

Challenges for standardization associated with the Machinery Regulation

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hEN



Main modifications between machinery Directive 2006/42 and Machinery Regulation 2023/1230 – Other items

- Part B – Section 1 – General principles

The risk assessment and risk reduction shall include hazards that might arise during the lifecycle of the machinery or related product that are foreseeable at the time of placing the machinery or related product on the market as an intended evolution of its fully or partially self-evolving behaviour or logic as a result of the machinery or related product designed to operate with varying levels of autonomy.



Main modifications between machinery Directive 2006/42 and Machinery Regulation 2023/1230 – Other items

- 1.1.2 Principles of safety integration (possibility for the user, to test the safety functions)
- 1.1.6 Ergonomics (work postures, introduction of self-evolving behaviour)
- 1.2.1 Safety and reliability of control systems (cyber-resilience, traceability, introduction of self-evolving behaviour)
- 1.2.6 Failure of the power supply or communication network connection
- 1.3.7 Risks related to moving parts (human-machine interaction or coexistence in a shared space)
- 1.6.2 Access to operating positions and servicing points (dimensioned and adapted for the use of rescue equipment)



Main modifications between machinery Directive 2006/42 and Machinery Regulation 2023/1230 – Other items

- 1.7.4.2 Contents of the instructions for use (addition for noise, rescue of persons, emissions of hazardous substances)
- 2.2.1 Portable machinery – General (exhaust system)
- 2.2.1.1 Portable machinery – Instructions for use (vibration)
- 3.2.2 Seating (restraint system)
- 3.2.4 and 3.3 Supervisory function
- 3.3.2 Starting/moving, 3.3.3 Travelling function and 3.3.5 Control circuit failure (autonomous mobile machinery)



Main modifications between machinery Directive 2006/42 and Machinery Regulation 2023/1230 – Other items

- 3.5.1 Batteries
- 3.5.3 Emissions of hazardous substances (filtration cabs)
- 3.5.4 Risk of contact with live overhead power lines
- 3.6.3.1 Vibrations for mobile machinery
- 3.6.3.3 Autonomous mobile machinery or related products (instructions for use)
- 6.2 Control devices for lifting of persons

See [this document](#) for comparison between MD and MR



Development of hEN in support of MR

Carry over of “old” hEN

- Journey from Machinery Directive 2006/42/EC (MD) to Machinery Regulation (EU) 2023/1230 (MR):
Ideally, as many harmonized MD-standards as possible should also be harmonized under new Machinery Regulation
- Challenge:
 - Most of today’s hENs do not necessarily cover new or strongly modified EHSRs of new MR
 - Revision or updating of all “old” hEN (taking account of all formal requirements etc.) to new MR-system is not feasible within < 3 years



Development of hEN in support of MR

Carry over of “old” hEN

Solution:

- Proposal to transfer – as far as feasible – “old” hENs under MD to OJEU for MR without regular revision or amendment (as a first step)
- Boundary conditions for such a procedure:
 - “Old” hEN under MD keep presumption of conformity only with respect to
 - those EHSRs that they used to address under the MD
 - and
 - those new EHSRs from MR that they happen to already cover today
- This needs to be indicated in the OJEU for MR



Gap analysis

Requested by EC to assess **impact of changes/new EHSRs** of MR on existing hENs under MD

- whether the modification in EHSR is relevant for the hEN?
- whether it is already covered by hEN?
- if covered by hEN – by which clauses of hEN?

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i Part B section 1 General principles

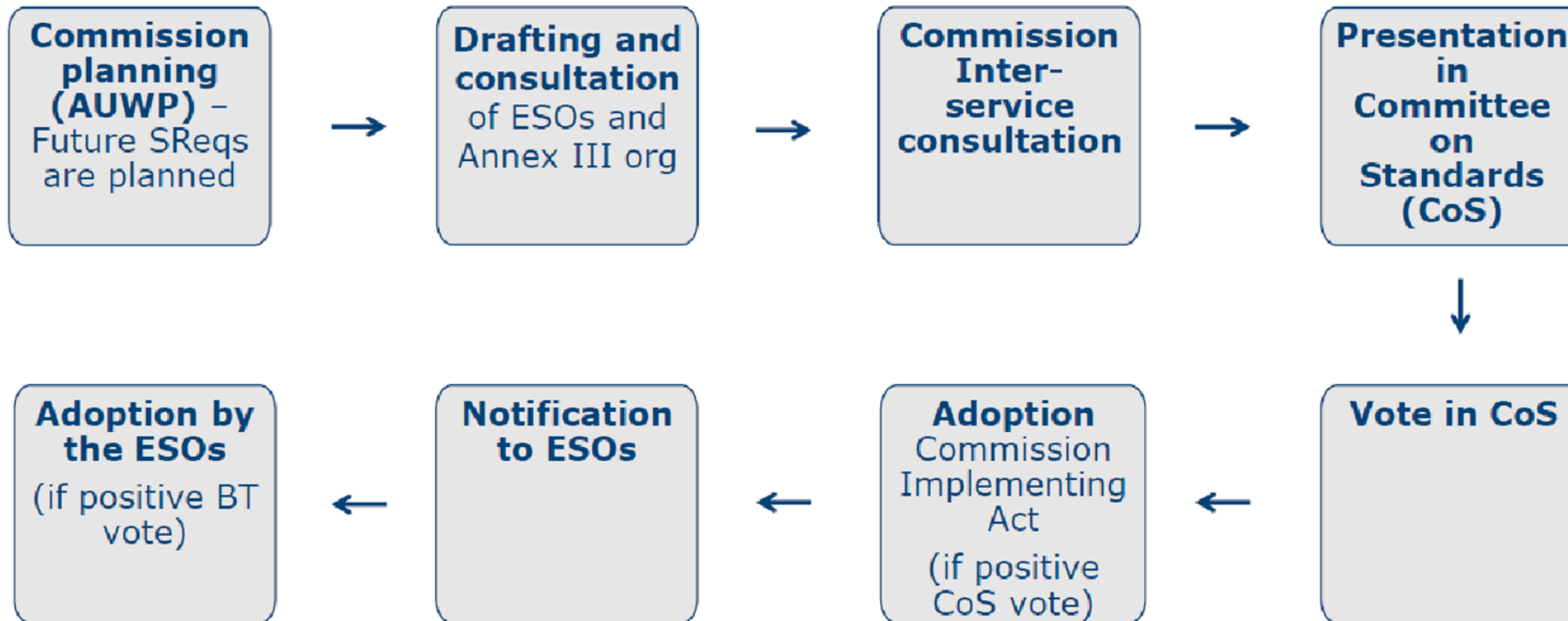
Relevant?	Already covered?
<input checked="" type="radio"/> Yes <input type="radio"/> No	<input checked="" type="radio"/> Yes <input type="radio"/> No

Reference of the corresponding subclause in the standard



Development of hEN in support of MR

Carry over of “new or revised” hEN



Development of hEN in support of MR

Carry over of “new or revised” hEN

Draft standardisation request

- Legal basis to develop harmonized standards for Machinery regulation (850 standards)
- **‘Thematic list’** for description of topics to be covered by hENs : exceptional approach related to the number of standards
- Two-phase approach on target dates for development of hENs:
 - Phase 1: January 2026 for priorities
 - Phase 2: 9 years from notification of SReq - for ‘follow-up’ standards
- New standards foreseen on IA, cybersecurity, autonomous mobile machinery



Harmonised standards and law

- Regulation EU 1025/2012 : it regulated the public/private relationship between the EU and the European Standardisation System : Legal basis to develop harmonized standards
- The EC shall ensure compliance of hEN with essential requirements before citation in OJEU
- James Elliott judgment : hEN reference in the OJEU are “by their nature measures implementing or applying an act of EU law” and “form part of EU law”
- Legal effect of a cited harmonized standard is limited to the legal requirements actually covered by it : [Annex Z](#)



Thank you

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