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Akin Intelligence



Nov-Dec 2024

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Welcome to the November-December edition of Akin Intelligence. As the end of 2024 approached, the European Union (EU) sustained progress on guidance and supporting materials for its AI Act and international AI Safety Institutes solidified their commitment to cooperation. Enforcement actions continued elsewhere, including the FTC's efforts to combat deceptive and misleading AI companies.

To ensure continued receipt, please subscribe to future issues [here](#) if you have not already done so. For past issues and other AI content, check out Akin's [AI & ML Insights](#) and [AI Law & Regulation Tracker](#).

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Akin Spotlight



BIS Issues New Framework for AI Diffusion

On January 13, 2025, the Bureau of Industry and Security (BIS) published a [Framework for Artificial Intelligence Diffusion](#) that revises the Export Administration Regulations' (EAR) controls on advanced computing integrated circuits (ICs) and adds a new control on artificial intelligence (AI) model weights for certain advanced closed-weight AI models. This framework seeks to control the spread of advanced AI technology in a manner that promotes its potential economic and social benefits, while also protecting U.S. national security and foreign policy interests. The rule requires compliance starting 120 days after the rule is published in the Federal Register—which is expected on January 15, setting a May 15, 2025 compliance date.

[Click here to read the full summary.](#)

Federal Action

Commerce and State Launch International Network of AISIs

On November 20, 2024, the Departments of Commerce and State [co-hosted](#) the inaugural meeting of the International Network of AI Safety Institutes (AISIs). The United States will serve as the inaugural chair, and the other initial members include Australia, Canada, the European Union, France, Japan, Kenya, South Korea, Singapore and the United Kingdom. The convening is structured as a technical working meeting to address three topics: managing risks from synthetic content, testing foundation models and conducting risk assessments for advanced AI systems.

BIS Announces New Semiconductor Manufacturing Equipment Rule

On December 2, 2024, the U.S. Department of Commerce, Bureau of Industry and Security (BIS) announced an [interim final rule](#) that significantly revises controls on advanced computing and semiconductor manufacturing items (the SME Rule). The SME Rule is highly complex and intended to inhibit China's ability to develop an indigenous semiconductor ecosystem, including capabilities to manufacture advanced semiconductors, and to slow the PRC's development of advanced AI. The SME Rule clarifies, *inter alia*, export restrictions applicable to software license keys. It states that software license keys, which allow users to use software or hardware that is "locked" and unusable without a license key, are classified and controlled under the same Export Control Classification Number as the corresponding software to which they provide access—or in the case of hardware, the corresponding software group. Another key aspect of the SME Rule is its addition of new controls and a corresponding license exception for high bandwidth memory (HBM), which is found in most advanced semiconductors that power advanced AI models. These controls will impact both HBM stacks and semiconductors that contain HBM stacks. BIS notes that "[a]ll HBM stacks currently in production" exceed the memory bandwidth density threshold specified in the new rule.

USAISI Establishes Task Force to Test AI Models

On November 20, 2024, the U.S. Artificial Intelligence Safety Institute (USAISI) at the Department of Commerce's National Institute of Standards and Technology (NIST) [announced](#) the formation of the Testing Risks of AI for National Security (TRAINS) Taskforce. This Taskforce will work to coordinate research and testing of advanced AI models across critical national security and public safety domains. The Taskforce is comprised of officials from the Departments of Defense, Energy, Homeland Security, and Health and Human Services.

NIST Releases Materials for ARIA Workshop

On November 7, 2024, NIST released information in preparation for a workshop kicking off its “Assessing Risks and Impacts of AI” (ARIA) program. The information included exercises allowing participants to help shape upcoming pilot projects for testing the reliability, safety, security and privacy of AI systems before being deployed. The workshop was held on November 12, 2024.

DHS Releases AI Deployment Framework

On November 14, 2024, the U.S. Department of Homeland Security (DHS) and its Artificial Intelligence Safety and Security Board (AISSB) published its *Roles and Responsibilities Framework for Artificial Intelligence in Critical Infrastructure*. The framework focuses on safeguarding America’s critical infrastructure, identifying AI-related risks and providing guidance to manage risks as AI systems are developed, accessed and integrated within larger systems. In summary, the framework:

- Identifies roles for AI safety in critical infrastructure: cloud and compute infrastructure providers, AI developers, critical infrastructure owners and operators, civil society and the public sector.
- Proposes voluntary responsibilities for those roles: responsible design, data governance, safe & secure deployment and ongoing monitoring.
- Offers technical and process improvements for AI safety and trustworthiness across 16 critical infrastructure sectors, including Communications, Energy and Public Health.

This framework seeks to further AI safety and security in critical infrastructure by harmonizing safety and security practices, improving the delivery of critical services, enhancing trust and transparency, protecting civil rights and liberties, and advanced AI safety and security research.

CDAO Announces Edge Data Integration Services Award

On December 3, 2024, The Department of Defense’s Chief Digital and Artificial Intelligence Office (CDAO) announced an award for a production agreement for edge data integration services, a data mesh solution that improves interoperability among legacy systems. The award was announced under CDAO’s Open Data and Applications Government-owned Interoperable Repositories, or Open DAGIR, multi-vendor ecosystem. The edge data integration services will provide an open government-owned data infrastructure that supports third-party data and applications via open Application Programming Interfaces.

Senators Ask GAO About AI Export Controls

On December 3, 2024, Senators Peter Welch and Ron Wyden sent a letter to the Government Accountability Office (GAO), focusing on the effectiveness of U.S. export controls on AI technologies with an emphasis on human rights risks. The letter requests the GAO to assess these controls, particularly their ability to prevent misuse by adversaries and foreign governments, such as using AI for surveillance and potential human rights abuses. The letter poses eight questions including the current scope of export controls, controls ensuring adherence to international humanitarian law (IHL) & international human rights obligations, and identifying legislative gaps that need to be addressed. The Senators stress the importance of balancing U.S. leadership in AI innovation with the mitigation of associated risks.



Sen. Welch Introduces Bill to Increase Transparency of AI Training Data

On November 21, 2024, Sen. Peter Welch (D-VT) introduced the Transparency and Responsibility for Artificial Intelligence Networks (TRAIN) Act ([S. 5379](#)), which seeks to protect copyright owners by allowing them to request information on training data from generative AI developers and deployers in order to determine if their copyrighted works were used in a model. The bill would create a new subpoena mechanism under the copyright statute and create a rebuttable presumption that works were copied for noncompliance with the subpoena. Several organizations in the creative community have voiced support for the bill, including the American Society of Composers, Authors and Publishers (ASCAP), Screen Actors Guild-American Federation of Television and Radio Artists (SAG-AFTRA) and Universal Music Group. The introduction of this bill follows a recent lawsuit brought by several major record labels alleging copyright infringement by AI music generator model owners Suno and Udio.

Health Care



FDA Digital Health Advisory Committee Addresses Generative AI

On November 20 & 21, 2024, the U.S. Food and Drug Administration (FDA) held its inaugural [Digital Health Advisory Committee meeting](#), which focused on whether and how generative AI should be regulated by the FDA. FDA and manufacturers discussed how generative AI-enabled medical devices pose unique challenges, including the adequacy of data sets used to test and evaluate AI once in the real world and the difficulty in providing FDA with a clear understanding of foundational models for devices that rely on generative AI. The agency has not yet cleared a medical device that uses generative AI but has authorized 950 AI/machine learning (ML)-enabled medical devices as of August 2024. The FDA noted that the agency may require special controls unique to generative AI-enabled devices, including requirements for post-market monitoring.

AdvaMed Releases AI White Paper

On November 11, 2024, AdvaMed, the world's largest medical technology association representing device, diagnostics and digital technology companies, released a [white paper](#) that reviews the current landscape of AI-based applications and products in the health care sector, and identifies steps to accelerate the use of AI in medical technologies. The trade association highlights two main types of tasks that AI is uniquely well suited to tackle: (1) identifying and analyzing patterns in patient charts that practitioners might miss; and (2) automating repetitive routine tasks. AI is being incorporated into a range of technologies in the health care sector, and AdvaMed's white paper focuses primarily on AI/ML-enabled medical devices, which are [regulated](#) by FDA. AdvaMed anticipates that the FDA will likely need to issue additional guidance to keep pace with development of AI models, including for adaptive models and approaches to mitigating bias. AdvaMed endorses FDA's use of "Predetermined Change Control Plans" (PCCPs), which permit manufacturers to outline approaches to future modifications as part of an initial submission, and states that PCCPs should evolve to allow for greater post-market modifications for adaptive algorithms. The trade association also calls for domestic and international harmonization of requirements,

including development of common AI standards to advance safe, secure and trustworthy use of AI.

NIH Develops AI Algorithm to Identify Potential Volunteers for Clinical Trials

On November 18, 2024, researchers from the National Institutes of Health (NIH) published a study on an algorithm that harnesses AI to help accelerate the process of matching potential volunteers for relevant clinical research trials. The algorithm, called TrialGPT, is intended to help clinicians navigate the vast range of clinical trials available to patients by identifying potential matches and providing a summary of how that person meets the criteria for study enrollment. The team of researchers used a large language model (LLM) to develop an innovative framework for TrialGPT and compared the algorithm to the results of three human clinicians who analyzed over 1,000 patient-criterion pairs. The team also conducted a pilot user study, where two human clinicians reviewed six anonymous patient summaries and matched them to potentially suitable clinical trials. When clinicians used TrialGPT as a starting point, they spent 40% less time screening patients and maintained the same level of accuracy. The research team was selected for the Director’s Challenge Innovation Award, which will allow the team to further assess the model’s performance and fairness in real-world clinical settings. The researchers “anticipate that this work could make clinical trial recruitment more effective and help reduce barriers to participation for populations underrepresented in clinical research.”

FDA Finalizes Guidance for AI-Enabled Medical Devices

On December 4, 2024, the Food and Drug Administration (FDA) issued final guidance to provide recommendations for predetermined change control plans (PCCPs) tailored to AI-enabled device software functions, applicable to De Novo, premarket approval (PMA), and premarket notification (510(k)) pathways. FDA recognizes that development of AI-enabled devices is an iterative process, and PCCPs are intended to allow developers to plan for modifications, while continuing to provide a reasonable assurance of safety and effectiveness. FDA’s guidance provides that a PCCP should include planned modifications; a methodology to develop, validate, and implement those modifications; and an assessment of an impact of those modifications. This guidance builds upon concepts for AI and machine learning that FDA initially introduced in 2019.

CMS Proposes Rules to Ensure AI Does Not Impede Equitable Access to Services

On December 10, 2024, the Centers for Medicare & Medicaid Services (CMS) proposed to require Medicare Advantage (MA) organizations that use AI to ensure that such use is equitable. Specifically, the regulation would require MA organizations to “ensure services are provided equitably irrespective of delivery method or origin, whether from human or automated systems.” The proposed regulation explicitly states that if AI or automated systems are used, they “must be used in a manner that preserves equitable access to MA services.” CMS noted that compliance with the proposal could include limiting the impact of biased data inputs in AI, implementing a process to regularly ensure AI use is non-discriminatory and not using outputs with a known discriminatory bias. MA organizations are already prohibited from discriminating against enrollees based on their health status, and CMS does not expect that this proposed regulation would impose new burdens on MA organizations.



FTC Charges AI-Enabled Review Platform to Protect Consumers

On November 6, 2024, the FTC charged that Sitejabber, a company offering an AI-enabled consumer review platform, deceived consumers by misrepresenting that ratings and reviews came from real customers, artificially inflating average ratings and review counts. A proposed order would prohibit Sitejabber from making such misrepresentations in the future. The FTC will publish a description of the agreement in the *Federal Register* soon, and it will then be subject to public comment.

FTC Continues Efforts Against Deceptive AI Practices

On November 26, 2024, the FTC announced a sixth action under its Operation AI Comply initiative targeting AI-related fraud and deception. The FTC alleged that Evolv Technologies deceptively advertised that its AI-powered security screening scanners would detect all weapons without misidentifying personal items. Evolv also allegedly made misleading claims about the accuracy and efficiency of its AI systems compared to traditional metal detectors. The FTC and Evolv reached a proposed settlement, which would allow K-12 school customers to opt out of their contracts with Evolv and would prohibit Evolv from misrepresenting the abilities of its AI system to distinguish between weapons and benign items, accuracy, speed and other similar information.

State Action

Massachusetts

Massachusetts Economic Development Bill to Strengthen AI

On November 20, 2024, Gov. Maura Healey (D-MA) signed the Mass Leads Act into law. The bill is intended to boost industries like applied AI and climate-tech as well as the general life science sector in the state. The support provided by the bill is intended to help businesses grow, emphasize workforce development, create jobs and support economic growth opportunities in the state. The Governor's office will begin implementing a \$500 million capital reauthorization of the state's Life Sciences Initiative over 10 years. Additional programs include: an expansion of a tax credit program intended to increase jobs and growth in the life sciences sector; an investment of \$400 million in climate-tech initiatives and a new tax incentive program to support climate-tech companies in the state; and \$100 million to create the Massachusetts AI Hub to increase innovation and attract AI talent to the state.

New Jersey

New Jersey Governor Releases Report from AI Task Force

On November 13, 2024, Gov. Phil Murphy (D-NJ) received the report from the state's AI Task Force, which was created in October 2023 to study the potential impacts of AI. The Task Force met with academic experts, consumer advocates and industry leaders to come to a list of recommendations for how to expand opportunities in AI. The following are some key takeaways from the Task Force's recommendations:

- Cross-sector collaboration is needed for AI to advance and grow within the state. Focus should go into areas like training programs and data accessibility.

- AI-specific training and education should be provided in schools and to the workforce. A range of education-related initiatives were recommended to promote AI literacy. Other initiatives include promoting AI-focused degree programs and providing free opportunities for individuals to learn about AI.
- Safeguards should be implemented to mitigate risks that persist as AI continues to advance.

EU and UK Updates



Overview of the EU AI Act's First Draft General-Purpose AI Code of Practice

On November 14, 2024, the European Union's AI Office unveiled the [first draft](#) of its General-Purpose AI Code of Practice. This landmark document is designed to assist developers of general-purpose AI models in complying with the upcoming EU AI Act, effective from August 2, 2025. This draft Code serves as a tool to help developers comply with their obligations under the EU AI Act, and addresses areas including transparency, copyright rules, risk identification, assessment and governance risk mitigation for systemic risks. Further drafts are expected over the next five months as the Working Groups continue discussions.

For more insights on the AI Code of Practice, check out our previous client alert published by Akin [here](#).

A key date of the EU AI Act is February 2, 2025, when the rules on prohibited AI systems (Art 5) and staff AI literacy (Art 4) will apply. Prohibitions include ban on placing on the EU market, putting into service or use of an AI system that is harmful, exploitative, uses subliminal techniques, remote real-time biometric systems, etc.

EU Comment Submissions on definition of 'AI System' and AI Act Article 5

The EU AI Office [accepted comments](#) from AI stakeholders regarding certain parts of the EU Artificial Intelligence Act (the "AI Act") through December 11, 2024. Specifically, the consultation sought commentary on the definition of an AI system under Article 3(1) and on the restrictions placed on some uses of AI systems under Article 5 of the AI Act. For additional information about key areas of interest and specific questions, please see Akin's writeup [here](#).

EuroHPC Selects First Sites for AI Factories in Europe

In September 2024, the European High Performance Computing Joint Undertaking ([EuroHPC](#)) [launched calls](#) for expressions of interest to select hosting entities for AI Factories, which will be "one-stop shops" across Europe for AI users, including start-ups, small and medium-sized enterprises (SMEs) and scientific researchers. On December 10, 2024, EuroHPC [announced](#) that the first seven locations had been selected to host AI Factories:

- Barcelona, Spain at the Barcelona Supercomputing Centre
- Bologna, Italy at CINECA - Bologna Tecnopolo
- Kajaani, Finland at CSC

- Bissen, Luxembourg at LuxProvide
- Linköping, Sweden at the University of Linköping
- Stuttgart, Germany at the University of Stuttgart
- Athens, Greece at GRNET

These first AI Factories will represent a €1.5 billion investment and are expected to boost European capabilities in AI by more than doubling the EuroHPC computing capacity. Expected to be deployed in 2025-2026, they will provide access to the substantial computing power required to develop AI models and systems.

Other Member States are invited to submit further proposals on AI Factories before the next cut-off date, February 1, 2025.

China Updates

Reference Guide on Artificial Intelligence Application Scenarios in the Health Sector

On November 14, 2024, the National Health Commission published a guide, which covers four major areas in health care: “AI +” medical service management, “AI +” primary public health services, “AI +” health industry development and “AI +” medical education and research. It outlines 13 categories and 84 specific scenarios in the above areas—and specifies basic concepts and application contexts—to facilitate the proactive development of innovative “AI +” applications within the health sector.

China’s First Contract Dispute Related to Virtual Anchor

In November 2024, a Suzhou local court ruled on a case involving a virtual avatar’s contract, marking the first of such cases in China. Shi signed a “Virtual Anchor Contract” with a Suzhou company, stipulating that Shi would use the “Cheng Huang” avatar (a virtual character mapped onto an actor) provided by the company to conduct live broadcasts on a designated platform, and the company would have management rights over the live broadcast account. Later in 2023, since Shi had not broadcast for three months, the company sued him in court. The court supported the company’s claim. This case sets a precedent for the judgment of virtual image reuse and the calculation of virtual image value.

Middle East Updates

Ruler of Abu Dhabi Chairs MGX’s 2024 Year-End Board Meeting

On December 20, 2024, the Ruler of Abu Dhabi (his Highness Sheikh Tahnoon bin Zayed Al Nahyan) chaired MGX’s final board meeting of the year, reiterating the United Arab Emirates (UAE)’s commitment to achieving leadership in the development and adoption of future technologies. MGX, a technology investment company aimed at accelerating the development and adoption of artificial intelligence (AI) in the UAE, was launched earlier this

year with a focus on AI infrastructure, semiconductors and AI-related technology. During the meeting, his Highness Sheikh Tahnoon acknowledged the UAE's commitment to advancing technological transformation by investing in AI infrastructure and advanced technology. Furthermore, his Highness Sheikh Tahnoon emphasized the importance of enhancing sustainability and competitiveness in this area and the UAE's focus on enabling entrepreneurs and emerging companies to advance their businesses in line with the UAE's digital transformation journey. Earlier in 2024, MGX participated as a significant investor in OpenAI's \$6.6 billion fund raising.

Akin Thought Leadership

[Live Now: Akin's Trump Executive Order Tracker](#) (January 20, 2025)

[USPTO Announces Artificial Intelligence Strategy](#) (January 16, 2025)

[BIS Issues New Framework for AI Diffusion](#) (January 14, 2025)

[CPPA Opens Public Comment Period for Proposed AI Regulations](#) (January 11, 2025)

[FDA Publishes a Wide Range of Guidances in the Final Days of the Biden Administration](#) (January 7, 2025)

[FDA's Idea Lab Seeks to Reimagine Device Use in the Home Through New Virtual Reality Prototype](#) (January 2, 2025)

[Post-Election Outlook | FCC Rules Under Scrutiny: Net Neutrality, Digital Discrimination, and Consumer Protections](#) (December 18, 2024)

[Post-Election Outlook | AI Regulation Under President-Elect Trump](#) (December 16, 2024)

[Lawmakers Advance AI Provisions in Must-Pass Defense Bill](#) (December 11, 2024)

[CFTC'S Year-End AI "Placeholder" Guidance](#) (December 9, 2024)

[EU AI Act Targeted Stakeholders Consultation on Prohibitions and Definition of AI Systems](#) (December 5, 2024)

[FDA Finalizes PCCP Guidance for AI-Enabled Medical Devices](#) (December 4, 2024)

[Post-Election Takeaways for TMT](#) (November 26, 2024)

[AdvaMed Releases AI White Paper](#) (November 25, 2024)

[Final Regulations Issued by Treasury Restrict US Investment in Chinese Tech Sector](#) (November 25, 2024)

[National Institutes of Health Develops AI Algorithm to Identify Potential Volunteers for Clinical Trials](#) (November 25, 2024)

[EU AI Act in Action: First Draft General-Purpose AI Code of Practice](#) (November 18, 2024)



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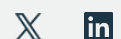


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