

Status of the new EU legislation

What information is relevant for technical writers?

IUNTC, 2024

2024-12-12

Susanna Akdut

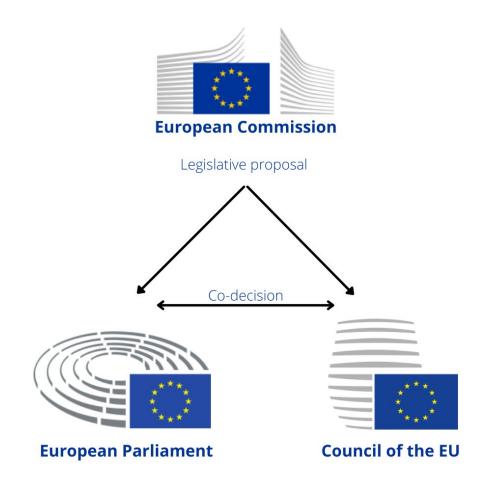


New EU legislation

Agenda

- > EU legislation (harmonised) standards: in a nutshell
- ➤ The European Green Deal Circular Economy legislation
- > A Europe fit for the digital age







ϵ

6 steps to affix a CE marking to your product:

- 1. Identify the applicable directive(s) / regulation(s) and harmonised standards
- Verify product-specific requirements
- 3. Identify whether an independent conformity assessment (by a notified body) is necessary
- 4. Test the product and check its conformity
- 5. Draw up and keep available the required **technical documentation**
- 6. Affix the CE marking and draw up the EU Declaration of conformity

https://single-market-economy.ec.europa.eu/single-market/ce-marking/manufacturers en

Product liability



EU legal acts



Binding legal acts

Regulation

Direct applicable in all EU Member States

Directive

Binding objectives to be achieved; transposed into national legislation

Machinery Directive 2006/42/EC

Machinery Regulation (EU) 2023/1230 Directive on the Repair on goods (EU) 2024/1799

Decision

Specific addressed

Non-binding legal acts

Recommendation

Direct applicable in all EU Member States

Opinion

https://eur-lex.europa.eu/collection/eu-law/legislation/recent.html



New Legislative Framework; NLF



Regulation (EC) 765/2008

Accreditation and market surveillance of products

Notified body

is an organisation designated by an EU country (designated by a national accreditation body) to assess the conformity of certain products before being placed on the market.



Decision 768/2008

Common framework for the marketing of products; product harmonisation **legislaton**

'Blue Guide'

On the implementation of **EU product rules**

Regulation (EU) 2019/1020

Market surveillance and compliance of products



- Alignment of product legislation
- 27 product legislative acts



Regulation (EU) 2019/1020 on market surveillance and compliance of products



New Legislative Framework

Economic operators

Source:

Regulation (EU) 2019/1020 on market surveillance and compliance of products, Chapter I General Provisions, Article 3, Definitions, (13)

Manufacturer

manufacturers and markets a product

Authorised representative

Mandate from the manufacturer

Importer

places a product from a third country on the EU market

Fulfilment service provider

Commercial activity without ownership of the products

Distributor

makes a product available on the market

EUR-Lex (EU) 2019/1020 market surveillance and compliance of product



Standardization organizations

International









Europe ESO







National NSB









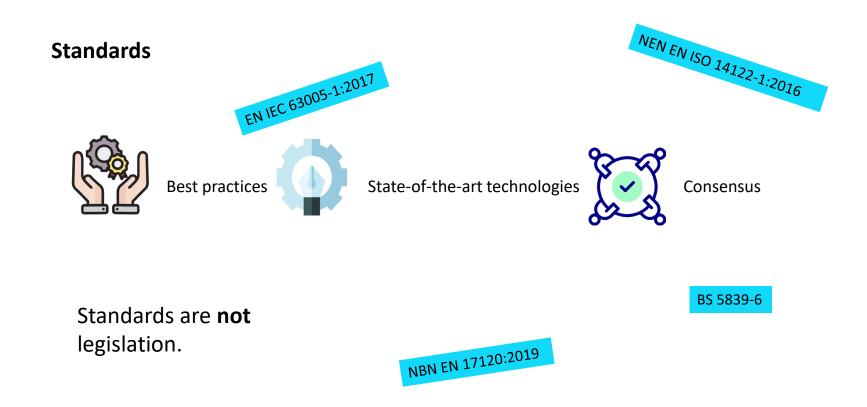








tekom Terms used in EU legislation





(Harmonised) European standards

- Regulation (EU) No 1025/2012
- > Standards ensure the interoperability of complementary products and services
- > Standards help to ensure the safety, health, security and environmental protection requirements
- But: Standards must be purchased at national standard bodies Copyright and intellectual property
- Harmonised standard = EN standard under a product legislative act
- Not all EN standards are harmonised standards

Presumption of conformity harmonised standard with the corresponding requirements of the regulation or directive

https://single-market-economy.ec.europa.eu/single-market/european-standards/standardisation-policy_en



CEAP Circular Economy Action Plan



https://www.construction-products.eu/publications/green-deal/



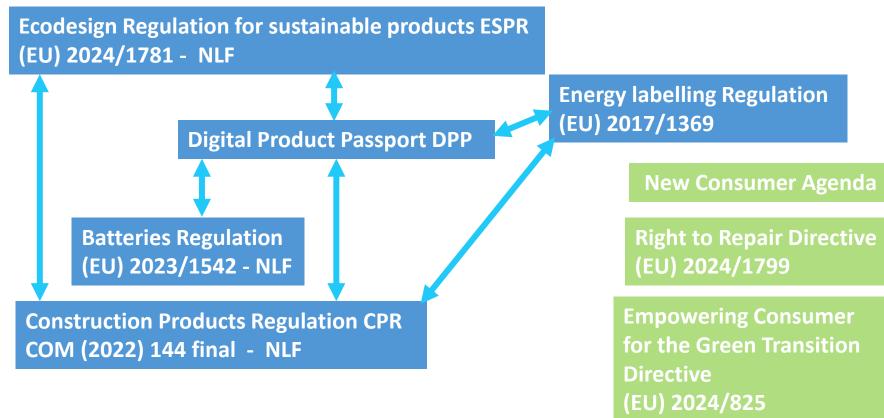








Examples



https://single-market-economy.ec.europa.eu/single-market/goods/new-legislative-framework_en_



Ecodesign Regulation for Sustainable Products (ESPR) (EU) 2024/1781

- Entered into force: 18 July 2024
- Repeals Framework for the Setting of Ecodesign Requirements Directive 2009/125/EC

Framework for setting ecodesign requirements to improve product aspects.

The product groups will be specified by delegated acts.

Article 4, Point 7: First delegated act shall not enter into force before 19 July 2025.

Scope

- > Any physical product including components, intermediate products
- Out of scope: food, feed, medicinal products, living beings, vehicles
- On long-term: All physical products

Independent operator:
Independent of the
manufacturer,
Refurbishers, repairers
or publishers of
technical information

Target audiences

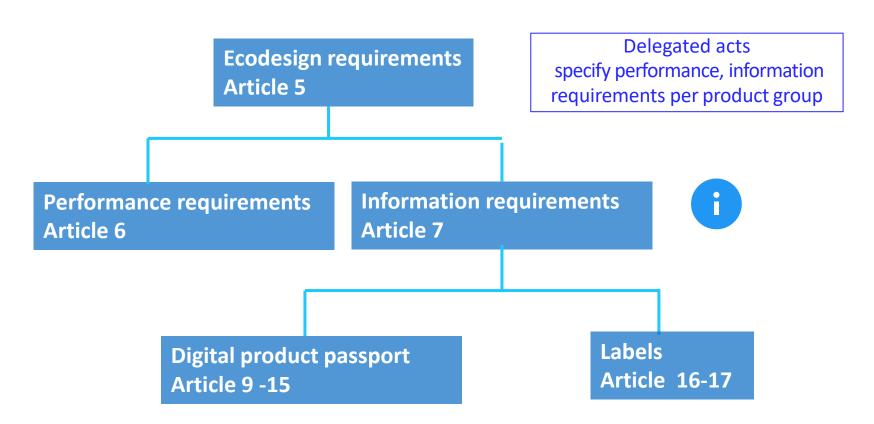
Customers, economic operators, independent operator, professional repairer, and so on Information

- Increased focus on product information:
 - Digital Product Passport (DPP)
 - Labels





Ecodesign Regulation for Sustainable Products (ESPR) (EU) 2024/1781





Ecodesign Regulation for Sustainable Products (ESPR) (EU) 2024/1781

ESPR Working Plan: 2025-2027

First working plan, which shall be adopted by 19 April 2025

Article 18

- (a) iron and steel;
- (b) aluminium;
- (c) textiles, in particulier garments and footwear;
- (d) furniture, including mattresses;
- (e) tyres;
- (f) detergents;
- (g) paints;
- (h) lubricants;
- (i) chemicals;
- (j) energy related products for which ecodesign requirements are to be set for the first time or for which existing measures adopted pursuant to Directive 2009/125/EC are to be reviewed under this Regulation; and
- (k) information and communication technology products and other electronics.

First planned product group: Steel as of 2025



Ecodesign Regulation for Sustainable Products (ESPR) (EU) 2024/1781

Ecodesign requirements, Article 5

- (a) durability:
- (b) reliability;
- (c) reusability;
- (d) upgradability:
- (e) repairability;
- (f) the possibility of maintenance and refurbishment;
- (g) the presence of substances of concern;
- (h) energy use and energy efficiency;
- (i) water use and water efficiency;
- (j) resource use and resource efficiency;
- (k) recycled content;
- (I) the possibility of remanufacturing;
- (m) recyclability;
- (n) the possibility of the recovery of materials;
- (o) environmental impacts, including footprint and environmental footprint;
- (p) expected generation of waste.

Performance requirements, Article 6

Related to the product aspects —
as laid down in the delegated acts
Setting of performance requirements shall
also, where appropriate, reduce significant
risks to human health or the environment

Ecodesign requirements:
Material, products, substances
Energy, resources
Circular aspects



Ecodesign Regulation for Sustainable Products (ESPR) (EU) 2024/1781

Information requirements, Article 7 Some examples:

6

Content

- Information on performances
- Information about 'substances of concern'
- Information for customers and other actors on how to install, use, maintain, and repair products
- Information about disassembly, (preparation for) reuse, refurbishment, recycling, disposal at end-of-life
- Other information that could influence sustainable product choices for customers
- Clear, easily understandable, tailored to the characteristics of the product groups and the target audiences
- Relevant instructions for the safe use of the product
- Shall indicate the way the required information is to be made available: on the product itself, packaging, user manual accompanying the product, website



Ecodesign Regulation for Sustainable Products (ESPR) (EU) 2024/1781



- Check the information requirements in the ESPR.
- Check the information requirements in the delegated act of the concerned product group.
- Check the information requirements in the product legislative act (NLF; sector-specific).



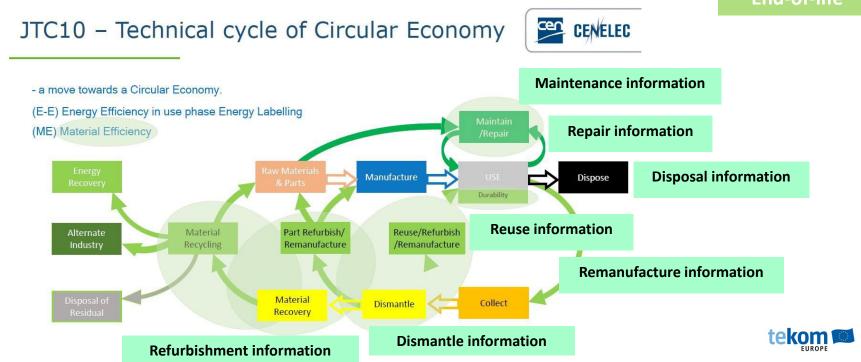
© CEN-CENELEC 2020

The European Green Deal

Ecodesign Regulation for Sustainable Products (ESPR) (EU) 2024/1781

Supply chain

Life-cycle Second-life End-of-life



"European standards addressing material efficiency aspects"

2020-12-01



Ecodesign Regulation for Sustainable Products (ESPR) (EU) 2024/1781

Digital product passport (DPP)

Chapter III, Annex III



DPP Objective

- Digital access to relevant product-specific information on sustainability, circularity, and legal compliance
- Products, components, materials
- EU DPP registry: Economic operators, market surveillance, customs authorities
- **Web portal** for stakeholders, customers

DPP Applications

- > ESPR
- New Construction Products Regulation
- Batteries Regulation
- Detergents Regulation
- Critical Raw Material Act



source: european parliament



Ecodesign Regulation for Sustainable Products (ESPR) (EU) 2024/1781

Examples

DPP information about sustainability aspects

- Product parameters given in Annex I
- Environmental information
- Used materials
- Environmental footprint
- Consumption of energy, water, other resources
- Substances of concern
- Durability and reliability
- Ease of repair, maintenance
- Ease of upgrading, reuse, remanufacturing, refurbishment
- Recycling
- Functional performance, conditions of use

Digital product passport (DPP)



User manuals, instructions, warnings, safety information

Digital access to DPP information

- Declaration of conformity, technical documentation or conformity certificates
- User manuals, instructions, warnings, safety information
- Tracking-information
- Information requirements conform applicable EU legislative act



Ecodesign Regulation for Sustainable Products (ESPR) (EU) 2024/1781

Ecodesign smartphones and tablets (EU) 2023/1670

- Framework; Delegated Acts
- Shall apply from 20 June 2025 onwards.

6

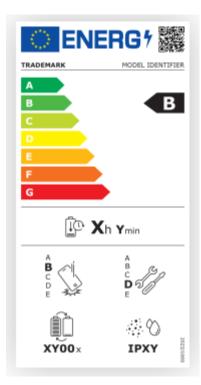
Information

- List of spare parts + availability (professional repairers and end users)
- Repair instructions (end users) publicly available
- > Repair and maintenance information (professional repairer): Register
- Dismantling information needed to access products components (15y)

Energy Labelling Regulation (EU) 2017/1369

- Framework
- Energy-related products, not second-hand
- Information to be entered into the product database, Annex I
- > Shall apply for smartphones and tablets from **20 June 2025** onwards
- European Product Registry for Energy Labelling (EPREL): platform that suppliers must use for registering their product models

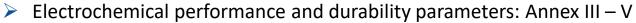






Batteries regulation (EU) 2023/1542

- apply 18 February 2024
- Management of waste batteries, Chapter V
 - End users: Article 64 how to discard waste batteries: Information
 - Digital Battery Passport: Chapter IX, Annex XIII



- Portable batteries
- LMT batteries, industrial batteries capacity > 2 kWh, electrical vehicle batteries
- Safety parameters
- The state of health and expected lifetime, Annex VII
- Labelling, marking and information requirements, Annex VI
- Information about shipment, Annex XIV

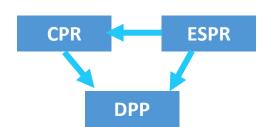






New Construction Product Regulation 'on the way' – Highlights

- New will replace on a long-term replace the CPR 305/2011.
- Requirements of the ESPR applicable
- Safety-, health and environmental requirements
- Sustainable construction products



- Digital product passport will be essential in the New CPR.
- > EU-database or –system accessible for all stakeholders
- Website accessible for consumers





Right to Repair Directive (EU) 2024/1799

- > Entry into force: 30 July 2024
- Member States shall apply those measures latest 31 July 2026.

Scope:

Consumer goods, see Annex III

B2C-context

Target audiences

Consumers

Repair information



Information requirements

- Information on repair obligation Article 5
- Easily accessible, clear and comprehensible manner, Article 6
- European repair form: information about type of repair, the price and the repair time, Article 4
- European repair platform: to find repairers, sellers of refurbished goods, buyers of defective goods in EU, Article 7
- Vulnerable consumers, consumers with disabilities



Annex III

- 1. Household washing machines, household washer-dryers
- Household dishwashers
- 3. Refrigerating appliances
- 4. Electronic displays
- 5. Welding equipment
- 6. Vacuum cleaners
- 7. Servers and data storage products
- 8. Mobile phones, cordless phones and slate tablets
- For goods incorporating light means of transport batteries
- 10. Goods incorporating light means of transport batteries



Empowering Consumer for the Green Transition Directive (EU) 2024/825

B2C-context

Measures shall apply from 27 September 2026.

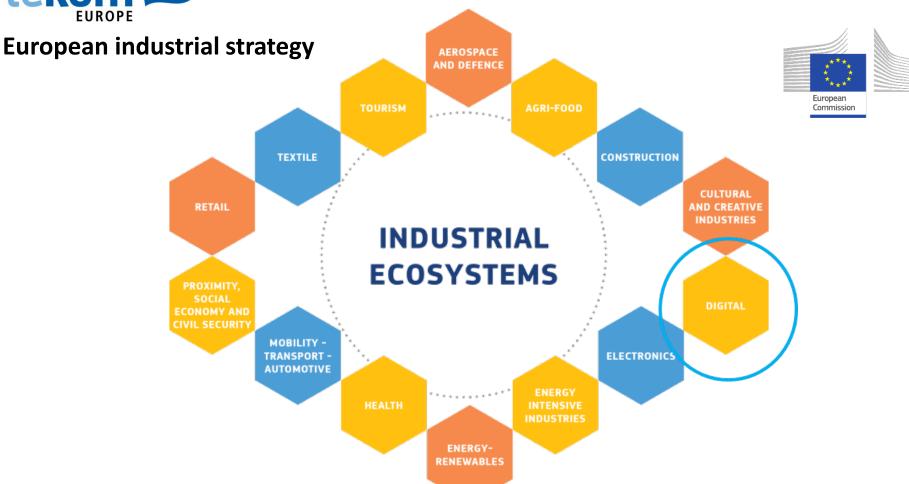


- Through better protection against unfair practices and better information:
 Green Washing ban
- To avoid misleading information about environmental and social characteristics of the product.
- Environmental claims have to comply with high-quality data.
 All information: websites, instructions, labelling, catalogues,...: Consistency
- The verification of the claims shall be documented.

Transparency

All information must be clear and correct.









Artificial Intelligence Act (EU) 2024/1689

Cyber Resilience Act CRA (EU) 2024/2847



© Quardia Inc. / Adobe Stock



Artificial Intelligence Act (EU) 2024/1689 – some highlights



Scope/Roles

- Provider, a person, company or organisation that develops an Al system, Article 3(3)
- Deployer, a person, company or organisation that uses an AI system under its authority, Article 3(4)
- Economic operators
- Affected persons

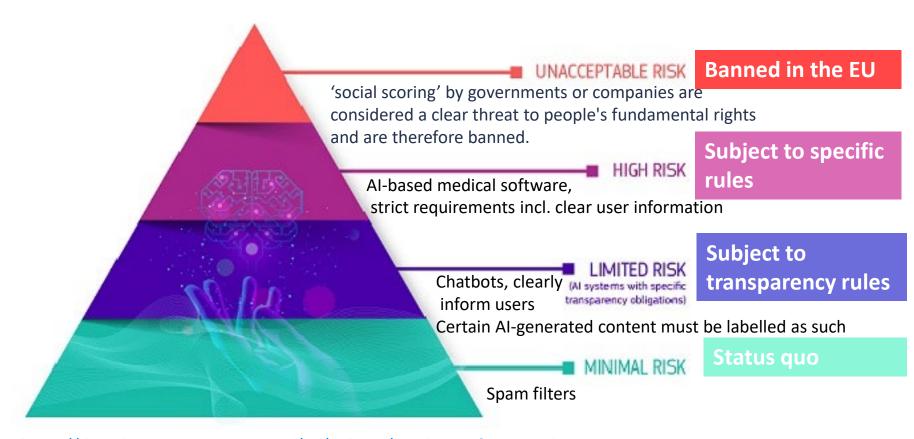
Safety component, Article 3

Component of a product or of an AI system which fulfils a safety function for that product or AI system or the malfunctioning of which endangers the health and safety of persons or property

Transparency



Artificial Intelligence Act (EU) 2024/1689 - some highlights The risk approach



https://digital-strategy.ec.europa.eu/en/policies/regulatory-framework-aihttps://commission.europa.eu/news/ai-act-enters-force-2024-08-01 en



Artificial Intelligence Act (EU) 2024/1689 - some highlights

Timeline	
12 July 2024	Publication in OJEU
2 August 2024	Entry into force
2 February 2025	General Provisions (Title I) apply
2 February 2025	Prohibited AI Systems (Title II) apply
2 August 2025	Application data for main articles – General purpose AI, Governance
2 August 2026	Application for High-Risk AI Systems – Digital applications (Annex III)
2 August 2027	Application for High-Risk AI Systems – Safety components of products (Annex I a)



Artificial Intelligence Act (EU) 2024/1689 - some highlights

High-risk AI systems – Technical documentation, Article 11, Annex IV

- Before being placed on the market or put into service
- Shall be kept up-to-date

High-risk AI systems - Record-keeping, Article 12

Shall technically allow for the automatic recording of events (logs) over the lifetime of the system

High-risk AI systems – Instructions for use, Article 13

- Shall be accompanied by instructions for use
- In an appropriate digital format or otherwise
- Concise, complete and clear information
- Relevant, accessible and comprehensible for the deployer
- Characteristics, capabilities, limitations of performance
- Intended purpose, foreseeable misuse
- Cybersecurity

Compliance with requirements, applicable under EU legislation

- NLF, Annex I, Section A
- Other Union harmonisation legislation, Annex I, Section B



Traceability

Transparency

Continuous monitoring during AI system life cycle



Cyber Resilience Act (EU) 2024/2847

Entered into force: 10 December 2024, shall apply from 11 December 2027



Scope

Products with digital elements: intended purpose or reasonably foreseeable use includes a direct or indirect logical or physical data connection to a device or network.

Hardware products and components placed on the market separately: laptops, mobile phones, network equipment

Connectable devices

Software products and components placed on the market separately: operating systems, word processing, games or mobile apps

Accessed by e-mail, stream, download

- Includes remote data processing solutions if performing a product function.
- Important products with digital elements: Annex III
- Critical products with digital elements: Annex IV

https://economictimes.indiatimes.com/tech/technology/afp-targeted-in-cyberattack/articleshow/113766822.cms?from=mdr



Cyber Resilience Act (EU) 2024/2847

Out of scope

- Non-commercial projects, including open source
- Spare parts
- Cloud/Software-as-a-Service, except remote data processing

Open-source software steward

- legal person, other than a manufacturer systematically providing support on a sustained basis
- free and open-source software
- intended for commercial activities
- ensures the viabiliy of those products

Outright exclusions

Products regulated on cybersecurity:

Medical devices (EU) 2017/745, In vitro diagnostic medical devices (EU) 2017/746, cars (EU) 2019/2144 certified aeronautical equipment/civil aviation (EU) 2018/1139, products exclusively for national security/defence

Target audiences

Consumers, users, economic operators, market surveillance authorities, notifying authorities, notified bodies, open-source software steward



Cyber Resilience Act (EU) 2024/2847

Essential cybersecurity requirements Annex I, Part I

- (1) Appropriate level of security
- (2) Based on the cybersecurity risk assessment

Examples:

- Be made available on the market without known vulnerability
- Security by default configuration
- Possibility to reset product to its original state
- Protection from unauthorised access

Annex I, Part II Vulnerability handling requirements

Examples:

Identify and document vulnerabilities and components, including SBoM

Software Bill of Material

formal record containing details and supply chain

elements of a product with digital elements

relationships of components included in the software

- Share and publicly disclose information about fixed vulnerabilities
- Security updates delivered without delay, free of charge

Traceability

Transparency

Cybersecurity



Cyber Resilience Act (EU) 2024/2847

Information and instructions to the user, Annex II



Manufacturers, importers, distributors

- shall ensure that products with digital elements are accompanied by the information and instructions to the user
- > In paper or electronic form
- > In a language which can be easily understood by users and market surveillance authorities
- > The instructions shall be clear, understandable, intelligible and legible.

Technical documentation, Annex VII

- Manufacturers shall draw up the technical documentation
- Includes user information and instructions



Cyber Resilience Act (EU) 2024/2847

Information and instructions to the user, Annex II

- Manufacturer's name, postal address, email address
- Contact information to report vulnerabilities
- > Intended purpose including the foreseen security environment
- Any known or foreseeable circumstances, reasonably foreseeable misuse: may lead to significant cybersecurity risks
- EU Declaration of Conformity, CE marking
- Type of technical security support offered by the manufacturer, end-date of support period, receive security updates
- Detailed instructions or internet address for detailed instructions and information on
 - secure use throughout the lifetime
 - how changes to the product can affect the security of data
 - how security-relevant updates can be installed
 - Secure decommissioning, removal of data
 - where the SBoM can be accessed if made available



Software Bill of Material



Cyber Resilience Act (EU) 2024/2847 - AI Act (EU) 2024/1689

Intended purpose - CRA

the use of which a product with digital elements is intended by the manufacturer, including the specific context and conditions of use, as specified in the information supplied by the manufacturer in the instructions for use, promotional or sales materials and statemens, as well as in the technical documentation

Article 3, Definitions, (23)

Intended purpose – AI Act

the use for which an AI system is intended by the provider, including the specific context and conditions of use, as specified in the information supplied by the provider in the instructions for use, promotional or sales materials and statements, as well as in the technical documentation

Article 3, Definitions, (12)



Machinery Regulation (EU) 2023/1230

New Legislative Framework

B2B market

B2C market



Green Deal

Scope MR / ESPR

- Machinery products and related products, partly completed machinery
- ESPR is or will become applicable, see machinery product is in the scope. To follow up the delegated acts

Target audiences

> Professional user, non-professional users, economic operators, other stakeholders

Connectable machine

- Smart machines: Internet of Things, Artificial Intelligence
- > Safety component: physical and digital component; High-risk AI system
- Including software
- > Integral approach to safety: Physical safety AND digital security

Entered into force: 18 July 2023 Shall apply: 14 January 2027 **Digital age**



Machinery Regulation (EU) 2023/1230 - highlights

New Legislative Framework

Risk assessment

- Environmental and other requirements of the ESPR, other legislative acts
- Software, Al-system as safety component, cybersecurity assessment



Requirements for software-upgrade and mechanical upgrade of machines

Update must meet the same strict safety and quality requirements as the original machine

Instructions/Information, Annex III

Instructions for use, safety instructions, assembly instructions for partly completed machinery, Entire lifetime, expected lifetime

Paper for consumers

Paper - Printable - Digital

Instructions, other relevant documentation may be provided in a digital printable format.

➤ Guide to application of the **Machinery Directive 2006/42/EC** Edition 2.3 – April 2024: Some concerns to use the Guide



The European legislation

- tekom Europe is working on a whitepaper on the ESPR.
- > tekom Europe is working on a whitepaper on the Right to Repair Directive.
- > tekom Europe is working on a whitepaper on the Construction Products Regulation.
- > tekom Europe is working on a whitepaper on the AI Act.
- > Tekom Europe is working on a whitepaper on the Cyberresilience Act.



Key takeaways

New EU legislative acts under the Green Deal and the Digital Age

- With impact on existing product and sector-specific legislation
- Supply chain: supplier to new economic operators of second-life
- Product & Handlings & Information in the life-cycle / second life-cycle

Target audiences

- Known and new stakeholders and economic operators
- Requirements, expectations, knowledge

Technical communication must handle

- More types of information, instructions, data records
- More detailed information is required
- More output-formats: data, video, labels, print on demand...
- Higher requirements about information quality

Technical documentation

- Dynamic, continuous monitoring
- More detailed risk assessments; more detailed residual risks: essential health, safety and environmental requirements and IT-security





EU legislative sites

EUR-Lex

Legislative Train Schedule

<u>Legislative Observatory European Parliament</u>

tekom Europe

tekom website

tekom publications: Whitepapers, Position papers

tcworld conference / tekom Tagung 2024 sessions



susanna.akdut@roxell.com; www.roxell.com

https://be.linkedin.com/in/susanna-akdut-167a9071 tekom Europe e.V.: Home Belgium

