

PRESS RELEASE

Brussels, 21 April 2021

European Regulation on Artificial Intelligence – Orgalim calls for legal clarity and workability

The European Commission has issued today its proposal for a Regulation on Artificial Intelligence (AI). Orgalim supports the goal to further strengthen Europe's leadership and the trustworthiness of this technology. AI is an area of strategic importance for Orgalim and the industries we represent, and a key driver of economic development. However, the approach to AI proposed in the Regulation raises a number of concerns, as it risks being too rigid for such a new technology and may therefore hinder its development and innovation in general.

In this context Orgalim calls for industry and policymakers to continue working together to ensure a clear, workable, and future proof legal framework for industry to operate, notably:

- **There is a need to improve the definition of "AI systems"**, as the proposal creates uncertainty regarding such a definition within the scope of this legislation.
- **Orgalim welcomes the proposed risk-based approach. However, Orgalim calls for stricter legal certainty**, to ensure that industrial AI is not considered as high-risk AI systems. This should be defined in cooperation with industry, based on risk-benefit considerations and adjusted when necessary.
- The consequence of being a high-risk AI system is that it could **be subject to** third-party certification. This is part of a worrying wider trend where third-party certification is increasingly seen as the better way to increase safety. While third-party certification does add significant costs for manufacturers, **there is no evidence that third-party certification procedures lead to higher levels of safety than self-certification.**
- Orgalim is pleased to see its calls **for regulatory sandboxing schemes** being reflected.
- We welcome the creation of the European Artificial Intelligence Board (the 'Board'). However, we call for **strong stakeholder involvement**, including from industry, in the implementation of this regulation and providing advice and expertise to the Board.

Orgalim represents Europe's technology industries, comprised of 770,000 companies that innovate at the crossroads of digital and physical technology. Our industries develop and manufacture the products, systems and services that enable a prosperous and sustainable future. Ranging from large globally active corporations to regionally anchored small and medium-sized enterprises, the companies we represent directly employ 11.55 million people across Europe and generate an annual turnover of €2,298 billion. Orgalim is registered under the European Union Transparency Register – ID number: 20210641335-88.

The proposed AI Regulation also aims to ensure that the machines using this technology remain safe and secure. In this context, there is also a connection to another proposal released today by the European Commission for a new Machinery Regulation. Read [here](#) our comments. The current Machinery Directive has worked well for the past decade, thanks also to its flexibility for evolution through the principle of a technology neutral approach. We therefore call on policymakers to ensure consistency between both legislative proposals.

Orgalim will continue to work with policymakers to ensure a legislative framework that will boost Europe's manufacturing position at the forefront of this technology.

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Notes for Editors:

About [Orgalim](#)

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Orgalim is the foremost voice of Europe's technology industries at the EU level, working with policymakers to strengthen their sectors' growth and global leadership, maximise their contribution to Europe's economy and society and foster a new relationship of trust between businesses and citizens. We are shaping a future that's good.

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