



 Orgalim **Policy** Exchange

# Policy Exchange on Machinery Regulation Impact on our industries

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30 March 2023 | 10.00 – 11.30

**orgalim** | EUROPE'S  
TECHNOLOGY  
INDUSTRIES

A vertical image on the left side of the slide showing an orange industrial robot arm in a factory setting, with sparks flying from its end. The background is a light gray geometric pattern.

# Before we start...

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- The event is recorded and will be shared afterwards
- All attendees are muted; however, if you want to ask a question you can use the chat
- You will find in the Handouts section a copy of the agenda and the speakers' bios

[@Orgalim\\_EU](#) [#EUIndustry](#) [#Machinery4EU](#) [#machinery](#)

# Opening remarks

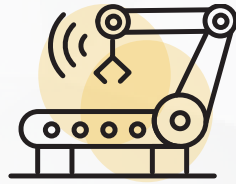
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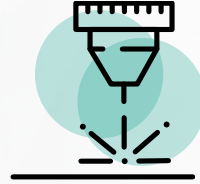
**Daniel Wennick**

Policy Director, Orgalim Europe's Technology Industries

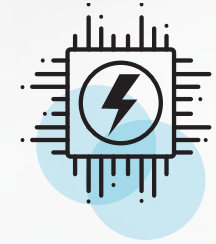
# Orgalim, Europe's technology industries at a glance



Mechanical  
Engineering



Metal  
Technology



Electrical Engineering,  
Electronics, ICT



Annual turnover

**2,497**

billion EUR



Direct employment

**10.97**

million people



Annual exports

**664**

billion EUR



Our industries comprise of

**770,000**

companies



A vertical image on the left side of the slide showing an orange industrial robot arm in a factory setting, with sparks flying from its tool head.

# Agenda

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**10.00 - 10.07**

Welcome, house rules, introduction

**10.07 - 10.27**

Keynote speaker

**10.27 - 11.17**

Moderated panel discussion

**11.17 - 11.27**

Q&A with audience

**11.27 - 11.30**

Closing remarks



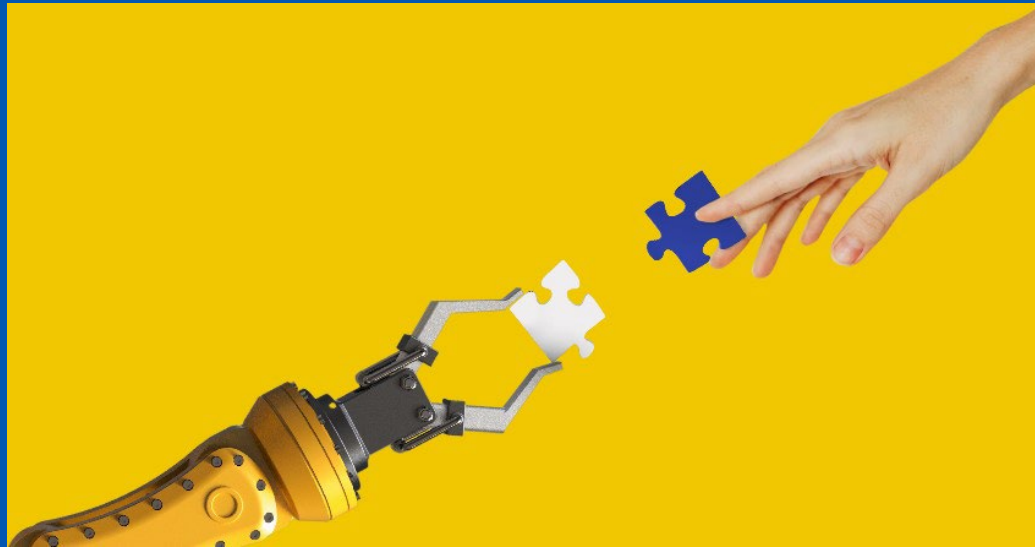
# Keynote

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**Mehdi Hocine**

Head of Unit, Machinery and Equipment,  
European Commission, DG GROW



# Machinery Regulation

## Key Provisions

*Directorate-General for Internal Market, Industry,  
Entrepreneurship and SMEs*

*GROW H.2 Machinery and Equipment – Head of Unit*

Mehdi HOCINE

Orgalim Policy Exchange MR impact on industry  
30 March 2023

# 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 cybersafety.
- Boosting **innovation**
- Embrace digitalisation and reduce costs



# Machinery Regulation – Planning

- **Publication** in the Official Journal expected early **July 2023**
- **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 in January 2027**
  - Except for certain provisions that will apply before:
    - **Reporting obligation for Member States** (after 24 months)
    - **Safeguard Procedures** (upon entry into force)

# 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
- **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

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

- Clear and transparent criteria to populate the list (currently 6 categories)
- Harmonized template for Member States Reporting with guidance
- Possibility to for the Commission to develop harmonized methodology if need be
- Regular update of the list 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

# Digitalisation of paper documents

- **Digital instructions** and **digital EU Declarations** will help to achieve € 16.6 billion savings in printing costs each year
- Mark **directly on machinery** how to access (e.g. QR code)
- Must be **downloadable** and **printable** (also when embedded)
- If online, available for at least **10 years** after placing on the market
- Paper instruction only on request at the time of the purchase
- Safety information **must remain in paper** format non-professional users

# The road ahead (1)

- The **Standardisation Request** must be issued by end-2023
  - 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



# 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:

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs  
Machinery and Equipment Unit

DG GROW – Unit H.2

[grow-H2@ec.europa.eu](mailto:grow-H2@ec.europa.eu)



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# Panel discussion

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**Mehdi Hocine**

Head of Unit, Machinery and Equipment, European Commission, DG GROW



**Thomas Kraus**

Advisor Technical Affairs, EU Regulations, VDMA and Chair of the Orgalim Machinery Task Force



**Maureen Logghe**

Director General Quality and Safety, FPS Economy Belgium and President of the European Cooperation for Accreditation



**Francisco Luis Arribas Martin**

Project Manager industry and equipment, Asociación Española de Normalización – UNE



# Panellist

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**Thomas Kraus**

Advisor Technical Affairs, EU Regulations, VDMA  
and Chair of the Orgalim Machinery Task Force

# Preparation of the application – real life is coming

- Amendment of the current Guide to application – the Commission's announcement is very welcome
- Updating the interpretation on the form of the instructions for Machinery and related products
- Partly completed machinery: which essential health and safety requirements have to be applied?
- Key date regulation for the application of the new EU Machinery Regulation
- Common specifications - the planned fallback solution must not become the rule





# Panellist

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## Maureen Logghe

Director General Quality and Safety, FPS Economy Belgium, SME's, Self Employed and Energy and President of the European Cooperation for Accreditation



# Challenges in market surveillance

- Higher complexity
  - Technological evolution
  - New economic operators, online sales, fast changing market,...
- Knowing the market permits a better focus of market surveillance
  - Input of industry is very welcome



# Panellist

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**Francisco Luis Arribas Martin**

Project Manager Industry and Equipment,  
Asociación Española de Normalización – UNE

# Harmonised Standards supporting EU Harmonisation Legislation



EUROPEAN COMMISSION  
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Aerospace, security, defence and equipment  
**Mechanical and electrical equipment**

Brussels, 19<sup>th</sup> December 2006  
M/396 EN

**Mandate to CEN and Cenelec for standardisation  
in the field of machinery**



**More than 30 technical bodies from CEN and CENELEC, dealing with the wide range of machinery used by the industries**



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# Q&A

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**Mehdi Hocine**

Head of Unit, Machinery and Equipment, European Commission, DG GROW



**Thomas Kraus**

Advisor Technical Affairs, EU Regulations, VDMA and Chair of the Orgalim Machinery Task Force



**Maureen Logghe**

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**Francisco Luis Arribas Martin**

Project Manager industry and equipment, Asociación Española de Normalización – UNE



# Closing remarks

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**Daniel Wennick**

Policy Director, Orgalim Europe's Technology Industries

# Thank you for joining!

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- The recording of the event will be available soon. You will receive an email with the link to the recording; a news article about the event will be published on Orgalim website
- Register to the [Orgalim newsletter](#) to keep up-to-date with our latest news and events

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# SHAPING A FUTURE THAT'S GOOD

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Thank you!



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