



# VDMA Seminar

## “Safe Framework of Standard and the Upcoming challenges of Machinery Safety in India”

**EU-India Co-operation- Overview of Standards and Policies**

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**Project SESEI**

(18-07-2023)

# Outline

- EU-INDIA: Growing Partnership
  - Partnership Instruments
  - Project SESEI
- European Commission: Machinery Regulation
  - Machinery Directive 2006/42/EC → New Machinery Regulation 2023/1230
- ISO Guide 78/ CEN Guide 414: Safety of machinery
- CEN and ISO Standards for Safety of Machinery
- @BIS around Standards for Safety of Machinery
- Conclusion



# Europe-India: Growing Partnership



- ▶ EU is India's 2nd largest trading partner - €120 billion of trade in goods in 2022 or 10.8% of total Indian trade.
- ▶ India is EU's 10th largest trading partner - 2% of EU total trade in goods.
- ▶ EU-India trade in services €40 billion in 2021
- ▶ EU-India partnership instruments (next slide)

# EU-India Partnership Instruments

- EU-India Strategic Partnership: [A Roadmap to 2025](#) , [Joint Declaration of May 2021](#)
  - **Cooperation around Standardisation and its harmonisation to International Standards and promotion of existing international standards** is key.
  - Cooperation on digital standards and network security, 5G technology and beyond 5G, Joint Task Force on Artificial Intelligence, Quantum and High-Performance Computing, protection of personal data and privacy, Climate Change, Clean Tech, Renewables, Clean Energy, Circular Economy and Resource Efficiency Partnership, Partnership on Smart and Sustainable Urbanization, Research & Innovation, RAIL etc.
- Establishment of a [Trade and Technology Council \(TTC\)](#) between the two regions
  - [Three working groups — on digital governance and connectivity, green tech, and trade,](#)
- EU-India [Connectivity Partnership](#) aligned with EU's [Global Gateway](#)
  - Support sustainable digital, transport and energy networks, based on Sustainable Development Goals principles and commitment to **implementing relevant international standards**, to ensure a level playing field.
- Re-launch of [EU-India Free Trade Agreement](#) negotiations etc.



# TTC – What's in it



## **WG1: Strategic technologies, digital governance and digital connectivity**

### Areas to be explored:

- Digital connectivity
- Artificial Intelligence
- 5G/6G
- High performance and Quantum computing
- Semiconductors
- Cloud systems
- Cybersecurity
- Digital skills
- Digital platforms

## **WG 2: Green & clean technologies**

The group will focus on **standards**, emphasis on research and innovation.

### Areas to be explored :

- Research and Innovation
- Wastewater treatment
- Recyclable Plastics
- Waste to Energy
- E-mobility and battery performance and recycling
- Green hydrogen and green ammonia
- Liquid fertilizers

## **WG 3: Trade, investment and resilient value chains**

- ▶ The resilience of supply chains and access to critical components, energy, and raw materials.
- ▶ To resolve identified trade barriers and global trade challenges by promoting cooperation in multilateral fora.
- ▶ Towards **promotion of international standards** and cooperation on addressing global geopolitical challenges.

# SESEI Project is a local presence in India

**SESEI** (Seconded European Standardization Expert in India)  
*is a local face for the European standardization community in India: Dinesh Chand Sharma*



**Why SESEI:** India is a major trade partners for EU/EFTA, Increasing role of standards to gain market access, evolving & complex nature of regulatory and standardization landscapes, sharing best practices, and work together as partners

**Priority Sectors/topics:** Aligned with EU-INDIA TTC, Connectivity Partnership

**Digitization:** Strategic technologies, digital governance, and digital connectivity

Smart Cities/Urban Development, ITS, Quantum Technologies, Smart Grid/Meter, Artificial Intelligence, 5G/6G, Open RAN, M2M/IoT (Cyber-Physical Systems), DECT, Data Privacy, Satellite Communication, Blockchain, Digital Signature, Smart Manufacturing, e-Accessibility, cybersecurity, digital skills, digital platforms including Research and Innovation etc.

**Green & Clean technologies :** Clean Energy, Energy Efficiency (Green ICT), Environment, Circular Economy including Resource Efficiency, Waste Management, Energy storage technologies, Electric mobility, Green Hydrogen, Advanced biofuels including R&I etc.

**Other topics** of mutual interests such as Rail, Ropeways, **Machinery Safety** etc.

[www.sesei.eu](http://www.sesei.eu) , [www.sesei.in](http://www.sesei.in)



# Project Objectives

- ✓ to promote the European standardization model and standards in India and facilitate a dialogue
- ✓ to improve contacts between partners and relevant players in the Indian administration, industry and standardization bodies
- ✓ to monitor and gather regulatory and standardization info and raise level of awareness in EC, EFTA and ESOs
- ✓ to facilitate technical discussions
- ✓ to build and animate a network of specialists (among stakeholders and stakeholder's memberships) capable of addressing specific and/or technical issues;
- ✓ to address EU/EFTA/INDIA Industry queries around Standards & Regulations.
- ✓ technical Synergy with other EU-INDIA Projects

Project SESEI works on “**National Standardization Approach / Policy/ Legislation, IPR and TBT**” topic as an overall horizontal topic along with specific priority sectors and on topics mutual interest



# Engagement with BIS



- ▶ CEN-CENELEC- BIS MoU specific to adoption of EN-115 in April 2017
  - ▶ IS 4591 Part 1, 2 & 3 on Escalators and Moving Walks
- ▶ BIS – ETSI MoU signed in Dec'21, includes condition of copyright and adoption
  - ▶ IS 17802 Part 1 & Part 2 being technical adoption of EN 301 549 (Accessibility for the ICT Products and Services, which is included in RPwD act through an amendment)
  - ▶ Indian Standard on Electronic Signatures and Infrastructures (ESI) under Wide Circulation is Technical adoption of EN 119 101 and EN 319 102 is under study for adoption
  - ▶ Indian Standard on Smart Infrastructure (Smart Cities): IoT System Part 1 Reference Architecture (IS 18004 : Part 1 : 2021) is based on oneM2M CSF and Unified Data Exchange Part 2 API specifications (IS 18003 : Part 2 : 2021) includes NGSI-LD (ETSI CIM)
- ▶ Successful organization of Training cum exposure visit of BIS officers to visit EC, CEN-CENELEC, ETSI, AFNOR, LABS etc. in June-July'22
- ▶ BIS – CEN CENELEC MoU signed in March'22: Framework License agreement to be concluded separately.
  - ▶ CEN-CENELEC Framework Copyright License agreement submitted July'22, and its closure will allow access to BIS the CEN-CENELEC Standards for study and easy/faster adoption



# EC: Machinery Regulation



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# Machinery Directive 2006/42/EC

- Machinery Directive 2006/42/EC
- **Over 800** harmonised standards in the **Official Journal of the EU**
- Ensuring a high level of **safety and protection** for users of machinery and other people exposed to it

Document 32006L0042  
 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)  
 (Text with EEA relevance)  
 OJ L 157, 8.6.2006, p. 24-88 (ES, CS, DA, DE, ET, EL, EN, FR, IT, LV, LT, HU, MT, NL, PL, PT, SK, SL, FI, SV)  
 Special edition in Bulgarian: Chapter 13 Volume 053 P. 120 - 182  
 Special edition in Romanian: Chapter 13 Volume 053 P. 120 - 182  
 Special edition in Croatian: Chapter 13 Volume 059 P. 74 - 136  
 In force: This act has been changed. Current consolidated version: 26/07/2019  
 EEL: <http://data.europa.eu/eu/eli/dir/2006/42/vj>

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19.	EN ISO 16092-3:2018 Machine tools safety — Presses — Part 3: Safety requirements for hydraulic presses (ISO 16092-3:2017)	C
20.	EN 16719:2018 Transport platforms	C
21.	EN 16952:2018 Agricultural machinery — Rough-terrain Work Platforms for Orchard's operations (WPO) – Safety	C
22.	EN 17059:2018 Plating and anodizing lines — Safety requirements	C
23.	EN ISO 19085-4:2018 Woodworking machines — Safety — Part 4: Vertical panel circular sawing machines (ISO 19085-4:2018)	C



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# New Machinery Regulation 2023/1230

- New Regulation 2023/1230, superseding the previous Machinery Directive 2006/42/EC, and is published on June 29, 2023
  - Lays down health and safety requirements for the design and construction of machinery, related products to be made available on the market or put into service while ensuring a high level of protection of the health and safety of persons, in particular consumers and professional users [...].
- **Entry into force** (20 days after publication) on **July 19, 2023**
- **Transitional period** provided in the new Regulation is **42 months / 3½ years**
  - **Application date in January 2027**
  - Except for certain provisions that will apply before:
    - **Safeguard Procedures** (upon entry into force)
    - **Reporting obligation** for **Member States** (after 24 months)
- Any relevant **preparatory work** (e.g., standardisation request, new standards) can start now

# Aims of the revised Machinery Regulation

- Create a **level playing field** for economic operators and consolidate the leadership of the EU machinery industry
- Establish a **high level of trust** in **digital innovative technologies** for consumers and users by addressing the **risks of emerging digital technologies** AI and ensuring cyber-safety.
- Boosting **innovation**
- **Embrace digitalisation** and **reduce costs** (€ 16.6 billion savings in printing costs of instructions, each year)

# Key changes compared to Machinery Directive

- Increased **legal certainty and** uniform application
- Integration of **Artificial Intelligence** related provisions for safety functions
- Integration of **Cyber Safety** related provisions for safety control systems and compliance related software and data
- **Autonomous** and **remote-controlled** machinery
- **Digitalisation** of instructions for use, assembly instructions and EU Declaration of Conformity and Incorporation
- **Mandatory Notified Body conformity assessment** for 6 product categories
- **Common specifications** as a fallback option when suitable harmonised standards are not available
- Streamlined **Safeguard Procedures**, aligned with other legislation

# Essential Health and Safety Requirements “EHSRs”

## Essential Health and Safety Requirements “EHSRs” (Annex III):

- Modifications in some existing EHSRs e.g.:
  - 1.1.6 on ergonomics
  - 1.2.1 on control systems
  - 2.2.1.1 on vibrations (CEN/TC 231 considers addressing this change)
  - 3.2.2 on seating
  - 3.5.1 on batteries → new requirement for batteries with automatic charging for mobile machinery
  - 3.6.3.3 on autonomous mobile machinery or related products



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# Essential Health and Safety Requirements “EHSRs”

## New EHSRs:

- 1.1.9 ‘Protection against corruption’ – type-B standard is planned (CLC/TC 44x)
- 3.2.4. ‘Supervisory control function’ – type-C standards
  - Relevant e.g. for CEN/TC 10, CEN/TC 144, CEN/TC 150, CEN/TC 151, CEN/TC 183, CEN/TC 196, CEN/TC 310, CLC/TC 44x, CLC/TC 61
- 3.5.4 ‘Risk of contact with live overhead power lines’ – type-C standards:
  - Relevant e.g. for CEN/TC 98, CEN/TC 144, CEN/TC 147, CEN/TC 150, CEN/TC 151, CLC/TC 44x
  - Task Force in SF to prepare interpretation of this EHSR in coordination with TCs and submit to EC



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# The road ahead

- The **Standardisation Request** must be prepared by end-2023, for adoption early 2024
  - **Focus** will be on **Artificial Intelligence** and **Cyber Resilience**
  - Also, **update** of the **current stock of harmonised standards** that will be carried over from the Machinery Directive 2006/42/EC (including checking and addressing changes in Essential Health and Safety Requirements)
  - Inclusion of **predictive maintenance** and **areas of interest for international cooperation** identified with third countries and other regions
- Preparation of **Commission Implementing Decision** with the full list of harmonised standards – target to be finalised by end of 2026
- Plan to **update the Guide** to application of the Machinery Regulation – no timeline yet



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# ISO Guide 78 CEN Guide 414

*Safety of machinery – Rules for the drafting and presentation of safety standards*



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# ISO Guide 78 / CEN Guide 414

- Defines Type-A, Type-B, Type-C Standards
  - Type-A, basic safety standard - basic concepts, general aspects
  - Type-B, generic safety standard - one safety aspect or safeguard for use across a wide range of machinery
  - Type-C, machine safety standard - detailed safety requirements for a particular machine or group of machines
- Presents rules for the drafting and presentation of Standards dealing with machinery safety
- Primarily intended for the drafting of type-C standards (model); also applicable to the drafting of type-B standards

**Important to review in order to align to Machinery Regulation if needed**



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# Standards for Machinery Safety

(ISO/TC 199 and CEN/TC 114)



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# CEN TC 114: Safety of machinery'

- **CEN/TC 114 'Safety of machinery'** is responsible for producing standards and other documents on general principles for the safety of machinery, including terminology and methodology.
  - Nearly 100% of the standards published by CEN/TC 114 are developed in cooperation with ISO/TC 199, and most of them support the Machinery Directive (2006/42/EC).
- Among portfolio of CEN/TC 114 is **EN ISO 12100:2010 'Safety of machinery - General principles for design - Risk assessment and risk reduction'**, which translates the requirements of the Directive on machinery (2006/42/EC) into a hazard-based approach.
- List of Standards published by CEN/TC 114 is available [here>>](#)



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# Current activities in ISO/TC 199 and CEN/TC 114

- **ISO/CD TR 21260**: Safety of machinery — Mechanical safety data for physical contacts between moving machinery or moving parts of machinery and persons
- **prEN ISO 11161** : Safety of machinery - Integration of machinery into a system - Basic requirements (ISO/DIS 11161:2023) (Under Approval)
- **prEN ISO 12895**: Safety of machinery -- Identification of whole-body access and prevention of derived risks ((Under drafting)
- **prEN ISO 13855** : Safety of machinery - Positioning of safeguards with respect to the approach of the human body (ISO/DIS 13855:2022) (Under Approval)
- **prEN ISO 14119** : Safety of machinery - Interlocking devices associated with guards - Principles for design and selection (ISO/DIS 14119.2:2022) (Under Approval)
- Cooperation with CLC/TC 44X on the new type-B standard to address EHSR 1.1.9



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# @BIS

- MED 40-Safety of Machinery is mirror committee for ISO TC 199 - Safety of Machinery - Principle (P)
- ETD 44 ( Safety Of Machinery- Electrotechnical Aspects ) is mirror committee for IEC TC 44 - Safety of machinery - Electrotechnical aspects - Principle (P)
- SNAP 2022 - Machinery, Engineering and Manufacturing:
  - Safety of press brakes (High)
  - Safety of mobile machines working underground (High)
  - Adoption of functional safety standard for earth moving machines (Medium)
  - Functional safety standard on agriculture machines (Medium)
  - Ropeways: Safety in rides (High)



# Conclusion

- European Commission is preparing the SReq to:
  - Ensure the adaptation of the harmonised standards (hENs) for machinery to the changes which have been made by the Machinery Regulation in particular in the Essential Health and Safety Requirements (Annex III to the Machinery Regulation).
- The draft SReq asks CEN and CENELEC TCs to:
  - develop brand new standards and revise the existing European hENs within the respective deadlines (Annex I, Tables 1 and 2) and these standards need to meet the requirements indicated in Annex II.
- In line with CEN and CENELEC rules, the Standardization Request Ad-Hoc Group 'Machinery' (SRAHG 'Machinery') is being set up and it will prepare the comments on the draft SReq to be submitted to the EC



thank you!

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