

Factsheet #6.

Legal Dimension of Responsible Robotics

This document provides an overview of the legal considerations relevant for the robotics industry, focusing on non-technical aspects. It serves as a reminder for designers, manufacturers, integrators, and deployers of robots, highlighting the key factors to ensure a compliant AI-driven robot's successful launch in the market. While not exhaustive, the references in this overview offer guidance for exploring legal issues and solutions in automated systems.

Disclaimer This factsheet is based on research conducted by the Robotics4EU, as well as second-hand data.



STANDARDS & REGULATIONS

Robots empowered by artificial intelligence are progressively gaining the ability to autonomously make decisions and perform intricate tasks. To mitigate potential safety and ethical risks posed by autonomous robots during interactions with individuals or while operating in shared environments, it is imperative to dedicate meticulous attention to adhering to safety and ethical standards, regulations, and guidelines. Ensuring the secure deployment of robotic solutions requires a comprehensive overview of key horizontal regulations pertaining to safety, liability, and beyond.

The first step to approach this question is to focus on the horizontal standards and regulations that could prevent harm and ensure the safe development of robotic solutions:

International Standards (ISO) such as **ISO / TC 299**, which deals with the safety of industrial robots and service robots.

The main standards to follow include:

- **ISO 13849-1:2023** Safety of machinery
- **ISO 26262-1:2018** Road vehicles – Functional safety
- **ISO 10218-1:2011** and **ISO 10218-2:2011** Safety requirements for industrial robots
- **ISO 13482:2014** Safety requirements for personal care robots
- **ISO/TS 15066:2016** Safety requirements for collaborative industrial robot systems and work environment

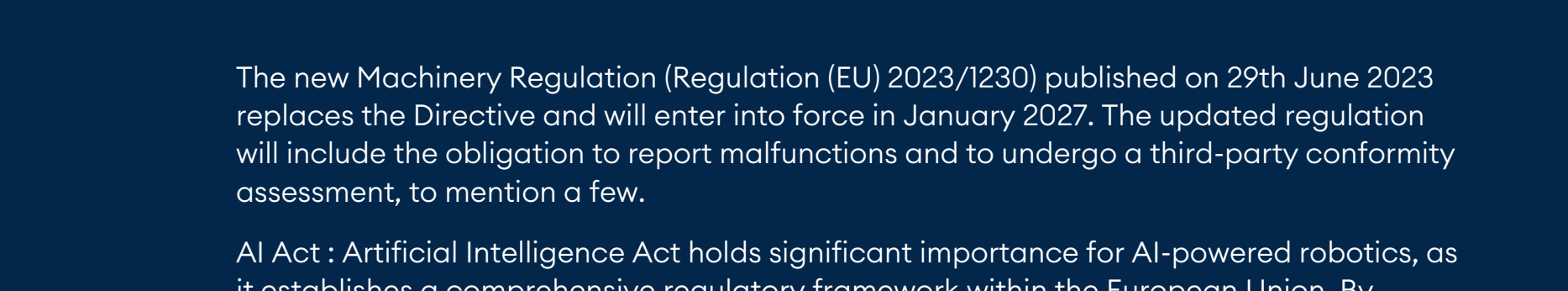
International Electrotechnical Commission (IEC) publishes international standards for electrical and electronic products, including robots. These standards cover safety aspects related to electrical systems and can be crucial for ensuring robot safety. This includes **IEC 61508-1:2010** – Functional safety of electrical/electronic/programmable electronic safety-related systems.

National Regulations which vary across countries, govern the safety of robots in different application areas. National product liability laws are as important for complying with industry-specific safety standards (e.g. healthcare robots must comply with healthcare regulations).

EU Level Directives/Regulation like the **Machinery Directive 2006/42/EC**, which covers essential safety and health requirements:

- Risk of loss of machine control;
- Risk of safety function failure;
- Reasonable foreseeable use³.

Machinery directive is interpreted with the help of harmonised standards like **EN ISO 12100:2010 Safety of machinery – General principles for design – Risk assessment and risk reduction**, which specifies basic terminology, principles and methodology for achieving safety in the design of machinery. It specifies principles of risk assessment and risk reduction to help designers achieve this objective⁴ Following the standard, designers have to:



The new Machinery Regulation (Regulation (EU) 2023/1230) published on 29th June 2023 replaces the Directive and will enter into force in January 2027. The updated regulation will include the obligation to report malfunctions and to undergo a third-party conformity assessment, to mention a few.

AI Act: Artificial Intelligence Act holds significant importance for AI-powered robotics, as it establishes a comprehensive regulatory framework within the European Union. By defining rules and obligations for developing and deploying artificial intelligence, the Act aims to ensure ethical and responsible AI practices, including transparency, risk assessments, and the prohibition of specific AI systems like predictive policing. The regulatory clarity provided by the AI Act provides a structured approach that balances technological advancements with ethical considerations, contributing to the responsible and safe development of AI-powered robotics in the EU. After adoption by both Parliament and the Council, the AI Act will enter into force in 2026 (though some provisions apply).

Other relevant EU directives include:

Directive 2014/53/EU of 16.04.2014 on the harmonisation of the laws of Member States in relation to making radio equipment available on the market.

Directive 2001/95/EC of 3.12. 2001 on general product safety.

Product Liability Directive 85/577

Digital Content Directive 2019/770

Sale of Goods Directive 2019/771

³“1. Robot (AI-based robots under the AIA)” by Vera Lúcia Raposo, NOVA School of Law, NOVA University of Lisbon (Portugal), Presentation at Robotics4EU workshop “Regulating AI: The impact of the EU AI ACT on robotics for agile production” 4ISO 12100:2010

IP PROTECTION

AI-powered robots are capable of innovative problem-solving, leading to outputs that could potentially be classified as intellectual property (IP). The **legal status of robots and the extent of their rights is a fundamental topic** surrounding AI, raising the question of how the legal system can adequately safeguard the inventions of AI-powered robotics. While the possibility of listing an AI system as the owner/user of an invention is discussed⁵ **only a human inventor can be listed to acquire a patent as of 2023**.

PRIVACY REGULATION

Privacy and data security issues represent the most important issues as seen by citizens, having a strong impact on how they view robotics and robotic technology in general. It is essential to establish a robust approach to privacy and cyber security early in the robot's life-cycle. This proactive user-centric approach not only prevents potential regulatory issues that may arise but also builds trust with users. Addressing privacy concerns at the outset helps mitigate most risks, ensuring secure integration of the technology into society with proper data collection, management and storage practices aligned with citizens' expectations.

Alongside guiding the safe design, development and deployment of robotics, the EU has proposed related data management measures:

- **General Data Protection Regulation (GDPR)**
Data privacy and protection law enacted in the European Union to safeguard individuals' personal data and regulate its processing by organisations.
- **Cybersecurity Act**
The Cybersecurity Act, adopted in 2019, aims to strengthen the EU's cybersecurity framework.
- **eIDAS Regulation**
eIDAS is a key enabler for secure cross-border transactions.

⁵ <https://www.epo.org/en/boards-of-appeal/decisions/200008eu1>

SELECTION OF IMPORTANT RESOURCES

- **SIENNA project**, in the **“Analysis of the legal and human rights requirements for AI and robotics in and outside the EU”** provides a comprehensive list of legal issues on robotics and AI, including:
 - **Legislative documents** on AI and Robotics by United Nations, World Trade Organization, Council of Europe and the European Union;
 - **Recommendations** on enhancing existing legal frameworks for genomics, human enhancement and AI and robotics.
- EU-funded **project COVR** has published:
 - A paper on **“Validating Safety in Human-Robot Collaboration: Standards and New Perspectives”**, which discusses a cross-domain approach towards the definition of **step-by-step validation procedures for collaborative robotic applications**;
 - A toolkit for coboteers to determine how to test and validate safety for their collaborative robot application or component is available online.
- **European Agency for Safety and Health at Work (EU OSHA)** provides information, research and guidance to employers, workers and policymakers across Europe to **promote safe and healthy working conditions**.
- **Robotics & AI Law Society (RAILS)** works on a legal framework that facilitates technical developments, avoids discrimination, ensures equal treatment and transparency, protects fundamental democratic principles and ensures that all parties involved participate in the economic results of digitalisation.

GAPS, CHALLENGES AND CITIZENS' CONCERNS

Robotics4EU conducted comprehensive citizen, end-user and robotics community engagement activities with 740 respondents to understand the attitude and concerns of the general public towards the more prevalent adoption of robotics. Here's what the citizens thought about the legal landscape and its compatibility with the needs and issues in the industry that curb the advancement towards responsible robotics adoption.

Need for Harmonising Regulations

In general, the existing EU legal framework is sufficient to cover the challenges posed by AI-driven robotics, tackling human rights, data protection, product liability and safety. The development of the regulation is on a solid track of a coherent strategy, which is based on the devotion to innovation support and competitiveness but some **gaps in legislation on the EU / national level are yet to be filled**.

Missing Proper Frameworks for Testing

The robotics community engagement events highlighted some recurring issues, especially in the fields where robotics are deployed in the public spheres. As the **strictness of regulation and safety standards limit testing** robotic solutions in public spaces, regulatory sandboxes are needed to safely and effectively robots in real-world environments.⁶

Low Awareness of the Legal Landscape

According to the Robotics4EU Needs Analysis,⁷only half of the robotics community members believe themselves to be somewhat familiar with the current regulations and only 14% of respondents that are not affiliated with robotics companies declare having such knowledge. These results could be interpreted as a call **for more education on the functioning of regulations** and for a more transparent and accessible system.⁸

Citizens Expect Self-regulation and Supportive Legislation

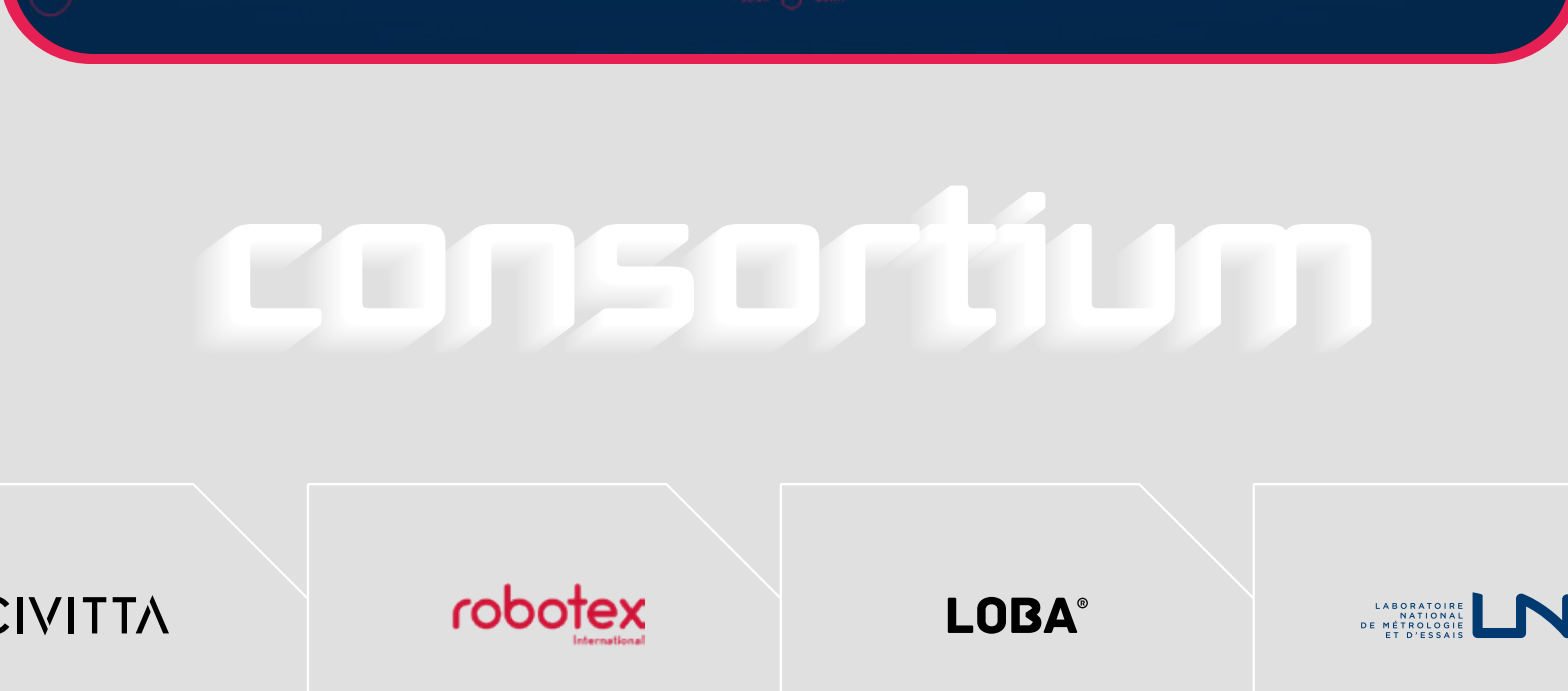
The most commonly given answer in the Citizen Consultations was that“Actors responsible for developing the software and technology” should be held responsible for the actions of automated systems. The second most popular opinion was that “International institutions such as the EU” should be held accountable, and the developers of the products were placed in third place. These responses suggest that citizens anticipate robust **self-regulation within the robotics field to accompany action from international institutions and national governments**.

Therefore, the **commitment to upholding social and ethical norms within organisations should extend beyond legal compliance**. For instance, organisations engaged in robotics research, development, and deployment must establish internal protocols, rules, and supportive environments that align with these ethical and social imperatives.

⁶Rovena Rodrigues, Konrad Siemaszko, & Zuzanna Warsa. (2019). SIENNA D4.2: Analysis of the legal and human rights requirements for AI and robotics in and outside the EU (V2.0). Zenodo. <https://doi.org/10.5281/zenodo.4066812> p. 73

⁷<https://www.robotics4eu.eu/publications/deliverable-2-robotics-community-citizens-and-policy-makers-needs-analysis/>

⁸Reference: citizen consultations 9/1d



consortium

