

EIOPA-26/323

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Makis KERAVNOS,
President in-Office of the Economic and Financial
Affairs ECOFIN Council

Petra Hielkema
Chairperson

Maria Luís Albuquerque
Commissioner in charge of Financial services,
Financial Stability and Capital Markets Union

Aurore Lalucq
Chair of the Committee on Economic and
Monetary Affairs (ECON) European Parliament

Henna Virkkunen
Executive Vice-President for Tech Sovereignty,
Security and Democracy

Subject: AI Act and EU Insurance legislation proposal for clarifying application of the AI Act

Dear Mr. Keravnos, Commissioner Albuquerque, Ms. Lalucq, Executive-Vice-President Virkkunen,

EIOPA welcomes the objectives of Regulation (EU) 2024/1689 (Artificial Intelligence Act, “AI Act”), which lays down harmonised rules on artificial intelligence. EIOPA is actively engaged in supporting the European Commission’s work to ensure a coordinated and consistent implementation of the AI Act across the EU insurance sector, taking into account existing sectoral rules and their supervision, including through its role as observer in the EU AI Board’s Subgroup on Financial Services.

In the past months, EIOPA has cooperated closely with the European Commission by sharing information about the interplay between the AI Act and insurance legislation and actively participated as observer in the meetings of the AI Board’s Subgroup on Financial Services.

The objective of this letter and its Annex is to present a limited number of targeted suggestions for clarifying the AI Act aimed at ensuring that the objectives of the AI Act in the insurance sector are achieved without creating unnecessary burden for both insurance undertakings and the respective supervisors.

The principle of this letter and key points were agreed at the EIOPA Board of Supervisors meeting held on 24 March 2026.

First, EIOPA notes that for the insurance sector two main sets of requirements apply to supervised entities using AI systems: insurance sector legislation¹ and the AI Act. The implementation of the AI Act, which operates within an existing sectoral framework, may entail managing areas of overlap and reconciling different but complementary objectives, in particular those related to the protection of fundamental rights under the AI Act and the prudential and consumer protection objectives stemming from sectoral legislation.

The importance of ensuring a coherent supervision of the AI Act and relevant Union insurance legislation is also reflected in Article 74(6) of the AI Act, which provide that the relevant national authorities responsible for the financial supervision shall be designated as market surveillance authorities (MSAs), as regards high-risk AI systems provided or used by regulated and supervised financial institutions. Moreover, since this special rule specifically pertains to high-risk use cases, Member States may decide to extend the designation of financial supervisors to other AI systems placed on the market, put into service or used by regulated financial institutions based on the general rule pursuant to Article 70(1)².

At the same time, if Member States decide to designate another authority as a MSA for AI systems provided or used by financial institutions, effective coordination between all authorities involved—taking into account differing levels of institutional complexity at national level — will be essential in governing the interplay between the AI Act and sectoral legislation

Acknowledging the valuable work being conducted by the Commission in this area, EIOPA stands ready to continue providing support to the Commission in the development of guidelines on *the interplay between the AI Act and the Union legislation on financial services*³, ensuring greater clarity in the articulation between the two regulatory frameworks.

Scope of application of the definition of AI system and AI High-Risk Use Cases according to Article 6 and Annex III of the AI Act

Article 6(2) of the AI Act provides that AI systems referred to in Annex III are deemed to be high-risk AI systems. Among the systems listed in Annex III, those relating to access to and enjoyment of essential private services and essential public services and benefits include AI systems intended to be used for risk assessment and pricing in relation to natural persons in the case of life and health insurance. These AI systems are therefore classified as high-risk use cases.

A key issue for market participants, in particular insurance undertakings using AI for risk assessment and pricing in life and health insurance, is to determine which techniques fall within the definition of an AI system⁴ and which do not, as well as which techniques qualify as ‘high-risk’ under the AI Act.

¹ The European insurance sector legislation includes *inter alia*: Directive 2009/138/EC (Solvency II Directive), Directive (EU) 2016/97 (Insurance Distribution Directive) and Regulation (EU) 2022/2554 (Digital Operational Resilience Act – DORA)

² European Commission services note on the *Designation of market surveillance authorities according to Article 74(6) and (7) of the AI Act and corresponding supervision of high-risk AI systems, October 15th, 2025*.

³ These guidelines are planned to be issued by the AI Office according to Article 96(1) point (e) of the AI Act. In support of this work, EIOPA provided on 20 November 2025 a contribution on the interplay between the insurance legislation and the AI Act.

⁴ Article 3(1) of the AI Act defines ‘AI system’ as a machine-based system that is designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment, and that, for explicit or

Further clarification on the scope of application of the AI Act would be appropriate. Particularly by expressly excluding generalised linear models (GLMs), for instance linear or logistic regressions, from the scope of the AI Act's definition of an AI system, or at least from the scope of high-risk AI systems, when used for risk assessment and pricing in life and health insurance, given their high degree of explainability and transparency. As suggested by the European Central Bank⁵, such a clarification could be reflected in the AI Act, and/or the Commission Guidelines on the definition of an artificial intelligence system established by Regulation (EU) 2024/1689.

The use of GLMs, including linear and logistic regression, as well as generalised additive models (GAMs), has been widely established in the insurance industry since at least the 1980s, particularly in the context of risk assessment and pricing. While most prominent in non-life insurance, such models are also used in life and health insurance alongside other actuarial techniques.⁶

Both undertakings and insurance supervisors have extensive experience with these models and a sound understanding of the associated risks, including those relating to the protection of consumers.

The operation of these models is generally based on a limited and stable set of parameters whose influence on outcomes can be directly interpreted and assessed using well-established statistical methods. As a result, these models are generally transparent and interpretable, and do not in themselves exhibit the 'black-box' characteristics that underpin the AI Act's enhanced governance and risk-mitigation requirements, which are primarily designed to address the challenges posed by complex, non-linear, self-learning systems, for which more specific governance concerns need taking into account.

In addition, such models are typically deterministic for a given set of inputs and parameters and are embedded within established actuarial governance frameworks, including human oversight, validation, and model control processes.

In this context, and in line with the criteria set out in Article 7(2) of the AI Act, which guide the assessment of whether AI systems pose a significant risk of harm to the health, safety or fundamental rights of natural persons, further elements support the exclusion of GLMs and GAMs from the category of high-risk AI systems. In particular, these models are not autonomous, as they operate strictly according to predefined instructions and require human intervention for retraining and any material modification in accordance with Article 7(2), point (d) of the AI Act. Moreover, their outcomes are generally easily corrigible or reversible in accordance with Article 7(2), point (i). Finally, EIOPA and its members have no evidence to date that the use of such models has led to significant adverse effects on fundamental rights Article 7(2), point(e).

The inclusion of generalised linear models, including linear and logistic regression and generalised additive models, both within the scope of the AI Act and high-risk AI systems would not materially reduce the risks associated with these models, which as explained are already well understood and supervised in the insurance sector. Such inclusion would rather create

implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments.

⁵ See European Central Bank Opinion of 13 March 2026 on a proposal for a regulation as regards the simplification of the implementation of harmonised rules on artificial intelligence (CON/2026/10)

⁶ See for example: Haberman, Steven & Renshaw, Arthur. (1996). Generalized Linear Models and Actuarial Science. *The Statistician*. 45. 407. 10.2307/2988543.

unnecessary compliance burdens for both insurance undertakings and supervisors, without bringing added value to consumers' protection.

At the same time, even if such models were excluded from high-risk classification of the AI Act, existing prudential, consumer and data protection rules would continue to apply.

Requiring a focus on these well understood models would also risk drawing finite resources away from assessing more novel, and potentially riskier or less well understood, applications of AI in life and health insurance risk assessment and pricing. Moreover, treating those algorithms equally to more complex and novel modelling methods used for risk assessment and pricing in relation to natural persons (in the case of life and health insurance) would be in contrast with the stated simplification objectives of the proposed Digital Omnibus.

Attached to this letter are a limited number of possible amendments to the Digital Omnibus on AI⁷ aimed at improving the legislative text along these lines. We believe that these amendments would be in line with the proposal's introduction of targeted simplification measures to ensure timely, smooth, and proportionate implementation of the AI Act's provisions.

EIOPA and the European insurance supervisory community remain fully committed to supporting a regulatory framework that enables the safe and responsible use of artificial intelligence, while maintaining a proportionate, risk-based, and innovation-friendly approach aligned with the Union's broader financial services acquis.

Yours sincerely,

[signed]

Petra Hielkema

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⁷ Proposal for a Regulation amending Regulations (EU) 2024/1689 and (EU) 2018/1139 as regards the simplification of the implementation of harmonised rules on artificial intelligence (Digital Omnibus on AI)

Annex - Drafting proposals in relation to the proposed amendments to Regulation (EU) 2024/1689 (the AI Act)

Text proposed by the Commission	Amendments proposed by EIOPA ⁸
Amendment 1 Article 1, point (28a), of the proposed regulation (Digital Omnibus on AI) (Article 96 of the AI Act)	
No text ‘	<p>(28a) in Article 96, the following paragraph 3 is added:</p> <p>“The European Banking Authority, the European Securities and Markets Authority, and the European Insurance and Occupational Pensions Authority may provide input for the development of guidelines or guidance in relation to the application of this Regulation in the context of credit institutions, investment firms and insurance and reinsurance undertakings regulated by Union legal acts”.</p>
<p style="text-align: center;"><u>Explanation</u></p> <p><i>Insurance and reinsurance undertakings are subject to comprehensive governance, risk management and supervisory requirements under Union law, including Directive 2009/138/EC (Solvency II), Directive (EU) 2016/97 (Insurance Distribution Directive), and Regulation (EU) 2022/2554 (Digital Operational Resilience Act). These frameworks already address, in a sector-specific and operationally mature manner, many of the risks that the AI Act seeks to mitigate.</i></p> <p><i>In this context, and taking into account both the European Parliament resolution on the impact of artificial intelligence on the financial sector (2025/2056(INI)) and the objectives of the Digital Omnibus on AI⁹, enabling European Insurance and Occupational Pensions Authority, European Banking Authority and European Securities and Markets Authority (collectively, the ESAs) to contribute to the development of guidelines by the AI Office would significantly reduce the risk of duplication and regulatory overlap between the AI Act and existing sectoral frameworks, thereby supporting better regulation.</i></p> <p><i>The ESAs are uniquely positioned to identify overlaps, complementarities and potential inconsistencies between the AI Act requirements and existing financial services legislation. Their involvement would ensure a coherent, consistent and proportionate application of the regulatory framework. Moreover, the ESAs possess deep sector-specific expertise that would materially enhance the work of the AI Office.</i></p> <p><i>Finally, the structured involvement of the ESAs would support a proportionate, risk-based supervisory approach that duly recognises the maturity and effectiveness of the governance and control frameworks already implemented by financial entities, including regulated insurance undertakings</i></p>	

⁸ Bold in the body of the text indicates where EIOPA proposes inserting new text. Strikethrough in the body of the text indicates where EIOPA proposes deleting text.

⁹ Proposal for a Regulation amending Regulations (EU) 2024/1689 and (EU) 2018/1139 as regards the simplification of the implementation of harmonised rules on artificial intelligence (Digital Omnibus on AI)

<p>Amendment 2 Article 1, point (31b), of the proposed regulation (Digital Omnibus on AI) (Article 96 of the AI Act)</p>	
<p>No text ‘</p>	<p>‘(31a) In Annex III, paragraph 5 point (c) is replaced by the following:</p> <p>“(c) AI systems intended to be used for risk assessment and pricing in relation to natural persons in the case of life and health insurance, with the exception of AI systems relying solely on generalised linear models, including linear or logistic regression, and generalised additive models under human supervision”.</p>
<p><u>Explanation</u></p> <p><i>With regard to AI systems intended to be used for risk assessment and pricing in relation to natural persons in the case of life and health insurance that rely solely on linear or logistic regression or decision trees under human supervision, generalised linear models, including generalised additive models, are widely used by insurance and reinsurance undertakings and are inherently transparent and interpretable and do not raise the risks that justify the AI Act’s enhanced governance requirements</i></p> <p><i>See section “Scope of application of the definition of AI system and AI High-Risk Use Cases according to Article 6 and Annex III of the AI Act” of EIOPA’s letter.</i></p>	