



Brussels, 9 March 2022

## Orgalim amendments to the AI Act

### Executive summary

Orgalim, representing Europe's technology industries, fully supports the overall policy aim to strengthen the uptake of AI, to support investment and innovation across the EU, and to guarantee the safety and fundamental rights of people while supporting businesses. In our view, the upcoming AI Act must therefore be fundamentally streamlined and simplified by focusing more on the protection of fundamental rights and exempting already regulated areas, while at the same time creating more flexibility for risk-based, case-specific implementation of the requirements. Particularly in industrial applications, AI must not be over-regulated to ensure that we can further increase Europe's leadership in this area.

## 1. Introduction

The implementation of software techniques and approaches commonly referred to as "Artificial Intelligence" (AI) is not a novelty. Machinery using this technology is already in place on the market and in service. AI is used to control self-driving machinery, to improve the reliability of components, to implement predictive monitoring and maintenance, to increase the lifespan of machinery, to optimise energy efficiency, and to adapt production to customer demand. The deployment of these techniques represents a cornerstone for the competitiveness of the European Union, and it is imperative to foster innovation and digital transition in this sector.

It appears that the AI Act has been developed without considering that many such industrial products, already regulated by a New Approach Regulation, incorporate AI as a safety function. Notably, machinery subject to the provisions of Directive 2006/42/EC already covers the safety aspects of integrating AI in the framework of the risk analysis<sup>1</sup>.

We therefore believe that certain changes are needed to ensure the AI Act is targeted in its focus, and will enable Europe's industries to continue their digital transition and be innovative – especially when it comes to Industrial AI – in order to build a global leadership role.

We propose to examine:

1. The various definitions of AI systems (Article 3, Article 4 and Annex I)
2. Classification as high-risk (Article 6),
3. The obligations stemming from the qualification as high-risk, specifically Articles 10 and 14,
4. Coherence with other related legislative proposals, to avoid potential duplicated or contradictory requirements.

## 2. Definition of AI systems: Article 3, Article 4 and Annex I

Orgalim's opinion is that the current definition of "AI systems" is too broad for the purpose of the AI Act and requires fine-tuning in the interconnected articles; Article 3, Article 4 and Annex I. For example, Annex I covers systems using deductive logic, used since the 1960's (e.g. expert systems) that have not generated risks and biases. Therefore, Orgalim proposes three amendments:

- **Article 3(1):** We believe that the definition of AI needs to ensure the clarity of the regulation. In such a sensitive field of technological innovation, this uncertainty could hamper the future development of desirable technologies, and ultimately harm the market that well-conceived regulatory intervention otherwise aims to foster. Therefore, we support the Council's version of the text, as it defines AI as a "system" rather than "software", which better encapsulates the variety of AI applications in their entirety (AI as a system that uses software). Moreover, the Council's text has been improved by the addition of the sequence of the key words "receives", "infers" and "generates".
- **Article 4:** Clarify that any delegated act to update the list in Annex I is closely tied to the definition as put forward in Article 3(1). The proposed language to do so "on the basis of characteristics that are *similar* to the techniques and approaches" creates legal uncertainty. In order to know which techniques are *similar* to those in Annex I, we need to define AI. The definition in the Regulation needs to answer the question of what AI *is* and what it *is not*.

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<sup>1</sup> A full analysis of how of the main articles of Annex I of the Machinery Directive already guarantee the placing on the market of safe machines, including those integrating AI, is available in our position paper from [February 2019](#).

- **Annex I:** We propose to delete Annex I (b) and (c), because the current approaches in Annex I are far too broad and should be narrowed down, especially regarding the inclusion of “*statistical approaches*” and “*logic- and knowledge-based approaches*”. The current wording could significantly extend the intended scope of the regulation to include long-established data analysis tools. By including logic- and knowledge-based approaches as well as statistical methods in the techniques and approaches defining AI in Annex I, the regulation would make it impossible to differentiate AI software from conventional data analysis tools (e.g. programmable logic controllers in applications of safety in machinery, software to optimise appointment scheduling in hospitals, etc.).

Commission proposal	Council proposal	Orgalim suggested amendments	Comments on amendments
<p>Article 3 (1)</p> <p><i>'artificial intelligence system' (AI system) means software that is developed with one or more of the techniques and approaches listed in Annex I and can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with;</i></p>	<p>Article 3 (1) as presented in the Council partial compromise text of 29 November</p> <p><i>'artificial intelligence system' (AI system) means a system that</i></p> <p><i>(i) receives machine and/or human-based data and inputs,</i></p> <p><i>(ii) infers how to achieve a given set of human-defined objectives using learning, reasoning or modelling implemented with the techniques and approaches listed in Annex I, and</i></p> <p><i>(iii) generates outputs in the form of content (generative AI systems), predictions, recommendations or decisions, which influence the environments it interacts with;</i></p>	<p>Article 3 (1) as presented in the Council partial compromise text of 29 November</p> <p><i>'artificial intelligence system' (AI system) means a system <b>that within a given framework</b></i></p> <p><i>(i) receives machine and/or human-based data and inputs, <b>and</b></i></p> <p><i>(ii) infers how to achieve a given set of human-defined objectives using learning, reasoning or modelling implemented with the techniques and approaches listed in Annex I, and</i></p> <p><i>(iii) generates outputs in the form of content (generative AI systems), predictions, recommendations or decisions, which influence the environments it interacts with;</i></p>	<p><b>Orgalim supports the definition prepared by the Council.</b></p> <p>– Defining AI as a “system” instead of “software” is one of the major changes in the current Council compromise, which seems to better encompass the variety of AI applications in its entirety (AI as a system that uses software). Moreover, the Council’s text has been improved by the addition of the sequence of the key words “receives”, “infers” and “generates”.</p> <p>An “and” should be added at the end of bullet (i) to ensure that all three conditions need to be fulfilled to consider a system as AI.</p>
<p>Article 4</p> <p><i>Amendments to Annex I</i></p> <p><i>The Commission is empowered to adopt delegated acts in accordance with Article 73 to amend the list of</i></p>	<p>Article 4 as presented in the Council partial compromise text of 29 November</p> <p><i>Amendments to Annex I</i></p> <p><i>The Commission is empowered to adopt delegated acts in accordance with Article</i></p>	<p>Article 4</p> <p><i>Amendments to Annex I</i></p> <p><i>The Commission is empowered to adopt delegated acts in accordance with Article 73 to amend the list of techniques and approaches</i></p>	<p>– Bearing in mind that the technology is still developing, new AI techniques may be based on totally new methods and processes that might be far from those</p>

<p>techniques and approaches listed in Annex I, in order to update that list to market and technological developments on the basis of characteristics that are similar to the techniques and approaches listed therein.</p>	<p>73 to amend the list of techniques and approaches listed in Annex I <b>within the scope of the definition of an AI system as provided for in Article 3(1)</b>, in order to update that list to market and technological developments on the basis of characteristics that are similar to the techniques and approaches listed therein.</p>	<p>listed in Annex I <b>within the scope of the definition of an AI system as provided for in Article 3(1)</b>, in order to update that list to market and technological developments on the basis of characteristics <b>and hazards</b> that are similar to the techniques and approaches listed therein.</p>	<p>currently listed. Orgalim is concerned by the use of “similar” techniques.</p>
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Commission proposal	Council proposal	Orgalim suggested amendments	Comments on amendments
<p>Annex I</p> <p><i>Artificial Intelligence Techniques and approaches referred to in Article 3, Point 1</i></p> <p>(a) Machine learning approaches, including supervised, unsupervised and reinforcement learning, using a wide variety of methods including deep learning;</p> <p>(b) Logic- and knowledge-based approaches, including knowledge representation, inductive (logic) programming, knowledge bases, inference and deductive engines, (symbolic) reasoning and expert systems;</p>	<p>Annex I as presented in the Council partial compromise text of 29 November</p> <p><del>Artificial Intelligence</del> <i>Techniques and approaches referred to in Article 3, Point 1</i></p> <p>(a) Machine learning approaches, including supervised, unsupervised and reinforcement learning, using a wide variety of methods including deep learning;</p> <p>(b) Logic- and knowledge-based approaches, including knowledge representation, inductive (logic) programming, knowledge bases, inference and deductive engines, (symbolic) reasoning and expert systems;</p> <p>(c) Statistical approaches, Bayesian estimation, search and optimization methods.</p>	<p>Annex I</p> <p><del>Artificial Intelligence</del> <i>Techniques and approaches referred to in Article 3, Point 1</i></p> <p>(a) Machine learning approaches, including supervised, unsupervised and reinforcement learning, using a wide variety of methods including deep learning;</p> <p>(b) <del>Logic- and knowledge-based approaches, including knowledge representation, inductive (logic) programming, knowledge bases, inference and deductive engines, (symbolic) reasoning and expert systems;</del></p> <p>(c) <del>Statistical approaches, Bayesian estimation, search and optimization methods.</del></p>	<p>– The current approach in Annex I is far too broad and should be narrowed down, especially regarding the inclusion of “statistical approaches” and “logic- and knowledge-based approaches”. The current wording could significantly extend the intended scope of the regulation to include long-established data analysis tools. By including logic- and knowledge-based approaches as well as statistical methods in the techniques and approaches defining AI in Annex I, the regulation would make it impossible to differentiate AI software from conventional data analysis tools (e.g. programmable logic controllers in applications of safety in machinery, software to optimise appointment scheduling in hospitals, etc.).</p>

(c) <i>Statistical approaches, Bayesian estimation, search and optimization methods.</i>			
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### 3. Classification as high-risk

Under the New Legislative Framework (NLF), legislation forbids the sale of products that pose a high risk. According to the current legal provisions, which have been successfully applied for example in the sector of industrial machines, only machines whose risks have been eliminated or reduced to the lowest possible level on the basis of the state-of-the-art may be marketed<sup>2</sup>. We question the necessity to focus on these pieces of legislation per se, with the additional risk of creating duplication and confusion.

In industrial applications, the presence of an AI component does not make a product automatically unsafe, considering that other safety measures are often in place to mitigate safety risks. In fact, AI safety components in industrial applications often significantly contribute to the safety of the machinery, for example by removing the operator from the direct hazard zone<sup>3</sup>. Orgalim proposes that AI should be considered as high-risk if the AI system is the only component required for the safe functioning of the entire product in which it is embedded.

Orgalim also calls for a clear distinction between AI systems generating **decisions as an output** and AI systems generating **recommendations and predictions as an output**. An AI system that only provides a recommendation or prediction, and hence still requires a human intervention to convert it to a decision, should not be classified as high-risk. We believe that such “non-deciding AI” cannot be harmful on its own and should therefore not be considered as high-risk. It is the duty of the human intervention to refrain from the application of any recommendation that could generate a risk.

Commission proposal	Council proposal	Orgalim suggested amendments	Comments on amendments
Article 6 <i>Classification rules for high-risk AI systems</i>  <i>1. Irrespective of whether an AI system is placed on the market or put into</i>	Article 6 as presented in the Council partial compromise text of 29 November <i>Classification rules for high-risk AI systems</i>  <b>1. An AI system that is itself a product covered by the Union harmonisation</b>	Article 6 <i>Classification rules for high-risk AI systems</i>  <i>1. Irrespective of whether an AI system is placed on the market or put into service independently from the products referred to in points (a) and (b), that</i>	1. Insertion of “only”  – Products covered by NLF safety legislation already follow requirements ensuring the safety of products.

<sup>2</sup> Orgalim [input to the EC Consultation on the proposal for a new Machinery Products Regulation](#)

<sup>3</sup> See also the Orgalim position on [third party certification of what are referred to as "high-risk" machines](#)

<p>service independently from the products referred to in points (a) and (b), that AI system shall be considered high-risk where both of the following conditions are fulfilled:</p> <p>(a) the AI system is intended to be used as a safety component of a product, or is itself a product, covered by the Union harmonisation legislation listed in Annex II;</p> <p>(b) the product whose safety component is the AI system, or the AI system itself as a product, is required to undergo a third-party conformity assessment with a view to the placing on the market or putting into service of that product pursuant to the Union harmonisation legislation listed in Annex II.</p> <p>2. In addition to the high-risk AI systems referred to in paragraph 1, AI systems referred to in Annex III shall also be considered high-risk.</p>	<p><b>legislation listed in Annex II shall be considered as high risk if it is required to undergo a third-party conformity assessment with a view to the placing on the market or putting into service of that product pursuant to the above mentioned legislation.</b></p> <p><b>2. An AI system intended to be used as a safety component of a product covered by the legislation referred to in paragraph 1 shall be considered as high risk if it is required to undergo a third-party conformity assessment with a view to the placing on the market or putting into service of that product pursuant to above mentioned legislation. This provision shall apply irrespective of whether the AI system is placed on the market or put into service independently from the product.</b></p> <p><b>3. AI systems referred to in Annex III shall be considered high-risk.</b></p>	<p>AI system shall be considered high-risk where <b>all</b> <del>both</del> of the following conditions are fulfilled:</p> <p>(a) the AI system is intended to be used as <b>the only</b> <del>a</del> safety component of a product, or is itself a product, covered by the Union harmonisation legislation listed in Annex II;</p> <p><b>(b) the AI system has an evolving behaviour</b></p> <p>(c) the product whose safety component is the AI system, or the AI system itself as a product, is required to undergo a third-party conformity assessment with a view to the placing on the market or putting into service of that product pursuant to the Union harmonisation legislation listed in Annex II.</p> <p>2. In addition to the high-risk AI systems referred to in paragraph 1, AI systems referred to in Annex III shall also be considered high-risk.</p> <p><b>3. The classification as high-risk as a consequence of Article 6(1) and 6(2) shall be disregarded for AI systems whose intended purpose demonstrates that the generated output is a recommendation requiring a human intervention to convert this recommendation into a decision and for AI systems which do not lead to autonomous decisions or actions of the overall system.</b></p>	<p>In industrial applications, the presence of an AI component does not make a product automatically unsafe, especially considering that:</p> <ul style="list-style-type: none"> <li>• there might be other non-AI components sufficiently contributing to the safety of the product;</li> <li>• the AI component might not be relevant to the safety of the product.</li> </ul> <p>We therefore propose to insert “<i>the only</i>” to highlight that AI does not necessarily make a system unsafe, especially when there are other safety systems in place.</p> <p>2. Insertion of new (b)</p> <p>The classification for high-risk systems must be adapted to insert a cumulative criterion that ensures high-risk classification focuses only on systems with evolving behaviour, excluding traditional deterministic systems that do not change their behaviour based on input data.</p> <p>3. Insertion of new Article 3.</p> <p>Orgalim calls for a clear distinction between AI systems generating <b>decisions as an output</b> and AI systems</p>
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			generating <b>recommendations and predictions as an output</b> . An AI system that only provides a recommendation or prediction, and hence still requires a human intervention to convert it to a decision, should not be classified as high-risk. We believe that such “non-deciding AI” cannot be harmful on its own and should therefore not be considered as high-risk. It is the duty of the human intervention to refrain from the application of any recommendation that could generate a risk.
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## 4. Obligations for high-risk AI

Orgalim stresses that some of the requirements such as risk and quality management, logging obligations, data governance or post-market monitoring can lead to significant financial and administrative burdens, especially for SMEs. We fear that they will be too prescriptive and sometimes contradict the nature of AI systems.

For example, it is hardly possible to guarantee that training data is error-free, and machine learning methods cannot fully explain how the results are produced.

Moreover, Article 14 is problematic in the context of industrial or agricultural use, as the main AI use in these sectors concerns driverless machines. This will constrain the development and use of AI technologies and create innovation barriers. These obligations need to be proportionate to the risks associated with high-risk AI systems.

We believe that different provisions of Articles 9 to 15 seem to be disproportionate to the objective of the AI Regulation. Moreover, the risks these provisions address have already been taken into account by the essential requirements of the various regulations listed in Annex II, Section A, in particular Directive 2006/42/EC.

Commission proposal	Council proposal	Orgalim suggested amendments	Comments on amendments
Article 10 <i>Data and data governance</i> 3. <i>Training, validation and testing data sets shall be relevant,</i>	Article 10 as presented in the Council partial compromise text of 13 January <i>Data and data governance</i>	Article 10 <i>Data and data governance</i> 3. <i>Training, validation and testing data sets should be <b>sufficiently relevant,</b> and</i>	– Nobody can prove that a data set is error-free or complete. Only a design process targeted to minimise the errors in the data sets should be ensured. The requirements for data governance in

<p><i>representative, free of errors and complete. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. These characteristics of the data sets may be met at the level of individual data sets or a combination thereof.</i></p>	<p><i>3. Training, validation and testing data sets shall be relevant, representative, <b>and to the best extent possible</b>, free of errors and complete. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. These characteristics of the data sets may be met at the level of individual data sets or a combination thereof.</i></p>	<p><del><i>representative, free of errors and complete.</i></del> <i>They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. These characteristics of the data sets may be met at the level of individual data sets or a combination thereof.</i></p>	<p>10(2) are sufficient to ensure minimisation of errors in the data sets. Hence the wording “free of errors and complete” should be removed.</p>
<p>Article 14 <i>Human oversight</i></p> <p><i>1. High-risk AI systems shall be designed and developed in such a way, including with appropriate human-machine interface tools, that they can be effectively overseen by natural persons during the period in which the AI system is in use.</i></p>	<p>Article 14 as presented in the Council partial compromise text of 13 January <i>Human oversight</i></p> <p><i>1. High-risk AI systems shall be designed and developed in such a way, including with appropriate human-machine interface tools, that they can be effectively overseen by natural persons during the period in which the AI system is in use.</i></p>	<p>Article 14 <i>Human oversight</i></p> <p><i>1. High-risk AI systems shall be designed and developed in such a way, including with appropriate human-machine interface tools, that they can be effectively overseen by natural persons during the period in which the AI system is in use, <b>where required by the risk analysis as foreseen in the product legislations listed in Annex II.</b></i></p>	

## 5. Legislative Coherence

Orgalim considers that the essential health and safety requirements set out in NLF product regulations such as Directive 2014/53/EU radio equipment, or the future Regulation on Machinery Products, are well suited to ensure that the product is safe at the moment it is placed on the market<sup>4</sup>. After that, the product falls under other EU legislation, such as the Product Liability Directive 85/374/EEC or the Use of Work Equipment Directive 2009/104/EC unless a substantial modification is made (see below).

<sup>4</sup> Sold for the first time in the EU

The requirements that are proposed in the AI regulation create duplications of these existing requirements or introduce requirements that are too prescriptive or extend beyond the control of the manufacturer's initial design.

Specifically, we want to put forward two examples that need to be addressed.

First, according to the Blue Guide<sup>5</sup>, when modifications are made to a product after it is placed on the market new risks may occur. If these new risks were not present during the original conformity assessment, the modification is considered substantial, and a new conformity assessment should be undertaken by the entity that carries out the modification for the parts that were modified. However, the criteria to define whether a modification should be considered substantial should be defined by product-specific legislation. In the AI Regulation, which covers a wide variety of applications, this definition and criteria could be a source of legal insecurity. Orgalim therefore calls for the deletion of the concept of substantial modification from the AI Regulatory proposal.

A second example is the possibility to develop common specifications via implementing acts (Article 41) rather than the established standardisation procedures. We believe this is also not in line with NLF principles. Standardisation is, and should remain, market driven. Its procedures are inclusive and consensus-based, while the procedure the Commission would adopt to develop common specifications remains unclear. This could lead stakeholders to disengage from the standardisation process. We therefore propose to delete Article 41.

Commission proposal	Council proposal	Orgalim suggested amendments	Comments on amendments
<p>Article 3 (23)</p> <p><i>'substantial modification' means a change to the AI system following its placing on the market or putting into service which affects the compliance of the AI system with the requirements set out in Title III, Chapter 2 of this Regulation or results in a modification to the intended purpose for which the AI system has been assessed;</i></p>	<p>Article 3 (23) as presented in the Council partial compromise text of 29 November</p> <p><i>'substantial modification' means a change to the AI system following its placing on the market or putting into service which affects the compliance of the AI system with the requirements set out in Title III, Chapter 2 of this Regulation or results in a modification to the intended purpose for which the AI system has been assessed;</i></p>	<p><del>Article 3 (23)</del></p> <p><del><i>'substantial modification' means a change to the AI system following its placing on the market or putting into service which affects the compliance of the AI system with the requirements set out in Title III, Chapter 2 of this Regulation or results in a modification to the intended purpose for which the AI system has been assessed</i></del></p>	<p>– The introduction of the substantial modification concept in the AI Regulation is a source of legal uncertainty.</p>

<sup>5</sup> The ['Blue Guide' on the implementation of EU products rules 2016](#)

<p>Article 41(1)</p> <p><i>Where harmonised standards referred to in Article 40 do not exist or where the Commission considers that the relevant harmonised standards are insufficient or that there is a need to address specific safety or fundamental right concerns, the Commission may, by means of implementing acts, adopt common specifications in respect of the requirements set out in Chapter 2 of this Title. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 74(2).</i></p>	<p>Article 41(1)</p> <p><i>Where harmonised standards referred to in Article 40 do not exist or where the Commission considers that the relevant harmonised standards are insufficient or that there is a need to address specific safety or fundamental right concerns, the Commission may, by means of implementing acts, adopt common specifications in respect of the requirements set out in Chapter 2 of this Title. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 74(2).</i></p>	<p>Article 41</p> <p><b>Delete this article</b></p>	<p>– Orgalim strongly feels that such an empowerment is not necessary. This provision risks undermining the standardisation work and driving away companies that are active in such work. Moreover, the proposed procedure considerably weakens the position of harmonised standards and even calls them into question. Furthermore, it is not clear which experts should draw up the intended specifications. Experts are already active in standardisation, but there is a risk that in the future such experts will not be available to draw up these specifications.</p>
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Orgalim represents Europe's technology industries, comprised of 770,000 innovative companies spanning the mechanical engineering, electrical engineering, electronics, ICT and metal technology branches. Together they represent the EU's largest manufacturing sector, generating annual turnover of over €2,076 billion, manufacturing one-third of all European exports and providing 11.33 million direct jobs. Orgalim is registered under the European Union Transparency Register – ID number: 20210641335-88.

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