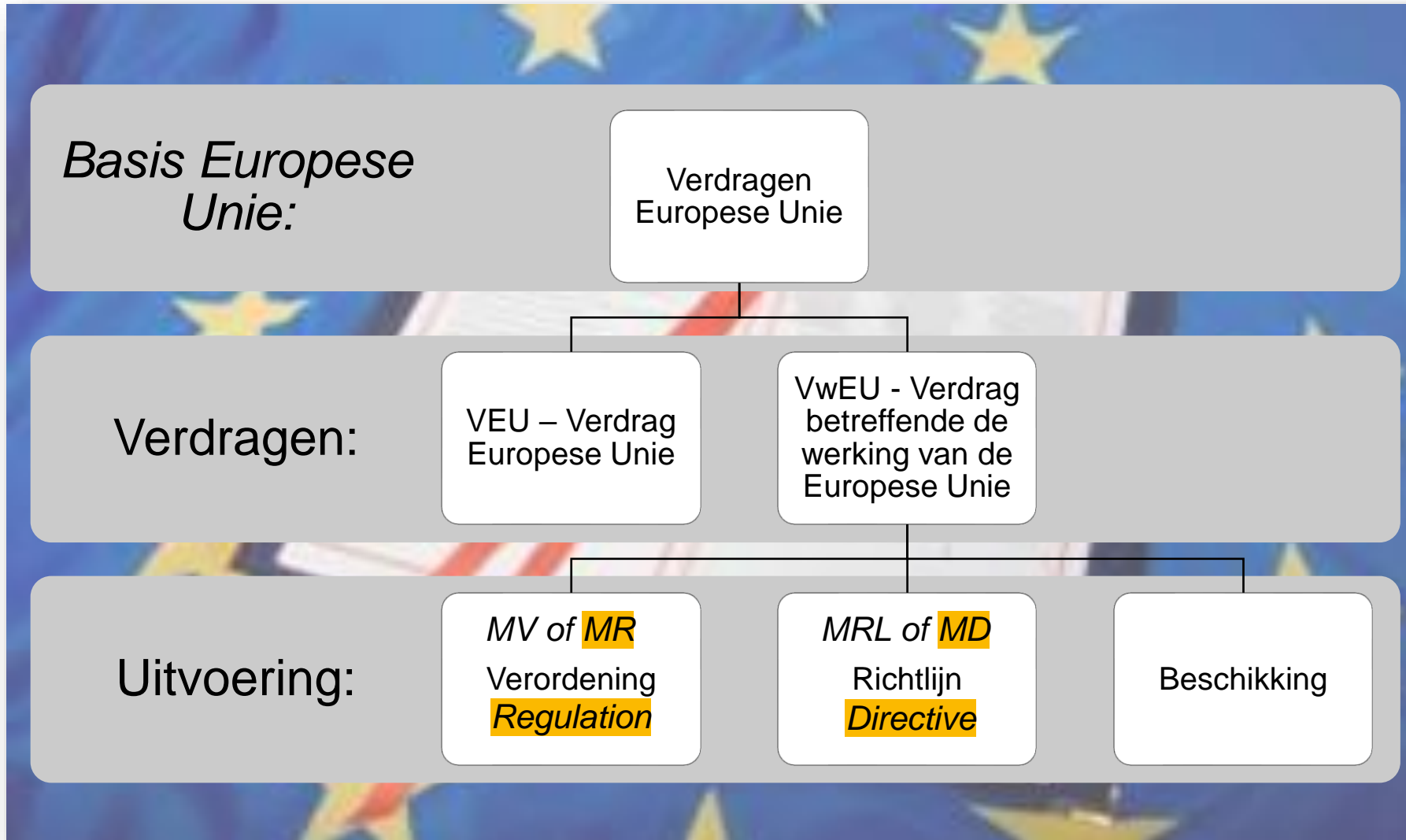
: EU-Machineverordening 2027

PILZ
THE SPIRIT OF SAFETY

01

- ▶ Publication of the new Machinery Regulation - Introduction

► Even opfrissen: De sheet over wetgeving uit de Pilz Master Class

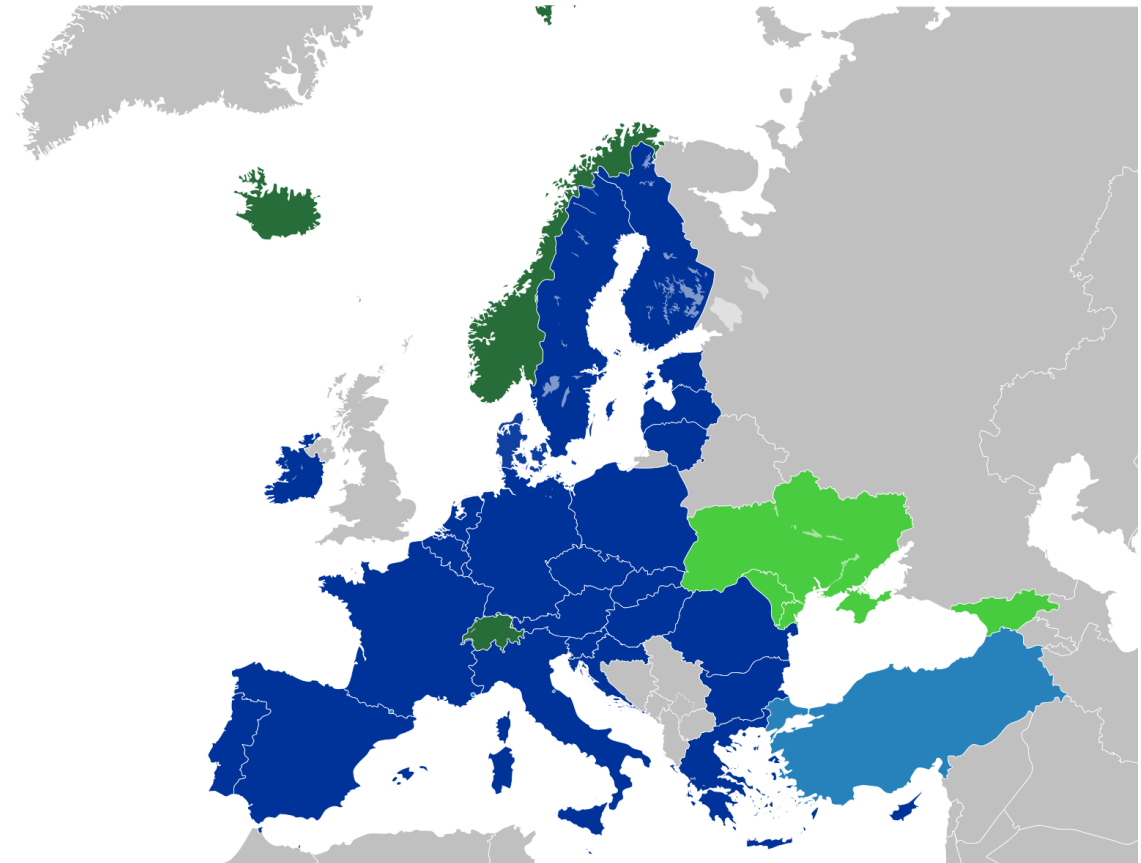


*In het geel:
De Engelse termen
en afkorting*

► Publication of the new Machinery Regulation 2023/1230

Basic information

- Successor to the **Machinery Directive 2006/42/EC**
- **Publication in the EU Official Journal**
 - 29.06.2023
 - 01st corrigendum on July, 04th, 2023
- **Validity starts on January 20th, 2027**
 - After 01st corrigendum on July 04th, 2023 the start was moved from January 14th to 20th!
 - No national transposing legislation required!
 - UK situation open
(mutual acceptance of CE – UKCA Mark)



This file is licensed under the [Creative Commons Attribution-Share Alike 4.0 International](https://creativecommons.org/licenses/by-sa/4.0/)

Dark Blue	European Union (EU)
Dark Green	European Free Trade Association (EFTA)
Light Green	Deep and Comprehensive Free Trade Area (DCFTA)
Medium Blue	European Union Customs Union (EUCU)

► Publication of the new Machinery Regulation

The Directive is becoming a Regulation – what were the problems ? (and how they were addressed)

- **Problem 1:** The MD does not sufficiently cover new risks originating from emerging technologies
→ **Security & AI**
- **Problem 2:** Legal uncertainty due to a lack of clarity on the scope and definitions and possible safety gaps in traditional technologies
→ **Definition of substantial modification**
- **Problem 3:** Insufficient provisions for high-risk machines
→ **Segregation of high-risk machines into two groups/parts**
- **Problem 4:** Monetary and environmental costs due to extensive paper-based documentation
→ **Digital instructions**
- **Problem 5:** Inconsistencies with other pieces of Union product safety legislation
→ **Alignment to „New Legislative Framework“ (NLF)**
- **Problem 6:** Divergences in interpretation due to transposition
→ **Turning it into a Regulation**



Problem Source: 2021/0105 (COD)

► 2023/1230 EU Machinery Regulation



Some changes concerning structure

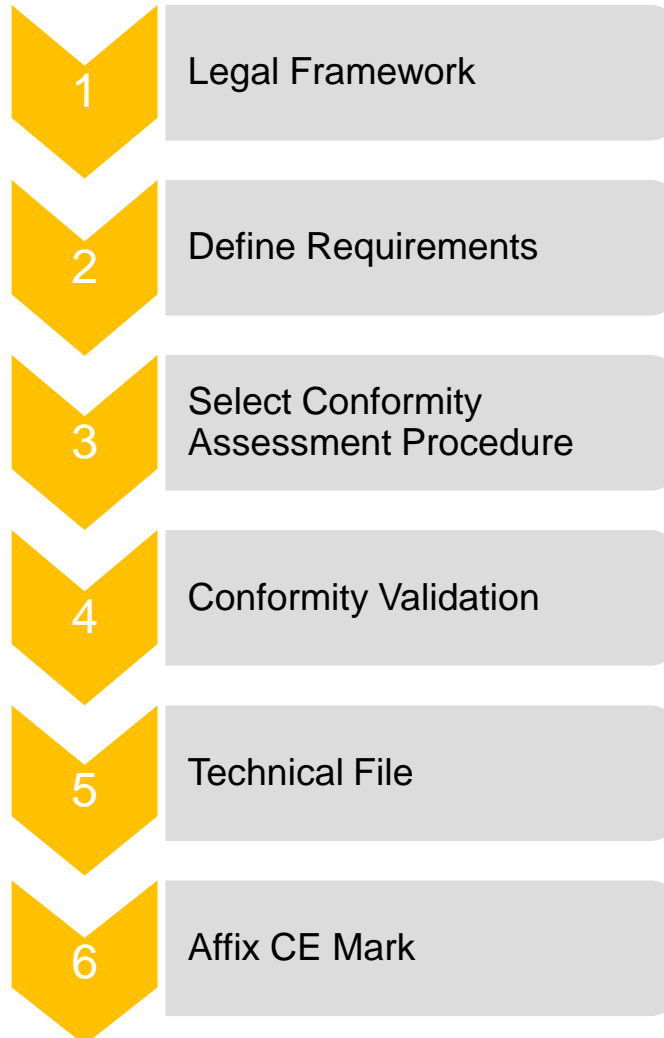
EU Machinery Directive (2006/42/EC)	Subject	EU Machinery Regulation (2023/1230)
63	# of pages	102
29	# of articles	54
12	# of Annexes	12
Annex I	Essential Health & Safety Requirements	Annex III
Annex II	Declarations	Annex V
Annex III, XI	CE Marking, Notified bodies	See Articles and Reg 765/2008
Annex IV	Machine Categories	Annex I, Part A&B
Annex V	Safety Components	Annex II
Annex VI	Assembly Instructions	Annex XI
Annex VII	Technical Documentation	Annex IV
Annex VIII, IX, X	Conformity assessment procedures	Annex VI, VII, VIII, IX, X

02

- ▶ Procedural and organisational changes

► Procedural and organisational changes

CE Marking Process Alignments and Harmonisation



The overall CE marking process with the 6 steps remain the same.

The Machine regulation has made some clarifications and alignments in relation to each of these steps.

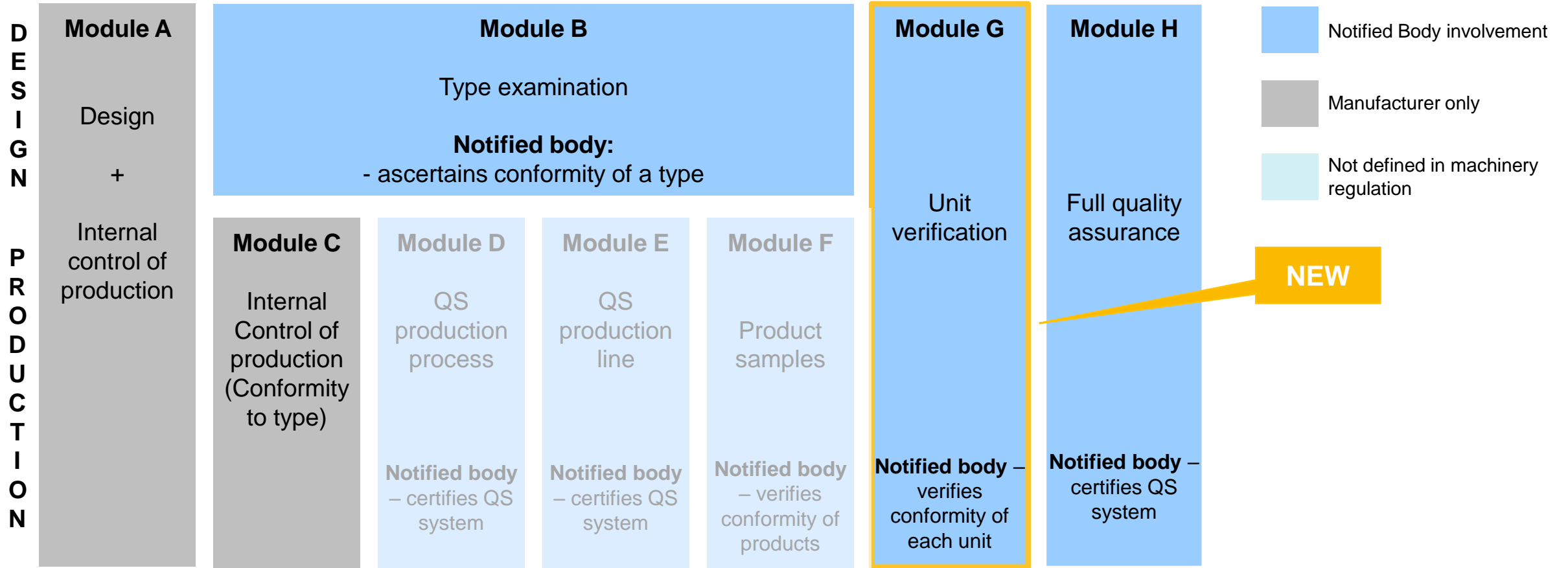
Principles and processes are now synchronised to already existing EU legislation and interpretations including:

- Regulation (EC) No 765/2008 & Decision No 768/2008/EC for a comprehensive regulatory framework to operate effectively for the safety and compliance of industrial products – also known as New Legislative Framework (NLF)
- Interpretation given in the ‘Blue Guide’ on the implementation of EU products rules (2016/C 272/01)
- Regulation (EU) 2019/1020 on market surveillance and compliance of products



► Procedural and organisational changes

Conformity assessment procedures based on modules of the New Legislation Framework (NLF)



- Annex I – Part A "High – Risk" → Modules B&C or Module H or Module G
- Annex I – Part B "Standard – Risk" → Module A or Modules B&C or Module H or Module G
- Not in Annex I → Module A

► Procedural and organisational changes

Introducing: important new features of the Machinery Regulation

“Substantial modification”

NEW

- A modification of machinery may eventually mean a substantial modification if
 - new hazards or higher risks are created
 - the existing safety concept is not sufficient
 - substantial modification can be software driven
- Substantial modification means the design of a new machine. The existing documentation shall remain valid for the unmodified part.



► Procedural and organisational changes

Introducing: important new features of the Machinery Regulation

“Authorised representative”

MODIFIED

- The authorised representative role has been redefined. The role includes the provision of documents (DOC, machine documentation, CE Mark)
- Note: Design related work cannot be performed by the AR

“Duties for distributors and importers”

NEW

- Distributors and importers are way more involved in the machinery safety process as before
- If for non-EU manufacturers no AR is present, they need to provide access to the technical documentation and cooperate with authorities



03

- ▶ Key technical changes

► Key technical changes

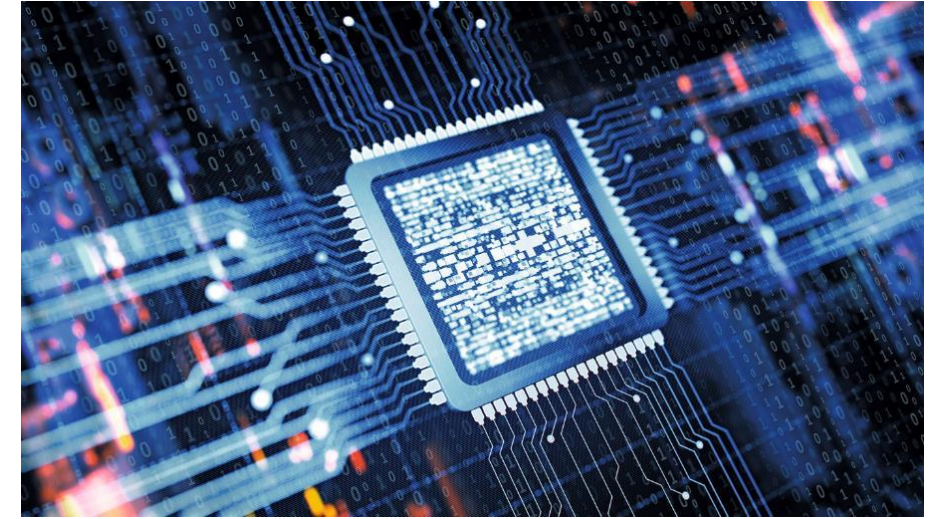
Introducing: important new features of the Machinery Regulation

Emerging digital technologies

NEW

- “AI” is not specified, but included in...
 - ... *fully or partially evolving behaviour* [...]
 - ... *machine learning* [...]
 - ... *varying levels of autonomy* [...]

This must be evaluated in Risk Assessment



Supplementary Essential Health and Safety Requirements for autonomous mobile machinery

NEW

- Autonomous mobile machinery are now specifically mentioned in the Annex III



► Key technical changes

Introducing: important new features of the Machinery Regulation

“Testing of Safety Functions” from the Manufacturer to the User

► Essential Health and Safety Requirements

NEW

- Machinery or related products shall be designed and constructed in such a way that it is possible for the user, where applicable, to **test the safety functions**. The machinery or related product shall be supplied with all the special equipment and accessories, and where appropriate, with the description of specific functional test procedures, essential to enable it to be tested, adjusted, maintained and used safely

► Key technical changes

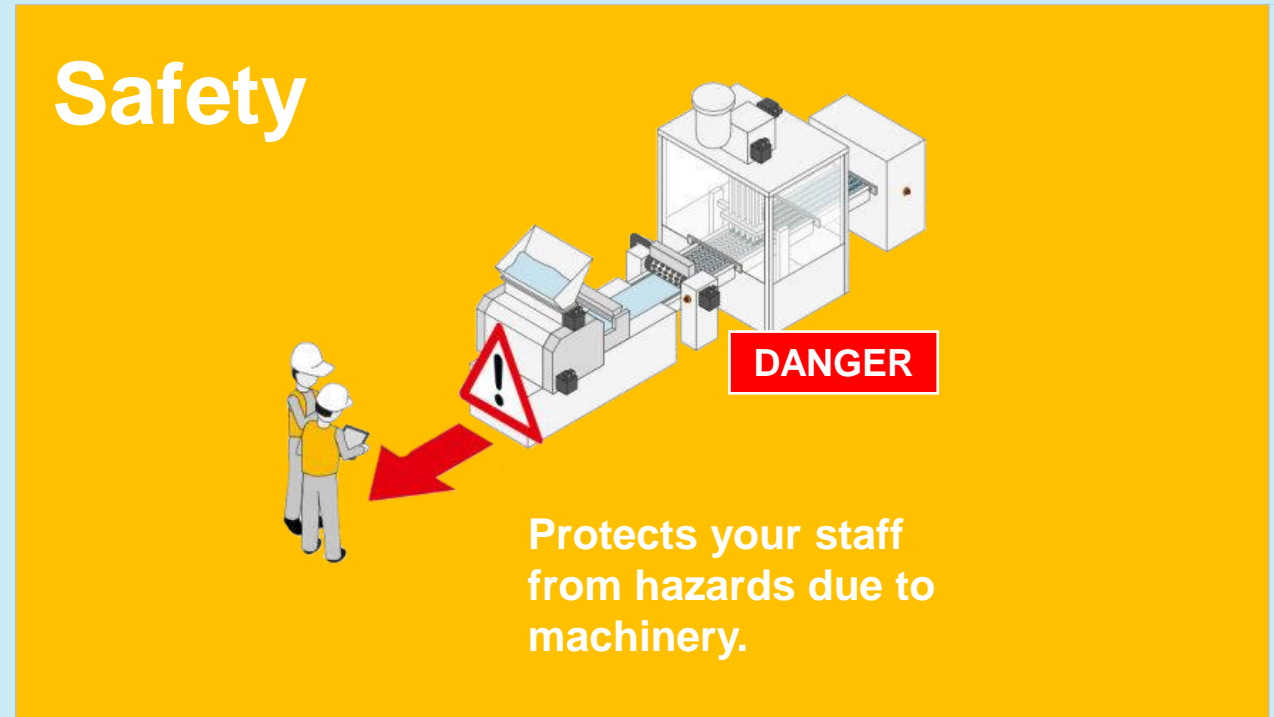
Safety and Industrial Security – different "protection" functions

Security

“HW moet beschermd zijn tegen al dan niet opzettelijke corruptie” door “redelijkerwijs voorzienbare kwaadwillige pogingen van derden die tot een gevaarlijke situatie kan leiden”



Safety



► Key technical changes

Machinery Safety and Industrial Security in transformation



Machinery Regulation

(Published on 29th of June 2023)

Requirements for **machinery**:
Protection against corruption
(with focus on machinery safety functions)

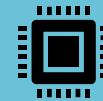


Network and Information Systems (NIS 2)

(Published in the Official Journal of the European Union
on 27th of December 2022)

Addresses „**essential and important entities**“:

- Measures to manage cybersecurity risks
- Compliance with technical and organisational measures
- Incident reporting obligations



Cyber Resilience Act (CRA)

(First draft from September 2022)

Manufacturers obligation for **products with digital elements**:

- Secure Development Lifecycle Process
- EU-type examinations for critical products
- Report vulnerabilities
- Providing Security updates

► Key technical changes

Introducing: important new features of the Machinery Regulation

“Digital instructions” for documentation

NEW

- ...finally...
 - In future, it will be possible to deliver machinery with digital instructions (Only);
 - Paper version to be provided on request (free of charge within first month)
- The EC Declaration of Conformity can also be provided in digital form
- Partly completed machinery can be delivered with digital assembly instructions as well as with a digital declaration of incorporation
- Keep it available for 10 years in digital format



04

► Summary

► Summary

Most important changes

- The application area of the Machinery Regulation has **NOT** changed compared to the Machinery Directive
 - The application area includes machinery and now: “related products”
- New expansions of terminology and clarifications
 - e.g. inclusion of the principle of “substantial modification”
- Procedures aligned to other European legislation and to „New Legislative Framework“ (NLF)
- Inclusion of so-called “emerging digital technologies” (AI) and industrial security aspects
- Increased Focus on Testing of Safety Functions
- Digital instructions are permissible



► Bedankt voor uw aandacht!

1. Meer weten? Volg onze training "Van de Machinerichtlijn naar de Machineverordening,,

1 ochtend met aansluitend lunch | Pilz Academy in Vianen | €270,- per deelnemer | 20 september a.s.



Direct inschrijven!



2. Uw kennis over Machineveiligheid bijspijkeren in de zomer?

Volg de Masterclass Machineveiligheid Summer Course op 15, 16, 17 en 18 juli a.s. in de Pilz Academy in Vianen.



Direct inschrijven!



PILZ
THE SPIRIT OF SAFETY