



# Machinery Regulation

## Key Provisions

agROBOfood Seminar  
Unlocking the Power of Robotics in Agri-Food  
11 May 2023

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# Aims of the revised Machinery Regulation

- Keep ensuring the well-functioning of the **single market**
- Create a **level playing field** for economic operators and preserve the competitiveness of the machinery sector in **global markets**
- Establish a **high level of trust** in **digital innovative technologies** for consumers and users
- Adapt to the **risks of emerging digital technologies**
- Boosting **innovation**
- **Reduce cost** for the industry, in particular SMEs, save natural resources, ...
- **Digital instructions** and **EU Declaration of Conformity**
- Regulation through **Essential Health and Safety Requirements** supported by harmonised standards **cited in the EU OJ**

# New Machinery Regulation – key dates

- **Political agreement** reached on 15 December 2022
- January to March 2023 used for the **lawyer-linguistic review**
  - **Corrections and improvements** to the text to facilitate **understanding** and **translations**
- **Final votes** in **European Parliament** and the **Council** are almost done
- **Publication and entry into force** (20 days after publication) **July 2023**
- **Transitional period** provided in the new Regulation is **42 months**
  - **No voluntary application** of Machinery Regulation **before** the application date
- **Application date for industry sectors from January 2027**

# Key changes compared to Machinery Directive

- Increased **legal certainty**, uniform application (e.g. substantial modification)
- 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
- **Digital instructions** and other digital EU declarations
- **Mandatory Notified Body conformity assessment** notably for AI-based safety systems
- **Common specifications** as a fallback option when suitable harmonised standards are not available



# List of product categories with Notified Body conformity assessment

- Annex I Part A **machinery** with **mandatory** Notified Body assessment
  - 1) to 4) vehicle service lifts, impact fixing equipment, ...
  - 5) Safety components with fully or partially self-evolving behaviour using machine learning approaches ensuring safety functions
  - 6) Machinery that has embedded systems with fully or partially self-evolving behaviour using machine learning approaches ensuring safety functions that have not been placed independently on the market, in respect only of those systems
- Annex I Part B lists **machinery** with **optional** Notified Body assessment
  - 1) to 19) saws, presses, garbage trucks, lifts, ...

# Product categories with mandatory Notified Body conformity assessment (Annex I Part A)

- Clear and transparent **criteria to populate the list** (currently 6 categories)
- **Regular update** of the list by the Commission, based on
  - Seriousness of the inherent potential risk
  - Nature, frequency and duration of the hazard inherent to the function of the machinery
  - Number and severity of potential harm
- Harmonised **template** for individual Member States Reporting, with **guidance**
  - Indications of harm that have been caused
  - Safety defects
  - Known accidents and serious close calls
- Option for Commission to develop a **harmonised methodology**, if necessary

# Artificial Intelligence related provisions

- Annex I Part A (mandatory third-party assessment)
- Item 5) Relevant for safety components with AI (e.g. software) **ensuring safety functions**
- Item 6) Relevant for machinery with embedded AI software that **ensures safety functions**

# Artificial Intelligence general principles

- Annex III Part B General principles
- The risk assessment shall include **hazards that might arise during the lifecycle** of the machinery that are foreseeable at the time of placing the machinery on the market **as an intended evolution of its fully or partially self-evolving behaviour**



# Artificial Intelligence detailed provisions

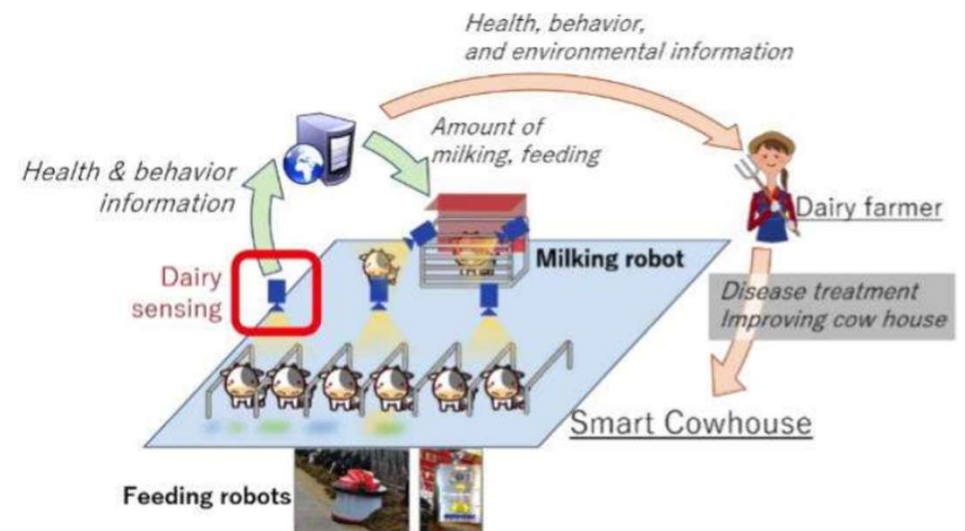
- Annex III Part B Essential Health and Safety Requirements
- Section 1.1.6. Ergonomics – AI may be used but must not make worse
  - (f) ... **adapting the human-machine interface** to the foreseeable characteristics of the operators, including with respect to machinery or a related product with intended fully or partially **self-evolving behaviour** ...
  - (g) ... **adapting** machinery or a related product with intended fully or partially **self-evolving behaviour** ... **to respond to people** ... (such as verbally through words and non-verbally through gestures, facial expressions or body movement) ...
- Section 1.2.1. Safety and reliability of control systems – if self-evolving:
  - (a) ... not ... beyond ... **defined task and movement** ...
  - (b) ... **recording of data** on the safety related decision-making process ...
  - (c) ... possible at all times **to correct** ... in order to maintain its inherent safety ...

# Cyber-safety related provisions

- Annex III Part B Essential Health and Safety Requirements
- Section 1.1.9. Protection against corruption:
  - ... software and data that are **critical for the compliance ... shall be adequately protected** against accidental or intentional corruption
- Section 1.2.1. Safety and reliability of control systems:
  - (a) ... designed and constructed ... withstand ... intended and unintended external influences, including reasonably foreseeable **malicious attempts from third parties** leading to a hazardous situation

# Artificial Intelligence and Cyber-safety

- The **European Standardisation Organisations** will be asked to develop the harmonised standards, following the Standardisation Request under preparation by the Commission



# Interface with other legislative initiatives

- New initiative on **Artificial Intelligence Act** concerning broad horizontal and key issues
  - Risk-based classification of AI systems, governance and effective enforcement of the law on fundamental rights and safety
  - For high-risk AI systems to which the Machinery Regulation applies, the manufacturer should follow the relevant conformity assessment as required under Machinery Regulation
- New initiative on **Cyber Resilience Act** for product life-time security
  - Cybersecurity rules for placing on the market hardware and software, including cybersecurity essential requirements across the life-cycle
  - Products with digital elements (hardware or software), with some exclusions
  - Machinery products covered by CRA: separate conformity assessments, but discussion still ongoing on the interface to minimise burden for manufacturers
- Revision of the **Product Liability Directive**
  - Extending product liability rules to software and related services

# The road ahead (1)

- The **Standardisation Request** must be ready for its start of the adoption process by end-2023 (in that case adoption at the end of Q1 in 2024)
  - Upon the acceptance of the request, the **European Standardisation Organisations** will develop the harmonised standards
  - **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
- Preparation of **Commission Implementing Decision** with the full list of harmonised standards that will provide the presumption of conformity

## The road ahead (2)

- **Future updates of Annex I** for machinery presenting a **higher risk factor**
  - **Commission** to provide a reporting **template and guidance** to Member States on the collection and transmission of accident data
    - by **mid-2024**
  - **Member States** to provide data on **fatal/severe injury-accidents** and ‘**close calls**’
    - from **mid-2025**, and **every 5 years** thereafter
  - **Commission** to carry out the **assessment** for reported product categories
    - by **mid-2026**, and **every 5 years** thereafter, and propose to **add** or **remove** product categories from Annex I
- **Plan to update the Guide** to application of the Machinery Regulation
  - no timeline yet

# Thank you

For further information:

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Images: JRC report Artificial Intelligence and EU Agriculture (Loudjani, et al 2020)

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