Inspectorate SZW
Ministry of Social Affairs and Employment

Conformity assessment in the Machinery Directive

Webinar SBS

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Introduction

Rachel Tijink and Otto Hermkens

Senior Inspector Certification & Specialist Certification
→ at Netherlands Labour Authority

Senior Inspector:
- Surveillance of Dutch EU-CAB (NoBo)
- Assessing the working of the certification system (effectiveness)

Specialist:
- Support inspectors Market Surveillance products about certification
- Tactical and strategical advice regarding surveillance of certification system, EU-CABs and holders of certificates

Certification – Machinery

What comes to mind?

- Please type one or a few words in the chat in Zoom

What we like to share

- Objectives of the Machinery Directive
- Conformity assessment process
- What we see in the field (examples and improvements)
- Proposed Machinery Regulation (what is going to change)

Objectives of the Machinery Directive

- The general objectives of the MD are to:
  - ensure free movement of machinery within the internal market; and
  - ensure a high level of protection for users and other exposed persons.
- How?
  - General essential health & safety requirements (annex I)
  - Non-binding technical specifications through harmonised standards / normalisation process
  - Stopping non-conform products from being on the EEA market by:
    - Preventing that non-conform products are placed onto the EEA market
    - The removal of non-conform products from the EEA market
    - Enhancing the level playing field aimed at a broad approach of the market
- Responsibility / liability lies with the manufacturer (also when EU-CAB gave certificate)
- Market surveillance by member states is last safety net

Conformity Assessment Process

- Check product design against essential health and safety requirements; ensure conformity
- Product Risk Assessment: iterative process
- Preparing the Technical File
- *If applicable* EU-type examination or full quality assurance by a EU-CAB (design assessment, examinations and tests)
- Draw up the EU Declaration of Conformity
- Affix the CE Marking

Conformity Assessment Process

- Define the relevant product safety legislations (MD or also EMC, ATEX, etc.) and the applicable standards.
- Determine if a EU-CAB should be involved (= dependent on risk):

Machinery Directive	**Proposed Machinery Regulation**
Annex IV Machinery?	Annex I Machinery?
Harmonised Standards fully applicable and applied? -> No Third Party certification required	
No harmonised standards fully applicable -> Third party certification by a EU-CAB	Third party certification by a EU-CAB

The procedure of type-examination

- Manufacturer chooses a EU-CAB (change to another EU-CAB is not allowed) who is notified for the Machinery Directive (contract, acceptability of the request and Technical File).
- Document review (drawings, calculations, circuit diagrams, certificates/declarations related to other directives, risk assessment, test reports, manufacturing procedures, list of applied standards, instructions, etc.)
- Inspection (correspondence between the actual machine and the machine as described in the technical file, validate safety functions, overload test, check on warnings, conformity of markings, etc.)
- Issue of a test and inspection report and EC type approval certificate

Requirements for EU-CABs (Appendix XI)

- The body and its personnel shall not be the designer, manufacturer, supplier or installer of machines which they inspect, nor the authorized representative of any of these parties.
- The body and its staff shall carry out the verification tests with the highest degree of professional integrity and technical competence and shall be free from all pressures and inducements,
- The body must possess personnel with technical knowledge and sufficient and appropriate experience to perform a conformity assessment.
- The impartiality of inspection staff shall be guaranteed.
- CABs shall participate in coordination activities. They shall also take part directly or be represented in European standardisation, or ensure that they know the situation in respect of relevant standards.
- Preferred way of proving conformity: Accreditation
- Notification by member states, the Member States shall ensure that the notified bodies are monitored regularly to check that they comply at all times with the criteria set out in Annex XI.

What we see in the field

- Missing, false or misleading certificates
- Machinery with certificates, which do not fulfil the ESHRs
- Manufacturers: Lack of CE / legal knowledge MD
- Standards lag behind technical development
- Machinery referring to harmonised standards, which are not fully applicable for that specific machinery
- Interpretation differences between member states on obligations when modifying machinery by other than original manufacturer
- Modifications to Machinery without an assessment of the modification. Be aware that if you modify a machine, without permission of the original manufacturer, you will be the new manufacturer and legally responsible for the machinery.
- EU-CABs that certify modified machinery without the full technical file (satisfied with only file for modification-impact) → modification by other party than original manufacturer
- EU-CABs that start certification long before product & file are complete → risk for independence / impartiality

Proposed Machinery Regulation

- Self-certification for annex I (formerly Annex IV) machinery is no longer permitted, all Annex I machinery has to be assessed by a Third party EU-CAB
- Annex I: added:
  - 24. Software ensuring safety functions, including AI systems.
  - 25. Machinery embedding AI systems ensuring safety functions.
- Annex II (formerly Annex V) added:
  - 18. Software ensuring safety functions, including AI systems.
  - 19. Filtration systems intended to be integrated into machinery cabins in order to protect operators or other persons against hazardous materials and substances, including pesticides, and filters for such filtration systems.
- The Commission is empowered to adopt delegated acts to amend Annex I in view of technical progress and knowledge or new scientific evidence by including in the list of high-risk machinery products a new machinery product or withdrawing an existing machinery product from that list.

Proposed Machinery Regulation

- There is a new definition of substantial modification to ensure that machinery, placed on the market and/or put into service, that suffers substantial modifications is in conformity with the essential health and safety requirements in Annex III (formerly Annex I):
  - ‘substantial modification’ means a modification of a machinery product, by physical or digital means after that machinery product has been placed on the market or put into service, which is not foreseen by the manufacturer and as a result of which the compliance of the machinery product with the relevant essential health and safety requirements may be affected;
  - A natural or legal person, other than the manufacturer that carries out a substantial modification of the machinery product shall be considered a manufacturer for the purposes of this Regulation.
- The manufacturer shall inform the notified body that holds the technical documentation relating to the EU type- examination certificate of all modifications to the approved type and of all modifications to the technical documentation **that may affect the conformity of the machinery product with the applicable essential health and safety requirements or the conditions for validity of that certificate**. Such modifications shall require additional approval in the form of an addition to the original EU type-examination certificate.

Proposed Machinery Regulation

- The proposed Regulation adapts or adds EHSRs to address specific machinery risks:
  - Principles of safety integration
  - Digital documentation
  - New digital technologies (Cyber security, Human-machinery interaction, Machinery with evolving capacity, Traceability of machinery safety)

  - The proposed Regulation will become applicable 30 months after its entry into force to allow manufacturers, notified bodies and Member States time to adapt to the new requirements -> 2025??

Questions?