

Targeted stakeholder consultation on classification of AI systems as high-risk

Fields marked with * are mandatory.

Targeted stakeholder consultation on the implementation of the AI Act's rules for high-risk AI systems

Disclaimer: This document is a working document of the AI Office for the purpose of consultation and does not prejudice the final decision that the Commission may take on the final guidelines. The responses to this consultation paper will provide important input to the Commission when preparing the guidelines.

This consultation is targeted to stakeholders of different categories. These categories include, but are not limited to, providers and deployers of (high-risk) AI systems, other industry organisations, as well as academia, other independent experts, civil society organisations, and public authorities.

The Artificial Intelligence Act (the 'AI Act')[1], which entered into force on 1 August 2024, creates a single market and harmonised rules for trustworthy and human-centric Artificial Intelligence (AI) in the EU.[2] It aims to promote innovation and uptake of AI, while ensuring a high level of protection of health, safety and fundamental rights, including democracy and the rule of law. The AI Act follows a risk-based approach classifying AI systems into different risk categories, one of which is the high-risk AI systems (Chapter III of the AI Act). The relevant obligations for those systems will be applicable two years after the entry into force of the AI Act, as from 2 August 2026.

The AI Act distinguishes between two categories of AI systems that are considered as 'high-risk' set out in Article 6(1) and 6(2) AI Act. Article 6(1) AI Act covers AI systems that are embedded as safety components in products or that themselves are products covered by Union legislation in Annex I, which could have an adverse impact on health and safety of persons. Article 6(2) AI Act covers AI systems that in view of their intended purpose are considered to pose a significant risk to health, safety or fundamental rights. The AI Act lists eight areas in which AI systems could pose such significant risk to health, safety or fundamental rights in Annex III and, within each area, lists specific use-cases that are to be classified as high-risk. Article 6(3) AI Act provides for exemptions for AI systems that are intended to be used for one of the cases listed in Annex III, but which do not pose significant risk since they fall under one of the exceptions listed in Article 6(3).

AI systems that classify as high-risk must be developed and designed to meet the requirements set out in Chapter III Section 2, in relation to data and data governance, documentation and recording keeping, transparency and provision of information to users, human oversight, robustness, accuracy and security. Providers of high-risk AI systems must ensure that their high-risk AI system is compliant with these requirements and must themselves comply with a number of obligations set out in Chapter III Section 3, notably the obligation to put in place a quality management system and ensure that the high-risk AI system undergoes a conformity assessment prior to its being placed on the market or put into service. The AI Act also sets out obligations for deployers of high-risk AI systems, related to the correct use, human oversight, monitoring the operation of the high-risk AI system and, in certain cases, to transparency vis-à-vis affected persons.

Pursuant to Article 6(5) AI Act, the Commission is required to provide guidelines specifying the practical implementation of Article 6, which sets out the rules for high-risk classification, by 2 February 2026. It is further required that these guidelines should be accompanied with a comprehensive list of practical examples of use cases of AI systems that are high-risk and not high-risk. Moreover, pursuant to Article 96(1)(a) AI Act, the Commission is required to develop guidelines on the practical application of the requirements for high-risk AI systems and obligation for operators, including the responsibilities along the AI value chain set out in Article 25.

The purpose of the present targeted stakeholder consultation is to collect input from stakeholders on practical examples of AI systems and issues to be clarified in the Commission's **guidelines** on the classification of high-risk AI systems and future guidelines on high-risk requirements and obligations, as well as responsibilities along the AI value chain.

As not all questions may be relevant for all stakeholders, respondents may reply only to the section(s) and the questions they would like. Respondents are encouraged to provide **explanations and practical cases** as a part of their responses to support the practical usefulness of the guidelines.

The targeted consultation is available in English only and will be open for **6 weeks starting on 6 June until 18 July 2025**.

The questionnaire for this consultation is structured along 5 sections with several questions.

Regarding section 1 and 2, respondents will be asked to provide answers pursuant to the parts of the survey they expressed interest for in Question 13, whereas all participants are kindly asked to provide input for section 3, 4 and 5.

Section 1. Questions in relation to the classification rules of high-risk AI systems in Article 6(1) and the Annex I to the AI Act

- This section includes questions on the concept of a safety component and on each product category listed in Annex I of the AI Act.

Section 2. Questions in relation to the classification of high-risk AI systems in Article 6(2) and the Annex III of the AI Act. This category includes questions related to:

- AI systems in each use case under the 8 areas referred to in Annex III.
- The filter mechanism of Article 6(3) AI Act allowing to exempt certain AI systems from being classified as high-risk under certain conditions.
- If pertinent: Need for clarification of the distinction between the classification as a high-risk AI system and AI practices that are prohibited under Article 5 AI Act (and further specified in the Commission's guidelines on prohibited AI practices^[3] from 3 February 2025) and interplay of the classification with other Union legislation.

Section 3. General questions for high-risk classification. This category includes questions related to:

- The notion of intended purpose, including its interplay with general purpose AI systems.
- Cases of potential overlaps within the AI Act classification system under Annex I and III.

Section 4. Questions in relation to requirements and obligations for high-risk AI systems and value chain obligations. This category includes questions related to:

- the requirements for high-risk AI systems and obligations of providers.
- the obligations of deployers of high-risk AI systems.
- the concept of substantial modification and the value chain obligations in Article 25 AI Act.

Section 5. Questions in relation to the need for amendment of the list of high-risk use cases in Annex III and of prohibited AI practices laid down in Article 5.

- Input for the mandatory annual assessment of the need for amendment of the list of high-risk use-cases set out in Annex III
- Input for the mandatory annual assessment of the list of prohibited AI practices laid down in Article 5

All contributions to this consultation may be made publicly available. Therefore, please do not share any confidential information in your contribution. Individuals can request to have their contribution anonymised. Personal data will be anonymised.

The AI Office will publish a summary of the results of the consultation. Results will be based on aggregated data and respondents will not be directly quoted.

[1] Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) (OJ L, 2024/1689).

[2] Article 1(1) AI Act.

Information about the respondent

* First name

Stephanos

* Surname

Hadjistyllis

* Email address

info@actuary.eu

* Do you represent an organisation (e.g., think tank or civil society/consumer organisation) or act in your personal capacity (e.g., independent expert or from a downstream provider)?

- Organisation
 In a personal capacity

* Name of the organisation

Actuarial Association of Europe

* Type of organisation

Association

* Is a representation of the organisation located in the EU?

- The organisation's headquarter is located in the EU
 A branch office, or any representation of the organisation is located in the EU
 None of the representations of the organisation is located in the EU

* Select the EU member state where the organisation's headquarter, or representation is located

BE - Belgium

* Select the size of the organisation

Othe (e.g. multiple organisations)

* Sector(s) of activity

- Information technology Employment Transport

- | | | |
|--|--|--|
| <input type="checkbox"/> Public administration | <input type="checkbox"/> Education and training | <input type="checkbox"/> Telecommunications |
| <input type="checkbox"/> Law enforcement | <input type="checkbox"/> Consumer services | <input type="checkbox"/> Retail |
| <input type="checkbox"/> Justice sector | <input type="checkbox"/> Business services | <input type="checkbox"/> E-commerce |
| <input type="checkbox"/> Legal services sector | <input checked="" type="checkbox"/> Banking and finances | <input type="checkbox"/> Advertising |
| <input type="checkbox"/> Cultural and creative sector, including media | <input type="checkbox"/> Manufacturing | <input type="checkbox"/> Consumer protection |
| <input type="checkbox"/> Healthcare | <input type="checkbox"/> Energy | <input checked="" type="checkbox"/> Others |

* Please, specify

30 character(s) maximum

Insurance, Pensions, and Risk

* Describe the activities of your organisation or yourself

1300 character(s) maximum

The Actuarial Association of Europe (AAE) was established in 1978 under the name Groupe Consultatif to represent actuarial associations in Europe. Its purpose is to provide advice and opinions to the various organisations of the European Union – the Commission, the Council of Ministers, the European Parliament, EIOPA and their various committees – on actuarial issues in European legislation. The AAE currently has 38 member associations in 37 European countries, representing over 29,000 actuaries. Advice and comments provided by the AAE on behalf of the European actuarial profession are totally independent of industry interests.

* All contributions to this consultation may be made publicly available. Therefore, please do not share any confidential information in your contribution. Your e-mail address will never be published. Should your contribution be anonymised in the instance that all contributions are made publicly available?

If you act in your personal capacity: All contributions to this consultation may be made publicly available. You can choose whether you would like your details to be made public or to remain anonymous. The type of respondent that you responded to this consultation as, your answer regarding residence, and your contribution may be published as received. Your name will not be published. Please do not include any personal data in the contribution itself.

If you represent one or more organisations: All contributions to this consultation may be made publicly available. You can choose whether you would like respondent details to be made public or to remain anonymous. Only organisation details may be published: The type of respondent that you responded to this consultation as, the name of the organisation on whose behalf you reply as well as its size, its presence in or outside the EU and your contribution may be published as received. Your name will not be published. Please do not include any personal data in the contribution itself if you want to remain anonymous.

- Yes, please anonymise my contribution.
- No

* Do you agree that we may contact you in the event of follow-up questions or if we want to learn more about your responses?

- Yes
- No

I acknowledge the attached privacy statement.

[Privacy_statement_high_risks.pdf](#)

*** On which part(s) of the public consultation are you interested to contribute to?** *Multiple answers are possible. Please note that selecting a particular answer will direct you to a set of questions specifically related to subject specified.*

- Questions in relation to **Annex I of the AI Act.** (Section 1)
- Questions in relation to **Annex III of the AI Act.** (Section 2)
- Questions on **horizontal aspects** of the high-risk classification. (Section 3)
- Questions in relation to **requirements and obligations for high-risk AI systems and value chain obligations.** (Section 4)
- Questions in relation to the **need for possible amendments of high-risk use cases in Annex III and of prohibited practices in Article 5.** (Section 5)

Section 1. Questions in relation to the classification rules of high-risk AI systems in Article 6(1) AI Act and Annex I to the AI Act

According to Article 6(1) AI Act, irrespective of whether an AI system is placed on the market or put into service independently of the products referred to in points (a) and (b), that AI system shall be considered to be high-risk where both of the following conditions are fulfilled:

*a) the AI system is intended to be used as a **safety component** of a product, or the AI system is itself a product, covered by the Union harmonisation legislation listed in Annex I;*

*b) the product whose safety component pursuant to point 1 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 the putting into service of that product pursuant to the Union harmonisation legislation listed in Annex I.*

Question 1. Do you consider yourself being already or becoming in the future a provider or a deployer of AI systems covered by Annex I of the AI Act (e.g. machinery, medical devices, toys, lifts, etc.)?

- Yes
- No

*** Please specify**

1500 character(s) maximum

While the Actuarial Association of Europe (AAE) as an organisation does not act as a deployer or provider of AI systems under Annex I of the AI Act, we note that many individual actuaries or their employers may do so now or in the near future. In particular, actuaries working in the insurance, pensions or financial sectors may contribute to the development or use of AI tools that support risk modelling, pricing or claims processes. Where

such tools are commercialised, some actuaries may effectively act as providers. More commonly, actuaries are expected to act as deployers of AI, applying such systems in professional settings. Given their expertise in data, modelling and risk management, actuaries are well placed to contribute to the responsible implementation and oversight of AI systems. To provide context, actuaries currently engage with AI systems in several specific ways: actuarial consultancies develop and license predictive models to insurance clients (acting as providers), insurance companies deploy third-party AI tools for automated underwriting and claims processing (acting as deployers), and actuaries validate and oversee AI models used in regulatory capital calculations under Solvency II. Applications are expanding, and AI deployment is expected to increase within core actuarial work over the short term. We suggest that the actuarial profession be recognised as a relevant and trusted stakeholder in the ongoing governance and regulation of high-risk AI systems.

Regarding the first condition 'safety component' for classification of a high-risk AI system, Article 6(1)(a) AI Act provides two options:

- Either the AI system is intended to be used as a **safety component of a product covered by the Union harmonisation legislation listed in Annex I.**
- Or the AI system **itself is a product**, covered by Union harmonisation legislation listed in Annex I.

Question 2. The AI Act defines a 'safety component' as follows (Article 3(14) AI Act): 'safety component of a product or system' means a component of a product or of a system which fulfils a safety function for that product or system, or the failure or malfunctioning of which endangers the health and safety of persons or property. Based on this definition, in your opinion, what components listed below are covered by the AI Act definition of a 'safety component'?

- A component of a product or of a system which is intended to **monitor and detect** situations which may lead to physical harm to people or property (e.g. AI system detecting abnormal system behaviour);
- A component of a product or of a system which is intended to **monitor and detect** the need to schedule maintenance and inspections, which, if not conducted, may lead to physical harm to people or property (e.g. AI system detecting whether parts of a product are worn and may need replacement or maintenance);
- A component of a product or of a system which is intended to **prevent** a physical harm to people or property (e.g. AI system preventing a start of a system if an abnormal behaviour is detected);
- A component of a product or of a system which is intended to **control or limit** possible physical harm to people or property (e.g. AI system controlling specific behaviour or function of a system and adjusting its function accordingly);
- A component of a product or of a system which is intended to **mitigate consequences** of possible physical harm to people or property (e.g. AI system that triggers action such as safe-stop if dangerous condition occurs);
- A component of a product or of a system which **controls or supervises** another system that performs a safety function (e.g. AI systems supervisor through sensors an operation in real time of a safety component that directly performs the safety function);
- A component of a product or of a system that **optimises a performance of a product** (e.g. efficiency; user preferences) but the failure of which would not directly lead to risks to health or safety of persons or property;
- A component of a product or of a system that is critical for the **core functionality of the product** (whether or not related to safety);
- Other
- Can't answer this question.

* Please specify

1500 character(s) maximum

We understand that the definition of 'safety component' under Article 3(14) is specifically focused on physical safety within the context of products covered by Union harmonisation legislation listed in Annex I. The components listed above that relate to preventing, detecting, or mitigating physical harm would clearly fall within this definition. However, we note that in regulated sectors like insurance and finance, there may be AI components that serve analogous protective functions—preventing, detecting, or mitigating significant non-physical harms such as financial loss, exclusion from essential services, or discriminatory treatment. While we recognise these fall outside the current Article 3(14) scope, we suggest that future regulatory development consider whether similar protective principles might apply to AI systems that serve comparable risk mitigation functions in non-physical domains. We also highlight the need for clarity regarding overlaps between safety, security and performance optimisation functions, particularly where a system component serves multiple roles within products covered by Annex I legislation.

Question 3. Do you have or know practical examples of AI systems that in your opinion are a **component** that is part of a **product** covered by Union harmonisation legislation listed in Annex I of the AI Act, which has to undergo a third-party conformity assessment, and that **fulfils a safety function**?

	The respective Union harmonisation legislation	Short description of the use case	Points where you need further clarification
1	<p><i>Legislation's name</i></p> <ul style="list-style-type: none"> <input type="radio"/> Directive 2006/42/EC <input type="radio"/> Directive 2009/48/EC <input type="radio"/> Directive 2013/53/EU <input type="radio"/> Directive 2014/33/EU <input type="radio"/> Directive 2014/34/EU <input type="radio"/> Directive 2014/53/EU <input type="radio"/> Directive 2014/68/EU <input type="radio"/> Regulation (EU) 2016/424 <input type="radio"/> Regulation (EU) 2016/425 <input type="radio"/> Regulation (EU) 2016/426 <input type="radio"/> Regulation (EU) 2017/745 <input type="radio"/> Regulation (EU) 2017/746 <input type="radio"/> Regulation (EC) No 300/2008 <input type="radio"/> Regulation (EU) No 168/2013 <input type="radio"/> Regulation (EU) No 167/2013 <input type="radio"/> Directive 2014/90/EU <input type="radio"/> Directive (EU) 2016/797 <input type="radio"/> Regulation (EU) 2018/858 <input type="radio"/> Regulation (EU) 2019/2144 <input type="radio"/> Regulation (EU) 2018/1139 	<p><i>Description</i></p> <p><i>750 character(s) maximum</i></p>	<p><i>Explain</i></p> <p><i>500 character(s) maximum</i></p>
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If you have more examples, please enter them in the section below, following the structure of question 3.

In motor insurance, vehicles equipped with AI-driven Advanced Driver Assistance Systems (ADAS)—such as emergency braking or lane-keeping—clearly serve safety functions and are subject to conformity assessments under EU vehicle safety legislation. Similarly, in health insurance, AI tools for claims triage or early detection of medical need may play a preventive safety role. While such systems are not always embedded in Annex I products, they can influence access to safety-critical services. In insurance more broadly, AI systems used for telematics or risk prevention could be considered safety-relevant where they contribute to contract fulfilment and risk mitigation. We suggest that guidelines clarify the treatment of such preventive functions, especially in sectors like insurance.

Question 4. The AI Act defines a **'safety component'** as follows (Article 3(14) AI Act): 'safety component of a product or system' means a component of a product or of a system which fulfils a safety function for that product or system, or the failure or malfunctioning of which endangers the health and safety of persons or property.

Do you have or know concrete examples of AI systems that in your opinion are **components** that are part of **a product** covered by Union harmonisation legislation listed in Annex I of the AI Act that **do not fulfil a safety function**, but whose **failure or malfunctioning may endanger the health and safety of persons or property**?

	The respective Union harmonisation legislation	Short description of the use case	Points where you need further clarification
1	<p><i>Legislation's name</i></p> <ul style="list-style-type: none"> <input type="radio"/> Directive 2006/42/EC <input type="radio"/> Directive 2009/48/EC <input type="radio"/> Directive 2013/53/EU <input type="radio"/> Directive 2014/33/EU <input type="radio"/> Directive 2014/34/EU <input type="radio"/> Directive 2014/53/EU <input type="radio"/> Directive 2014/68/EU <input type="radio"/> Regulation (EU) 2016/424 <input type="radio"/> Regulation (EU) 2016/425 <input type="radio"/> Regulation (EU) 2016/426 <input type="radio"/> Regulation (EU) 2017/745 <input type="radio"/> Regulation (EU) 2017/746 <input type="radio"/> Regulation (EC) No 300/2008 <input type="radio"/> Regulation (EU) No 168/2013 <input type="radio"/> Regulation (EU) No 167/2013 <input type="radio"/> Directive 2014/90/EU <input type="radio"/> Directive (EU) 2016/797 <input type="radio"/> Regulation (EU) 2018/858 <input type="radio"/> Regulation (EU) 2019/2144 <input type="radio"/> Regulation (EU) 2018/1139 	<p><i>Description</i></p> <p><i>750 character(s) maximum</i></p>	<p><i>Explain</i></p> <p><i>500 character(s) maximum</i></p>

2	<p><i>Legislation's name</i></p> <ul style="list-style-type: none"> <input type="radio"/> Directive 2006/42/EC <input type="radio"/> Directive 2009/48/EC <input type="radio"/> Directive 2013/53/EU <input type="radio"/> Directive 2014/33/EU <input type="radio"/> Directive 2014/34/EU <input type="radio"/> Directive 2014/53/EU <input type="radio"/> Directive 2014/68/EU <input type="radio"/> Regulation (EU) 2016/424 <input type="radio"/> Regulation (EU) 2016/425 <input type="radio"/> Regulation (EU) 2016/426 <input type="radio"/> Regulation (EU) 2017/745 <input type="radio"/> Regulation (EU) 2017/746 <input type="radio"/> Regulation (EC) No 300/2008 <input type="radio"/> Regulation (EU) No 168/2013 <input type="radio"/> Regulation (EU) No 167/2013 <input type="radio"/> Directive 2014/90/EU <input type="radio"/> Directive (EU) 2016/797 <input type="radio"/> Regulation (EU) 2018/858 <input type="radio"/> Regulation (EU) 2019/2144 <input type="radio"/> Regulation (EU) 2018/1139 	<p><i>Description</i></p> <p><i>750 character(s) maximum</i></p>	<p><i>Explain</i></p> <p><i>500 character(s) maximum</i></p>
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3	<ul style="list-style-type: none"> <input type="radio"/> Regulation (EU) 2016/426 <input type="radio"/> Regulation (EU) 2017/745 <input type="radio"/> Regulation (EU) 2017/746 <input type="radio"/> Regulation (EC) No 300/2008 <input type="radio"/> Regulation (EU) No 168/2013 <input type="radio"/> Regulation (EU) No 167/2013 <input type="radio"/> Directive 2014/90/EU <input type="radio"/> Directive (EU) 2016/797 <input type="radio"/> Regulation (EU) 2018/858 <input type="radio"/> Regulation (EU) 2019/2144 <input type="radio"/> Regulation (EU) 2018/1139 	<p><i>Description</i></p> <p><i>750 character(s) maximum</i></p>	<p><i>Explain</i></p> <p><i>500 character(s) maximum</i></p>
4	<p><i>Legislation's name</i></p> <ul style="list-style-type: none"> <input type="radio"/> Directive 2006/42/EC <input type="radio"/> Directive 2009/48/EC <input type="radio"/> Directive 2013/53/EU <input type="radio"/> Directive 2014/33/EU <input type="radio"/> Directive 2014/34/EU <input type="radio"/> Directive 2014/53/EU <input type="radio"/> Directive 2014/68/EU <input type="radio"/> Regulation (EU) 2016/424 <input type="radio"/> Regulation (EU) 2016/425 <input type="radio"/> Regulation (EU) 2016/426 <input type="radio"/> Regulation (EU) 2017/745 <input type="radio"/> Regulation (EU) 2017/746 <input type="radio"/> Regulation (EC) No 300/2008 <input type="radio"/> Regulation (EU) No 168/2013 <input type="radio"/> Regulation (EU) No 167/2013 <input type="radio"/> Directive 2014/90/EU <input type="radio"/> Directive (EU) 2016/797 <input type="radio"/> Regulation (EU) 2018/858 <input type="radio"/> Regulation (EU) 2019/2144 	<p><i>Description</i></p> <p><i>750 character(s) maximum</i></p>	<p><i>Explain</i></p> <p><i>500 character(s) maximum</i></p>

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5	<p><i>Legislation's name</i></p> <input type="radio"/> Directive 2006/42/EC <input type="radio"/> Directive 2009/48/EC <input type="radio"/> Directive 2013/53/EU <input type="radio"/> Directive 2014/33/EU <input type="radio"/> Directive 2014/34/EU <input type="radio"/> Directive 2014/53/EU <input type="radio"/> Directive 2014/68/EU <input type="radio"/> Regulation (EU) 2016/424 <input type="radio"/> Regulation (EU) 2016/425 <input type="radio"/> Regulation (EU) 2016/426 <input type="radio"/> Regulation (EU) 2017/745 <input type="radio"/> Regulation (EU) 2017/746 <input type="radio"/> Regulation (EC) No 300/2008 <input type="radio"/> Regulation (EU) No 168/2013 <input type="radio"/> Regulation (EU) No 167/2013 <input type="radio"/> Directive 2014/90/EU <input type="radio"/> Directive (EU) 2016/797 <input type="radio"/> Regulation (EU) 2018/858 <input type="radio"/> Regulation (EU) 2019/2144 <input type="radio"/> Regulation (EU) 2018/1139	<p><i>Description</i></p> <p>750 character(s) maximum</p>	<p><i>Explain</i></p> <p>500 character(s) maximum</p>
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6	<ul style="list-style-type: none"> <input type="radio"/> Regulation (EU) 2016/425 <input type="radio"/> Regulation (EU) 2016/426 <input type="radio"/> Regulation (EU) 2017/745 <input type="radio"/> Regulation (EU) 2017/746 <input type="radio"/> Regulation (EC) No 300/2008 <input type="radio"/> Regulation (EU) No 168/2013 <input type="radio"/> Regulation (EU) No 167/2013 <input type="radio"/> Directive 2014/90/EU <input type="radio"/> Directive (EU) 2016/797 <input type="radio"/> Regulation (EU) 2018/858 <input type="radio"/> Regulation (EU) 2019/2144 <input type="radio"/> Regulation (EU) 2018/1139 	<p><i>Description</i></p> <p>750 character(s) maximum</p>	<p><i>Explain</i></p> <p>500 character(s) maximum</p>
7	<p><i>Legislation's name</i></p> <ul style="list-style-type: none"> <input type="radio"/> Directive 2006/42/EC <input type="radio"/> Directive 2009/48/EC <input type="radio"/> Directive 2013/53/EU <input type="radio"/> Directive 2014/33/EU <input type="radio"/> Directive 2014/34/EU <input type="radio"/> Directive 2014/53/EU <input type="radio"/> Directive 2014/68/EU <input type="radio"/> Regulation (EU) 2016/424 <input type="radio"/> Regulation (EU) 2016/425 <input type="radio"/> Regulation (EU) 2016/426 <input type="radio"/> Regulation (EU) 2017/745 <input type="radio"/> Regulation (EU) 2017/746 <input type="radio"/> Regulation (EC) No 300/2008 <input type="radio"/> Regulation (EU) No 168/2013 <input type="radio"/> Regulation (EU) No 167/2013 <input type="radio"/> Directive 2014/90/EU <input type="radio"/> Directive (EU) 2016/797 <input type="radio"/> Regulation (EU) 2018/858 	<p><i>Description</i></p> <p>750 character(s) maximum</p>	<p><i>Explain</i></p> <p>500 character(s) maximum</p>

	<input type="radio"/> Regulation (EU) 2019/2144 <input type="radio"/> Regulation (EU) 2018/1139		
8	<i>Legislation's name</i> <input type="radio"/> Directive 2006/42/EC <input type="radio"/> Directive 2009/48/EC <input type="radio"/> Directive 2013/53/EU <input type="radio"/> Directive 2014/33/EU <input type="radio"/> Directive 2014/34/EU <input type="radio"/> Directive 2014/53/EU <input type="radio"/> Directive 2014/68/EU <input type="radio"/> Regulation (EU) 2016/424 <input type="radio"/> Regulation (EU) 2016/425 <input type="radio"/> Regulation (EU) 2016/426 <input type="radio"/> Regulation (EU) 2017/745 <input type="radio"/> Regulation (EU) 2017/746 <input type="radio"/> Regulation (EC) No 300/2008 <input type="radio"/> Regulation (EU) No 168/2013 <input type="radio"/> Regulation (EU) No 167/2013 <input type="radio"/> Directive 2014/90/EU <input type="radio"/> Directive (EU) 2016/797 <input type="radio"/> Regulation (EU) 2018/858 <input type="radio"/> Regulation (EU) 2019/2144 <input type="radio"/> Regulation (EU) 2018/1139	<i>Description</i> 750 character(s) maximum	<i>Explain</i> 500 character(s) maximum
	<i>Legislation's name</i> <input type="radio"/> Directive 2006/42/EC <input type="radio"/> Directive 2009/48/EC <input type="radio"/> Directive 2013/53/EU <input type="radio"/> Directive 2014/33/EU <input type="radio"/> Directive 2014/34/EU <input type="radio"/> Directive 2014/53/EU <input type="radio"/> Directive 2014/68/EU		

9	<ul style="list-style-type: none"> <input type="radio"/> Regulation (EU) 2016/424 <input type="radio"/> Regulation (EU) 2016/425 <input type="radio"/> Regulation (EU) 2016/426 <input type="radio"/> Regulation (EU) 2017/745 <input type="radio"/> Regulation (EU) 2017/746 <input type="radio"/> Regulation (EC) No 300/2008 <input type="radio"/> Regulation (EU) No 168/2013 <input type="radio"/> Regulation (EU) No 167/2013 <input type="radio"/> Directive 2014/90/EU <input type="radio"/> Directive (EU) 2016/797 <input type="radio"/> Regulation (EU) 2018/858 <input type="radio"/> Regulation (EU) 2019/2144 <input type="radio"/> Regulation (EU) 2018/1139 	<p><i>Description</i></p> <p><i>750 character(s) maximum</i></p>	<p><i>Explain</i></p> <p><i>500 character(s) maximum</i></p>
10	<p><i>Legislation's name</i></p> <ul style="list-style-type: none"> <input type="radio"/> Directive 2006/42/EC <input type="radio"/> Directive 2009/48/EC <input type="radio"/> Directive 2013/53/EU <input type="radio"/> Directive 2014/33/EU <input type="radio"/> Directive 2014/34/EU <input type="radio"/> Directive 2014/53/EU <input type="radio"/> Directive 2014/68/EU <input type="radio"/> Regulation (EU) 2016/424 <input type="radio"/> Regulation (EU) 2016/425 <input type="radio"/> Regulation (EU) 2016/426 <input type="radio"/> Regulation (EU) 2017/745 <input type="radio"/> Regulation (EU) 2017/746 <input type="radio"/> Regulation (EC) No 300/2008 <input type="radio"/> Regulation (EU) No 168/2013 <input type="radio"/> Regulation (EU) No 167/2013 <input type="radio"/> Directive 2014/90/EU <input type="radio"/> Directive (EU) 2016/797 	<p><i>Description</i></p> <p><i>750 character(s) maximum</i></p>	<p><i>Explain</i></p> <p><i>500 character(s) maximum</i></p>

- Regulation (EU) 2018/858
- Regulation (EU) 2019/2144
- Regulation (EU) 2018/1139

If you have more examples, please enter them in the section below, following the structure of question 4.

We note that some AI systems embedded in products may influence user behaviour in ways that could indirectly affect safety, even if they are not designed to fulfil a safety function. For example, in-cabin AI monitoring systems used to personalise entertainment based on driver mood could unintentionally affect driving attention or behaviour. While such systems may not currently meet the criteria for classification as fulfilling a safety function, their potential to impact safety outcomes highlights a grey area that may warrant further scrutiny. It might be helpful for future guidance to clarify how to treat AI components whose primary purpose is not safety-related, but which may create secondary effects that pose risks to health or safety.

*Regarding AI systems that are a component of an **AI system that is itself a product** covered by Union harmonisation legislation listed in Annex I:*

Question 5. Do you have or know practical examples of an AI system that in your opinion is **itself a product** covered by Union harmonisation legislation listed in Annex I of the AI Act, and that has to undergo a third-party conformity assessment pursuant to the Union harmonisation legislation listed in Annex I of the AI Act?

	The respective Union harmonisation legislation	Short description of the use case	Points where you need further clarification
1	<p><i>Legislation's name</i></p> <ul style="list-style-type: none"> <input type="radio"/> Directive 2006/42/EC <input type="radio"/> Directive 2009/48/EC <input type="radio"/> Directive 2013/53/EU <input type="radio"/> Directive 2014/33/EU <input type="radio"/> Directive 2014/34/EU <input type="radio"/> Directive 2014/53/EU <input type="radio"/> Directive 2014/68/EU <input type="radio"/> Regulation (EU) 2016/424 <input type="radio"/> Regulation (EU) 2016/425 <input type="radio"/> Regulation (EU) 2016/426 <input type="radio"/> Regulation (EU) 2017/745 <input type="radio"/> Regulation (EU) 2017/746 <input type="radio"/> Regulation (EC) No 300/2008 <input type="radio"/> Regulation (EU) No 168/2013 <input type="radio"/> Regulation (EU) No 167/2013 <input type="radio"/> Directive 2014/90/EU <input type="radio"/> Directive (EU) 2016/797 <input type="radio"/> Regulation (EU) 2018/858 <input type="radio"/> Regulation (EU) 2019/2144 <input type="radio"/> Regulation (EU) 2018/1139 	<p><i>Description</i></p> <p><i>750 character(s) maximum</i></p>	<p><i>Explain</i></p> <p><i>500 character(s) maximum</i></p>
	<p><i>Legislation's name</i></p> <ul style="list-style-type: none"> <input type="radio"/> Directive 2006/42/EC <input type="radio"/> Directive 2009/48/EC <input type="radio"/> Directive 2013/53/EU <input type="radio"/> Directive 2014/33/EU <input type="radio"/> Directive 2014/34/EU 		

2	<ul style="list-style-type: none"> <input type="radio"/> Directive 2014/53/EU <input type="radio"/> Directive 2014/68/EU <input type="radio"/> Regulation (EU) 2016/424 <input type="radio"/> Regulation (EU) 2016/425 <input type="radio"/> Regulation (EU) 2016/426 <input type="radio"/> Regulation (EU) 2017/745 <input type="radio"/> Regulation (EU) 2017/746 <input type="radio"/> Regulation (EC) No 300/2008 <input type="radio"/> Regulation (EU) No 168/2013 <input type="radio"/> Regulation (EU) No 167/2013 <input type="radio"/> Directive 2014/90/EU <input type="radio"/> Directive (EU) 2016/797 <input type="radio"/> Regulation (EU) 2018/858 <input type="radio"/> Regulation (EU) 2019/2144 <input type="radio"/> Regulation (EU) 2018/1139 	<p><i>Description</i></p> <p><i>750 character(s) maximum</i></p>	<p><i>Explain</i></p> <p><i>500 character(s) maximum</i></p>
3	<p><i>Legislation's name</i></p> <ul style="list-style-type: none"> <input type="radio"/> Directive 2006/42/EC <input type="radio"/> Directive 2009/48/EC <input type="radio"/> Directive 2013/53/EU <input type="radio"/> Directive 2014/33/EU <input type="radio"/> Directive 2014/34/EU <input type="radio"/> Directive 2014/53/EU <input type="radio"/> Directive 2014/68/EU <input type="radio"/> Regulation (EU) 2016/424 <input type="radio"/> Regulation (EU) 2016/425 <input type="radio"/> Regulation (EU) 2016/426 <input type="radio"/> Regulation (EU) 2017/745 <input type="radio"/> Regulation (EU) 2017/746 <input type="radio"/> Regulation (EC) No 300/2008 <input type="radio"/> Regulation (EU) No 168/2013 <input type="radio"/> Regulation (EU) No 167/2013 	<p><i>Description</i></p> <p><i>750 character(s) maximum</i></p>	<p><i>Explain</i></p> <p><i>500 character(s) maximum</i></p>

	<input type="radio"/> Directive 2014/90/EU <input type="radio"/> Directive (EU) 2016/797 <input type="radio"/> Regulation (EU) 2018/858 <input type="radio"/> Regulation (EU) 2019/2144 <input type="radio"/> Regulation (EU) 2018/1139		
4	<i>Legislation's name</i> <input type="radio"/> Directive 2006/42/EC <input type="radio"/> Directive 2009/48/EC <input type="radio"/> Directive 2013/53/EU <input type="radio"/> Directive 2014/33/EU <input type="radio"/> Directive 2014/34/EU <input type="radio"/> Directive 2014/53/EU <input type="radio"/> Directive 2014/68/EU <input type="radio"/> Regulation (EU) 2016/424 <input type="radio"/> Regulation (EU) 2016/425 <input type="radio"/> Regulation (EU) 2016/426 <input type="radio"/> Regulation (EU) 2017/745 <input type="radio"/> Regulation (EU) 2017/746 <input type="radio"/> Regulation (EC) No 300/2008 <input type="radio"/> Regulation (EU) No 168/2013 <input type="radio"/> Regulation (EU) No 167/2013 <input type="radio"/> Directive 2014/90/EU <input type="radio"/> Directive (EU) 2016/797 <input type="radio"/> Regulation (EU) 2018/858 <input type="radio"/> Regulation (EU) 2019/2144 <input type="radio"/> Regulation (EU) 2018/1139	<i>Description</i> 750 character(s) maximum	<i>Explain</i> 500 character(s) maximum
	<i>Legislation's name</i> <input type="radio"/> Directive 2006/42/EC <input type="radio"/> Directive 2009/48/EC <input type="radio"/> Directive 2013/53/EU <input type="radio"/> Directive 2014/33/EU		

5	<ul style="list-style-type: none"> <input type="radio"/> Directive 2014/34/EU <input type="radio"/> Directive 2014/53/EU <input type="radio"/> Directive 2014/68/EU <input type="radio"/> Regulation (EU) 2016/424 <input type="radio"/> Regulation (EU) 2016/425 <input type="radio"/> Regulation (EU) 2016/426 <input type="radio"/> Regulation (EU) 2017/745 <input type="radio"/> Regulation (EU) 2017/746 <input type="radio"/> Regulation (EC) No 300/2008 <input type="radio"/> Regulation (EU) No 168/2013 <input type="radio"/> Regulation (EU) No 167/2013 <input type="radio"/> Directive 2014/90/EU <input type="radio"/> Directive (EU) 2016/797 <input type="radio"/> Regulation (EU) 2018/858 <input type="radio"/> Regulation (EU) 2019/2144 <input type="radio"/> Regulation (EU) 2018/1139 	<p><i>Description</i></p> <p><i>750 character(s) maximum</i></p>	<p><i>Explain</i></p> <p><i>500 character(s) maximum</i></p>
6	<p><i>Legislation's name</i></p> <ul style="list-style-type: none"> <input type="radio"/> Directive 2006/42/EC <input type="radio"/> Directive 2009/48/EC <input type="radio"/> Directive 2013/53/EU <input type="radio"/> Directive 2014/33/EU <input type="radio"/> Directive 2014/34/EU <input type="radio"/> Directive 2014/53/EU <input type="radio"/> Directive 2014/68/EU <input type="radio"/> Regulation (EU) 2016/424 <input type="radio"/> Regulation (EU) 2016/425 <input type="radio"/> Regulation (EU) 2016/426 <input type="radio"/> Regulation (EU) 2017/745 <input type="radio"/> Regulation (EU) 2017/746 <input type="radio"/> Regulation (EC) No 300/2008 <input type="radio"/> Regulation (EU) No 168/2013 	<p><i>Description</i></p> <p><i>750 character(s) maximum</i></p>	<p><i>Explain</i></p> <p><i>500 character(s) maximum</i></p>

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7	<i>Legislation's name</i> <input type="radio"/> Directive 2006/42/EC <input type="radio"/> Directive 2009/48/EC <input type="radio"/> Directive 2013/53/EU <input type="radio"/> Directive 2014/33/EU <input type="radio"/> Directive 2014/34/EU <input type="radio"/> Directive 2014/53/EU <input type="radio"/> Directive 2014/68/EU <input type="radio"/> Regulation (EU) 2016/424 <input type="radio"/> Regulation (EU) 2016/425 <input type="radio"/> Regulation (EU) 2016/426 <input type="radio"/> Regulation (EU) 2017/745 <input type="radio"/> Regulation (EU) 2017/746 <input type="radio"/> Regulation (EC) No 300/2008 <input type="radio"/> Regulation (EU) No 168/2013 <input type="radio"/> Regulation (EU) No 167/2013 <input type="radio"/> Directive 2014/90/EU <input type="radio"/> Directive (EU) 2016/797 <input type="radio"/> Regulation (EU) 2018/858 <input type="radio"/> Regulation (EU) 2019/2144 <input type="radio"/> Regulation (EU) 2018/1139	<i>Description</i> 750 character(s) maximum	<i>Explain</i> 500 character(s) maximum
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10	<p><i>Legislation's name</i></p> <ul style="list-style-type: none"> <input type="radio"/> Directive 2006/42/EC <input type="radio"/> Directive 2009/48/EC <input type="radio"/> Directive 2013/53/EU <input type="radio"/> Directive 2014/33/EU <input type="radio"/> Directive 2014/34/EU <input type="radio"/> Directive 2014/53/EU <input type="radio"/> Directive 2014/68/EU <input type="radio"/> Regulation (EU) 2016/424 <input type="radio"/> Regulation (EU) 2016/425 <input type="radio"/> Regulation (EU) 2016/426 <input type="radio"/> Regulation (EU) 2017/745 <input type="radio"/> Regulation (EU) 2017/746 <input type="radio"/> Regulation (EC) No 300/2008 <input type="radio"/> Regulation (EU) No 168/2013 <input type="radio"/> Regulation (EU) No 167/2013 <input type="radio"/> Directive 2014/90/EU <input type="radio"/> Directive (EU) 2016/797 <input type="radio"/> Regulation (EU) 2018/858 <input type="radio"/> Regulation (EU) 2019/2144 <input type="radio"/> Regulation (EU) 2018/1139 	<p><i>Description</i></p> <p><i>750 character(s) maximum</i></p>	<p><i>Explain</i></p> <p><i>500 character(s) maximum</i></p>

If you have more examples, please enter them in the section below, following the structure of question 5.

An illustrative example of an AI system that could be considered a standalone high-risk product under Annex I is diagnostic software embedded in wearable health devices, such as arrhythmia detection algorithms in smartwatches. These systems may be regulated as medical devices and subject to conformity assessment, particularly where they make autonomous decisions without human oversight. The classification of such systems under the AI Act depends on the specific design and oversight mechanisms. While not directly within the scope of actuarial practice, these developments are of interest to insurers, particularly in the context of underwriting and assessing health risks. Further clarity on how such borderline systems are to be treated would be helpful.

Question 6. Do you have any additional feedback or suggestions for developing guidelines to support the implementation of Article 6(1) of the AI Act? If you do, please specify what specific elements of the definition require further clarification.

3000 character(s) maximum

We suggest that future guidance on Article 6(1) provide clearer distinctions between AI systems embedded in physical products and those used in analytical or administrative contexts, particularly in the financial and insurance sectors. In our view, AI models used for pricing, underwriting or reserving in insurance—while important for consumer outcomes—do not typically perform a safety function as defined under the AI Act. Clarifying that such systems are generally out of scope for classification under Article 6(1) would prevent misinterpretation. Further clarification is also needed where AI is embedded in multi-function systems. For example, the same AI model might be used both to support underwriting decisions and to provide general customer support. Only the former may significantly affect access to financial services or individual rights. Guidance would benefit from distinguishing between auxiliary functions and those that are core to a system's risk or safety profile. Finally, we note that some interpretations of safety include preventive functions in contexts like insurance. While we recognise the importance of prevention, we believe that such interpretations should not extend the definition of a safety component beyond its intended legal scope unless physical safety risks are genuinely present. We recommend that the guidelines include examples and decision criteria to support consistent interpretation, especially for AI systems in sectors like insurance that use predictive modelling without direct implications for physical safety. A more structured framework for assessing the intended purpose and its relationship to safety functions—particularly where AI tools have multiple applications—would enhance clarity and implementation.

Section 2. Questions in relation to the classification rules of high-risk AI systems in Article 6(2) and (3) AI Act and Annex III to the AI Act

AI systems classified as high-risk by Article 6(2) AI Act are AI systems which pose a significant risk of harm to the health, safety or fundamental rights of natural persons, and which are intended to be used for specific use cases as explicitly specified in Annex III under each area (cf. Annex III):

- *Biometrics.*
- *Critical infrastructure.*
- *Education and vocational training.*
- *Employment, workers' management and access to self-employment.*

- *Access to and enjoyment of essential private services and essential public services and benefits.*
- *Law enforcement.*
- *Migration, asylum and border control management.*
- *Administration of justice and democratic processes.*

However, in certain cases the use of an AI system does not risk leading to a significant risk of harm to the health, safety or fundamental rights of natural persons, for example by not materially influencing the outcome of decision making. Therefore, even if the AI systems may be referred to in Annex III, paragraph 3 of article 6 AI Act envisages situations when such AI systems would not be classified as high-risk if one or more of the following conditions are fulfilled:

- (a) the AI system is intended to perform a narrow procedural task;*
- (b) the AI system is intended to improve the result of a previously completed human activity;*
- (c) the AI system is intended to detect decision-making patterns or deviations from prior decision-making patterns and is not meant to replace or influence the previously completed human assessment, without proper human review; or*
- (d) the AI system is intended to perform a preparatory task to an assessment relevant for the purposes of the use cases listed in Annex III.*

However, this exception cannot be applied if the AI system performs profiling of natural persons. A provider who considers that an AI system referred to in Annex III falls within one or more of the exceptions should document its assessment before that system is placed on the market or put into service and register it according to Article 49(2).

Questions in relation to **Annex III of the AI Act**. *Multiple answers are possible*

- Biometrics
- Critical infrastructure
- Education and vocational training
- Employment, workers' management and access to self-employment
- Access to and enjoyment of essential private services and essential public services and benefits
- Law enforcement
- Migration, asylum and border control management
- Administration of justice and democratic processes

Section 3. Questions on horizontal aspects of the high-risk classification

The classification of AI systems as high-risk is made depending on the intended purpose of the AI system.

The intended purpose is defined by Article 3(12) AI Act as the use for which an AI system is intended by the

provider, including the specific context and conditions of use, as specified in the information supplied by the provider in the instructions for use, promotional or sales materials and statements, as well as in the technical documentation.

Question 33. What aspects of the definition of the intended purpose, as outlined in Article 3(12) AI Act, need additional clarification?

Please specify the concrete elements and the issues for which you need further clarification; please provide concrete examples

1500 character(s) maximum

We suggest clarifying how “intended purpose” is to be interpreted in practice, particularly in insurance contexts where models often serve multiple functions. Providers should not be able to narrowly define purpose to reduce compliance obligations. Guidance should specify that intended purpose must reflect actual usage and foresee reasonably expected applications. In actuarial practice, the same model might support underwriting, claims, and customer service, each with different risks. Clear criteria would help determine when a function materially affects rights or safety and warrants high-risk classification. This is especially important for adaptive or repurposed systems. For general-purpose AI or fine-tuned models, guidance should also clarify how changes to data, context, or deployment alter the original intended purpose—and whether such changes trigger new provider obligations. We recommend including examples across sectors to promote consistent interpretation.

While the high-risk classification pursuant to Article 6(1) and Annex I AI Act is based on the concept of an AI system being used as a safety component of products regulated under Union harmonisation laws referred to in Annex I, Article 6(2) and Annex III AI Act list certain use cases considered to be high-risk. The two categories are in principle intended not to overlap.

Question 34. If you have or know practical examples of AI systems that in your opinion could be relevant for the high-risk classification according to **both Article 6(1) and 6(2) AI Act** and **thus require further clarification**, please specify the concrete AI system, how it is used in practice and how all the necessary elements described above are fulfilled

1500 character(s) maximum

We agree that systems may fall under both Article 6(1) and 6(2). For example, telematics-based pricing tools in vehicles may contribute to safety (6(1)) and also influence underwriting or premiums (6(2)). Similarly, diagnostic models in wearables may affect access to insurance and care. We also wish to highlight that traditional actuarial models, such as generalised linear models (GLMs), are typically transparent, interpretable, and subject to professional oversight. These models are typically manually configured and do not operate autonomously. They should not fall within scope of the AI Act unless used in a way that produces high-risk outcomes without human review. We recommend that dual-classification guidance be introduced to distinguish between analytical tools with explainable outputs and autonomous, adaptive systems with direct individual impact. The latter should be the focus of high-risk classification.

Section 4 – Questions in relation to requirements and obligations for high-risk AI systems and value chain obligations

A. Requirements for high-risk AI systems

The AI Act sets mandatory requirements for high-risk AI systems as regards risk management (Article 9), data and data governance (Article 10), technical documentation (Article 11) and record-keeping (Article 12), transparency and the provision of information to deployers (Article 13), human oversight (Article 14), and robustness, accuracy and cybersecurity (Article 15).

Providers are obliged to ensure that their high-risk AI system is compliant with those requirements before it is placed on the market. Harmonised standards will play a key role to provide technical solutions to providers that can voluntarily rely on them to ensure compliance and rely on a presumption of conformity. The Commission has requested the European standardisation organisations CEN and CENELEC to develop standards in support of the AI Act. This work is currently under preparation.

Question 35. Beyond the technical standards under preparation by the European Standardisation Organisations, are there further aspects related to the AI Act's requirements for high-risk AI systems in Articles 9-15 for which you would seek clarification, for example through guidelines?

If so, please elaborate on which specific questions you would seek further clarification.

3000 character(s) maximum

Clarification is needed to ensure proportional and consistent application of Articles 9–15 in sectors already governed by strong regulatory frameworks. Many requirements in Articles 9–15, such as risk management (Article 9), data governance (Article 10), and human oversight (Article 14), overlap with existing standards under Solvency II and EIOPA guidelines. We recommend that guidance explicitly recognise equivalence where sectoral compliance already achieves the intended objectives, to avoid duplication. Further clarity is also needed for models developed collaboratively. If an actuarial firm builds a model that is later modified by an insurer, who holds responsibility? A framework for shared or tiered obligations across the AI lifecycle would help. In addition, sector-specific guidance could improve consistency in applying Articles 9–15. For example: • Under Article 10, how should insurers address historical bias in claims data or synthetic variables? • Under Article 13, what constitutes appropriate transparency in probabilistic pricing models? • Under Article 14, what are the minimum competence levels expected of human overseers? We also reiterate that actuarial pricing models are typically explainable and overseen by professionals. They should not be considered high-risk solely due to complexity or statistical nature.

Question 36. Are there aspects related to the requirements for high-risk AI systems in Articles 9-15 which require clarification regarding their interplay with other Union legislation?

If so, please elaborate which specific aspects require clarification regarding their interplay with other Union legislation and point to concrete provisions of specific other Union law.

3000 character(s) maximum

Yes, we suggest further clarification of how Articles 9–15 interact with existing regulation, particularly Solvency II, DORA, and GDPR, all of which impose extensive obligations in insurance. For example, Solvency II already mandates model governance and documentation. Clarifying when these processes meet AI Act requirements (e.g. Article 11 technical documentation) would reduce duplication. Similarly, insurers are already bound by GDPR rules for personal data reuse in model training. Clear guidance on reconciling GDPR and Article 10 would help

align compliance expectations. We also suggest that Article 7 guidance clarify when actuarial tools—such as life pricing models—are in scope. Many are non-adaptive and used to inform decisions, not to make them autonomously. More broadly, there is a need to reconcile overlaps across regimes, including NIS2, the Machinery Directive, and product safety law. Sector-specific guidance can help align obligations and avoid fragmented interpretation across Member States.

B. Obligations for providers of high-risk AI systems

Beyond ensuring that a high-risk AI system is compliant with the requirements in Articles 9-15, providers of high-risk AI systems have several other obligations as listed in Article 16 and further specified in other corresponding provisions of the AI Act. These include:

- *Indicate on the high-risk AI system or, where that is not possible, on its packaging or its accompanying documentation, as applicable, their name, registered trade name or registered trademark, the address at which they can be contacted;*
- *Have a quality management system in place which complies with Article 17;*
- *Keep the documentation referred to in Article 18;*
- *When under their control, keep the logs automatically generated by their high-risk AI systems as referred to in Article 19;*
- *Ensure that the high-risk AI system undergoes the relevant conformity assessment procedure as referred to in Article 43;*
- *Draw up an EU declaration of conformity in accordance with Article 47;*
- *Affix the CE marking to the high-risk AI system, in accordance with Article 48;*
- *Comply with the registration obligations referred to in Article 49(1);*
- *Take the necessary corrective actions and provide information as required in Article 20;*
- *Cooperate with national competent authorities as required in Article 21;*
- *Ensure that the high-risk AI system complies with accessibility requirements in accordance with Directives (EU) 2016/2102 and (EU) 2019/882.*

Question 37. Are there aspects related to the AI Act’s obligations for providers of high-risk AI systems for which you would seek clarification, for example through guidelines?

If so, please elaborate on which specific questions you would seek further clarification.

3000 character(s) maximum

Yes. In the insurance value chain, it is often unclear who qualifies as the “provider.” If a model is co-developed by a vendor and an insurer, or if proprietary tools are fine-tuned on client data, responsibility for compliance under Articles 16–24 needs clarification. Further, the level of documentation providers must supply to deployers remains uncertain. Balancing deployer needs against provider confidentiality is essential. Sectoral standards (e. g., Solvency II documentation) could serve as a baseline for compliance. Technical points requiring guidance include: • Whether ISO 9001 QMS is sufficient under Article 17, or if sector-specific standards apply. • Whether logging (Article 19) must support encryption and inter-party access. • How quickly providers must act under

Article 20 when issues arise. Finally, insurers developing in-house models must fulfil both provider and deployer obligations. Clearer instructions and recognition of actuarial standards would improve compliance and foster innovation.

Question 38. Are there aspects related to the obligations for providers of high-risk AI systems which require clarification regarding their interplay with other Union legislation?

If so, please elaborate which specific aspects require clarification regarding their interplay with other Union legislation and point to concrete provisions of specific other Union law.

3000 character(s) maximum

We believe further clarification is needed on how the obligations for providers of high-risk AI systems under the AI Act interact with existing Union legislation. In the financial and insurance sectors, overlapping requirements may create duplication, legal uncertainty, or conflicting obligations if not properly harmonised. For example, Solvency II already imposes detailed requirements on model governance, documentation, and risk oversight. Where insurers act as AI providers—particularly in developing and managing internal pricing or underwriting models—it would be beneficial to clarify how these obligations align with Articles 16–24 of the AI Act. In particular, documentation, change logs, and model validation protocols required under Solvency II may satisfy AI Act requirements, but this should be explicitly recognised to avoid redundant compliance burdens. We also highlight potential overlap with the Digital Operational Resilience Act (DORA), which governs operational risk management in financial services. For instance, model change logs, incident response plans, and cyber-resilience measures are regulated under both the AI Act and DORA. Clear guidance is needed to prevent conflict or dual compliance requirements. This is especially relevant for providers supplying AI models to financial institutions, including actuarial consultancies and insurtechs. In addition, clarification is needed regarding interactions with product safety and liability frameworks. For example:

- When AI models are embedded in medical devices, the relationship between the AI Act’s Declaration of Conformity and the CE marking required under the Medical Devices Regulation should be clarified.
- In cases of harm caused by high-risk AI systems, the obligations for issuing public warnings or implementing corrective actions under Article 20 of the AI Act may overlap with obligations under the Product Liability Directive (85/374/EEC). Further, Article 25 (3) introduces uncertainty around the designation of “providers” where high-risk AI systems are also components of regulated products (e.g. vehicles). This creates potential overlaps with the revised Product Liability Directive, which now considers AI systems as products and holds manufacturers liable for post-market learning or adaptation. It is unclear how provider responsibilities under the AI Act interact with product liability provisions in these scenarios. We recommend that the Commission develop cross-reference tables or interpretative guidance to help providers, particularly those in regulated sectors like insurance, understand how to meet AI Act obligations without unnecessary duplication. Clarity on precedence, equivalence of standards, and regulatory interoperability will be essential to ensure both compliance and innovation.

C. Obligations for deployers of high-risk AI systems

Article 3(4) defines a deployer as a natural or legal person, public authority, agency or other body using an AI system under its authority except where the AI system is used in the course of a personal non-professional activity.

Deployers of high-risk AI systems have specific responsibilities under the AI Act. Transversally, Article 26 obliges all deployers of high-risk AI systems to:

- *Take appropriate technical and organisational measures to ensure that AI systems are used in accordance with the instructions accompanying the AI systems;*
- *Assign human oversight to natural persons who have the necessary competence, training and authority, as well as the necessary support;*
- *Ensure that input data is relevant and sufficiently representative in view of the intended purpose of the high-risk AI system;*
- *Monitor the operation of the high-risk AI system on the basis of the instructions for use and, where relevant, inform providers in accordance with Article 72;*
- *Keep the logs automatically generated by that high-risk AI system to the extent such logs are under their control, for a period appropriate to the intended purpose of the high-risk AI system of at least six months.*

Additionally, Article 26 foresees the following obligations in specific cases:

- *For high-risk AI system at the workplace, deployers who are employers shall inform workers' representatives and the affected workers that they will be subject to the use of the high-risk AI system;*
- *Specific authorization requirements and restrictions apply to the deployer of a high-risk AI system for post-remote biometric identification for law enforcement purposes;*
- *Deployers of high-risk AI systems referred to in Annex III that make decisions or assist in making decisions related to natural persons shall inform the natural persons that they are subject to the use of the high-risk AI system.*

Question 39. Are there aspects related to the AI Act's obligations for deployers of high-risk AI systems listed in Article 26 for which you would seek clarification, for example through guidelines?

If so, please elaborate on which specific questions you would seek further clarification.

3000 character(s) maximum

We believe further clarification is needed on the obligations of deployers under Article 26 of the AI Act, particularly for insurance undertakings and actuarial functions. First, it is unclear how these obligations apply in cross-border contexts. For example, if an EU-based insurer reinsures part of its portfolio through entities outside the Union (e.g., in the US or Bermuda), the extent to which deployer obligations extend to such arrangements remains ambiguous. Second, guidance is needed on the division of responsibilities between providers and deployers, especially regarding documentation. When models are externally developed and include proprietary components, deployers may lack access to technical details but are still expected to comply. Clarity is needed on what constitutes "sufficient" documentation and transparency in such cases. The classification of certain actuarial tools as high-risk AI also has communication implications. Article 26(11) requires informing individuals when high-risk AI is used in decisions. For pricing models like generalised linear models (GLMs), this may create confusion or concern, despite their transparency and human oversight. Clarification is needed on whether customers can refuse such processing and how such rights interact with insurers' risk assessment duties. The phrase "appropriate technical and organisational measures" in Article 26(2) is vague. Deployers would benefit from sector-specific guidance or checklists that set out expected standards for risk monitoring, explainability, and data handling—tailored to financial services and insurance. Further clarification is needed on:

- The level of documentation and logs deployers must maintain to demonstrate compliance.
- The meaning

of “human oversight” in pricing and underwriting systems, and what constitutes sufficient evidence. • Expectations for monitoring system outputs, particularly in detecting and addressing bias. • Criteria for determining whether input data is “sufficiently representative,” and how to document this to regulators. • What qualifies as a “serious incident” in insurance, and when this must be reported. Finally, we ask whether deployers must fulfil information obligations towards subcontracted or gig workers in operational roles (e.g. in distribution or claims processing). We recommend the development of insurance-specific implementation guidance for Article 26, aligned with existing governance requirements such as Solvency II, to help avoid regulatory overlap and support compliance.

Question 40. Are there aspects related to the obligations for deployers of high-risk AI systems listed in Article 26 which require clarification regarding their interplay with other Union legislation?

If so, please elaborate which specific aspects require clarification regarding their interplay with other Union legislation and point to concrete provisions of specific other Union law.

3000 character(s) maximum

Further clarification is needed on how the obligations for deployers under Article 26 of the AI Act interact with other Union legislation. This is particularly important for insurers and financial services firms, which are already subject to detailed regulatory frameworks such as the GDPR and Solvency II. One key area of overlap concerns data protection. Article 26(3) requires deployers to conduct a Data Protection Impact Assessment (DPIA) where personal data is processed. This mirrors the requirement in GDPR Article 35. It is unclear whether a single DPIA can satisfy both the GDPR and the AI Act, or whether separate assessments are required. We suggest clarifying whether the Fundamental Rights Impact Assessment (FRIA) introduced in Article 27 of the AI Act can be treated as a component or extension of the GDPR DPIA. This would help streamline compliance and reduce administrative burden. In the context of profiling and automated decision-making, insurers using AI for dynamic pricing or risk scoring must comply with both the AI Act and Article 22 of the GDPR. Without clear guidance, inconsistent interpretations may arise. We recommend that the Commission work with the European Data Protection Board (EDPB) and EIOPA to publish joint guidelines addressing these overlaps. Another area requiring clarification is how deployers should reconcile obligations under the AI Act with existing occupational health and safety legislation, such as the OSH Framework Directive (89/391/EEC). For example, if AI systems are used in workplace risk monitoring or scheduling, how should employers align AI Act compliance with their health and safety duties? Additionally, in financial services and insurance, Article 26 obligations may interact with existing product governance and customer fairness rules, such as those in the Insurance Distribution Directive. For example, transparency and explainability duties under Article 26 may overlap with existing expectations around fair treatment and suitability assessments. Finally, at a structural level, some Member States already impose risk management regulations on insurers. The AI Act should be implemented in a way that avoids regulatory arbitrage, where providers or deployers may choose jurisdictions with lighter oversight. The Commission could consider issuing interpretative guidance or minimum harmonisation benchmarks to prevent fragmentation and ensure consistent application across the EU. We recommend aligning Article 26 obligations with existing frameworks wherever possible to avoid duplication and support proportional, effective compliance.

*Moreover, according to Article 27, deployers of high-risk AI systems that are bodies governed by public law, or are private entities providing public services, and deployers of high-risk AI systems referred to in points 5 (b) and (c) of Annex III, shall perform an **assessment of the impact on fundamental rights** that the use of such system may produce. The AI Office is currently preparing a template that should facilitate compliance with this obligation.*

Article 27 specifies that where any of its obligations are already met through the data protection impact assessment conducted pursuant to Article 35 of Regulation (EU) 2016/679 or Article 27 of Directive (EU) 2016/680, the fundamental rights impact assessment referred to in paragraph 1 of this Article shall complement that data protection impact assessment.

Question 41. Are there aspects related to the AI Act's obligations for deployers of high-risk AI systems for the fundamental rights impact assessment for which you would seek clarification in the template?

3000 character(s) maximum

We believe that further clarification is needed on the requirements for the Fundamental Rights Impact Assessment (FRIA) under the AI Act, especially for insurers and other users of AI systems in regulated financial services. There is significant potential for confusion between the FRIA and the Data Protection Impact Assessment (DPIA) required under GDPR Article 35. Many insurers already carry out DPIAs when processing personal data. Clarification is needed on whether the FRIA is intended to duplicate, supplement, or replace aspects of the DPIA, and how the two assessments can be integrated efficiently. We also seek greater clarity on the scope of the FRIA. For example, should it include potential effects on financial inclusion, access to insurance, or algorithmic discrimination—areas not typically captured by DPIAs? It would be helpful for the Commission to specify the domains that must be addressed under FRIA obligations, particularly for high-risk applications such as life and health insurance pricing. We recommend that the Commission develop sector-specific FRIA templates, tailored to the particular risks and use cases of different industries. For insurance, this should include guidance on how to evaluate:

- Unintended discriminatory outcomes in pricing or underwriting.
- Power imbalances between insurers and customers.
- Potential disproportionate effects on vulnerable groups, such as the elderly or those with pre-existing health conditions.
- The right of customers to understand, contest, and seek redress for decisions made using AI systems.

It would also be helpful to clarify the procedures for assessing the fundamental rights impacts of systems that are updated or redeployed. Must a new FRIA be conducted for each model iteration, or only when there is a material change in system function, input data, or output impact? Further clarification is also needed in situations where AI systems are used across overlapping domains. For example, fraud detection models may be applied in health insurance contexts involving bodily injury claims. Should the FRIA assess this as a health-related use (potentially high-risk under Annex III), or as a fraud-related system (not listed as high-risk)? The FRIA framework should include practical guidance on:

- The role of internal governance, complaints, and incident response mechanisms.
- Minimum standards for accessibility, response time, and escalation.
- How to document and demonstrate effective redress.
- The involvement of external oversight bodies, regulators, or judicial remedies where applicable.

We also note that actuaries are trained to assess unintended consequences and regularly perform similar evaluations in their risk management processes. Their existing frameworks could provide a solid foundation for developing practical, proportionate FRIA practices in the insurance sector.

Question 42. In your view, how can complementarity of the fundamental rights impact assessment and the data protection impact assessment be ensured, while avoiding overlaps?

3000 character(s) maximum

To ensure complementarity between the Fundamental Rights Impact Assessment (FRIA) and the Data Protection Impact Assessment (DPIA), we suggest adopting an integrated yet modular approach. This would allow both assessments to be conducted in a coordinated manner, while still respecting their distinct legal purposes. One practical solution would be to structure the FRIA as an extension or dedicated section of the DPIA when the AI system processes personal data. The DPIA could be annexed to the FRIA, with the latter going beyond personal data issues to examine broader fundamental rights implications. This might include potential impacts on access to services, fairness in decision-making, proxy discrimination, and disproportionate effects on vulnerable or minority groups. We support the development of a joint assessment framework that

includes: • Data protection risks (DPIA), • Fundamental rights risks (FRIA), • Optional societal or structural risks for high-impact systems. This would reduce duplication, provide a holistic risk view, and support practical implementation, particularly for insurers already subject to robust compliance obligations under GDPR and Solvency II. Where DPIA tools are already in use, such as those provided by data protection authorities, it would be helpful if automated FRIA tools could build upon or interface with them. This would facilitate information reuse and reduce administrative burden while ensuring both assessments are comprehensive. To prevent conflict between different regulatory regimes (e.g., Solvency II, GDPR, and the AI Act), the Commission could develop clear guidance on precedence and compatibility. For example, if data quality standards under Solvency II differ from those in the AI Act, there should be a method for reconciling discrepancies in a manner that ensures consistency and legal certainty. We also recommend identifying shared principles—such as proportionality, transparency, and fairness—that should underpin both assessments. In cases where these principles may conflict (e.g., transparency vs. data minimisation), a clear balancing framework should be introduced to guide trade-offs and help institutions choose the least harmful option. Furthermore, FRIA should address not only data-related risks but also how the AI system is designed, deployed, and monitored. This includes algorithmic fairness, the choice of modelling methods, and safeguards against indirect discrimination. Finally, we note that actuaries already apply professional standards related to data governance and fairness. Where DPIA and FRIA requirements overlap with these, guidance should ensure alignment and interoperability to avoid regulatory fragmentation.

Finally, deployers of high-risk AI systems may have to provide an explanation to an affected person upon their request. This right is granted by Article 86 AI Act to affected persons which are subject to a decision, which is taken on the basis of the output from a high-risk AI system listed in Annex III and which produces legal effects or similarly significantly affects that person in a way that they consider to have an adverse impact on their health, safety or fundamental rights.

Question 43. Are there aspects related to the AI Act’s right to request an explanation in Article 86 for which you would seek clarification, for example through guidelines?

If so, please elaborate on which specific questions you would seek further clarification.

3000 character(s) maximum

We welcome the right to request an explanation under Article 86 as a means to improve transparency and trust in high-risk AI systems. However, further clarification is needed to ensure that explanations are both meaningful to individuals and practicable for providers and deployers. In insurance, Article 86 could apply to decisions such as pricing, underwriting, or claims assessment. These are often based on statistical or AI models that range in complexity—from traditional Generalised Linear Models (GLMs) to advanced machine learning algorithms. It is not clear whether explanations must include technical detail on model internals, or whether simplified, model-agnostic descriptions are sufficient. A plain-language explanation of key influencing factors (e.g. age, claims history) may be appropriate in most cases. We suggest the Commission clarify: • Who is responsible for providing the explanation: the provider, the deployer, or both? • What specific elements must be included in an explanation: = The rationale for the decision? = The main data sources used? = Confidence levels or alternative outcomes? • Whether proprietary information, including model architecture or coefficients, must be disclosed, and how to balance this against intellectual property (IP) rights and risks of model gaming or anti-selection. We propose that guidance be issued on: • Minimum standards for explanation content, tailored to different sectors. • Example templates for providing explanations in insurance, credit scoring, and other high-risk areas. • The acceptable level of abstraction—whether simplified summaries are sufficient if the underlying model is too complex to explain fully in lay terms. It is also important to align Article 86 with existing rights under GDPR, such as the right to obtain “meaningful information about the logic involved” in automated decision-making (Article 15

(1)(h) and Article 22). The interplay with national consumer protection laws should also be clarified to prevent overlapping or contradictory obligations. Finally, we would like to emphasise that actuaries are trained to ensure transparency and explainability of models. Actuarial practice already includes the documentation and communication of key risk drivers and modelling assumptions to a wide range of stakeholders. This expertise can help operationalise Article 86 in a proportionate, reliable, and sector-appropriate way.

D. Substantial modification (Article 25 (1) AI Act)

Article 3 (23) defines a substantial modification as a change to an AI system after its placing on the market or putting into service which is not foreseen or planned in the initial conformity assessment carried out by the provider. As a result of such a change, the compliance of the AI system with the requirements for high-risk AI systems is either affected or results in a modification to the intended purpose for which the AI system has been assessed.

The concept of ‘substantial modification’ is central to the understanding of the requirement for the system to undergo a new conformity assessment. Pursuant to Article 43(4), the high-risk AI system should be considered a new AI system which should undergo a new conformity assessment in the event of a substantial modification.

This concept is also central for the understanding of the scope of obligations between a provider of a high-risk AI system and other actors operating in the value chain (distributor, importer or deployer of a high-risk AI system). Pursuant to Article 25, any distributor, importer, deployer or other third-party shall be considered to be a provider of a high-risk AI system and shall be subject to the obligations of the provider, in any of the following circumstances:

(a), they put their name or trademark on a high-risk AI system already placed on the market or put into service, without prejudice to contractual arrangements stipulating that the obligations are otherwise allocated;

(b), they make a substantial modification to a high-risk AI system that has already been placed on the market or has already been put into service in such a way that it remains a high-risk AI system;

(c), they modify the intended purpose of an AI system, including a general-purpose AI system, which has not been classified as high-risk and has already been placed on the market or put into service in such a way that the AI system concerned becomes a high-risk AI system.

Question 44. Do you have any feedback on issues that need clarification as well as practical examples on the application of the concept of 'substantial modification' to a high-risk AI system.

3000 character(s) maximum

We agree that the concept of “substantial modification” is central to ensuring the continued trustworthiness of high-risk AI systems, and we welcome clarification on its application to actuarial and insurance use cases. In practice, AI systems—particularly those used in risk assessment or pricing—may undergo regular updates, including data refreshes, recalibrations, or minor adjustments to model parameters. These routine maintenance activities should not automatically trigger reclassification or full reassessment. We propose that “substantial

modification” be reserved for fundamental changes to methodology, architecture, intended use, or decision-making scope. We suggest the Commission provide sector-specific guidance to help determine when a modification is substantial. For example:

- Retraining an existing model on newer data, where the model architecture and function remain unchanged, should typically not be considered a substantial modification.
- Replacing standard mortality tables with updated ones should not trigger re-assessment, provided the model’s use and outputs remain consistent.
- Modifying an algorithm to serve a new population (e.g., fine-tuning a mortality model for diabetic applicants) may be substantial if the model is applied in new contexts or its outputs affect access to critical services.
- Structural changes to model architecture (e.g. adding neural layers, changing activation functions, or switching modelling paradigms) could materially alter the system’s behaviour and should likely qualify as substantial. There is also uncertainty around “cascading modifications”—where a deployer updates a third-party model that has itself been recently modified. Clarification is needed on how liability and regulatory obligations are distributed across the supply chain in such cases. We further suggest:
- Clear thresholds or criteria (e.g. based on performance shifts, use-case changes, or feature engineering changes) to define when a modification is substantial.
- Flexibility for sectors such as insurance, where model oversight is already subject to established actuarial standards and governance frameworks, such as under Solvency II.
- Avoiding overly broad definitions, which might discourage continuous improvement and innovation due to excessive reassessment burdens. Actuaries are well-placed to help develop practical criteria for differentiating significant versus minor updates, and we would welcome further engagement on this topic.

Article 43(4) second sentence describes the circumstances under which the change does not qualify as a substantial modification: ‘For high-risk AI systems that continue to learn after being placed on the market or put into service, changes to the high-risk AI system and its performance that have been pre-determined by the provider at the moment of the initial conformity assessment and are part of the information contained in the technical documentation referred to in point 2(f) of Annex IV, shall not constitute a substantial modification.’

Question 45. Do you have any feedback on issues that need clarification as well as practical example of pre-determined changes which should not be considered as a substantial modification within the meaning the Article 43(4) of the AI Act.

3000 character(s) maximum

We support the need for practical guidance on what constitutes pre-determined changes that should not be treated as “substantial modifications” under Article 43(4). In sectors such as insurance, actuarial models are routinely updated as part of established governance processes. These updates often do not affect the core logic or intended purpose of the AI system, and imposing reassessment obligations could generate unnecessary regulatory burden. We suggest that the following types of pre-specified, routine updates should generally not be considered substantial modifications:

- Annual or periodic data updates, such as including one additional year of policyholder or claims data, where model variables and structure remain unchanged.
- Scheduled updates of reference data, such as the use of updated mortality tables or inflation indices, which change inputs but not model logic.
- Rolling model recalibrations, e.g., quarterly refreshes based on latest claims experience or seasonal factors (such as flu season adjustments), provided these are part of a documented and pre-approved update plan.
- Parameter tuning within approved thresholds, where predefined boundaries are set (e.g., for risk tolerances or underwriting margins).
- Technical maintenance, such as software bug fixes, performance optimisation, or updates to user interfaces that do not affect the model’s decision-making core.
- Explainability or transparency enhancements, such as updating SHAP value outputs or improving documentation for end-users.

To avoid ambiguity, we propose that providers and deployers be allowed to define a “model lifecycle plan” at the time of conformity assessment. This plan could outline which model updates are foreseen and fall within acceptable non-substantial change parameters, subject to regulator

review or validation. We also recommend that the Commission publish illustrative examples, tailored to different sectors, to clarify the boundary between substantial and non-substantial changes. This will help ensure proportional implementation of the AI Act while allowing model improvements and recalibrations that maintain accuracy and relevance in fast-evolving environments. Such flexibility is essential to support responsible AI innovation while maintaining regulatory certainty and user trust.

E. Questions related to the value chain roles and obligations

Throughout the AI value chain, multiple parties contribute to the development of AI systems by supplying tools, services, components, or processes. These parties play a crucial role in ensuring the provider of the high-risk AI system can comply with regulatory obligations. To facilitate compliance with regulatory obligations, Article 25(4) require these parties to provide the high-risk AI system provider with necessary information, capabilities, technical access and other assistance through written agreements, enabling them to fully meet the requirements outlined in the AI Act.

However, third parties making tools, services, or AI components available under free and open-source licenses are exempt from complying with value chain obligations. Instead, providers of free and open-source AI solutions are encouraged to adopt widely accepted documentation practices, such as model cards and datasheets, to facilitate information sharing and promote trustworthy AI.

To support cooperation along the value chain, the Commission may develop and recommend voluntary model contractual terms between providers of high-risk AI systems and third-party suppliers.

Question 46. From your organisation's perspective, can you describe the current distribution of roles in the AI value chain, including the relationships between providers, suppliers, developers, and other stakeholders that your organisation interacts with?

3000 character(s) maximum

In the actuarial and insurance sectors, the roles within the AI value chain often overlap, and responsibilities may be shared across different stakeholders. Actuaries and data scientists are typically responsible for developing or adapting models. These often rely on third-party tools or libraries, such as open-source machine learning frameworks. Insurtech vendors may act as providers by supplying pre-built AI components, which insurers then integrate into internal systems for underwriting, pricing, or claims handling—thus acting as deployers. In some cases, insurance undertakings take on multiple roles simultaneously—developing, deploying, and overseeing AI tools in-house. Internal actuarial teams play a key role in ensuring professional oversight, especially in relation to model governance and validation. Intermediaries, such as brokers, may serve as data conduits but do not typically modify the AI system itself. As AI use expands, there is growing need for clear role definitions, particularly in complex supply chains where fine-tuning or re-use of general-purpose AI may involve multiple parties. Sector-specific guidance could help clarify responsibilities among developers, providers, and deployers, especially in contexts involving proprietary or hybrid model ownership.

Question 47 Do you have any feedback on potential dependencies and relationships throughout the AI value chain that should be taken into consideration when implementing the AI Act's obligations, including any

upstream or downstream dependencies between providers, suppliers, developers, and other stakeholders, which might impact the allocation of obligations and responsibilities between various actors under the AI Act? In particular, indicate how these dependencies affect SMEs, including start-ups.

3000 character(s) maximum

There are important dependencies throughout the AI value chain that should be carefully considered when implementing the AI Act's obligations. In the insurance sector, reinsurers frequently depend on cedants' AI systems for underwriting or claims analytics. If upstream models are opaque or biased, there is a risk that such issues propagate through the value chain. It would be helpful if transparency and accountability obligations extended appropriately to all relevant actors, including third-party providers of scoring or decision-support systems. A standardised due diligence protocol could support this. Cross-border groups often manage AI models across jurisdictions, which can create fragmented oversight responsibilities. The AI Act should consider mechanisms to support effective governance across such complex organisational structures. It may also be helpful to clarify how obligations should be distributed in multi-party arrangements. For example, placing disproportionate compliance burdens on small deployers or users—such as SMEs—may create barriers to adoption. Regulatory clarity and proportionality are especially important in contractual arrangements between providers, data suppliers, IT teams, and end-users. Contracts should facilitate transparency, shared monitoring responsibilities, and access to documentation or logs where needed.

Question 48. What information, capabilities, technical access and other assistance do you think are necessary for providers of high-risk AI systems to comply with the obligations under the AI Act, and how should these be further specified through written agreements?

3000 character(s) maximum

To support compliance with the AI Act, providers of high-risk AI systems would benefit from access to specific tools, guidance, and collaborative mechanisms. First, technical support should include access to model audit templates, documentation standards, and bias assessment tools tailored to the insurance sector—for example, metrics that evaluate disparate impact in underwriting or claims processing. Probabilistic pricing models also require sector-specific transparency frameworks that balance explainability with the nature of risk-based calculations. Second, compliance would be strengthened by model lifecycle traceability tools, allowing providers to monitor, log, and update AI systems transparently across development and deployment phases. Third, there is a need for training on the ethical and legal implications of AI use in sensitive domains such as insurance, where fairness and transparency are critical to public trust and regulatory compliance. Fourth, standardisation could be further enhanced through the publication of a model compliance guide. In addition, surveying stakeholders across sectors may help to identify challenges, align expectations, and promote shared best practices. Finally, smaller providers would particularly benefit from sector-specific guidance, regulatory sandboxes, and cooperative arrangements to ensure access to essential validation tools, data quality checks, and technical documentation—even where components are sourced from external vendors.

Question 49. Please specify the challenges in the application of the value chain obligations in your organisation for compliance with the AI Act's obligations for high-risk AI systems and the issues for which you need further clarification; please provide practical examples.

1500 character(s) maximum

Organisations face several challenges in applying value chain obligations under the AI Act. A key issue is the lack of visibility into third-party AI components—especially their origin, licensing terms, and training data—which hinders the ability to assess risks, ensure fairness, and document systems fully. Versioning problems also arise when vendors update models without clear audit trails. Another challenge is defining the boundary between AI systems and traditional models. In insurance, for instance, GLMs or pricing models may be

misclassified as high-risk AI due to their complexity, despite being transparent and subject to professional standards. Traceability is further complicated when third-party providers withhold key algorithmic details due to proprietary constraints. Internally, organisations must educate multi-disciplinary teams, align AI Act processes with established regulatory workflows (e.g., Solvency II), and assign clear roles in cross-border structures. The absence of finalised standards increases compliance uncertainty. We suggest that the EU formally recognise the role of actuaries, whose professional frameworks already promote transparency, fairness, and accountability, and involve them in developing practical compliance guidance for high-risk AI systems in insurance.

Section 5. Questions in relation to the need for possible amendments of high-risk use cases in Annex III and of prohibited practices in Article 5

Pursuant to Article 112(1) AI Act, the Commission shall assess the need to amend the list of use cases set out in Annex III and of the list of prohibited AI practices laid down in Article 5 by 2 August 2025 and once a year from then onwards.

The Commission is empowered to adopt delegated acts to amend Annex III by adding or modifying use-cases of high-risk AI systems pursuant to Article 7(1) AI Act. The findings of the assessment carried out under Article 112(1) AI Act are relevant in this context. The empowerment to amend Annex III requires that both of the following conditions are fulfilled:

- *the AI systems are intended to be used in any of the areas listed in Annex III and*
- *the AI systems pose a risk of harm to health and safety, or an adverse impact on fundamental rights, and that risk is equivalent to, or greater than, the risk of harm or of adverse impact posed by the high-risk AI systems already referred to in Annex III.*

Article 7(2) AI Act further specifies the criteria that the Commission shall take into account in order to evaluate the latter condition, including:

(a) the intended purpose of the AI system;

(b) the extent to which an AI system has been used or is likely to be used;

(c) the nature and amount of the data processed and used by the AI system, in particular whether special categories of personal data are processed;

(d) the extent to which the AI system acts autonomously and the possibility for a human to override a decision or recommendations that may lead to potential harm;

(e) the potential extent of such harm or such adverse impact, in particular in terms of its intensity and its ability to affect multiple persons or to disproportionately affect a particular group of persons;

(f) the extent to which the use of an AI system has already caused harm to health and safety, has had an adverse impact on fundamental rights or has given rise to significant concerns in relation to the likelihood of such harm or adverse impact, as demonstrated, for example, by reports or documented allegations submitted to national competent authorities or by other reports, as appropriate;

(g) the extent to which persons who are potentially harmed or suffer an adverse impact are dependent on the outcome produced with an AI system, in particular because for practical or legal reasons it is not reasonably possible to opt-out from that outcome;

(h) the extent to which there is an imbalance of power, or the persons who are potentially harmed or suffer an adverse impact are in a vulnerable position in relation to the deployer of an AI system, in particular due to status, authority, knowledge, economic or social circumstances, or age;

(i) the extent to which the outcome produced involving an AI system is easily corrigible or reversible, taking into account the technical solutions available to correct or reverse it, whereby outcomes having an adverse impact on health, safety or fundamental rights, shall not be considered to be easily corrigible or reversible;

(j) the magnitude and likelihood of benefit of the deployment of the AI system for individuals, groups, or society at large, including possible improvements in product safety;

(k) the extent to which existing Union law provides for:

- effective measures of redress in relation to the risks posed by an AI system, with the exclusion of claims for damages;

- effective measures to prevent or substantially minimise those risks.

Question 50. Do you have or know concrete examples of AI systems that in your opinion need **to be added to the list of use cases in Annex III, among the existing 8 areas, in the light of the criteria and the conditions in Article 7(1) and (2)** and should be integrated into the assessment pursuant to Article 112(1) AI Act?

If so, please specify the concrete AI system that fulfils those criteria as well as evidence and justify why you consider that this system should be classified as high-risk.

3000 character(s) maximum

We propose the following clarifications and additions to the Annex III use cases to ensure the AI Act captures applications with significant implications for individuals' access to financial services and social protection. First, automated underwriting systems in life, health, and credit-related insurance should be explicitly included. These systems directly affect individuals' eligibility, pricing, and access to essential services such as health coverage or mortgage protection. While some may argue these systems are already indirectly captured under point 5 of Annex III, an explicit reference would help reinforce their societal relevance and ensure appropriate regulatory safeguards are applied. Similarly, AI models used for pension allocation or annuity pricing—particularly in

public-private hybrid arrangements—should be considered for inclusion. These systems influence retirement income adequacy over long periods, and errors or biases in model assumptions could have far-reaching social consequences. We also suggest that insurance fraud detection systems be considered for inclusion when they lead to decisions with legal or similarly significant effects, such as placement on shared industry fraud databases. If individuals are wrongly added to such databases, they may be excluded from essential insurance products. These decisions warrant a high standard of accuracy, transparency, and recourse. A clear human-in-the-loop requirement should be enforced in such cases to prevent harm through automation errors. Importantly, we note that such risks are not limited to life or health insurance. The impact of exclusion due to fraud flags can be equally serious in areas like motor or property insurance. Safeguards should apply broadly across all lines of insurance where automatic exclusion from coverage may occur. At the same time, we reiterate that traditional actuarial tools used for pricing or reserving—such as generalised linear models—are typically not autonomous and are developed under professional oversight. They should not be classified as high-risk AI systems unless used in a way that produces direct, significant impacts on individuals’ rights.

Question 51. Do you consider that some of the use cases listed in Annex III require adaptation in order to fulfil the conditions laid down pursuant to Article 7(3) AI Act and should therefore **be amended** and should be integrated into the assessment pursuant to Article 112(1) AI Act?

- Yes
- No

Please justify why you consider that the use case needs to be adapted in order to fulfil the conditions as per Article 7(3) AI Act

3000 character(s) maximum

Yes – we believe Annex III should be amended to better reflect the varied and evolving AI use cases in insurance and financial services. We suggest the following adaptations: 1. Include motor insurance systems: AI systems used by insurers to deny, adjust pricing, or limit coverage for mandatory motor third-party liability (MTPL) insurance should be explicitly recognised as high-risk. In jurisdictions where MTPL is mandatory, automated denial or pricing decisions can directly restrict a person’s ability to drive, triggering significant societal consequences. 2. Annex III currently references “insurance, credit scoring, and risk assessment,” but could benefit from greater granularity: -Explicitly distinguish between fully automated systems (e.g., pricing or underwriting engines that operate without human intervention) and decision-support tools that aid actuaries or underwriters. -Include high-impact financial decision-making systems used in insurability assessments, premium fairness evaluations, and pension/annuity pricing. -Conversely, clarify that internal risk reserve models, reinsurance-specific tools, or claims adjustment systems should only be considered high-risk if they directly influence individual access, pricing, or coverage decisions. 3. Clarify overlaps for hybrid systems: Many AI tools serve dual purposes, such as underwriting and advisory. Annex III should clarify how these hybrid systems are classified, perhaps requiring high-risk treatment when they influence final decision-making independently of human oversight. These changes would ensure that AI systems with the potential to restrict access to essential insurance products—such as MTPL cover or life and health insurance—are consistently captured under the high-risk classification. This clarification will support proportional regulation, prevent unintended service denial, and uphold consumer rights.

Question 52. Do you consider that some of the use cases listed in Annex III no longer *fulfil* the conditions laid down pursuant to Article 7(3) AI Act and should therefore **be removed from the list of use cases in Annex III** and should be integrated into the assessment pursuant to Article 112(1) AI Act?

- Yes

No

Pursuant to Article 112(1) AI Act, the European Commission shall assess the need for amendment of the list of prohibited AI practices laid down in Article 5 once a year. In order to gather evidence of potential needs for amendments, respondents are invited to answer the following questions.

Question 53. Do you have or know concrete examples of AI practices that in your opinion contradict Union values of respect for human dignity, freedom, equality and no discrimination, democracy and the rule of law and fundamental rights enshrined in the Charter and for which there **is a regulatory gap because they are not addressed by other Union legislation?**

If so, please specify the concrete AI system that fulfils those criteria and justify why you consider that this system should be prohibited and why other Union legislation does not address this problem.

3000 character(s) maximum

Yes. We believe there are emerging AI practices in insurance that may contradict fundamental Union values such as equality, non-discrimination, and fairness, and which may not be adequately addressed under current Union legislation. One key area of concern is proxy discrimination. For example, using ZIP-code-based or demographic data for risk scoring may inadvertently result in indirect discrimination, such as racial or socio-economic profiling, even if sensitive attributes are not explicitly used. These practices can conflict with EU values and fundamental rights, yet they are not clearly prohibited under existing regulations. The AI Act could offer more explicit safeguards in this respect—such as restricting the use of correlates to sensitive data unless their use is demonstrably justified, monitored for bias, and proportionate to the legitimate aim pursued. Another concern is behavioural price optimisation, where AI is used to personalise insurance pricing based not on actual risk but on consumers' perceived willingness to pay. This practice may disproportionately affect vulnerable groups and erode fairness and trust. While this is not currently prohibited, it raises ethical questions that might justify further regulatory or ethical guidance at the EU level. Both examples point to potential gaps in the current legislative framework and highlight the need for clearer ethical guardrails and sector-specific guidance to ensure that AI practices in financial services remain aligned with the Union's core values.

Question 54. Do you consider that some of the prohibitions listed in Article 5 AI Act are already sufficiently addressed by other Union legislation and should therefore **be removed from the list of prohibited practices in Article 5 AI Act?**

Yes

No

Contact

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