FEEDBACK STATEMENT

Consultation Paper on Opinion on Artificial Intelligence Governance and Risk Management

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1. INTRODUCTION

The European Insurance and Occupational Pensions Authority (EIOPA) would like to thank all the participants in the public consultation for their comments on the draft Opinion on Artificial Intelligence Governance and Risk Management (hereinafter "the Opinion").

The contributions received provided important input and guidance to aid EIOPA in finalising the Opinion. All the comments submitted were given careful consideration. The individual comments received and EIOPA's response to them are published as a separate document

2. BACKGROUND AND OBJECTIVE

2.1. SUMMARY OF STAKEHOLDER FEEDBACK

Several stakeholders expressed support for the Opinion's objective, principles-based approach, and emphasis on risk-based and proportionality considerations. The alignment of the Opinion with the underlying general principles of the AI Act and similar initiatives from international standard-setting bodies was also welcomed.

However, some stakeholders raised concerns that the Opinion could create new obligations or quasi-obligations, particularly due to the use of the word "should" throughout the document. More specifically, some stakeholders were concerned that the Opinion could be particularly burdensome for smaller undertakings and for low-risk AI systems. These stakeholders suggested that the Opinion should be presented as a recommendation rather than setting out clear expectations, in order to avoid creating unintended regulatory burdens.

On the contrary, some stakeholders requested more detailed guidance in certain areas of the Opinion, such as the development of a detailed list of risk assessment criteria or the creation of standardized templates for record-keeping. They argued that this would facilitate the implementation of the Opinion, making it more actionable and effective.

Finally, stakeholders held differing views on the timing of the Opinion, with some preferring to wait for the AI Act implementing measures to be finalized or for the European Commission to clarify its intentions on possible guidelines for the financial sector. Others, however, considered the Opinion

timely, as most uses of AI systems are not considered high-risk or prohibited practices under the AI Act, and believed that it would be better to develop guidelines now to support consistency in approaches and supervisory convergence across the sector.

2.2. EIOPA'S ANSWER

EIOPA acknowledges the importance of international convergence around key generally accepted principles of AI governance, which should be implemented in a manner that considers sector-specificities, as reflected in this Opinion. EIOPA is also actively promoting this approach within the International Association of Insurance Supervisors, which has recently issued an Application Paper on the subject.

The Opinion does not establish new requirements but rather provides guidance on how different provisions of insurance sector legislation should be interpreted in the context of AI systems, which did not exist or were not widely used at the time the legislation was approved. The use of terminology such as "should" is common in similar guidance documents developed by EIOPA in the past. The Opinion does not establish a supervisory checklist, but rather it follows a holistic approach to AI governance and risk management anchored in risk-based and proportionality considerations.

The revised Opinion includes additional references under each of the principles to the need to follow a risk-based and proportional approach, thereby highlighting a key aspect of the Opinion. It has also been clarified that AI impact assessment can itself be proportionate to the potential impact of the specific AI system(s) used by the undertaking (for further details see also point 4 below) — the greater the risks, the more detailed the assessment needed.

Finally, in line with the Opinion's Impact Assessment, EIOPA will focus on providing high-level guidance at this stage. This approach is complemented by specific examples included in the Annex, which are not intended to be considered prescriptive guidance but rather illustrate possible practical ways to implement some of the high-level principles included in this Opinion. Moreover, based on the AI governance framework proposed in this Opinion, EIOPA envisages subsequently developing more detailed analysis on specific AI systems or issues arising from the use of AI systems in insurance and providing further guidance, as relevant.

3. SCOPE

3.1. SUMMARY OF STAKEHOLDER FEEDBACK

Several stakeholders expressed support for the scope of the Opinion, which applies to AI systems used in the insurance sector that are not classified as prohibited AI practices or high-risk AI systems under the AI Act. However, some stakeholders raised questions regarding the distinction between high-risk AI systems as defined in the AI Act and those AI systems that may be deemed to pose a high risk following the conclusion of an impact assessment, as contemplated in the Opinion. Some stakeholders also suggested that EIOPA should assess whether additional AI systems should be considered high-risk under the AI Act.

Stakeholders also expressed support for utilising the definition of AI systems outlined in the AI Act, with a view to ensuring consistency at the European level. Nevertheless, some stakeholders requested further clarification on whether traditional mathematical models commonly used in the insurance sector, such as Generalized Linear Models (GLMs), would fall within the scope of the AI Act's definition of AI systems.

Certain stakeholders also expressed concerns that the Opinion's references to Solvency II and the Insurance Distribution Directive (IDD) could unintentionally broaden their regulatory perimeter. For instance, they queried whether the Opinion's reference to data management under Solvency II could be interpreted as applying Solvency II requirements to all insurance distributors, or whether the references to fair treatment of consumers could be interpreted as imposing IDD requirements on undertakings that are not currently subject to the IDD.

3.2. EIOPA'S ANSWER

The scope of the Opinion has been maintained to cover AI systems used in insurance that are not considered prohibited AI practices or high-risk under the AI Act, in order to avoid creating unnecessary overlaps and regulatory burdens. The Opinion explicitly states that it does not extend the requirements of the AI Act to all uses of AI systems in insurance and that there are varying levels of risk among AI systems that are not prohibited or considered high-risk under the AI Act. The consideration of high-risk AI systems in the AI Act has its own meaning and legal implications, which are independent of the outcome of the impact assessment foreseen in the Opinion.

Regarding the definition of AI systems, the Opinion now includes an explicit reference to the European Commission's Guidelines on the AI system definition. The Guidelines include explicit references to linear and logistic regression models. EIOPA acknowledges that further guidance from the European Commission's AI Office (e.g., in the form of Q&As) may be provided at a later stage.

Finally, the references in the Opinion to articles from Solvency II, DORA, and IDD, which are not exhaustive, do not affect their scope of application. However, the principles laid out in the Opinion

(e.g., fairness, human oversight, data management etc.) remain applicable to the use of AI systems in insurance, since similar principles underline sectoral legislation and no regulatory gaps have been identified. For example, data governance is fundamental to ensuring that consumers are treated fairly, and therefore, insurance distributors not subject to Solvency II should also adopt, following a risk-based and proportionate approach, sound data governance practices, such as those described in the Opinion, when using AI systems. Among other things, this would ensure that customers are treated fairly. Furthermore, as highlighted in the Opinion, governance and risk management measures need to be adapted and proportionate to specific uses of AI systems, which, for instance, would enable avoiding placing excessive emphasis on fairness and ethical considerations on purely prudential AI systems with no direct impact on customers.

4. RISK BASED APPROACH AND PROPORTIONALITY

4.1. SUMMARY OF STAKEHOLDER FEEDBACK

Several stakeholders expressed support for the risk-based and proportionate approach outlined in the Opinion. However, some stakeholders also raised concerns regarding the potential compliance costs associated with the Opinion for low-risk AI systems, as well as for smaller undertakings.

Some stakeholders also requested more detailed guidance on the impact assessment and the criteria that should be used. In particular, some stakeholders suggested differentiating between customer-facing and internal AI systems, as well as between newer AI systems, such as generative AI systems, and more established machine learning technologies. Some stakeholders also advocated for considering environmental impact as part of the impact assessment of AI systems.

Some stakeholders also asked for clarification on whether the impact assessment should be based on the nature of the AI systems or on their potential impact. They explained that Solvency II focuses on the "nature, scale, and complexity" of undertakings, while the IDD and other papers on AI such as the AI governance principles report developed by EIOPA's stakeholder group on digital ethics consider the potential impact on consumers. For example, while the scale of a given AI system may be small, its potential impact could be significant.

While supporting the risk-based and proportionate approach outlined in the Opinion, some stakeholders expressed concerns that it could have an unintended negative consequence, namely undermining supervisory convergence at the European level.

4.2. EIOPA'S ANSWER

EIOPA has retained the risk-based and proportionate approach of the Opinion, which aims to balance the opportunities and risks arising from AI systems, while keeping the compliance burden limited for low-risk AI systems and smaller undertakings. In this regard, a reference to the need to follow a risk-based and proportionate approach has now been clearly included at the beginning of each principle outlined in the Opinion. EIOPA has also clarified that the supervisory expectations for lower-risk AI systems will be very limited, with impacts related mostly to the steps needed to ascertain that an AI system is low-risk. In this regard, it has also been clarified that the impact assessment should be limited in cases where AI systems can be reasonably assumed to have a limited impact.

In addition, while not providing an exhaustive list, the Opinion now includes further examples of the criteria that could be included in the impact assessment, such as the differentiation between consumer-facing applications and purely internal purposes that do not involve decision-making with a direct customer impact, or the number of retail customers affected. Further examples are also included in the Annex. The Opinion now more clearly explains that the impact assessment should consider both the impact on consumers and on undertakings, including by considering the nature and complexity of AI systems.

At this stage, the environmental impact of AI systems will not be considered as a separate criterion for assessment, given that it is still an area of ongoing research and may be difficult to assess. However, EIOPA is collecting further input on this topic in its ongoing generative AI market survey. More detailed guidance may be provided by EIOPA at a later stage when it assesses specific uses of AI systems in insurance.

5. RISK MANAGEMENT SYSTEMS AND THIRD PARTIES

5.1. SUMMARY OF STAKEHOLDER FEEDBACK

Some stakeholders would welcome further clarification that undertakings can leverage their existing Enterprise Risk Management (ERM) frameworks, model risk management, or Product Oversight and Governance (POG) arrangements to govern the use of AI systems in their organisations. They considered that it should not be necessary to develop new frameworks specific to AI systems.

Several stakeholders suggested that the Opinion should draw a distinction between the responsibilities of "developers" and "deployers" of AI systems, similar to the approach taken in the AI Act. They argued that it may not be feasible for undertakings to guarantee adequate data governance or explainability for tools that were outsourced from third-party providers, in particular for tools such as Generative AI.

5.2. EIOPA'S ANSWER

EIOPA has clarified that when developing risk management systems in relation to AI systems, undertakings may leverage existing or updated Enterprise Risk Management (ERM), model risk management, Product Oversight and Governance (POG) frameworks, or other policy frameworks (e.g., IT strategy, Data strategy, AI strategy, etc.), insofar as they reflect the key principles included in the Opinion.

Concerning the issue of AI systems and data from third parties, it is essential to bear in mind that undertakings are ultimately responsible for the AI systems they use, regardless of whether the AI systems are developed in-house or in collaboration with third-party service providers. However, it is also acknowledged that due to intellectual property rights of third parties or the specificities of certain AI systems, it may be challenging to implement some of the principles outlined in the Opinion. EIOPA has noted that third-party service providers play a crucial role in AI governance, and undertakings should seek sufficient information and assurances from these providers regarding the characteristics, capabilities, and limitations of the AI systems they supply. When certain governance or risk management measures—such as data governance or explainability—are difficult to implement, undertakings should mitigate these gaps. This can be done by adopting complementary governance measures, as well as by taking additional steps, such as incorporating relevant clauses in contracts and service level agreements, conducting external audits, or carrying out due diligence and ongoing monitoring.

6. MISCELLANEOUS ISSUES

6.1. SUMMARY OF STAKEHOLDER FEEDBACK

In the fairness and ethics section, some stakeholders emphasised the need to distinguish between risk differentiation and unlawful discrimination. Some also questioned the relevance of the fairness

metrics included in the Annex, while others suggested that they should be mandatory. Additionally, the need to prevent the use of unlawful proxy discriminatory variables was highlighted.

Moreover, in the data governance section, several stakeholders noted that the inherent characteristics of some AI systems, such as generative AI systems, make it difficult to ensure sound data management practices, particularly when purchased from third parties. It was also mentioned that all types of data contain some level of bias or inaccuracy.

Concerning the documentation and record-keeping section, some stakeholders considered that the example included in the Annex for higher-risk AI systems could potentially be used by supervisors as a de facto standard and suggested that it should be removed.

As far as the transparency and explainability section is concerned, some stakeholders pointed out limitations with explainability tools such as LIME and SHAP and cautioned against explicitly referencing these tools. It was also highlighted that insurance intermediaries should receive relevant information from insurance undertakings about the use of AI systems.

In the Human Oversight section, some stakeholders mentioned that the risk management function and the Chief Risk Information Officer (CRIO) also play an important role in the context of AI systems. Some stakeholders further highlighted the potential impact of AI systems on employees and emphasized the role of social partners in ensuring responsible AI development.

In the accuracy, robustness, and cybersecurity section, some stakeholders raised again the challenges arising from third-party AI systems.

Finally, only a reduced number of stakeholders provided comments on the Impact Assessment accompanying the Opinion, primarily to support the approach and policy option chosen.

6.2. EIOPA'S ANSWER

The revised Opinion now includes an explicit reference to risk-based underwriting practices in insurance and highlights the need to prevent the use of unlawful proxy discriminatory variables. EIOPA acknowledges that different uses of AI systems may require different fairness metrics and has clarified that the examples included in Annex I are not meant to be prescriptive guidance.

In addition, while noting that certain variables need to be used to underwrite risks in insurance, the Opinion clarifies that undertakings should make reasonable efforts to remove biases in the data, including potential unlawful proxy discriminatory variables.

Moreover, several cross-references have been included in different sections of the Opinion to the risk management section that discusses third parties, reinforcing the holistic approach of the Opinion to Al governance and risk management.

Furthermore, the references to LIME and SHAP have been moved to a footnote to keep the text of the Opinion adaptable to potential future developments in this area. Additionally, an explicit reference to the information to be provided to insurance intermediaries has been included in this section.

While EIOPA acknowledges that the risk management function and the Chief Risk Information Officer (CRIO) may also play an important role in the context of AI systems in some organizations, they have not been explicitly referenced in the Opinion, since in line with its principles-based and proportional approach, it focuses on those roles and functions that play a more prominent role. Similarly, a reference to the potential role of social partners has been included but noting that this may not be relevant for all organisations.

EIOPA

Westhafen Tower, Westhafenplatz 1
60327 Frankfurt – Germany
Tel. + 49 69-951119-20
info@eiopa.europa.eu