

**The Machinery Regulation and its links with the AI
and Cyber Resilience Acts**

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Moving from 2006/42/EC to the new Regulation (EU) 2023/1230

Why was it necessary?

- Machinery Directive 2006/42/EC probably is the Directive with the largest variety products (for investment goods), > 15 years old
- Technical:
Product portfolio affected by many technological developments (e.g. artificial intelligence, new fabrication methods, cybersecurity)
- Formal:
“Old” Machinery Directive not yet aligned with New Legislative Framework (NLF):
Divergences in definition and concepts, need for consistency with other directives



The new Machinery Regulation (EU) 2023/1230 – essential dates

- Publication in Official Journal of the European Union (OJEU) on 29 June 2023
- Official coming into force 20 days after its publication
- Mandatory date of applicability: 20 January 2027
- No real transition period, switch from MD to MR occurs from 19 to 20 January 2027
- No longer a directive, but a European regulation
⇒ applies directly throughout the whole EEA (European Economic Area), national ordinances for implementing the old MD will be withdrawn by 20 January 2027



From Directive 2006/42/EC to Regulation (EU) 2023/1230 Main features, conceptual modifications (only a small selection...)

- Only few modifications to basic concept and scope
- Introduction/adaptation of certain definitions according to NLF (legal obligations of market players, definition of importers, etc.)
- New: Concept for digital operating instructions
⇒ model case for other sectors as well?
- Introduction/precision of the term “substantial modification”
- New technological developments in focus:
 - Protection against corruption as a new Essential health and safety requirement (EHSR)
 - Self-evolving behavior as link to AI



From Directive 2006/42/EC to Regulation (EU) 2023/1230 Main features, conceptual modifications (some more...)

- Concept of common specifications as a potential alternative to harmonized standards (no experience so far)
- Only editorial, but important to know: EHSRs now in Annex III
- Quite a number of new or modified EHSRs (as you will see in Catherine's presentation)
- Annex I with machines/products that require particular consideration:
 - Part A: modules with third-party involvement
 - Part B: module A (internal production control) possible when manufactured according to harmonized standards



From Directive 2006/42/EC to Regulation (EU) 2023/1230

A word on common specifications

- EU-Commission:
Concept is not intended as a “threat” to standardizers in case of negative assessments or difficult consensus building
- Rather intended as fall-back option when harmonized standard is urgently needed, but does not exist
- Common Specs are to be withdrawn once that a hEN is published
- Application not mandatory, same approach in application as hEN



From Directive 2006/42/EC to Regulation (EU) 2023/1230 A short detour to the Annex-I-machines (formerly Annex IV)

Annex I A:

- Module(s) with third-party involvement for vehicle servicing lifts, mechanical transmission devices (plus guards), impact machinery, systems/safety components with self-evolving behavior

Annex I B:

- Basically the rest of the previous Annex-IV-machines (under MD), continuation of the established concept (Module A when using hENs)
- Compliance can also be achieved by fulfilling the EHSRs with several hENs

Both Annexes are regularly monitored, modifications possible



AI Act – state of play

- Aim: harmonized rules for placing on the market of AI systems, specific requirements for high-risk AI systems
- High-risk AI system:
 - AI system used as safety component for a product in CE-directives such as MR, PED, ATEX etc. (or is itself a product therein) and where the product has to undergo a third-party assessment
 - Safety components for critical infrastructure
- Guidance by the Commission about high-risk examples within 18 months
- Entry into force (only an estimate) probably in Q3 2024, stepwise application of certain elements in the subsequent months, full mandatory application typically 36 months later



Links between new Machinery Regulation and AI Act

- Machinery Regulation (MR) and AI Act formally “decoupled
- Particular emphasis is given in Machinery Regulation to safety components with “self-evolving behavior” or machines that have such systems embedded (Type-I-A-machines)
- General NLF approach: one product can fall under several regulations
⇒ no automatic exclusion from one regulation only because of being in the scope of another
- Nevertheless, duplications are to be avoided:
AI Act (probably) foresees procedure to integrate various processes into procedures under Machinery Regulation (Article 8(2) in EU Parliament text to AI Act)



Cyber Resilience Act (CRA) – state of play

- CE-Regulation for making available on the market
- Central elements of CRA:
 - Scope: Products with digital elements to ensure cybersecurity of such products
 - Essential requirements for design, development and production, obligation of economic operators
 - Vulnerability handling processes, rules on market surveillance
- Entry into force (only an estimate) probably in Q3 2024, mandatory application typically 36 months later



Links between new Machinery Regulation and the CRA

- Machinery Regulation (MR) and CRA formally “decoupled”, reference to new MR in Recital (30) to the CRA (latest draft)
- Also here NLF approach: If product falls into scope of both regulations, it has to fulfil both ⇒ no automatic exclusion
- Machinery Regulation addresses the subject in EHSR 1.1.9 (protection against corruption) and 1.2.1 (safety of control systems); ⇒ Strictly speaking, NOT necessarily cyber resilience, but rather protection against harm when the machine has been corrupted
- Potential synergies: Check/demonstrate if covering cybersecurity risks in accordance with CRA cover 1.1.9 and/or 1.2.1



Implementation of the Machinery Regulation in practice

Challenges for application and standardization

- Mandatory application of 2023/1230 with cut-off date
⇒ Declaration of Conformity has to comply with the date of placing on the market, pragmatic approaches are preferred
- Guide to Machinery Regulation will be updated (begin of work hopefully(?) autumn this year)
- Adaptation of digital operating instructions already now (modification to current guide has been recently published)
- Guidance papers on new EHSRs are being developed
- Modifications/additions to Annex III (formerly Annex I) have considerable impact on harmonized standards (next presentation 😊)



Thank you

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