

Annotated agenda – Nordic-Baltic coordination network on regulatory issues (NOBAREG)

16. and 17. June 2025

Venue: Qubus Hotel, Skierniewicka 18,

Participants:

Denmark	Iceland	Norway
Estonia	Latvia	Sweden
Finland	Lithuania	Aaland Island

This annotated agenda combines agenda descriptions with brief summaries of discussions and agreed next steps, and is intended as both meeting documentation and a reference for future NoBaReg work”

Monday 16. June 2025	
Topics	Annotation
Deliverables	<p>In preparations for the meeting, 6 synopses for possible deliverables for NoBaReg were outlined and shared with the group. After a discussion on the different suggestions, the group decided on going forward with the following two:</p> <p>Mapping the Governance Landscape of EU Digital Regulation Boards</p> <p>Background:</p> <p>The implementation of major EU digital regulations involves various governance bodies, including national and European-level boards and committees. These entities—such as the European Data Innovation Board (EDIB), the AI Act governance board, and the Data Act supervisory authorities—often have overlapping mandates and responsibilities. However, the lack of clarity on their specific roles, decision-making processes, and areas of overlap complicates cross-border cooperation and regulatory alignment.</p> <p>Project Description:</p> <p>This project seeks to create a comprehensive registry and interactive map of governance boards involved in the implementation of EU digital regulations. The registry will identify each board’s mandate, membership, decision-making powers, and areas of jurisdiction. The interactive map will illustrate overlaps, synergies, and governance gaps, serving as a practical</p>

	<p>tool for national authorities, policymakers, and stakeholders to navigate the regulatory landscape more effectively.</p> <p>Expected Impact:</p> <p>By providing transparency and clarity on the roles and interconnections of governance boards, this project will enhance coordination, reduce redundancy, and support the effective implementation of EU digital regulations across Europe. It will also aid in identifying governance gaps that could be addressed through future legislative refinement or cross-border cooperation initiatives</p> <p>Navigating the Interplay of EU Digital Regulations</p> <p>Background:</p> <p>The evolving landscape of EU digital regulations—including the AI Act, Data Act, Open Data Directive, Data Governance Act, and the Interoperable Europe Act—introduces complexities in understanding how these frameworks intersect. Stakeholders often face challenges in deciphering overlapping obligations, conflicting requirements, and opportunities for synergies across these legal instruments. This lack of clarity can lead to fragmented implementation, legal uncertainty, and inefficiencies, especially for cross-border digital services.</p> <p>Project Description:</p> <p>This call for tender aims to develop a comprehensive mapping and analysis tool that visualizes the interplay between key EU digital regulations. The project will involve a legal and technical analysis of obligations, rights, and governance structures across the different acts. The output should be an interactive, user-friendly platform that highlights points of overlap, conflict, and complementarity. In addition, the tool should offer scenario-based guidance for public sector bodies and private organizations to streamline their compliance efforts while maximizing interoperability and data flow across borders.</p> <p>Expected Impact:</p> <p>By clarifying the interdependencies and overlapping requirements of major EU digital regulations, this project will support smoother, more aligned implementation both in the Nordic-Baltic region and across Europe. It will also provide policymakers and implementers with a clear reference to reduce legal uncertainty, optimize regulatory compliance, and enhance cooperation.</p> <p>As the next steps, the PO and PL will revise as agreed upon and take the tenders forward considering the framework and formalities that steer these processes within the Danish Agency for Digitalisation.</p>
SEMIC2025	<p>Two concept notes had been shared with the national organisers of the SEMIC2025 conference, and during the meeting, NoBaReg and the organisers decided on both topics and possible participation and choreography.</p> <p>The PO and PL will keep the dialogue with the EC and the national organisers of the conference.</p>

Harmonised standards	<p>The starting point for this session, is that NoBaReg recognise that harmonised standards are used in EU-legislation, and that we see that this has some democratic challenges as, well las to the implementation and governance of the legislations.</p> <p><u>Definition of a harmonised standard:</u></p> <p>«A harmonised standard is a European standard developed by a recognised European Standards Organisation: CEN, CENELEC, or ETSI. It is created following a request from the European Commission to one of these organisations. Manufacturers, other economic operators, or conformity assessment bodies can use harmonised standards to demonstrate that products, services, or processes comply with relevant EU legislation.</p> <p>The references of harmonised standards must be published in the Official Journal of the European Union (OJEU). The purpose of this website is to provide access to the latest lists of references of harmonised standards and other European standards published in the OJEU. »¹</p> <p><u>We recognise several challenges to harmonised standards as a legal instrument:</u></p> <ul style="list-style-type: none"> • A democratic process worthy a rule of law system as the EU? • Who writes? Who has the final say? De facto and legally? • A legislative loop? Lawyers/technical/lawmakers/ and back again in the interpretation loop? <p>Accessibility could also be a challenge, see e.g., ECJ Case C-588/21 P</p> <p>«(...) arising from the principles of the rule of law, transparency, openness and good governance, and justifying the disclosure of the requested harmonised standards, since those standards form part of EU law owing to their legal effects. »</p> <p>The sessions discussion was based on a very insightful presentation based on the work of Dr. Eleni Tzoulia, Aristotle University of Thessaloniki School of Law:</p> <p>Introduction: Standards and Their Role</p> <p>The presentation opened by introducing standards as technical or quality specifications that set norms within a given field. Standards may concern products, services, methods or processes, and can vary along several dimensions, including whether they are technical or qualitative, voluntary or mandatory, private or public, and national, European or international. While standards are often perceived as technical instruments, the presentation illustrated their pervasive role in everyday life and their growing relevance for the functioning of EU law.</p> <p>Key Actors and Types of Standards</p> <p>The presentation distinguished between different standard-setting environments and actors. These include private or industry-driven standards developed by consortia such as IEEE or W3C, national standards produced by national standardisation bodies, international standards adopted through organisations such as ISO or IEC, and European standards developed by the European Standardisation Organisations (CEN, CENELEC and ETSI). European standardisation operates under</p>
-----------------------------	---

¹ https://single-market-economy.ec.europa.eu/single-market/european-standards/harmonised-standards_en

Regulation (EU) No 1025/2012 and involves close cooperation between national bodies, industry representatives and EU institutions.

Harmonised Standards: Definition and Legal Context

Harmonised standards were presented as a specific category of European standards developed by the European Standardisation Organisations following a formal request from the European Commission. These standards are referenced in EU legislation and are designed to support the implementation of legal requirements laid down in binding acts. Examples highlighted in the presentation include references to harmonised standards in the AI Act, the Data Act, the Digital Markets Act and the Eco design framework.

The presentation situated harmonised standards within a broader legal framework that includes Regulation 1025/2012, Decision 768/2008/EC, Regulation 182/2011, the Commission's "Blue Guide", and the EU Standardisation Strategy. International obligations under the WTO Agreement on Technical Barriers to Trade were also noted as part of the background.

Rationale of the EU Standardisation System

A central theme of the presentation was the logic underpinning the EU's reliance on harmonised standards. EU legislation typically limits itself to defining essential requirements and policy objectives, such as safety, transparency or explainability, while leaving the development of detailed technical specifications to standardisation bodies. This approach supports uniform implementation across Member States, facilitates market integration, and allows technical expertise to be mobilised in rapidly evolving fields. The presentation noted that this model is particularly relevant for digital regulation, where interoperability and technical precision are critical.

The Harmonised Standard-Setting Process

The presentation outlined the standard-setting process in detail. It begins with a formal standardisation request from the European Commission, following consultations with Member States and stakeholders. The Commission designates the relevant European Standardisation Organisation and specifies the requirements and deadlines. Throughout the drafting process, the Commission is kept informed. Once a draft standard is completed, the Commission evaluates whether it complies with the original request. If so, the reference to the standard is published in the Official Journal of the European Union, triggering a presumption of conformity with the relevant EU legislation and the withdrawal of conflicting national standards.

The objection procedure was also described. Member States and the European Parliament may challenge a harmonised standard if it does not satisfy the requirements of EU law. The Commission may then decide to maintain, withdraw or revise the reference, potentially subject to a transitional period during which both old and revised standards coexist.

The Legal Nature of Harmonised Standards

	<p>The core analytical focus of the presentation concerned the legal nature of harmonised standards. The central question posed was whether harmonised standards should be understood as private documents or as part of EU law. The presentation set out arguments on both sides.</p> <p>On the one hand, harmonised standards are formally voluntary, developed by private legal entities, and do not replace legally binding requirements. Alternative means of demonstrating compliance remain possible, and European Standardisation Organisations operate as private actors subject to competition law. On the other hand, harmonised standards are developed based on a legal mandate, published in the Official Journal, and produce legal effects by conferring a presumption of conformity. The relationship between the Commission and the standardisation bodies is structured through mandate, monitoring, approval and funding.</p> <p>Judicial Treatment and Practical Implications</p> <p>The presentation highlighted relevant case law of the Court of Justice of the European Union, including <i>James Elliott</i>, <i>Stichting Rookpreventie Jeugd</i>, <i>Fra.bo</i> and <i>Public.Resource.Org</i>. These cases support the view that harmonised standards may be considered part of EU law for certain purposes and are subject to judicial scrutiny.</p> <p>The legal classification of harmonised standards was shown to have significant practical consequences, including for access to standards, copyright claims, accountability, judicial review, democratic legitimacy and legal certainty. These issues were presented as particularly important where compliance with harmonised standards is, in practice, indispensable for economic operators.</p> <p>Concluding Perspective</p> <p>In conclusion, the presentation suggested that harmonised standards cannot be fully captured by a simple public–private dichotomy. Instead, they may be understood as hybrid instruments that combine technical standardisation with legal effects under EU law. This raises broader questions about governance, transparency and control, especially as harmonised standards play an increasingly central role in implementing EU digital and data-related legislation.</p>
--	---

Tuesday 17. June 2025	
Topics	Annotation
Update on evaluation process on ODD, DGA and FFDR	<p>The European Commission is conducting a comprehensive evaluation of the Open Data Directive (2019), the Data Governance Act (2022) and the Free Flow of Non-Personal Data Regulation (2019), accompanied by an impact assessment to inform possible legislative revisions. The evaluation aims to assess the effectiveness, relevance and coherence of the three instruments, combining legal, economic and technical analysis. Key questions include whether the interventions have achieved their intended objectives, how they have made a practical difference for public authorities and data users, and whether they remain fit for purpose considering rapid technological and regulatory developments.</p>

	<p>National inputs form a central part of the evaluation process. In the Nordic-Baltic context, experiences point to uneven practical impact across the three instruments. The Open Data Directive is generally seen as a useful framework for structuring national discussions on data reuse, but in some countries, it has largely reinforced pre-existing practices rather than driving significant change. The implementation of high-value datasets has improved findability and usability of data, yet alignment issues remain, particularly between metadata standards such as ISO 19115 and DCAT, and between the ODD and sectoral legislation.</p> <p>The Data Governance Act has so far had limited operational uptake, especially regarding the reuse of protected data and the emergence of data intermediation services and data altruism organisations. Persistent uncertainty around the relationship between the DGA and the GDPR, as well as unclear incentives and enforcement expectations, appear to be key barriers. Similarly, the Free Flow of Non-Personal Data Regulation is widely perceived as having had minimal tangible effect, as many Member States had already removed data localisation requirements prior to its adoption.</p> <p>Across all three instruments, a recurring theme is the need for better alignment and simplification, clearer delineation of scope, and stronger coherence with related legislation such as the GDPR, the Data Act and upcoming digital initiatives. Coordination among Member States, including through forums such as NoBaReg, is seen as valuable for sharing experiences, identifying common challenges and conveying consistent messages to the Commission during the evaluation process.</p>
Digital sovereignty/ GDPR	<p>Digital sovereignty refers to a state's or region's ability to control and govern its own digital infrastructure, data, technologies, and digital policies without undue reliance on foreign powers or external entities. It involves ensuring that critical digital assets—such as cloud services, data storage, algorithms, and networks—are secure, transparent, and aligned with local laws and values.</p> <p>In the European context, digital sovereignty is closely linked to the EU's ambition to reduce dependence on non-European tech providers and to safeguard citizens' rights, economic competitiveness, and democratic institutions in the digital realm. It includes regulatory initiatives like the GDPR, AI Act, and the Interoperable Europe Act, which aim to shape a trustworthy digital environment grounded in European principles.</p> <p>Achieving digital sovereignty does not imply isolation, but rather the strategic capacity to make autonomous choices about digital tools, platforms, and standards, while remaining open to international collaboration on fair and secure terms.</p> <p>We expect an adjustment/review of the GDPR in the not-so-distant future, and we have already seen some suggested changes in Omnibus package nr. 4. While these are quite limited in impact, NoBaReg sees an opportunity to start a dialogue to explore the</p>

	<p>possibility to perhaps coordinate and at least discuss based on set commonalities in the Nordic-Baltics.</p> <ul style="list-style-type: none"> • What are the main obstacles from the regulation so far? • What are the most positive outcomes of the GDPR? • How does the GDPR facilitate innovation and growth in Europe? • How is GDPR interplaying with other EU-legislation?
CADA/EDUS	<p>The Cloud and AI Development Act (CADA) and the European Data Union Strategy (EDUS) represent two closely linked, forward-looking initiatives that aim to strengthen Europe's capacity for data-driven innovation, artificial intelligence and digital sovereignty. CADA is expected to be proposed as a legal act in early 2026, following a public consultation in 2025, and will focus on cloud capacity, compute infrastructure and the development of AI capabilities within the EU. It is intended to provide a legal basis for public procurement, mandate the establishment of private AI "gigafactories", and support a broader strategy for compute capacity, including data centres.</p> <p>Discussions around CADA highlight the need to balance increased European digital autonomy with competitiveness and productivity. While there is broad recognition that the EU must invest more in cloud and compute capacity, there is scepticism towards heavy-handed regulation or direct subsidies. Instead, emphasis is placed on addressing vendor lock-in, service bundling and switching barriers, building on existing rules in the Free Flow of Data Regulation and the Data Act. The concept of "sovereign cloud" remains contested and is widely seen as requiring a clearer definition. Environmental sustainability is also a recurring concern, with calls for CADA to support the green transition through energy-efficient and low-latency solutions that combine edge and cloud computing.</p> <p>The European Data Union Strategy, expected to be launched in late 2025, complements CADA by focusing on improving the availability, quality and usability of data for AI and other data-driven applications. Central objectives include simplifying and aligning the EU data regulatory framework, ensuring legal clarity for data sharing, and maintaining strong data protection while enabling innovation. The strategy places particular emphasis on high-quality data, interoperability, and the role of digital tools such as digital identity wallets, business wallets and digital product passports. It also addresses international data flows, recognising the need for Europe to remain open while safeguarding core values and interests.</p> <p>Together, CADA and EDUS signal a shift towards a more strategic, integrated EU approach to data, cloud and AI, with significant implications for public administrations, cross-border cooperation and future regulatory alignment.</p>