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Mastering EU GPSR Compliance for Digital & AI Products - Webinar Report

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Executive Summary

This report summarizes the key insights from Nemko Digital's webinar on the EU's General Product Safety Regulation (GPSR), held on December 9, 2025. The session underscored the critical and immediate need for companies to address the GPSR, a "catch-all" regulation that is now in effect and applies to all consumer products with digital or AI components sold in the EU, regardless of their classification under the EU AI Act. The regulation introduces stringent new obligations, including comprehensive risk assessments, 10-year technical documentation, and lifecycle safety monitoring. Non-compliance carries severe penalties, including fines of up to 4% of global annual turnover and mandatory product removal from the market. The primary takeaway is that a documented, thorough risk assessment is the foundational and non-negotiable first step for any company to ensure compliance, de-risk market access, and uphold consumer trust in the digital age.

The Imperative of GPSR Compliance

On December 9, 2025, Nemko Digital hosted a crucial webinar to dissect the General Product Safety Regulation (GPSR), a pivotal piece of EU legislation that has significant implications for any company placing consumer products on the European market. The session, led by AI assurance experts Mónica Fernández Peñalver and Bas Overtoom, aimed to demystify the regulation, particularly its

impact on products with AI and digital components. The primary objective was to move beyond general awareness and provide attendees with a clear, actionable understanding of their compliance obligations, emphasizing that the GPSR is already in effect and being enforced.

The Main Theme: GPSR as a Comprehensive Safety Net

The central theme of the webinar was the positioning of the GPSR as a "catch-all regulation." The speakers repeatedly stressed that unlike the risk-based EU AI Act, the GPSR applies universally to all consumer products, including those with low-risk AI functionalities. A common and dangerous misconception that the webinar sought to dismantle is the belief that if a product is not classified as high-risk under the EU AI Act, it is exempt from AI-related safety obligations. The presenters made it clear that this is false; the GPSR serves as a foundational safety net, ensuring that even products outside the stringent scope of the AI Act are subject to rigorous safety assessments.

Key Discussions and Concepts Explained

The webinar methodically broke down the GPSR, contrasting it with its predecessor, the General Product Safety Directive (GPSD), and detailing its interaction with other major regulations.

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From Directive to Regulation: A Fundamental Shift

The transition from the GPSD to the GPSR marks a significant change in the EU's approach to product safety. The speakers highlighted the core differences to illustrate the increased gravity of the new framework.

Aspect	General Product Safety Directive (GPSD)	General Product Safety Regulation (GPSR)
Legal Force	Set general goals, allowing for varied implementation and enforcement across EU member states.	Applies directly and uniformly across all EU member states, ensuring consistent rules and standards.
Scope	Covered only consumer products not already regulated by other sector-specific laws.	Broadened to all consumer products, including those with existing sectoral legislation, and specifically addresses risks from digital, connected, and AI-enabled products.
Definition of Safety	Primarily focused on physical safety.	Expanded to include physical, mental, and social well-being, and explicitly incorporates risks related to the Internet of Things (IoT) and Artificial Intelligence (AI).

New Obligations for Economic Operators

Effective since December 2024, with market surveillance activities beginning in 2025, the GPSR introduces a suite of strengthened obligations for manufacturers, importers, and distributors. Non-compliance carries severe penalties, including fines of up to 4% of a company's global annual turnover and, critically, the mandatory removal of the product from the market.

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The core new obligations include:

- Comprehensive Technical Documentation: Maintaining detailed records for the product and its digital elements for up to 10 years.
- Thorough Risk Assessment: Conducting and documenting a risk analysis that covers physical, mental, AI, and cybersecurity risks.
- Lifecycle Monitoring: Implementing mechanisms for post-market monitoring to ensure products remain safe over time, including processes for updates and incident reporting.
- Cybersecurity and AI Safeguards: Ensuring cybersecurity features are in place to protect products from external threats and that AI functionalities have appropriate fail-safes and oversight.
- Significant Alteration Protocol: Recognizing that substantial software updates can be considered a "significant alteration," which may imply new liability and require a complete product reassessment.

The GPSR and EU AI Act: A Layered Approach

A significant portion of the webinar was dedicated to clarifying the interplay between the GPSR and the EU AI Act. The speakers presented a clear hierarchy of obligations, demonstrating that the two regulations are not mutually exclusive but work in tandem.

AI Risk Category (EU AI Act)	Combined Compliance Requirements
High-Risk AI	Must undergo the full EU AI Act conformity assessment AND meet all relevant GPSR requirements.
Limited-Risk AI	Must adhere to the EU AI Act's transparency requirements AND meet all relevant GPSR requirements.
Low-Risk AI	While having no specific obligations under the EU AI Act, these products MUST comply with all GPSR requirements if they are consumer products.

This layered model underscores the webinar's main takeaway: no AI-enabled consumer product is free from regulatory scrutiny. The GPSR ensures a baseline of safety and accountability for all.

A Framework for GPSR-Aligned Risk Assessment

To translate regulatory requirements into practice, Nemko Digital presented its structured approach to conducting a GPSR-aligned risk assessment for AI. This framework is built upon IBM's global AI Risk Atlas and organizes potential harms into 11 distinct categories:

1. Accuracy: Ensuring reliable and correct AI outputs.
2. Fairness: Preventing bias and ensuring equitable outcomes.
3. Robustness: Protecting AI systems from manipulation and attacks.
4. Privacy: Safeguarding personal data during AI processes.
5. Explainability: Making AI decisions transparent and understandable.
6. Misuse: Preventing harmful or deceptive applications of AI.
7. Alignment with Values: Ensuring AI aligns with ethical and societal norms.
8. Governance: Establishing clear oversight and documentation.
9. Intellectual Property: Protecting AI innovations and confidential data.
10. Legal Compliance: Adhering to regulations and avoiding legal issues.
11. Societal Impact: Minimizing broader harm to communities and the environment.

This comprehensive framework provides a systematic way for organizations to identify, analyze, and mitigate risks associated with their AI-enabled consumer products, forming the cornerstone of their GPSR compliance efforts.

Key Insights from the Q&A Session

The interactive Q&A session provided further clarity on practical compliance questions:

- On Integrating Assessments: Mónica Fernández confirmed that companies do not need to create a completely new risk assessment for GPSR. Instead, they

can and should expand their existing risk management processes (e.g., those for the Radio Equipment Directive) to incorporate the new requirements for AI and digital safety.
- On Risk Categorization vs. Risk Assessment: The speakers clarified the distinction between two key terms. Risk categorization is the process under the EU AI Act of classifying an AI system as high, limited, or low risk. Risk assessment, required by the GPSR, is the detailed process of identifying the specific safety risks a product poses and defining mitigation measures.
- On Human-in-the-Loop: The GPSR does not explicitly mandate human-in-the-loop as a universal requirement. However, if a company's own risk assessment identifies a risk that can only be mitigated through human oversight, then implementing such a measure becomes a necessary part of GPSR compliance.

Conclusion and Next Steps for Attendees

The webinar provided a clear and urgent call to action for all businesses involved in the consumer product lifecycle. The GPSR is not a future concern but a present-day reality. Its broad scope and significant penalties for non-compliance demand immediate attention.

The overall value for attendees was the transition from abstract regulatory awareness to a concrete understanding of the necessary steps for compliance. The key takeaway is that a comprehensive, documented risk assessment is the non-negotiable starting point for any AI-enabled consumer product being sold in the EU.

Potential next steps for attendees include:

1. Internal Review: Immediately review their product portfolio to identify all consumer products with digital or AI components.
2. Gap Analysis: Conduct a gap analysis of their existing risk management and technical documentation processes against the specific requirements of the GPSR.

3. Initiate Risk Assessment: Begin a formal, GPSR-aligned risk assessment for all in-scope products, leveraging established frameworks like the one presented.
4. Seek Expert Guidance: Engage with third-party experts like Nemko to validate their approach, ensure the completeness of their assessments, and de-risk their market access.

By taking these proactive steps, companies can not only ensure compliance and avoid severe penalties but also build greater trust with consumers by demonstrating a firm commitment to product safety in the digital age.