



 Orgalim **Policy** Exchange

Policy Exchange on Machinery Regulation Impact on our industries

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...

- 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](#)

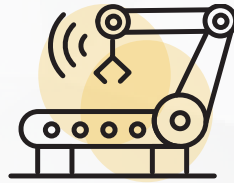
Opening remarks



Daniel Wennick

Policy Director, Orgalim Europe's Technology Industries

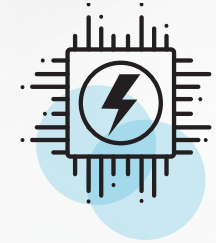
Orgalim, Europe's technology industries at a glance



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

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

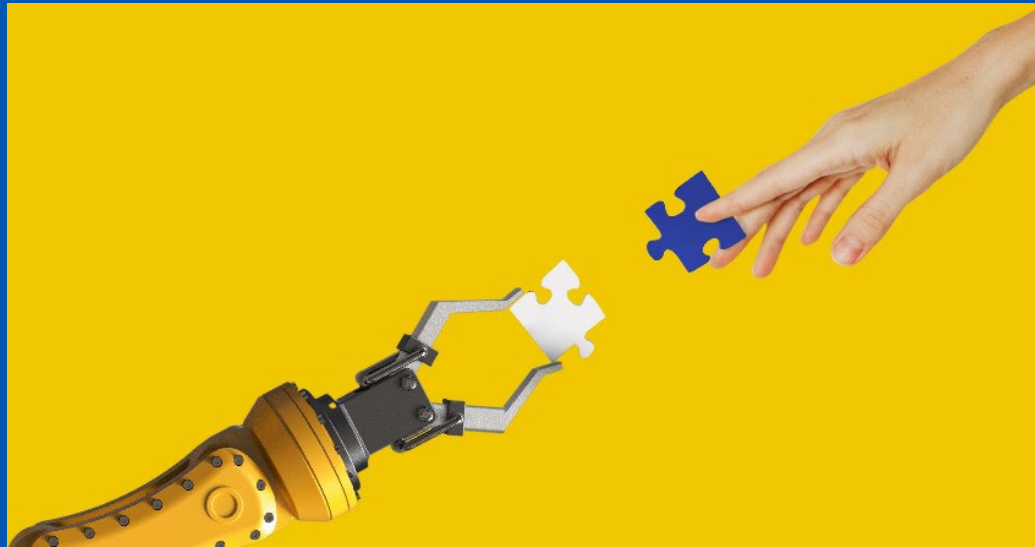
Closing remarks

Keynote



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



Except where otherwise noted, this presentation is © European Union and is licensed under the CC BY 4.0 license.



Panel discussion



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



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



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




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, 19th December 2006
M/396 EN

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

 European Commission

**Regulation on
European Standardisation
Reg.(EU) No 1025/2012**



- 50 Technical Bodies in the CEN-CENELEC machinery sector producing hENs in support of Machinery Directive
- 20 Technical Bodies which are not 'classic' machinery Technical Bodies but have a few or even a significant number of hENs in support of Machinery Directive.



Q&A



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



Closing remarks



Daniel Wennick

Policy Director, Orgalim Europe's Technology Industries

Thank you for joining!

- 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

@Orgalim_EU #EUIndustry #Machinery4EU #machinery

SHAPING A FUTURE THAT'S GOOD

Thank you!



www.orgalim.eu



[@Orgalim_EU](https://twitter.com/Orgalim_EU)



[Orgalim](https://www.linkedin.com/company/Orgalim)



This work is licensed by Orgalim under [CC BY-NC-SA 4.0](https://creativecommons.org/licenses/by-nc-sa/4.0/)
For more information, read our [Terms of Use](#).