

Impact Assessment of Opinion on AI governance and risk management

EIOPA-BoS-25-363

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1. BACKGROUND

According to Article 29(2) of the EIOPA Regulation,¹ the Authority conducts, where appropriate, an analysis of costs and benefits in the process of issuing Opinions or tools and instruments promoting supervisory convergence. The analysis of costs and benefits is undertaken according to an Impact Assessment methodology.

The European Insurance and Occupational Pensions Authority (EIOPA) provides the Opinion AI Governance and Risk Management (the Opinion), on the basis of Article 29(1)(a) of Regulation (EU) No 1094/2010². This Article mandates EIOPA to play an active role in building a common Union supervisory culture and consistent supervisory practices, as well as in ensuring uniform procedures and consistent approaches throughout the Union.

EIOPA delivers the Opinion on the basis of Articles 17, 20 and 25 of Directive (EU) 2016/972 (Insurance Distribution Directive),³ Articles 41, 46 and 82 of the Directive 2009 (2009/138/EC) (Solvency II Directive),⁴ Articles 4, 5, 6, 7 and 11 of the Regulation (EU) 2022/2554 (Digital Operational Resilience Act),⁵ Articles 258 and 260 of the Delegated Regulation 2015/35,⁶ and Articles 6, 7, 8 and 9 of the Delegated Regulation 2017/2358.⁷

The Opinion is addressed to the competent authorities⁸, as defined in Article 4(2) of Regulation (EU) No 1094/2010, and covers the activities of both insurance undertakings and intermediaries

¹ Regulation (EU) No 1094/2010 of the European Parliament and of the Council of 24 November 2010 establishing a European Supervisory Authority (European Insurance and Occupational Pensions Authority), amending Decision No 716/2009/EC and repealing Commission Decision 2009/79/EC (OJ L 331, 15.12.2010, p. 48).

² Regulation (EU) No 1094/2010 of the European Parliament and of the Council of 24 November 2010 establishing a European Supervisory Authority (European Insurance and Occupational Pensions Authority), amending Decision No 716/2009/EC and repealing Commission Decision 2009/79/EC (OJ L 331, 15.12.2010, p. 48).

³ Directive (EU) 2016/97 of the European Parliament and of the Council of 20 January 2016 on insurance distribution (OJ L 26, 2.2.2016, p. 19).

⁴ Directive 2009/138/EC of the European Parliament and of the Council of 25 November 2009 on the taking-up and pursuit of the business of Insurance and Reinsurance (OJ L 335, 17.12.2009, p. 1).

⁵ Regulation (EU) 2022/2554 of the European Parliament and of the Council of 14 December 2022 on digital operational resilience for the financial sector and amending Regulations (EC) No 1060/2009, (EU) No 648/2012, (EU) No 600/2014, (EU) No 909/2014 and (EU) 2016/1011 (OJ L 333, 27.12.2022, p. 1–79).

⁶ Commission Delegated Regulation (EU) 2015/35 of 10 October 2014 supplementing Directive 2009/138/EC of the European Parliament and of the Council on the taking-up and pursuit of the business of Insurance and Reinsurance (Solvency II) (OJ L 12, 17.1.2015, p. 1).

⁷ Commission Delegated Regulation (EU) 2017/2358 of 21 September 2017 supplementing Directive (EU) 2016/97 of the European Parliament and of the Council regarding product oversight and governance requirements for insurance undertakings and insurance distributors (OJ L 341, 20.12.2017, p. 1).

⁸ Notwithstanding the fact that specific points of the Opinion describe supervisory expectations for insurance and reinsurance undertakings, they are required to comply with the regulatory and supervisory framework applied by their competent authority based on Union or national law.

(hereafter jointly referred as undertakings), insofar as they may use AI systems within their respective areas of competence in the insurance value chain.

The Opinion builds on previous work developed by EIOPA, including the 2018 European Supervisory Authorities (ESAs) report (preceded by a public consultation) on the use of Big Data by financial institutions⁹ and EIOPA's 2019 thematic review on the use of Big Data Analytics (BDA) in motor and health insurance.¹⁰

The Opinion also leverages on the AI governance principles report¹¹ developed by EIOPA's stakeholder expert group on digital ethics in insurance, as well as on the regular monitoring conducted by EIOPA via its annual Customer Trends reports.¹² It also takes into account EIOPA's 2023 Supervisory Statement on Differential Pricing Practices¹³ as well as the findings of EIOPA's 2024 report on the Digitalisation of the insurance sector.¹⁴

Stakeholders' comments on the Consultation Paper and the Impact Assessment of EIOPA's Opinion on AI governance and risk management will serve as a valuable input in order to revise the proposed Opinion and its Impact Assessment.

2. PROBLEM DEFINITION

Artificial Intelligence (AI) is expected to play a pivotal role in the ongoing digital transformation in all industries, including the insurance sector, where there is a growing trend towards the use of AI systems throughout the insurance value chain.

Based on EIOPA's Digitalisation report published in May 2024, AI is already used by 50% of respondent insurance undertakings in non-life insurance and by 24% in life insurance. An additional 30% and 39% of respondents expect to use AI in the next three years in non-life and life insurance, respectively. Indeed, with the advent of new developments such as Generative AI and Foundation Models, the use of AI is expected to significantly increase in the years to come.

⁹ <https://esas-joint-committee.europa.eu/Publications/Reports/Final%20Report%20on%20Big%20Data.pdf>

¹⁰ https://www.eiopa.europa.eu/document-library/fact-sheet/big-data-analytics-motor-and-health-insurance_en

¹¹ <https://www.eiopa.europa.eu/sites/default/files/publications/reports/eiopa-ai-governance-principles-june-2021.pdf>

¹² https://www.eiopa.europa.eu/publications/customer-trends-report-2023_en

¹³ https://www.eiopa.europa.eu/system/files/2023-03/EIOPA-BoS-23-076-Supervisory-Statement-on-differential-pricing-practices_0.pdf

¹⁴ [EIOPA's Report on the digitalisation of the European insurance sector - EIOPA](#)

Irrespective of the line of business, AI is used throughout the insurance value chain, including pricing and underwriting, claims management, fraud detection and sales and distribution. AI systems are predominantly developed in-house by insurance undertakings themselves, although a high proportion of them have purchased components off-the-shelf from third-party service providers or developed in collaboration with them. Insurance undertakings report that they are currently mostly using simpler and more explainable AI algorithms, but the type of AI system depends on which area of the value chain one is looking at. Similarly, AI is most often used with human oversight, although some AI systems can be highly automated.

AI offers significant opportunities for the insurance sector. For example, the use of AI systems in claims handling can automate certain process such as invoice or image verification which can result in faster compensation pay outs. AI-powered chatbots can support customers to find information on the undertaking's website or help them navigate the first notification of loss process. Furthermore, AI systems can help fight against fraud more effectively and efficiently.

However, AI can also bring new risks or increase existing ones, namely due to the limited explainability of some AI systems (also known as the black-box effect), which makes it difficult to understand how an AI system reached a certain outcome. The reliance of AI systems on increasingly large datasets can also lead to discriminatory outcomes due to biases in the training datasets. The complexity of some AI systems and their capacity to capture non-linear correlations in the training datasets heightens the risk of biases or errors in the outcomes of AI systems. Furthermore, financial risks may also arise from the use of AI systems, for example as a result of potential inaccurate risk pricing, legal liabilities, cyber-attacks or supply chain failures. There can also be concentration risks, due to a relatively small number of AI system providers in terms of underlying technology.

Moreover, the increasingly granular risks assessments enabled by AI systems can contribute to the financial inclusion of certain customers (e.g. young drivers using telematics devices reportedly can have access to more affordable motor insurance), but at the same time they can also lead to high-risk insurance customers being denied insurance coverage, which is particularly concerning when vulnerable customers are affected. Furthermore, certain differential pricing practices enabled by AI systems such as those aimed to exploit the customer's "willingness to pay" or propensity to shop around can also raise significant consumer protection concerns.

Insurance undertakings need to develop adequate and proportionate risk management practices to maximize the benefits of AI while mitigating risks. Regulation (EU) 2024/1689 (the AI Act)¹⁵

¹⁵ Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonized 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, 12.7.2024.

establishes relevant governance and risk management practices, particularly regarding those AI systems that have been identified as high-risk under the AI Act (e.g., risk assessment and pricing in life and health insurance). The remaining AI systems that are not prohibited AI practices and that are not considered to be high-risk, without prejudice of Articles 6.3, 6.4 and 7 of the AI Act, continue to operate subject to existing sectoral legislation without new requirements, with a few exceptions.¹⁶

Existing sectoral legislation still applies to the use of AI systems in insurance. However, at the time the legislation was approved AI systems did not exist or they were not widely used. In this context, it is important to clarify the application of existing requirements to these new developments and to promote supervisory convergence at European level, amongst other things to reflect risk-based and proportionality considerations.

3. OBJECTIVE PURSUED

In the preparation of the Opinion, EIOPA took into consideration the general objectives of the Solvency II Directive and the Insurance Distribution Directive (IDD), particularly: the enhanced customer protection, promoting supervisory convergence and deepening the integration of the EU insurance market.

The provisions of the Opinion were also guided by EIOPA's objectives, as reflected in the EIOPA Regulation, to contribute to:

- improving the functioning of the internal market, including in particular a sound, effective and consistent level of regulation and supervision,
- ensuring the integrity, transparency, efficiency and orderly functioning of financial markets,
- preventing regulatory arbitrage and promoting equal conditions of competition,
- ensuring the taking of risks related to insurance, reinsurance and occupational pensions activities is appropriately regulated and supervised
- enhancing customer protection, and
- enhancing supervisory convergence across the internal market.

More particularly, the Opinion has the following objectives:

- Objective 1: to mitigate the risks arising from AI systems while maximising benefits

¹⁶ For example, they will have to comply with some limited transparency requirements (e.g., need to inform the customer that he is interacting with an AI system), the need to promote staff AI literacy, and the development of voluntary codes of conduct.

- Objective 2: to promote good supervisory practices and supervisory convergence

4. POLICY OPTIONS

With the intention to meet the objectives set out in the previous section, EIOPA has analysed different policy options throughout the policy development process.

The following table provides an overview of the most relevant policy issues that have been discussed in the policy development process and the main approaches considered. The preferred option for each policy issue is marked in bold.

Policy issue 1: Need for policy action

- Policy option 1.1 - Develop an Opinion on AI Governance and Risk Management
- Policy option 1.2 – Baseline – no intervention

Policy issue 2: Approach

- Policy option 2.1 - Development of an Opinion to provide high level guidance based on existing legislation
- Policy option 2.2 - Development of detailed guidance on specific use cases or issues

5. ANALYSIS OF IMPACT OF DIFFERENT POLICY OPTIONS

1.1. The following tables summarise the costs and benefits for the main options considered for stakeholders:

Policy issue 1: Need for policy action		
Option 1.1: Develop an Opinion on AI governance and risk management		
Costs	Customers	Customers may have less access to beneficial AI-based applications until undertakings develop adequate and proportionate AI governance and risk management measures, but the impact is expected to be limited given the high-level nature of the Opinion and the fact that undertakings already have to comply with existing insurance legislation.
	Industry	Undertakings may not immediately benefit from the opportunities offered by AI systems until they develop appropriate and proportionate governance measures, which

		could potentially affect their competitiveness or increase their compliance costs, but the impact is expected to be limited given the high-level nature of the Opinion and the fact that undertakings already have to comply with existing insurance legislation.
	Supervisors	Some potential costs are envisaged to adequately train staff on AI governance and risk management and develop new supervisory activities related to the use of AI systems by undertakings following a risk-based and proportionate approach, but the impact is expected to be limited given the high-level nature of the Opinion and the fact that supervisors already supervise the compliance of existing insurance legislation and therefore they already have teams capable of overseeing data, supply chain and model risks which are inherent to AI systems
	Other	N/A
Benefits	Customers	Customers will have access to an insurance sector that uses more ethical and trustworthy AI systems. This can be particularly relevant for customers from certain groups or backgrounds which may be more prone to suffer from biased or unfair AI systems. Improved trust in well-regulated sector can support acceleration in innovation in view of customer-centric products and services and financial inclusion.
	Industry	Greater clarity about the supervisory expectations regarding AI governance and risk management, including regarding proportionate and risk-based considerations, will improve compliance and could reduce costs with regards to legal obligations and encourage investments on AI systems. A common supervisory approach to AI governance and risk management will also promote a level playing field in the European market.
	Supervisors	Compliance by the industry with the provisions of the Opinion will reduce the number of situations where supervisory intervention is required to ensure the correct application of the legislative framework.
	Other	N/A
Option 1.2: No Action		

Costs	Customers	Some AI systems placed in the market may not follow adequate and proportionate governance and risk management measures, which entails risks, both for consumers as well as for the financial soundness of undertakings. There could thereby also be reduced trust in the insurance sector, cooling innovation and its potential to support financial inclusion.
	Industry	Lack of legal clarity could disincentive investments on AI systems. Costs might arise from unclear supervisory expectations and different approaches in different EU Member States. Potential level playing field issues between entities of different jurisdictions.
	Supervisors	Additional costs may arise from the need to enforce supervisory actions to ensure compliance with legislative framework. Furthermore, supervisors may have questions about how to apply existing legislation to AI systems used by undertakings.
	Other	N/A
Benefits	Customers	No material impact as the status quo would be maintained
	Industry	No material impact as the status quo would be maintained
	Supervisors	No material impact as the status quo would be maintained
	Other	No material impact as the status quo would be maintained
Policy issue 2: Approach		
Option 2.1: Develop an Opinion providing high level guidance based on existing legislation		
Costs	Customers	High level measures may not be sufficiently detailed for some AI use cases or issues, which could potentially result in AI systems being placed in the market without sufficiently appropriate and proportionate governance measures.
	Industry	Some additional costs may be needed to develop adequate and proportionate AI governance and risk management measures. The lack of legal clarity with regards to specific governance measures for specific AI use cases or issues could disincentive investments on such AI systems and give rise to level-playing field issues.

	Supervisors	Some potential costs are envisaged to adequately train staff on AI governance and risk management and develop new supervisory activities.
	Other	N/A
Benefits	Customers	High level measures would ensure that AI systems placed in the market, regardless of the AI use case at hand, are supported by adequate and proportionate AI governance and risk management measures.
	Industry	The high-level approach would leave greater flexibility and less prescriptiveness to implement the changes proposed, allowing undertakings to adapt the governance measures to their business model and their respective uses of AI systems.
	Supervisors	Less stringent requirements will allow supervisors to tailor their supervisory activities to the needs of their respective market following a risk-based and proportionate approach.
	Other	
Option 2.2: Develop detailed guidance on specific use cases or issues		
Costs	Customers	Customers may have less access to beneficial AI-based applications until undertakings develop adequate and proportionate AI governance and risk management measures, which could be costly if the requirements are very detailed. Detailed guidance would need to follow a step-by-step approach, so the guidance for certain use cases may be delayed, which could entail consumer protection and prudential risks.
	Industry	Undertakings could incur significant compliance costs to implement detailed guidance, which could disincentivise investments on AI. Undertakings may not be able to benefit from the opportunities offered by AI systems until they develop adequate governance measures.
	Supervisors	Some potential costs are envisaged to adequately train staff on AI governance and risk management and to ensure compliance with new rules.
	Other	N/A
Benefits	Customers	The risks arising from those AI use cases or issues subject to detailed guidance would largely be mitigated.

	Industry	A level-playing would be guaranteed for those specific AI use cases or issues subject to the guidance. This could also incentivise investments on those AI use cases subject to the guidance.
	Supervisors	Compliance by the industry with the provisions of the detailed guidance would reduce the number of situations where supervisory intervention is required for those specific AI use cases or issues subject to the guidance.
	Other	N/A

6. COMPARISON OF THE DIFFERENT POLICY OPTIONS

POLICY ISSUE 1: NEED FOR POLICY ACTION

- The preferred policy option for this issue is option 1.1 Develop an Opinion on AI Governance and Risk Management

There is already evidence available at EIOPA about the use of AI systems in the insurance sector, in particular in non-life insurance lines of business. Market trends such as strong competitive pressure as well as advances in AI systems (e.g. Generative AI and Foundation Models) suggest that the adoption of AI systems is likely to increase in the coming years.

However, the lack of clarity concerning the supervisory expectations could disincentivise investments in AI systems. Indeed, costs could arise from unclear supervisory expectations or different approaches followed in different EU Member States. This could negatively impact both the industry and consumers, since they could be prevented from accessing AI systems that are beneficial for both of them.

The recently approved AI Act already enhances supervisory expectations, in particular for high-risk AI use cases such as pricing and risk assessment in life and health insurance. Taking this into account, it would also be beneficial to provide guidance on how existing sectoral legislation should be interpreted in the context of the use of AI systems in insurance, including by highlighting risk-based and proportionality considerations.

Moreover, without the clarification of supervisory expectations at European level, the industry faces the risk of developing non-homogenous AI governance and risk management practices, harming the goal of achieving a level playing field in the market. Furthermore, if AI governance and risk management guidance was introduced at a later stage, the industry could face significant costs resulting from the need to adapt their AI governance and risk management measures which may not necessarily be in line with the new rules.

A supervisory action is also justified so as to clarify the questions that the supervisory community could have regarding the application to existing insurance legislation when undertakings use AI systems. This would also help promote supervisory convergence at European level. Furthermore, without the clarification of the regulatory framework supervisors could face additional costs from the need to enforce supervisory actions to ensure compliance with the legislative framework.

Providing further clarity about how sectoral legislation should be interpreted in the context of AI systems would also be beneficial from a consumer protection perspective, including the protection vulnerable consumers, since indeed existing legislation was approved without developments such as AI systems in mind.

POLICY ISSUE 2: APPROACH

The preferred policy option for this policy issue is option 2.1: Development of an Opinion providing high level guidance based on existing legislation.

Given that there is already a legislative framework in place that covers the use of AI systems by insurance undertakings, the Opinion focuses on explaining supervisory expectations with regards to the interpretation of this legislative framework in the context of AI systems. To avoid regulatory complexities and overlaps, the scope of the Opinion does not cover those AI systems that are considered as prohibited practices and high risk AI systems under the AI Act, and it is aligned with the high-level principles underlying the AI Act and other international initiatives in this area.

This approach would set a baseline for those AI systems in insurance; it is acknowledged that there are varying levels of risks amongst those AI use cases not prohibited or considered as high-risk under the AI Act. Therefore, the Opinion follows a risk-based and proportionate approach by stating that undertakings should assess the risks of different AI use cases and develop governance and risk management measures that are proportionate to such risks.

This approach would ensure that the AI systems placed in the market, regardless of the use case at hand, are supported by risk-based and proportionate AI governance and risk management measures. This would allow to mitigate the risks arising from AI systems while at the same time being a sufficiently flexible approach to adapt to market and technological developments over time. This approach also allows undertakings to adapt the AI governance and risk management measures to their business models and uses of AI systems.

Developing detailed guidance for all AI systems was not considered an appropriate option at this stage for different reasons, such as the fact that there is already legislation in place or the need to consider the specificities of certain AI use cases. From a proportionality perspective there is also a need to strike a balance between addressing the risks arising from AI systems and ensuring that stakeholders can leverage the benefits of AI systems.

Certain AI use cases or issues relating to AI systems could potentially benefit from more detailed guidance adapted to their specific characteristics. However, developing guidance for each and every

use case may not be practical, it would require extensive resources, and it would need to be progressively implemented over time. For this reason, it is preferred to develop a more general guidance at this stage. Subsequently, EIOPA can work on developing further guidance on specific AI use cases or issues, should the need arise.

7. MONITORING AND EVALUATION

EIOPA will continue working with competent authorities to facilitate a smooth implementation of applicable regulations to the use of AI in the insurance sector and support competent authorities in their supervisory work. Based on the proposed AI governance and risk management framework in the Opinion, EIOPA envisages to subsequently develop more detailed analysis on specific AI use cases or issues arising from the use of AI systems in insurance and provide further guidance, as relevant. EIOPA will also continue monitoring market developments via different tools in close collaboration with stakeholders.

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