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Editor's Note

Developments

Victoria Prussen Spears*

As the title of this journal makes clear, we cover global regulatory developments. Take a look at what we have for you in this issue.

Online Safety

We begin with an article titled "UK's Online Safety Act: New Obligations for Digital Service Providers Targeting the United Kingdom," by Mark Booth, Steven Farmer, and Scott Morton, attorneys with Pillsbury Winthrop Shaw Pittman LLP.

In this article, the authors discuss the specific assessments that are required of certain digital service providers under the UK's Online Safety Act 2023.

Monetary Penalty

The article that follows, titled "UK's Office of Financial Sanctions Implementation Imposes Monetary Penalty Against Former Moscow Office of International Law Firm for Sanctions Breaches," is by Jasper Helder, Chiara Klaui, Ross Denton, Stefan Tsakanakis, Imogen Brooks, James Matson, Simi Malhi, Charlotte Ezaz, Oliver Haynes, and Adam Keay, attorneys with Akin Gump Strauss Hauer & Feld LLP.

In this article, the authors discuss a monetary penalty issued by the UK's Office of Financial Sanctions Implementation (OFSI) against the former Moscow office of an international law firm for six payments the OFSI determined were made in breach of the UK's sanctions against Russia.

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Public Procurement

Then, in the article titled "UK's Public Procurement Landscape Is Transformed: What Does It Mean for Medicines?," Jacqueline Mulryne and Heba Jalil, attorneys with Arnold & Porter Kaye Scholer LLP, set out some of the key aspects of the UK's new public procurement landscape.

Global Approaches

Joe Cahill, an associate in the Washington, DC, office of Baker Botts LLP, is the author of the next piece, titled "Navigating Global Approaches to Artificial Intelligence Regulation."

In this article, the author provides an overview of how artificial intelligence (AI) regulation is being approached in the European Union, the United States, and the United Kingdom.

The Clean Industrial Deal

Ross Ferguson, Annie Herdman, Nicole Kar, Henrik Morch, and Rich Pepper, attorneys with Paul, Weiss, Rifkind, Wharton & Garrison LLP, next discuss the European Commission's recently unveiled Clean Industrial Deal initiative. The title of their piece: "The Impact on Dealmakers of the European Commission's Clean Industrial Deal: Boosting Growth With Re-Industrialisation of the EU's Economy."

The EU AI Act

In the article titled "European Commission Provides Guidance on Scope of Artificial Intelligence Systems Under the EU's AI Act," John Patten and Edmund Berney, attorneys with Paul, Weiss, Rifkind, Wharton & Garrison LLP, review guidance released by the European Commission on the scope of AI systems under the EU's Artificial Intelligence Act for businesses developing or using AI tools, and they identify key practical takeaways.

AI and Anticompetitive Agreements

The next article, titled "Artificial Intelligence and Anticompetitive Agreements in EU Law," is by Anne Vallery, Itsiq Benizri, and Ioannis Dellis, attorneys with Wilmer Cutler Pickering Hale and Dorr LLP.

Here, the authors explore the role of AI in anticompetitive horizontal and vertical agreements under Article 101 of the Treaty on the Functioning of the European Union, as well as how AI could assist regulators in enforcing competition law rules.

Regulatory and Tax Issues

Jason R. Nelms, Edward M. Bennett, Joel D. Almquist, Anu L. Jose, and Charmaine Mok, lawyers with K&L Gates, are the authors of the article titled "Navigating U.S. Regulatory and Tax Issues: A Primer for Singapore Managers Marketing Private Funds in the United States."

In this article, the authors summarize the key U.S. regulatory and U.S. tax considerations when marketing fund interests to U.S. investors, including a comparison with the corresponding Singapore rules.

Mexico

Then, in the article titled "Mexico's Federal Executive Publishes the Secondary Legislation on Energy Matters," Gabriel Ruiz, Rodolfo Rueda, Carlos Ochoa, Gerardo Prado Hernandez, Antonio Barrera, Mariana Salinas, and Adrián Ortiz de Elguea, attorneys with Holland & Knight LLP, review a new decree essentially establishing a new framework for the energy sector in Mexico.

Enjoy the issue!

Note

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Meyerowitz Communications. Ms. Spears, who also is Editor of *The Journal of Robotics, Artificial Intelligence & Law*, *The Journal of Federal Agency Action,* and *The Global Trade Law Journal*, can be reached at vpspears@meyerowitz communications.com.

UK's Online Safety Act: New Obligations for Digital Service Providers Targeting the United Kingdom

Mark Booth, Steven Farmer, and Scott Morton*

In this article, the authors discuss the specific assessments that are required of certain digital service providers under the UK's Online Safety Act 2023.

The UK's Online Safety Act 2023 (OSA) is a comprehensive piece of legislation designed to regulate social media companies and search services and to increase protections for individuals online. It draws comparisons to the EU's Digital Services Act, with both laws including provisions relating to safety and transparency—seeking to balance the need to protect people online with fundamental rights such as the right to freedom of expression and privacy. Importantly, it applies not just to digital service providers in the United Kingdom but to any service with links to the United Kingdom.

One key area in which the OSA goes further is in relation to the obligations on service providers to undertake specific assessments in relation to their services. The first of these assessments (the illegal content risk assessment—discussed in more detail below) had to be completed by all in-scope services by March 16, 2025.

OSA—Who Is In Scope?

- *Services in Scope*. The OSA applies to providers of user-to-user (U2U) services and search services:
  - *U2U Services*. Internet services through which content that is generated, uploaded, or shared by other users may be encountered by other users of the service. This could cover social media platforms, photo or video sharing platforms, chat and instant messaging services, blogs, online games, online dating platforms, online

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marketplaces, etc., including where such services are available through a web browser or mobile application.
- *Search Services*. Internet services that consist of, or include, the functionality for users to search multiple websites or databases (including services through which a user could in principle search all websites or databases). This could cover conventional search engines, reverse image lookups, content aggregators that allow users to search through multiple databases, artificial intelligence (AI)–powered search engines, etc.

Certain services are then subject to additional obligations, such as U2U or search services that publish pornographic content or that meet certain threshold conditions, based on the number of UK users and certain features of the service (Categorised Services).

- *Content in Scope*. The OSA defines "content" as anything communicated by means of an internet service, whether publicly or privately, including written material or messages, oral communications, photographs, videos, visual images, music, and data of any description. The OSA envisages several different categories of content:
  - *Illegal Content*. Content that amounts to a relevant offense, that is, a priority offense (such as offenses related to terrorism or child sexual exploitation or abuse (CSEA)) or another, non-priority, offense (such as cyberflashing, content that encourages or assists with self-harm, or threatening communications).
  - *Content That Is Harmful to Children*. Content that may not amount to illegal content but should be hidden from children. This is further grouped into primary priority content that is harmful to children (such as pornographic, suicide, self-harm, or eating disorder content), priority content that is harmful to children (such as abuse, hate, bullying or violent content, or content that encourages the consumption of harmful substances or the undertaking of dangerous stunts or challenges), and non-designated harmful content that otherwise presents a material risk of significant harm to an appreciable number of children in the United Kingdom.

Categorised Services are also subject to obligations relating to additional content categories, such as fraudulent adverts, content of democratic importance, and content that adults may wish to avoid encountering on a service (e.g., abusive content or content that encourages suicide or self-harm).

- *Territorial Jurisdiction*. Given the cross-border nature of the internet, the OSA's territorial application extends beyond services based in the United Kingdom. The OSA applies to any service that "has links with the United Kingdom." This criteria will be met where:
  - The service has a significant number of UK users,
  - The United Kingdom forms one of the target markets for the service, or
  - The service is capable of being used in the United Kingdom and there are reasonable grounds to believe there is a material risk of significant harm to individuals in the United Kingdom presented by content on the service.

What Are the Main Assessment Duties?

1. *Illegal Content Risk Assessment*. The first assessment that must be undertaken is an illegal content risk assessment. This is designed to improve a service provider's understanding of how risks of different kinds of illegal harms could arise on the service and what safety measures should be implemented to protect users. Illegal content risk assessments must be of a "suitable and sufficient" standard. Ofcom (the UK regulatory body with responsibility for the OSA) has published guidance on how to carry out an illegal content risk assessment, which sets out a four-step process:
    a. Understand the kinds of illegal content that needs to be assessed;
    b. Assess the risk of harm;
    c. Decide measures, implement, and record; and
    d. Report, review, and update.

   All in-scope services had to complete an illegal content risk assessment by March 16, 2025.

2. *Children's Access Assessment*. In-scope services must also undertake a children's access assessment to understand to what extent the service is "likely to be accessed by children" (meaning anyone under the age of 18). Where the assessment determines that a service is likely to be accessed by children, this triggers additional child protection duties (which may not apply if the children's access assessment determines that the services is not likely to be accessed by children). Importantly, if a children's access assessment is not completed, the service will be subject to the additional child protection duties in any event. All in-scope service had to complete a children's access assessment by April 16, 2025.
3. *Children's Risk Assessment*. If a service is considered "likely to be accessed by children," then service providers must undertake a children's risk assessment, which is separate and in addition to the overarching illegal content risk assessment. The children's risk assessment must assess the risks that exist specifically in relation to children on the service, taking into account any measures the service already has in place to protect children. Ofcom is currently consulting on guidance relating to the children's risk assessment. Relevant service providers must complete a children's risk assessment by 24 July 2025.
4. *User Empowerment Risk Assessment*. Certain Categorised Services may also need to complete an adult user empowerment assessment, to understand its user base, the likelihood of adult users encountering specific content that they may wish to avoid, and the impact that the service (including its design and operation) may have in relation to adults encountering such content and the impact that this may have. Ofcom will publish more details on this once it has finalized the thresholds to determine which services will be Categorised Services under the OSA.

Records must be maintained of all assessments carried out, including the process followed and the findings. Failure to complete an assessment where required under the act is an automatic breach, which could result in enforcement action and a civil penalty of up to 10 percent of revenue or £18 million (whichever is greater).

Additional Obligations

A core focus of the OSA is on "systems and processes"—Ofcom will regulate the measures taken by service providers to mitigate the risks identified in their assessments, ensuring that these measures are proportionate, as opposed to regulating individual pieces of content appearing on the services.

Service providers will also be expected to have in place content reporting and complaints procedures, and clear and accessible terms of service that address specific areas identified in the OSA (e.g., specifying how individuals are to be protected from illegal content).

Next Steps

Companies operating U2U or search services should consider to what extent they may be subject to the OSA (e.g., by analyzing any links they may have to the United Kingdom).

Note

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UK's Office of Financial Sanctions Implementation Imposes Monetary Penalty Against Former Moscow Office of International Law Firm for Sanctions Breaches

Jasper Helder, Chiara Klaui, Ross Denton, Stefan Tsakanakis, Imogen Brooks, James Matson, Simi Malhi, Charlotte Ezaz, Oliver Haynes, and Adam Keay*

In this article, the authors discuss a monetary penalty issued by the UK's Office of Financial Sanctions Implementation against the former Moscow office of an international law firm for six payments the OFSI determined were made in breach of the UK's sanctions against Russia.

The UK's Office of Financial Sanctions Implementation (OFSI) has announced that, in accordance with Section 146 of the Policing and Crime Act 2017 (PACA), a monetary penalty of £465,000 had been imposed against UK-registered Herbert Smith Freehills CIS LLP Moscow (HSF Moscow) for six payments made in breach of the UK's Russia (Sanctions) (EU Exit) Regulations 2019 (the Russia Regulations).

According to its Penalty Notice,[1] OFSI maintained that no findings have been made against Herbert Smith Freehills LLP (HSF London), the parent firm of HSF Moscow. OFSI noted that since HSF London, on behalf of HSF Moscow, provided prompt and detailed disclosure relating to all breaches, a 50 percent reduction was made to the final penalty amount. Absent such disclosure, OFSI would have imposed a penalty of £930,000.

Between May 25 and 31, 2022, HSF Moscow made six payments to three designated persons (DPs), including Alfa Bank JSC (Group ID: 15017), PJSC Sovcombank (Group ID: 14200), and PJSC Sberbank (Group ID: 15076), in breach of the Russia Regulations. The collective value of these payments was £3,932,392.10, which related

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to annual audit fees, life insurance policies, employee redundancy, and the transfer of an existing lease agreement between HSF Moscow and a local firm in Russia.

On June 1, 2022, HSF London submitted a voluntary notification to OFSI, explaining that HSF Moscow had made a lease payment to the DP Alfa Bank JSC, in breach of the Russia Regulations. Following this disclosure, HSF London voluntarily submitted a further breach report on July 15, 2022, relating to five earlier payments. These payments were made to two other DPs, namely, PJSC Sovcombank and PJSC Sberbank, which HSF Moscow and HSF London identified after conducting an internal investigation, following the initial lease payment breach report.

During its investigation, OFSI assessed HSF Moscow's actions with reference to the May 2, 2024, version of its Financial sanctions enforcement and monetary penalties guidance (the Enforcement Guidance),[2] and identified that the breaches committed by HSF Moscow occurred due to:

1. Employees conducting inadequate due diligence and sanctions screening in respect of outbound payments.
2. Errors caused by the expeditious closure of HSF Moscow's Russian offices, which resulted in the failure to sufficiently account for K. sanctions requirements.

Furthermore, with reference to its Enforcement Guidance, OFSI's identified the following aggravating factors:

- HSF Moscow made funds available directly to DPs or their wholly owned subsidiaries. While most of the payments were of lower value, the cumulative total and their repeated nature was serious, and the total value significant. Six payments were made to various DPs over successive days (factors B and I of the Enforcement Guidance).
- The harm or risk of harm to the regime's objective. All payments, including a very high payment, were made directly to DPs at a time when attempts to elicit behavioral change from Russian DPs were a critical priority for the K. government (factor C of the Enforcement Guidance).
- OFSI does not consider there to have been any intent or actual knowledge when making the payments that HSF Moscow's actions would be in breach of the Russia

Regulations. However, while HSF Moscow had significant awareness of the sanctions risk, it failed to take reasonable care. For all payments, HSF Moscow had reasonable cause to suspect their actions would result in a breach of the Russia Regulations (factor D of the Enforcement Guidance).

- Despite HSF Moscow having systems and policies in place to prevent sanctions breaches, and possessing widespread awareness of sanctions risk, these proved ineffective and were not properly followed in relation to these specific payments (factor E of the Enforcement Guidance).
- A clear failure by HSF Moscow's most senior finance staff to conduct proper due diligence or understand the application of ownership and control in the Russia Regulations. HSF Moscow relied on an informal response from HSF London as their sole basis for concluding that sanctions did not apply to Sovcombank Life, far below what would be expected from the office of a law firm operating in Russia during the first half of 2022 (factor F of the Enforcement Guidance).

OFSI's Penalty Notice states the following actions were identified as mitigating factors:

- HSF London's initial disclosure to OFSI was made almost immediately after the lease payment breach was discovered by HSF Moscow and was followed by further voluntary reporting five days later. OFSI notes that all reporting by HSF London was voluntary, prompt, and contained significant detail. In addition, HSF London conducted its own investigations and cooperated fully. OFSI states that HSF London's proactive actions were considered mitigating factors in the case against HSF Moscow given that HSF London was acting on its behalf (factors J and K of the Guidance).
- The breaches were committed by HSF Moscow while in the process of closing down its operations within Russia. This was in support of K. policy objectives (factor C of the Guidance).

In the context of these aggravating and mitigating factors, OFSI assessed this case to be "serious," as opposed to "most serious." As the total value of the breaches amounted to £3,932,392.10, the statutory maximum penalty in this case would have been £1,966,196.05.[3] However, when considering all of the aggravating and mitigating factors, OFSI concluded that it was reasonable and proportionate to impose a penalty of £930,000, which was further reduced by 50 percent due to HSF London, on behalf of HSF Moscow, having provided prompt and detailed disclosure relating to all breaches.

UK Nexus?

The risk of being subject to penalty under UK sanctions is not one which applies to all persons and entities. Per Section 21 of the Sanctions and Anti-Money Laundering Act 2018 (SAMLA),[4] UK sanctions apply to:

- Conduct in the United Kingdom or its territorial sea;
- UK nationals, wherever located;[5] and
- Any entity or body incorporated or constituted under the law of any part of the United Kingdom, wherever located.

Accordingly, while companies established in the United Kingdom are always required to comply with UK sanctions, regardless of where their actions take place, a Russia-incorporated subsidiary of a UK-established parent will not per se be subject to UK sanctions. In the case of HSF Moscow, this company was established in the United Kingdom and, as a result, this brought HSF Moscow within scope of the UK sanctions regime.

The broad territorial scope of UK financial sanctions was also highlighted by OFSI's enforcement action against Tracerco Limited, a UK-established company and UAE-based subsidiary of Johnson Matthey, which involved two payments made by Tracerco Limited to a DP in breach of the Syria (EU Financial Sanctions) Regulations 2012. In accordance with the Penalty Notice,[6] OFSI noted that "[a]ll companies with a UK nexus, not just traditional financial institutions, must make sure they comply with the restrictions in place, and this is especially important when operating internationally" (Paragraph 13). Further, in its recent Financial Services Threat Assessment,[7] OFSI noted that it had observed across different types of transactions failures to identify the involvement of UK nationals or entities in transaction chains.

Compliance Lessons

Since January 21, 2019, OFSI has taken 12 enforcement actions in respect of UK financial sanctions. Key lessons, in particular from the HSF Moscow enforcement action, include the following:

- First, firms must "understand their exposure to sanctions risks and to take appropriate action to address them. Firms operating in higher risk environments should educate themselves fully on the risks (including by properly engaging with the Enforcement Guidance and seeking professional advice on their sanctions obligations if necessary). In particular, parent companies with subsidiaries in areas that pose a heightened sanctions risk (such as offices overseas) should ensure they are providing suitable advice and assurance." Notably, in its enforcement action against Wise Payments Limited,[8] OFSI considered Wise's systems and controls, specifically surrounding debit card payments, to be inappropriate. This factor increased the severity of the breach to moderately severe as it failed to prevent funds from being made available to a company owned or controlled by a DP.
- Second, "the need for adherence to sanctions policies and processes that a firm has in place. Firms are expected to follow all relevant sanctions screening and due diligence measures they have in place. This applies equally to all individuals, regardless of seniority. While OFSI usually considers the existence of appropriate sanctions policies and procedures mitigating, the failure to follow and comply with them may significantly undermine the weight given to this factor and be aggravating overall when considered against OFSI's expectations of a firm." The HSF Moscow case highlights that the mere existence of a dedicated compliance function is not sufficient and may not result in a lower penalty if the measures are not actually implemented by those responsible for carrying out the transactions. Accordingly, companies subject to K. sanctions jurisdiction should make sure that all relevant employees, in particular those responsible for approving payments or entering into business relationships with other parties, have obtained

sanctions compliance training and are aware of the risks of sanctions breaches.

- Third, "the need to fully consider ownership and control beyond just whether an entity is directly subject to sanctions. Failure to properly consider and identify clear ownership is viewed more poorly by OFSI than an incorrect but good faith assessment of control."

Regarding self-disclosure and co-operation, the following should be noted in particular:

- *Voluntary, Prompt, and Complete Disclosure*. Firms that proactively make a voluntary, prompt, and complete disclosure relating to sanctions breaches may obtain relief of up to 50 percent (30 percent for cases assessed as "most serious") of the final monetary penalty imposed. Case examples include:
  - HSF Moscow (received 50 percent discount);
  - Tracerco Limited (received 50 percent discount);
  - Raphaels Bank (received 50 percent discount);[9]
  - Standard Chartered Bank (received 30 percent discount; since this case was assessed as "most serious" only reductions of up to 30 percent are possible);[10]
  - Clear Junction (received 26.7 percent discount; while Clear Junction disclosed eight transactions, OFSI identified further transactions which Clear Junction had not notified).[11]
- *Co-operation*. Where a firm has not made a voluntary disclosure to be eligible for relief, their full co-operation with OFSI during the investigation process will be considered a mitigating factor.

In Summary

- OFSI issued a monetary penalty of £465,000 against HSF Moscow for six payments made in breach of the UK sanctions against Russia.
- OFSI stresses that companies must understand their exposure to sanctions risks and take appropriate action to address them. The mere existence of a dedicated compliance function is not sufficient and will not result in a lower

penalty if the measures are not actually implemented by those responsible for carrying out the transactions.

- Where a breach has been identified, a voluntary and complete disclosure should be submitted to OFSI without delay. Such cooperation and disclosure may significantly mitigate any final monetary penalty imposed.

Notes

* The authors are attorneys with Akin Gump Strauss Hauer & Feld LLP.

1. https://assets.publishing.service.gov.uk/media/67dae19a1a60f79643028472/200325_HSF_PENALTY_NOTICE.pdf?utm_content=&utm_medium=email&utm_name=&utm_source=govdelivery.

2. https://www.gov.uk/government/publications/financial-sanctions-enforcement-and-monetary-penalties-guidance.

3. See Section 146(3) (PACA).

4. https://www.legislation.gov.uk/ukpga/2018/13/section/21.

5. The term "UK national" includes any individual who is a British citizen, a British overseas' territories citizen, a British National (Overseas) or a British Overseas citizen; a person who under the British Nationality Act 1981 is a British subject; as well as a British protected person within the meaning of that Act. UK sanctions can also extend to certain British Overseas Territories.

6. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1086645/29.06.22_Tracerco_monetary_penaly_notice.pdf.

7. https://assets.publishing.service.gov.uk/media/67f3f2467ed82b90fcf5bffc/OFSI_Financial_Services_Threat_Assessment_Report.pdf.

8. https://assets.publishing.service.gov.uk/media/64ef17f5da84510014632423/Wise_Payments_Limited_Disclosure_Notice_31AUGUST23.pdf.

9. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/804117/190502_Raphaels_revised_notice.pdf.

10. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/876971/200331_-_SCB_Penalty_Report.pdf.

11. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1056043/Clear_Junction_Penalty_Report_21.02.22.pdf.

UK's Public Procurement Landscape Is Transformed: What Does It Mean for Medicines?

Jacqueline Mulryne and Heba Jalil*

In this article, the authors set out some of the key aspects of the UK's new public procurement landscape.

New rules have come into force in the United Kingdom transforming the public procurement landscape. The new regime aims to provide a simplified and flexible framework for contracting authorities when conducting procurement processes, including the purchase of medicinal products by the National Health Service (NHS). This article sets out some of the key aspects of the new regime.

Structure of New Regime

The Procurement Act 2023 consolidates the previous public procurement legislation into a single framework. This is intended to simplify the rules, as the previous regime was spread across multiple pieces of legislation, but was primarily based on the Public Contracts Regulation 2015 (PCR) that implemented the EU Regulation into UK law.

Nonetheless, the Act is not the only applicable legislation to public procurement by the NHS in the United Kingdom. The Provider Selection Regime[1] came into force on January 1, 2024, by way of regulations made under the Health and Care Act 2022. This created a new set of rules for arranging healthcare services in England, and it takes NHS healthcare services outside the scope of the Act. This does not, however, apply to the supply of products.

The legislation that made up the previous framework will remain relevant for any procurements started before February 24, 2024. In those cases, the procurement process and the resulting

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contract will be governed throughout their life cycle by the relevant legislation that was applicable when the process commenced. In addition, both the Act and the Provider Selection Regime do not apply in Scotland, as these are devolved matters where the pre-existing regime will remain in place.

Key Changes to Procurement Processes

A number of elements of the new public procurement processes have now changed. For tenderers, the changes are mainly procedural, including the framework for the tender process and the timelines, rather than fundamental changes to how the procurement will operate. Nevertheless, it is important to take note of the new procedures.

- *New Procedures*. The regime streamlines the different types of procurement processes, and there will now be two procedure types:
    1. The open procedure, and
    2. The competitive flexible procedure.

  The second is intended to cater for more complex procurements, granting authorities greater flexibility by allowing for negotiations, commercial dialogues, and variant tenders (on the condition that these flexible features are adequately described in the tender notice). While we expect that the open procedure will often be used to procure medicinal products, the flexibility of the competitive flexible procedure may be used for tenders for complex medicinal products and therapies where the NHS prefers to conduct a "therapeutic tender" and where the relevant "solutions" cannot easily be determined without first engaging with suppliers.
- *Transparency*. The new framework introduces two voluntary notices that authorities may publish:
    1. The "Planned Procurement Notice"[2] is designed to give as much advance information to the market as possible.
    2. The "Preliminary Market Engagement Notice"[3] is designed to tell the market about the intention to carry out market engagement.

Both of these notices will serve a similar role to the Prior Information Notices under the PCR. But the amendments show the government's heightened emphasis on transparency from the beginning of the procurement process. This will be particularly important for companies where the NHS chooses to use the competitive flexible procedure, as it will set out some of the intentions for the procedure.

In addition, contracting authorities will be obliged to provide assessment summaries to each supplier that submitted an assessed tender. These notices serve the same function as Award Decision Notices under the PCR.

- *Procurement Principles*. The overarching procurement principles have been reformulated. Previously, contracting authorities had to have regard to equal treatment, non-discrimination, transparency, and proportionality.

  Equal treatment has been retained as a procurement "objective" under the Act, now being rephrased as an obligation to "treat suppliers the same unless a difference between the suppliers justifies different treatment," which is terminology based on case law arising from the hepatitis C tender. Transparency and proportionality are no longer mentioned as explicit principles or objectives, but are arguably implicit in the new requirements of the Act and will still be relevant to authorities. For example, the new pre-tender notices show that transparency remains important.

  In addition, contracting authorities must have regard to the importance of the following:

  1. Delivering value for money;
  2. Maximizing public benefit;
  3. Sharing information for the purpose of allowing suppliers and others to understand the authority's procurement policies and decisions; and
  4. Acting, and being seen to act, with integrity.

- *Moving from Most Economically Advantageous Tender to Most Advantageous Tender*. Under the previous regime, the legislation required contracting authorities to choose the most economically advantageous tender. The Act removes the term "economically," requiring contract awards to be made to the "most advantageous tender."

Pricing will still be a highly relevant consideration under the new regime. However, as we set out above, the Act introduces new factors that contracting authorities must regard when assessing tenders. For example, a broad range of factors could be considered under the heading "maximising public benefit," so its inclusion arguably represents a shift in the emphasis away from price. However, in relation to medicinal products, we anticipate that price will still be the primary factor in determining the outcome of a tender.

- *Framework Agreements*. Framework agreements have been retained under the Act, although can now be for up to eight years, rather than four. Further, the new regime has an additional "open framework" procedure. Authorities can use this procedure to appoint new suppliers within the lifetime of the framework agreement. We know that the NHS is keen to admit companies to a tender throughout the lifetime of the framework agreement; for example, if a new product is launched or a generic company enters the market. The new regime makes this process easier and more transparent.
- *Expanded List of Exclusions*. The Act introduces new mandatory and discretionary grounds for exclusion from a tender process. Discretionary grounds have been expanded in areas such as poor performance, labour misconduct, and national security threats, which the UK government says will enable "contracting authorities to take tougher action on underperforming suppliers and suppliers who pose unacceptable risks." It is currently unclear how product shortages would be seen under the provisions.

  The effort to exclude and discourage underperforming suppliers can also be seen in the new requirement for contracting authorities to establish key performance indicators (KPIs) in respect of contracts valued over £5 million, and to publish annual contract performance notices, detailing the success of the contract against these KPIs.

Challenging a Tender

The deadlines to challenge public procurement decisions remain extremely tight. Under the PCR, the publication of an

Award Decision Notice would trigger a standstill period of 10 calendar days, during which time the contracting authority was not permitted to enter into the contract. Under the Act, the mandatory standstill period is a similar period of eight working days.

Where a challenge is brought within eight working days from the date of the Contract Award Notice, an automatic suspension is granted. The legal test for whether the court should lift an automatic suspension has changed under the Act. Previously, the test largely favored the contracting authorities, as claimants had to demonstrate that damages would not be an adequate remedy. While this is still a feature of the test, this is now one factor for the court to consider, instead of a reason to strike out a claim. It remains to be seen whether there will be any difference to the judicial approach when automatic suspensions under the new regime are challenged.

The overall time limit for commencing proceedings for a challenge remains 30 calendar days from the date on which the bidder knew or first ought to have known about the circumstances giving rise to the claim. It is important to remember that this period may begin to run before the publication of the Contract Award Notice or assessment summary. For example, if an issue comes to light in the preliminary market engagement notice before a tender is even submitted, the clock would start as soon as the supplier was aware or should have been aware of their potential cause of action.

In Summary

- The Procurement Act 2023, now in force, consolidates the previous public procurement legislation into a single framework and came into force.
- The new procedures give much more flexibility to authorities in how to run the tender. Authorities may take advantage of the competitive flexible procedure to negotiate and discuss tenders with suppliers, but can do so only within the scope of the tender notice. We are increasingly seeing more complex processes being used by the NHS.
- Potential bidders can expect more early market engagement from contracting authorities. Make sure you review pre-tender notices as they give important information about the proposed tender.
- Suppliers should familiarize themselves with the new exclusion grounds, and if any of those apply, should be

prepared to provide explanations and mitigations in their tenders. Similarly, suppliers should review the KPIs associated with any new contract, and be aware that their performance may be publicized in a contract performance notice. There is a focus on "underperformance," though it is currently unclear how product shortages would be seen under these provisions.

- Framework agreements can be longer, and allow for new suppliers to be added within the lifetime of the framework agreement. The NHS has already been seeking to include this flexibility in existing tenders.
- The deadlines to issue the claim form for a challenge are still very short (30 days from when the grounds arose), and it is important to be organized and prepare your evidence and contemporaneous notes throughout the tender process.
- Remember that the NHS may also publish clinical guidance alongside the tender, and this may be subject to separate challenge or procedures.

Notes

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1. https://www.england.nhs.uk/commissioning/how-commissioning-is-changing/nhs-provider-selection-regime/.

2. https://www.gov.uk/government/publications/procurement-act-2023-guidance-documents-define-phase/guidance-planned-procurement-notice-html.

3. https://www.gov.uk/government/publications/procurement-act-2023-guidance-documents-define-phase/guidance-preliminary-market-engagement-html.

Navigating Global Approaches to Artificial Intelligence Regulation

Joe Cahill*

In this article, the author provides an overview of how artificial intelligence regulation is being approached in the European Union, the United States, and the United Kingdom.

As artificial intelligence (AI) continues to advance at a rapid pace, countries around the world are formulating strategies to balance the benefits of generative AI with its potential risks. This article provides an overview of how AI regulation is being approached in the European Union, the United States, and the United Kingdom.

The AI Act

The European Union has taken a pioneering step by enacting the world's first comprehensive legal framework for AI regulation through its AI Act. This legislation, which entered into force in August 2024, adopts a risk-based approach that categorizes AI systems based on their potential to cause harm. Oversight is divided between national authorities and the European Commission's newly established AI Office, which faces the significant task of implementing codes of practice and technical standards. The European Union aims to set a global standard with this legislation, but effective implementation and enforcement remain challenging tasks ahead.

The United States

In contrast, the United States has adopted (so far) an incremental approach, with concerns about hindering innovation influencing both federal and state legislative efforts. Rather than introducing a comprehensive federal law similar to the EU's, U.S. lawmakers

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plan to incorporate AI-related provisions within various legislative initiatives across different committees. This strategy focuses on preventing harm while also prioritizing investment in AI research and development.

At the state level, various regulations are emerging, particularly around issues like deepfakes and consumer protection, leading to concerns about creating a confusing regulatory landscape and potentially stifling start-ups. In the absence of overarching federal legislation, reliance has shifted toward self-regulation and voluntary commitments, with federal agencies increasing scrutiny to prevent misuse and protect competition. Notably, the new administration means there is a higher likelihood of this regulatory landscape changing in the coming years.

The United Kingdom

The United Kingdom is concentrating on empowering regulators rather than enacting new laws, aiming to foster innovation in its growing AI sector.[1] Recognizing AI's potential to enhance economic growth and productivity, the UK government is strengthening the capabilities of existing regulatory bodies. Initiatives such as the newly launched Regulatory Innovation Office are designed to assist regulators in removing barriers to technology adoption. Industry leaders advocate for a more adaptive and collaborative regulatory approach, emphasizing the need for regulators to work closely with businesses and respond swiftly to technological advancements. This strategy reflects the belief that flexible regulation can effectively address the challenges posed by AI without impeding innovation.

Conclusion

In summary, while the European Union has established a comprehensive legal framework aiming to set a global benchmark, the United States is proceeding with caution, integrating AI considerations into existing legislative processes. The United Kingdom, on the other hand, is enhancing regulatory capacities to adapt to technological changes without imposing new laws that might hinder innovation. It is still the early innings of AI regulation and each regulatory landscape is likely to change as time passes and the technology continues to progress.

With no signs that the AI boom is slowing down, the world's attention has shifted to how countries will manage the risks of generative AI along with its rewards.

Notes

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1. https://www.gov.uk/government/consultations/ai-regulation-a-pro-innovation-approach-policy-proposals/outcome/a-pro-innovation-approach-to-ai-regulation-government-response.

The Impact on Dealmakers of the European Commission's Clean Industrial Deal: Boosting Growth with Re-Industrialisation of the EU's Economy

Ross Ferguson, Annie Herdman, Nicole Kar, Henrik Morch, and Rich Pepper*

In this article, the authors discuss the European Commission's recently unveiled Clean Industrial Deal initiative.

The European Commission has unveiled its flagship initiative to enhance the competitiveness of European industries—the Clean Industrial Deal.[1] The Commission's new agenda is defined as Europe's transformational business plan for a thriving new industrial ecosystem of growth and prosperity. It covers a wide range of measures and initiatives, including a number with potential impact on the antitrust treatment of agreements, transactions, and funding.

State Aid Rules

Clean Industrial State Aid Framework

The Commission will give EU member states further leeway under EU state aid rules to support renewable energy, to subsidise the greening of companies' manufacturing processes (including steel, cement, textiles, chemicals, and pharma) and to provide investment aid to ensure sufficient clean tech capacity in the European Union (notably in relation to battery manufacturing, sustainable materials production, and electric vehicles).

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Simplified State Aid Framework

These new aid measures will be included in a new simplified state aid framework to be adopted by June 2025, in particular to facilitate the roll out of innovative clean tech industrial investments and projects to accelerate decarbonisation and enhance economic security.

General Block Exemption Regulation Review

To facilitate the rollout of these support measures without prior approval by the Commission, a safe harbour will be established for some of these measures in a new General Block Exemption Regulation.

Important Projects of Common European Interest

The Commission will work with member states to speed up the launch of new Important Projects of Common European Interests, which facilitate large-scale state-backed investment across the European Union in areas of strategic significance and priority.

Competition Policy—Antitrust

Guidance on Antitrust Compatibility

The Commission will provide informal guidance to companies on the antitrust compatibility of cooperation projects contributing to the achievement of EU priorities under the Clean Industrial Deal.

Merger Guidelines—A New Approach to Competition Policy

The Commission will update its guidelines for evaluating mergers to better incorporate the effects of the merger on the affordability of sustainable products, clean innovation, and the creation of efficiencies that yield sustainable benefits. Additionally, the revised guidelines will consider the impact on innovation, resilience, and the investment intensity of competition in specific strategic sectors.

Foreign Subsidies Regulation Guidelines

The Commission will adopt Guidelines by January 2026 to clarify key concepts under the Foreign Subsidies Regulation (FSR), such as assessing the distortive effects of foreign subsidies. The Commission will also make use of FSR ex officio investigations in strategic sectors, and will offer guidance on the circumstances under which it may call in a below-threshold merger that poses a risk to the level playing field in the European Union.

Trade Defence Instruments

The Commission will make fast, efficient, and systematic use of trade defence instruments, such as anti-dumping or anti-subsidy duties, to protect EU industries from unfair competition and ensure that "the EU market does not serve as an export destination for state-induced excess global capacity." The communication flags that the increase of trade protectionist measures around the globe may make the European Union a target destination for global overcapacities

Resilience Requirements for Foreign Direct Investment

The Commission will explore, in consultation with industry stakeholders and member states, how to ensure that foreign investments into the European Union feed into the long-term competitiveness of EU industry. This might include resilience conditions such as preserving EU ownership of equipment, EU-sourced inputs, EU-based staff recruitment, joint ventures, or intellectual property transfers. The Commission clearly wishes to ensure that EU economic sovereignty is boosted, not diminished, by foreign investment.

Conclusion

The Commission's Clean Industrial Deal sets out the steps it plans to take in the coming years to accelerate reindustrialisation and economic growth. It calls for a significant revision of EU state aid rules to enable the funding of decarbonisation and the development of European strategically important clean tech sectors. It also calls for further guidance and a change in the way the European Commission deals with mergers and antitrust, and foreign direct investment. It remains to be seen whether this will touch on the fundamental principles for assessing individual transactions. It appears likely, however, that, at a minimum, this will impact the detailed assessment of and considerations weighed in relation to deals.

Dealmakers and investors active in clean energy and in decarbonising traditional industries should take due note—it is an invitation to invest in the European Union. By contrast, suppliers into the European Union from low-cost countries may see stronger and potentially faster action being taken to level the EU's internal market playing field.

In Summary

- The Clean Industrial Deal strategy confirms a more geostrategic approach by the Commission, using its enforcement levers to protect and grow EU industry while accelerating decarbonisation and promoting the clean tech sector.
- Merger guidelines will be revised to ensure that both the impact of mergers on clean innovation and the investment intensity of competition in certain strategic sectors are better integrated in the competition analysis.
- Foreign subsidy controls and trade instruments will be used to prevent distortions in EU markets from extra-EU cost advantages (such as low energy costs) or oversupply (including because of tariffs restricting access to non-EU markets).
- The European Union expects to make available up to €100 billion to ensure investments in innovation and technology through the creation of an Industrial Decarbonisation Bank.
- EU member states will be given further leeway under EU state aid rules to subsidise the rollout of renewable energy, to green manufacturing processes, and to ramp up production capacity in clean tech.

Notes

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1. https://commission.europa.eu/document/download/9db1c5c8-9e82-467b-ab6a-905feeb4b6b0_en.

European Commission Provides Guidance on Scope of Artificial Intelligence Systems Under the EU's AI Act

John Patten and Edmund Berney*

In this article, the authors review guidance released by the European Commission on the scope of artificial intelligence (AI) systems under the EU's Artificial Intelligence Act for businesses developing or using AI tools, and they identify key practical takeaways.

As part of a flurry of guidance relating to the EU AI Act, the European Commission has released guidance on the scope of "AI Systems" as required under Article 96(1)(f) of the AI Act (the Guidance).[1] This quickly follows the Commission's non-binding guidance on the prohibitions contained in Article 5 of the AI Act. Although also not binding, the current guidance is also likely to be persuasive to competent authorities and courts when interpreting the AI Act. This article summarises the Guidance for businesses developing or using AI tools and identifies key practical takeaways.

Summary of Guidance

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 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.

The Guidance breaks down this definition into the following seven elements, which are dealt with in turn: "(1) a machine-based system; (2) that is designed to operate with varying levels

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of autonomy; (3) that may exhibit adaptiveness after deployment; (4) and that, for explicit or implicit objectives; (5) infers, from the input it receives, how to generate outputs (6) such as predictions, content, recommendations, or decisions (7) that can influence physical or virtual environments."

The Guidance emphasizes from the start that not each element need be continuously present throughout an AI System's life cycle (i.e., may only appear in one of the development or deployment stages), provided they all appear at some point in the life cycle.

Machine-Based System

The Guidance notes that all AI Systems must inherently run on machines because machines are required to enable AI to function. The term "machine" is broad and covers both hardware (i.e., physical elements such as processing units, memory, storage devices, networking units, and input/output interfaces) and software (e.g., code, instructions, programs, operating systems, and applications that handle how hardware performs).[2] Reflecting on its introductory comment that AI Systems will evolve over time, the Guidance hypothesises that advanced quantum computing systems would still be categorised as machines for the purposes of the definition, as would a biological or organic system, provided they provide some computational capacity.

Varying Degrees of Autonomy

Recital 12 of the AI Act clarifies that the concept of "varying degrees of autonomy" means that AI Systems should operate with "some degree of independence of actions from human involvement and of capabilities to operate without human intervention." As such, the Guidance notes that the core concept in considering autonomy for AI Systems is the human-machine interaction and whether there is a "reasonable" degree of independence. Any system designed to operate solely with full manual human involvement and intervention is excluded, whether such involvement/intervention is direct or indirect (e.g., through systems-based controls that allow human delegation, or only require supervision by humans, of system operations). Conversely, a system that requires manual inputs but generates an output by itself will have the necessary degree of independence. The Guidance adds that where less human intervention is required, the risks are higher and so more built-in human oversight may be required as part of risk mitigation.

Adaptiveness

Again, Recital 12 of the AI Act provides clarification that "adaptiveness" refers to self-learning capabilities that allow changes in system behaviour during use to produce different results based on the same inputs. However, the Guidance is clear that the use of the phrase "may" in the AI Act means that this is not a prerequisite for an AI System and a system can still be considered an AI System without this capability.

AI System Objectives

The AI Act notes that AI Systems must operate to one or more explicit or implicit objectives. The Guidance clarifies that explicit objectives refers to clearly stated goals that are directly encoded into the system (such as to optimise a cost function), whereas implicit objectives refers to goals that may be deduced from the systems behaviour or its underlying assumptions and arise from either the training or the deployment stage where the system interacts with the environment. The Guidance, by reference to Recital 12 and Article 3(12), also notes that an "objective" is different to an "intended purpose." The latter is the external context in which the system is intended to be deployed by the provider (i.e., the use case to assist a specific behaviour) as opposed to the objectives inherent to the system's analysis of its input data. The intended purpose relies on both the inherent objective plus other factors such as the integration of the system into other behaviours.

Inferring How to Generate Outputs

The Guidance critically examines this criterion, stating that this inference ability is a "key, indispensable" factor in determining an AI System (to differentiate from "simpler traditional systems or programming approaches"). Recital 12 clarifies that this capability is to "derive models or algorithms, or both, from inputs or data."[3] However, the Guidance notes that that "inference" should not be narrowly interpreted as only the ability of a system to derivate outputs from given outputs, but also relates to the "building" phase of AI development through the AI techniques incorporated into a system to enable inference (which then generate outputs, as discussed below). These AI techniques include "machine learning" approaches and "logic- and knowledge-based" approaches:

- *Machine Learning*. This encompasses approaches that learn from data on how to achieve certain objectives. It includes (1) supervised learning, where the system learns from human-labelled data to pair input data with a correct output (e.g., an AI-enabled email spam detection system, image classification systems); (2) unsupervised learning, where the system learns from unlabeled data and instead uses techniques such as clustering, anomality detection, and association rule learning to find patterns, structures, and relationships in data without any explicit guidance (e.g., an AI System for drug discovery); (3) self-supervised learning, as a form of unsupervised learning where the systems use unlabeled data and techniques such as contrastive learning to create its own labels or objectives (e.g., image recognition systems, predicative text models); (4) reinforcement learning, where systems learn from data they have collected before through a reward function, learning from trail-and-error experience rather than labelled data or patterns; and (5) deep learning, where layered architectures (such as neural networks) automatically learn features from large data volumes to create high accuracy outputs.
- *Logic- and Knowledge-Based Approaches*. This encompasses approaches that "infer[s] from encoded knowledge or symbolic representations of the task to be solved" (Recital 12). These systems use deductive or inductive engines, or techniques such as sorting, searching, matching, and chaining, to apply logic or reasoning to new situations, learning from rules, facts, and relationships encoded by humans, as opposed to learning from the underlying data (whether assisted by humans or not). Examples include classical language processing models regarding grammar or semantics rules to identify and then extract the meaning of a text,

and medical diagnosis systems that draw conclusions based on encoded symptoms.

The Guidance notes that certain simpler systems (including those with only a limited capacity to infer) will not be AI Systems, including:

1. Systems aimed at improving mathematical optimisation that may have the capacity to infer to improve efficiency but only at a level of basic data processing, such as physics-based simulations that are fed into established models (e.g., measure atmospheric processes to enable faster and more computationally efficient forecasts) and telecommunications systems that optimise bandwidth allocation based on predictions of resource requirements;
2. Basic data processing systems that follow predefined, explicit instructions or operations and do not undertake learning, reasoning, or modelling during their life cycle (e.g., database management systems and standard spreadsheet software);
3. Systems based on classical heuristics to more efficiently find approximate solutions where exact ones are impractical to find, which may employ pattern recognition but not via data-driven learning and do not show adaptability (e.g., a chess program, where the model cannot be adapted for anything other than chess once its inputs are defined); and
4. Simple prediction systems that use basic statistical learning rules (e.g., future stock price predictors that use historic average prices to make baseline predictions).

Outputs That Are Predictions, Content, Recommendations, or Decisions

The Guidance follows the AI Act to split outputs in four categories, which the Guidance notes, although not specific to AI Systems, are generated with more complexity in AI Systems.

- *Prediction*. An estimate as to an unknown value derived from known values. The Guidance notes that, although predictions are present in many types of non-AI-based software, the differentiating factor is the complexity of the predictions an AI System can make (the real-time predictions in driverless cars).

- *Content*. New materials generated by AI Systems, such as text, images, videos, or music. As the Guidance notes, although technically, the content may be seen as a type of prediction or decision, the AI Act treats them as a separate category of output (which is relevant for the rules around generative AI specifically, and other regulations such as the EU's Digital Services Act).
- *Recommendation*. Specific suggestions for specific actions, products, or services based on preferences, behaviours, or other data inputs.
- *Decision*. Conclusions or choices made by a system, including recommendations that are then automatically applied without any human oversight.

Influence Over Environment

The Guidance notes that this requires an "active" element to a system that impacts the environment of deployment, including physical objects (such as robot arms) or virtual environments (such as digital spaces, data flows, and software ecosystems). Interestingly, the Guidance does not interpret the phrase "can" in the same way as "may" is interpreted for adaptiveness, so it appears that the Commission's view is that an influence on a physical or virtual environments is a required feature for an AI System.

Conclusion

In its press release, the Commission notes that the Guidance is designed to evolve over time and will be updated as necessary—specifically referencing new use cases. For now, it appears that the Commission is interpreting the concept of AI System broadly, with the most complex consideration being whether the system is able to make inferences.

Interestingly, the concluding remarks note that, whether or not a system is determined to be an AI System under the AI Act, "the vast majority of systems . . . will not be subject to any regulatory requirements" (e.g., in relation to prohibited practices, high-risk obligations, etc.). The Guidance also seeks to remove basic machine learning and optimisation tools from the AI Act's scope and emphasises that high-risk AI Systems already on the market prior to August 2026 will not be caught (as per Article 111(2) of the AI Act). When read in combination with the recent guidance on prohibited practices, the Commission seems to focus on the impacts of relevant systems, rather than their fundamental programming or technology, to assess the scope of compliance obligations and necessary degree of regulation. It will be interesting to review the Commission's guidance on high-risk activities when released, to understand whether this direction of travel continues. More practically, five days after the Guidance was published, the Commission announced a €200 billion initiative to mobilise investment into AI (including specifically a €20 billion fund for AI gigafactories);[4] the European Union may be trying to tread a fine line between not stifling innovation while appeasing those member states that demand detailed regulatory oversight, especially given the regulatory divergence with other core jurisdictions.[5]

Practical Takeaways

1. *No Exhaustive List of AI Systems*. The Commission repeats in multiple places that it is not possible to provide an exhaustive list of AI Systems covered by the AI Act. The Guidance aims to provide a step-based formulation to assist in determining what is a relevant AI System, but there is need for flexibility to cover rapid technological developments.
2. *Ability to Infer Is Critical*. Many of the conditions for an AI System are stated to be fairly binary or easy to assess, with the most detailed consideration being a system's ability to infer (and to a lesser degree its level of autonomy in doing so). The Guidance makes clear that this capability is important to differentiate AI Systems that are subject to need regulation from simple systems that perform basic optimisation or other functions.

Notes

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1. https://digital-strategy.ec.europa.eu/en/library/commission-publishes-guidelines-ai-system-definition-facilitate-first-ai-acts-rules-application.

2. This aligns with the view put forward in a recent UK Court of Appeal judgment, which held that both software and hardware can constitute compute programmes (Emotional Perception v Comptroller 18 July CA-2024-000036).

3. The Guidance notes that this aligns with the concept of "inference" in the ISO/IEC 22989 standard, which defined inference as "reasoning by which conclusions are derived from known premises."

4. https://ec.europa.eu/commission/presscorner/detail/en/ip_25_467.

5. See, e.g., the United States and United Kingdom not signing the international agreement put forward at the Artificial Intelligence Action Summit in Paris on 10 - 11 February 2024, https://www.bbc.co.uk/news/articles/c8edn0n58gwo.

Artificial Intelligence and Anticompetitive Agreements in EU Law

Anne Vallery, Itsiq Benizri, and Ioannis Dellis*

In this article, the authors explore the role of artificial intelligence (AI) in anticompetitive horizontal and vertical agreements under Article 101 of the Treaty on the Functioning of the European Union, as well as how AI could assist regulators in enforcing competition law rules.

The rise of artificial intelligence (AI) and its widespread availability raise questions regarding its potential use in violating EU competition law. This issue is complex due to two characteristics of AI systems highlighted under the EU AI Act's definition of such systems: (1) they operate with varying levels of autonomy, and (2) they infer from the input they receive how to generate outputs such as predictions, recommendations, or decisions that can influence physical or virtual environments.[1]

This article explores the role of AI in anticompetitive horizontal and vertical agreements under Article 101 of the Treaty on the Functioning of the European Union,[2] as well as how AI could assist regulators in enforcing competition law rules.

Horizontal Agreements

AI may be used in cartels or hub-and-spoke arrangements. While autonomous price coordination does not violate EU competition law, it raises interesting questions for the future. Horizontal agreements in the AI market would be similar to those in other markets. However, due to AI's high importance and growing demand, and the scarcity of talent and AI skills, no-poach agreements[3] reducing competition in the labor market might be particularly noteworthy.

- *Cartels*. Explicit collusion is the clearest violation of EU competition rules, as competitors communicate directly

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to agree on anticompetitive practices such as price fixing or market sharing. However, once an agreement is established, participants might deviate from the plan to achieve favorable outcomes for themselves. AI can be used to address this issue and facilitate the formation of stable cartels. Typically, cartel participants may use AI to automatically implement agreements, thereby reducing the need for direct communication. AI can also be used to monitor individual behaviors to ensure cartel stability. These cases do not present new legal challenges, as competition law rules apply as usual. The main difficulty lies in detecting the cartel and understanding the use of AI for such anticompetitive purposes. The issue is not new. In 2016, the UK Competition Markets Authority found in *Posters*[4] that online sellers of posters and frames had used automated repricing software to monitor and adjust their prices and ensure that neither was undercutting the other. Cartel participants maintained contact to ensure the pricing arrangement was effective and to address issues with the operation of the repricing software.

- *Hub and Spoke*. Anticompetitive information exchange can occur indirectly,[5] typically where competitors are aware that the price is set by a third-party AI-based platform and do not distance themselves from such practice. For example, in *Eturas*, travel agencies were suspected of applying a common cap on discounts through a third-party online booking platform. The Court of Justice of the European Union[6] confirmed that online platform terms setting a discount cap can lead to anticompetitive collusion with travel agencies. Travel agencies could therefore be presumed to have participated in such collusion if they were aware of anticompetitive amendments to the terms unless they distanced themselves. Indirect information exchange can also occur when competitors use the same third-party AI price-setting tool. The European Commission's Horizontal Guidelines[7] state that using a shared algorithmic pricing rule (e.g., matching a competitor's price minus five percent) likely violates EU competition law, even in the absence of an explicit agreement. This view is untested under EU competition law, which requires an agreement. In *Eturas*, companies were found to have colluded because they knew of the anticompetitive practices using a common third-party tool and did not distance themselves. There was no violation where such knowledge could not be demonstrated.

- *Autonomous Price Coordination*. Competitors may independently employ distinct pricing AI tools using their own algorithm and data sets, through which they learn and adapt their price-setting strategies. Various experiments[8] suggest that when such AI systems interact in a market environment, they tend to reach a price equilibrium that is higher than competitive prices. However, these experiments remain theoretical,[9] and the evidence of algorithmic tacit collusion is limited. Competition authorities and academics are continuing to investigate this issue. Although tacit collusion does not currently fall within the scope of EU competition law, this issue might need to be reconsidered soon as AI becomes increasingly sophisticated and widespread. Rethinking tacit collusion could be theoretically possible, but it would be highly challenging, as it would involve questioning the core principles of EU competition law.

Vertical Agreements

Most vertical agreements, which involve competitors at different supply chain levels, do not breach EU competition law. The European Commission's Guidelines on Vertical Restraints[10] clarify that this is because the complementary nature of the activities performed by the parties involved in such agreements often means that pro-competitive actions by one party will benefit the other, ultimately benefiting consumers. However, certain vertical agreements may raise competition concerns under EU law.

- *Input Foreclosure*. There is potential for anticompetitive vertical arrangements resulting in the foreclosure of critical inputs[11] to downstream players. Typically, if two firms in different segments of the AI supply chain agree to grant each other exclusive access to a valuable resource, it could hinder other competitors from developing competitive products. An example of this situation could be an AI chip manufacturer and an AI developer agreeing to provide each other with exclusive access to their respective semiconductor technology and advanced training data sets, foreclosing rival AI firms from obtaining these critical inputs. Under EU law, such an agreement would generally be presumed legal. However, if the market share of the parties to this agreement exceeds 30 percent, they do not benefit from this presumption.

- *Hardcore Restrictions*. Vertical agreements are illegal even below the 30 percent threshold if they involve hardcore restrictions. Specifically, using AI to monitor or enforce resale price maintenance agreements, or exclusive or selective distribution systems, can violate EU competition law.
  - *Resale Price Maintenance Agreements*. Sellers are prohibited from setting a fixed or minimum sale price for buyers. The increasing use of AI-driven price-monitoring systems by sellers in online markets enhances market transparency through price recommendations. However, these systems are not inherently illegal. Buyers still have the freedom to engage in competitive price strategies. The use of such systems only becomes illegal when buyers and sellers agree to turn recommended prices into mandatory ones. In such cases, the price-monitoring systems serve as enforcement tools for resale price maintenance agreements and are therefore illegal. For example, in 2018, the European Commission fined consumer electronics suppliers more than €110 million for using monitoring software to detect price deviations by retailers and intervene when prices fell, thus fixing retail prices. Many retailers, under pressure from electronics manufacturers to comply with the "suggested" prices, used algorithmic systems to automatically adjust prices based on other retailers' prices, which affected overall prices more significantly than in offline contexts.
  - *Exclusive or Selective Distribution Systems*. AI-powered monitoring mechanisms can serve as auxiliary enforcing tools for implementing exclusive or selective distribution systems. For example, AI can be used to monitor compliance with restrictions on the territory in which or the customers to whom the buyer or its customers may sell, or restrictions of cross-supplies between members of a selective distribution system.

Enforcement

Competition authorities are considering using AI[12] to enhance case management and assist them in investigations by analyzing data and expanding e-discovery capabilities. This could help reduce the length of investigations, thereby limiting costs and uncertainty for companies under investigation. However, deploying AI for such purposes will likely take time, as it must be carefully designed and tested to ensure appropriate legal safeguards, including regarding the rights of defense, the right to good administration, and compliance with EU data protection and AI Act regulations, namely the General Data Protection Regulation and the AI Act.

Notes

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Navigating U.S. Regulatory and Tax Issues: A Primer for Singapore Managers Marketing Private Funds in the United States

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In this article, the authors summarize the key U.S. regulatory and U.S. tax considerations when marketing fund interests to U.S. investors, including a comparison with the corresponding Singapore rules.

As the United States remains a leading source of global private equity (PE), real estate (PERE), and venture capital (VC), many Singapore-based managers are increasingly seeking to market their funds to U.S. investors. While Singapore and other non-U.S. managers may be concerned about the regulatory and tax complexities of fund-raising in the United States, the benefits of such fund-raising can significantly outweigh the burdens of doing so with the support of practical and efficient legal advice.

This article summarizes the key U.S. regulatory and U.S. tax considerations when marketing fund interests to U.S. investors, including a comparison with the corresponding Singapore rules that Singapore managers will already be familiar with.

U.S. Investment Advisers Act

The Investment Advisers Act of 1940 is the primary law governing fund managers in the United States. Under the Advisers Act, fund managers engaging in investment advisory activities in the United States must register as an investment adviser (RIA) with one or more states or the U.S. Securities and Exchange Commission (SEC) unless an exemption applies. Exemptions available to a non-U.S. manager may include:

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1. The Foreign Private Adviser Exemption,
2. The Private Fund Adviser Exemption, and
3. The Venture Capital Adviser Exemption.

Singapore Comparison

The registration framework under the Advisers Act is analogous to Singapore's licensing framework with respect to Singapore managers under the Securities and Futures Act 2001 (SFA), whereby persons carrying out regulated activities in Singapore (such as fund management and investment advisory activities) must be licensed with the Monetary Authority of Singapore (MAS) unless an exemption applies.

The U.S. and Singapore frameworks are similar in that they each impose distinct levels of compliance requirements on a fund manager, depending on the applicable licensing or exemption category and perceived market risk. For example, as further discussed below, while a non-U.S. manager that relies on the Foreign Private Adviser Exemption need not make any Advisers Act filing (known as Form ADV), a manager that relies on either the Private Fund Adviser Exemption or the Venture Capital Adviser Exemption is required to make a truncated Form ADV filing, and an RIA is required to make a full Form ADV filing.

That being said, the types and parameters of licensing and registration categories and available exemptions differ significantly between the Advisers Act and the SFA. Accordingly, a Singapore manager that qualifies for a licensing exemption under the SFA is not necessarily exempt from U.S. registration and U.S. reporting requirements under the Advisers Act. Similarly, a manager that qualifies for an exemption from registration and reporting under the Advisers Act is not necessarily exempt from licensing with the MAS under the SFA.

For example, while a Singapore-based private equity real estate manager may be exempt from licensing with the MAS in reliance on the "immovable assets" exemption under the SFA, managers of real estate funds are typically still subject to registration under the Advisers Act. In that case, a Singapore manager would typically seek to rely on one of the U.S. exemptions described below.

Foreign Private Adviser Exemption

The least burdensome exemption for a non-U.S. manager is to qualify for the Foreign Private Adviser Exemption, with no Form ADV or other affirmative notice filing required to claim the exemption. In general, a non-U.S. manager with no place of business in the United States may rely on this exemption if it, across all funds that it advises:

1. Has less than 15 clients and investors in the United States (subject to certain look-through rules),
2. Has less than US$25 million of aggregate assets under management (AUM) (including uncalled capital commitments) attributable to U.S. investors and U.S. clients, and
3. Does not hold itself out to the U.S. public as an investment adviser.

Managers often will outgrow the thresholds under the Foreign Private Adviser Exemption as they begin to accept more U.S. capital. In that case, a manager typically will rely on either the Private Fund Adviser Exemption or the Venture Capital Adviser Exemption (each summarized below). As noted above, managers that rely on either of these two exemptions are known as "Exempt Reporting Advisers" (ERAs) because they are required to report to the SEC and the relevant State regulator by making a truncated Form ADV filing but are exempt from many of the requirements otherwise applicable to registered investment advisers. An ERA must file a Form ADV within 60 days after first relying on the exemption and annually thereafter (and upon certain material changes). Accordingly, these filings and the related analysis can often be finalized after a fund's initial closing that causes the manager to exceed the AUM and investor thresholds, but this will depend on the specific facts.

Singapore Comparison

There is no analogous regime under Singapore's licensing framework for foreign fund managers. Instead, there is a presumption, broadly speaking, that approaching any potential investors in Singapore is intended to have an "effect" in Singapore and is therefore prima facie a regulated activity. Accordingly, foreign managers need to look to the private placement and other exemptions, generally limited to certain types of fund offerings to institutional and accredited investors, to avoid triggering the need for a full capital markets services (CMS) license from the MAS.

Private Fund Adviser Exemption

To qualify for the Private Fund Adviser Exemption, a manager must (1) advise only "private funds," and (2) have less than US$150 million of aggregate AUM in the United States. A manager that has its principal office and place of business in the United States is deemed to manage all of its assets in the United States. A manager with its principal office and place of business outside the United States generally (1) must include only assets managed at a place of business in the United States, and (2) may exclude consideration of assets managed on behalf of non-U.S. clients (e.g., a Singapore limited partnership) toward the US$150 million threshold. Therefore, a non-U.S. manager may rely on the exemption if (1) all of its clients that are U.S. persons are private funds (even if some or all of the non-U.S. clients are not), and (2) management activities in the United States are limited to US$150 million in private fund assets. Accordingly, it is possible for a Singapore manager (or any other non-U.S. manager) to continue to rely on the Private Fund Adviser Exemption even if it has exceeded such dollar threshold in total AUM.

Singapore Comparison

As mentioned above, the Singapore licensing framework does not provide a separate category of license for a fund manager with Singapore investors on the basis that the manager has no physical presence in Singapore. Also, while there was until recently a lighter-touch licensing regime for fund managers in Singapore with no Singapore retail investors and AUM of no more than S$250 million (the Registered Fund Management Company or RFMC regime), that regime was abolished by MAS streamlining measures in early 2024. Accordingly, all fund managers formerly operating as RFMCs have needed to give up their licensed status altogether or convert to being full CMS license-holders with the incrementally greater compliance burden that comes with that status.

Venture Capital Adviser Exemption

To qualify for the Venture Capital Adviser Exemption, a manager must advise solely "venture capital funds," defined as a private fund that meets the following conditions. Each such fund:

1. Represents to its actual and potential investors that it pursues a venture capital strategy;
2. Invests no more than 20 percent of its total assets (including uncalled capital commitments) in nonqualifying investments;
3. Does not incur leverage in excess of 15 percent of its capital contributions and uncalled capital commitments; and
4. Does not provide any redemption rights for investors except in extraordinary circumstances (i.e., each such fund must be a closed-end fund), among other technical requirements.

Notably, secondary transactions (e.g., acquiring interests in a start-up from an existing owner) are "nonqualifying investments" such that managers relying on the Venture Capital Adviser Exemption may only participate in such transactions on a limited basis.

Singapore Comparison

In 2017, the MAS introduced the Venture Capital Fund Management license regime, a simplified set of regulations for managers of venture capital funds, with the objective of lowering the regulatory compliance burden and shortening the authorization process for fund managers in the VC space and to facilitate start-ups' access to capital. The lighter compliance burden, relative to a full CMS license for fund management, is reflected in several different aspects, including in relation to the requirements for key executive experience, minimum regulatory capital and an internal compliance function. The corollary is that a Singapore VCFM licensee must invest at least 80 percent of fund capital in companies less than 10 years old, cannot invest in any listed assets and is restricted to offering closed-ended strategies to institutional and accredited investors. The simplified regulatory regime is designed to take into account the extent of contractual safeguards typically found in fund documentation negotiated by VC managers' sophisticated investor client base.

U.S. Securities Act and U.S. Investment Company Act

In addition to compliance with the Advisers Act, managers conducting U.S. offerings of fund interests should (1) confirm that each U.S. investor (i.e., an investor that is resident or domiciled in the United States) is an "accredited investor" under Regulation D of the U.S. Securities Act of 1933, and (2) ensure that there is no "general solicitation" of the fund interests in the United States (unless relying on Rule 506(c) as discussed below) to avoid registration of fund interests with the SEC under the Securities Act.

It is also important for managers conducting their U.S. offerings to seek to either (1) subject to certain look-through rules, admit to the fund no more than 100 beneficial owners (i.e., the 3(c)(1) exemption), or (2) admit as investors only "qualified purchasers" (i.e., the 3(c)(7) exemption), in order to avoid registration of the fund as an "investment company" under the Investment Company Act of 1940. In the case of a non-U.S. domiciled fund (e.g., Singapore or the Cayman Islands), a manager is only required to count U.S. investors toward the 100 beneficial owner and "qualified purchaser" tests.

Singapore Comparison

The U.S. private placement rules described above are substantially similar to the private fund offering rules in Singapore, whereby under the SFA, it is important to ensure that there is no "broad marketing" of fund interests to the Singapore public. Otherwise, the fund manager will need to obtain MAS approval for the offering. Similar to the rules in Singapore, the prohibition of "general solicitation" in the United States means that there should be no broad dissemination of information relating to the offering, such as through social media, publicly available websites, press releases, public conferences, or otherwise.

The U.S. rules on investor suitability described above are also similar to the rules in Singapore in that a manager must offer fund interests only to investors that meet a certain suitability threshold to avoid certain registration requirements. This is analogous to the prospectus requirement in Singapore, whereby a fund manager is required to "lodge a prospectus" with the MAS unless the offering is made only to (1) "accredited investors" (as defined under the

SFA), (2) investors with a capital commitment of at least S$200,000 (i.e., the Restricted Scheme Exemption), or (3) "institutional investors" (as defined under the SFA) (i.e., the Institutional Investor Exemption), subject to certain other conditions (e.g., restrictions on advertising costs). Notably, unlike in other key jurisdictions such as the European Union and South Korea, there is no "reverse solicitation" exemption or safe harbor under either the Singapore or U.S. securities laws to avoid such registration requirements.

Form D

For a U.S. private offering of fund interests, a fund typically will file a Form D notice of sale with the SEC to affirm reliance on the private placement "safe harbor" provided in Regulation D under the Securities Act. As a practical matter, most practitioners advise clients to file Form D within 15 days following the date the first U.S. investor is admitted to the fund. It is common for a fund to "pre-file" Form D before the fund's initial U.S. closing. Depending on the circumstances, an issuer may not be required to disclose the dollar amount of securities sold in the Form D if the form is filed prior to closing.

Some funds may determine not to file a Form D or rely on Regulation D at all, and may instead rely on the statutory "private placement exemption" available under Section 4(a)(2) of the Securities Act. The Securities Act does not define "public offering," but relevant case law and SEC rulings have introduced several factors that may help determine whether an offering should be deemed public, including (1) whether investors are "sophisticated investors" (i.e., have sufficient knowledge and experience in finance and business), (2) whether there is any general solicitation and advertising involved, and (3) the number of investors in the fund (i.e., the fewer the investors, the less likely the offering is considered public), among others. While relying on this self-invoking statutory exemption can reduce costs, it also introduces greater regulatory risk and uncertainty, especially given that (1) the SEC has expressed a strong preference for complying with Regulation D and filing Form D, and (2) the precise limits of the statutory private placement exemption are not as clearly defined as the parameters of the Regulation D safe harbor. In addition, institutional and other sophisticated investors will often insist that the fund comply with Regulation D and file Form D.

Singapore Comparison

There is no Singapore equivalent to the SEC's Form D. To the extent a fund manager is relying in Singapore on the equivalent private placement exemption under the SFA, the main route is to offer interests to no more than 50 persons (on a look-through basis in relation to any feeder vehicle) in any 12-month period. This is a self-invoking exemption that does not require a filing but would have to be validated if ever scrutinized by the MAS, reinforcing the need for good record-keeping in the fund marketing phase.

General Solicitation–Rule 506(c)

In 2013, the SEC adopted Rule 506(c), which permits managers to offer interests in a fund by "general solicitation," marking a major shift from the traditional restrictions mentioned above. However, Rule 506(c) comes with additional procedural and investor verification requirements. The SEC also has been strict in scrutinizing offerings under these more permissive rules. Accordingly, fund managers should carefully weigh the advantages of general solicitation—often meaning access to a broader base of smaller, noninstitutional investors—against the increased cost and associated risks before engaging Rule 506(c).

Singapore Comparison

There is no equivalent to this "general solicitation" approach in Singapore. Any general solicitation of investors in Singapore will fall outside the private placement exemption routes under the SFA, unless the total value of the offering is very small. Accordingly, unless the manager is confident that the solicitation is only made to institutional and accredited investors (in which case, at the very least and subject to certain other advertising spend and other restrictions, a "restricted scheme" notification in relation to the fund would have to be made to MAS), the offering would be highly likely to trigger the full prospectus filing requirements for retail regulated securities (including fund interest) offerings under the SFA.

U.S. AML and CFT Rules

In August 2024, the U.S. Department of Treasury's Financial Crimes Enforcement Network (FinCEN) finalized rules (AML (anti–money laundering) Rule) requiring RIAs and ERAs to comply with certain AML and countering the financing of terrorism (CFT) measures with effect from 1 January 2026.

The AML Rule, as adopted, excludes certain types of advisers, including non-U.S. managers that rely on the Foreign Private Adviser Exemption. On the other hand, ERAs (including foreign-located ERAs) are subject to the AML Rule. Accordingly, a Singapore-based manager that is registered with the SEC, or reports as an ERA in reliance on the Private Fund Adviser Exemption or the Venture Capital Adviser Exemption, is subject to the AML Rule.

Key obligations of the AML Rule include:

1. Maintaining a risk-based program requiring AML and CFT measures,
2. Reporting to authority of any suspicious activity,
3. Complying with record-keeping obligations, and
4. Adopting special information-sharing procedures.

Singapore Comparison

The U.S. AML requirements and the Singapore AML requirements as applied to fund managers are in substance similar. Singapore managers will note, for example, that the U.S. requirements described in 1 to 4 above apply to managers subject to the Singapore AML rules. Most notably, regarding the implementation of the AML and CFT program, both U.S. and Singapore rules require that a manager:

1. Establish a "risk-based" program (i.e., to conduct risk assessments and tailor controls accordingly),
2. Provide an independent audit function to test such program,
3. Designate a compliance officer to oversee such program,
4. Conduct ongoing monitoring of client accounts and transactions, and
5. Carry out ongoing employee training.

That being said, the Singapore requirements are generally a bit more onerous and detailed than the U.S. requirements. For example, the Singapore rules provide specific guidelines on customer due diligence and risk assessment, whereas the U.S. rules are more principles-based on that topic. Accordingly, compliance with the Singapore requirements likely would cover compliance with the U.S. requirements in substance, although a manager should confirm its compliance in each jurisdiction separately as application of the rules evolves. One unique element of the U.S. rules is that any reportable transactions must be filed with FinCEN.

U.S. Tax Considerations

If a fund will take in U.S. investors, a fund manager should consider (1) what types of U.S. investors there will be for tax purposes, and (2) whether the fund will be treated as a partnership or a corporation for U.S. tax purposes. From a U.S. tax perspective, there are two main types of U.S. investors: (1) U.S. taxable investors, which generally include all U.S. citizens, Green Card holders, and U.S.-domiciled entities, in addition to any other U.S. tax residents; and (2) U.S. tax-exempts, which generally include pension plans, retirement funds, private foundations, and charities.

Singapore Comparison

In addition to these U.S. tax issues, Singapore managers are already confronted with complex Singapore tax considerations, including (1) seeking tax exemptions under Sections 13D, 13O, or 13U, which allow for tax exemption on specified income and gains derived from designated investments; (2) seeking treaty benefits under relevant tax treaties, which may reduce withholding tax on certain income streams and provide clarity on tax obligations; and (3) ensuring that the gains on the dispositions of investments are classified correctly to benefit from the preferential tax policies in Singapore. Accordingly, when Singapore managers offer fund interests to U.S. investors, they will need to consider the unique U.S. issues as an overlay to the existing Singapore and regional structuring concerns.

Similar to many other types of limited partnerships globally, a fund structured as a Singapore limited partnership should automatically be treated as a partnership for U.S. tax purposes. A

Singapore Pte. Ltd. or Singapore VCC (and its sub-funds), on the other hand, will be classified by default as a corporation for U.S. tax purposes. Accordingly, a manager would need to affirmatively make a "check-the-box" U.S. tax election in order for a Singapore Pte. Ltd. or Singapore VCC (and its sub-funds) to be classified as a partnership for U.S. tax purposes.

While the Internal Revenue Service (IRS) has not issued any specific guidance on whether a U.S. tax election could be made for a single sub-fund of a Singapore VCC (or a single series of a non-U.S. series or cell entities generally), the IRS has in the past issued proposed regulations permitting (1) certain types of vehicles (e.g., separate series of a U.S. series entity and separate series of a Bermuda series entity engaged in the insurance business specifically) be treated as separate entities for U.S. tax purposes, and (2) separate series entities elect different U.S. tax classifications, with some being treated as partnerships and others being treated as corporations for U.S. tax purposes. That being said, the IRS has not expressly blessed this approach in the case of a Singapore VCC or its sub-funds.

For the above reasons, most market practitioners would suggest setting up a separate vehicle, rather than seeking to make the election for a specific sub-fund of a VCC, when electing for a VCC to be taxable as a partnership for U.S. tax purposes to avoid the risk of unintended consequences for the VCC's other sub-funds and investors.

U.S. Taxable Investors

U.S. taxable investors typically would prefer to invest into a fund treated as a partnership for U.S. tax purposes so that the fund's income and gains are subject to income tax only at the partner level, allowing individual partners to receive the benefit of reduced U.S. income tax rates for long-term capital gain produced by fund investments, as well as avoiding an entity level tax on the partnership itself. Generally, an entity structured as a limited partnership will automatically be treated as a partnership for U.S. tax purposes. However, as noted above, a non-U.S. entity structured as a corporation will need to affirmatively make a "check-the-box" U.S. tax election to be treated as a partnership for U.S. tax purposes.

The election should be effective prior to the date any U.S. taxable investors join the fund.

U.S. Tax Exempt Investors

On the other hand, U.S. tax exempts may prefer to invest into a fund treated as a corporation for U.S. tax purposes. If the fund's investment strategy will generate income that is either "unrelated business taxable income" or "unrelated debt-financed income" (collectively, UBTI) that would be subject to U.S. income tax when received by a U.S. tax exempt entity investing through a partnership.

Generally, an entity that is structured as a corporation will automatically be treated as a corporation for U.S. tax purposes if no "check-the-box" U.S. tax election is made, whereas a fund structured otherwise would need to make a "check-the-box" U.S. tax election for it to be treated as a corporation for U.S. tax purposes.

U.S. tax exempts may require that a manager of a fund partnership set up a "blocker" that is treated as a corporation for U.S. tax purposes to block UBTI the tax exempts would receive if they were to invest directly into the fund. The foregoing issues are also similar to the types of issues that certain non-U.S. investors (e.g., sovereign investors) may encounter.

While setting up "blockers" can significantly increase the costs of a fund offering, these costs can be reduced if, from the outset, the fund is structured, and the governing agreements are drafted, in a manner that provides flexibility to accommodate such investors.

U.S. Tax Filings

U.S. investors often will require that a fund treated as a partnership for U.S. tax purposes provide annual U.S. informational returns known as "Schedule K-1s" for the U.S. investors in order to prepare their own U.S. tax returns. Typically, U.S. accounting firms would prepare these Schedule K-1s based on the fund's financial statements. In addition, U.S. investors might request that the fund's governing agreements include specific provisions relating to U.S. partnership tax rules, such as income allocation for U.S. tax purposes and the handling of U.S. tax audits. The fund manager will then have to assess the downside, that is, time and cost of providing information on this basis, against the benefit of satisfying the U.S. investors' request in this regard.

Non-U.S. Investors Generally

U.S. taxation of non-U.S. investors in a fund for U.S. tax purposes typically depends on whether the fund's income will be treated as being related to a trade or business in the United States. If a fund is engaged in a U.S. trade or business (e.g., the fund invests in certain U.S. operating businesses), non-U.S. investors typically would be subject to U.S. income tax on any fund income that is "effectively connected" with such U.S. trade or business. Accordingly, non-U.S. investors generally would seek to avoid such "effectively connected income." One solution would be for the fund to invest in such U.S. investments indirectly through a corporate blocker, which is often a subsidiary to the fund. Sovereign investors face similar issues with respect to investments that constitute commercial activities.

However, in practice, many non-U.S. investors (generally other than anchor investors, institutional investors, and sovereigns) simply rely on a manager in good faith to structure U.S. investments properly without the use of a blocker.

Other U.S. Regulatory Issues

The foregoing discussions summarize the primary U.S. regulatory and U.S. tax issues typically relevant to any private fund offering to U.S. investors by a non-U.S. manager. The following is a brief summary of certain additional U.S. issues that may come to play depending on the specific facts and circumstances.

Commodity Futures Trading Commission

If a fund's investment strategy includes options, futures, swaps, or similar derivatives in respect of commodities, the fund will generally be subject to regulation by the Commodity Futures Trading Commission (CFTC) pursuant to the Commodities Exchange Act and the rules thereunder, unless an exemption applies. Note that the CFTC has classified digital assets and certain cryptocurrencies (such as Bitcoin) as commodities, such that derivatives thereon could be subject to CFTC regulation. Typically, CFTC issues are more pertinent to hedge funds than to PE, PERE, or VC funds, as hedge funds are more likely to trade in commodity interests and derivatives thereon. PE, PERE, and VC funds that have some exposure to derivatives in respect of commodity interests (such as via hedging transactions) often would seek to rely on the "de minimis" exemption from registration with the CFTC as a commodity pool operator, on the basis that they stay within the thresholds on their relevant positions.

Singapore Comparison

There is no express Singapore equivalent to the U.S. commodities regulations as they apply to fund managers, whether in terms of having a dedicated commodities and derivatives regulator or having a regulatory framework for commodities and derivatives transactions which has a direct impact on the investment activity of Singapore hedge fund managers. Dealing in these types of assets, to the extent they are regulated products in Singapore, generally falls within the automatic "dealing" permission which the SFA includes as an ancillary function within the CMS license for fund management.

Broker-Dealer Rules (Placement Agents, Finders)

The Securities Exchange Act of 1934 provides that, in general, placement agents, finders and similar service providers that receive compensation for raising capital are required to be registered as "broker dealers" with the SEC. This registration requirement applies both to the individuals involved in fund-raising as well as the firms that employ them. However, many sponsors of PE, PERE, and VC funds seek to satisfy the conditions of the "issuer exemption" in order that they need not register as brokers. This exemption is based on the SEC's interpretation that issuers of securities are generally not acting as broker dealers when selling their own securities (i.e., fund managers marketing their own funds). Note that the exemption is defined narrowly and may not be available in some cases, such as with respect to in-house fund-raising professionals who are compensated based on amounts raised.

Singapore Comparison

The Singapore regime is broadly equivalent here. Prima facie, placement agents, finders, and similar service providers that receive compensation for raising capital must hold a CMS license for dealing in regulated products and providing corporate finance services. However, a fund manager sponsoring its own funds generally does not need a separate permission from MAS, since dealing and corporate finance activities are considered ancillary functions within the ambit of its CMS license for fund management.

New Issues Under FINRA

The Financial Industry Regulatory Authority (FINRA) has established Rule 5130 and Rule 5131 to protect the integrity of the initial public offerings (IPO) process. In general, these rules prohibit FINRA member broker-dealers and their affiliates from selling or allocating shares in IPOs of equity securities (New Issues) to funds with significant interests held by certain restricted persons, including broker-dealers, portfolio managers, banks, executive officers, and directors of the relevant portfolio company. In January 2020, FINRA amended Rules 5130 and 5131 to provide that the allocation restrictions do not apply to a non-U.S. broker-dealer that allocates New Issues to non-U.S. persons, provided that these allocation decisions are made independently without influence from a U.S. broker-dealer. Broadly speaking, a fund that is domiciled and managed by a non-U.S. manager outside the United States is considered a non-U.S. person. Accordingly, such funds may participate in New Issues through a non-U.S. broker-dealer without being subject to the requirements of Rules 5130 and 5131, regardless of the nationality of the fund's underlying investors.

Singapore Comparison

Beyond the more generically stated MAS guidelines on mitigation of conflicts of interest (set out in the Guidelines on Licensing and Conduct of Business for Fund Management Companies), there is no Singapore equivalent to FINRA or its regulatory regime in the United States as it applies to fund managers.

ERISA

U.S. pension plan investors are a significant source of capital for private funds globally. However, unless an exception is available, the U.S. Employee Retirement Income Security Act of 1974 (ERISA) imposes strict fiduciary duties and prohibited transaction restrictions on funds with ERISA and similar investors, such as U.S. private pension plans. Most non-U.S.-based managers are able to avoid the application of ERISA by ensuring that the aggregate participation of ERISA and similar investors (which do not include U.S. state and local government pension plans) is less than 25 percent of each class of equity interests in the fund. Managers that are unable to comply with the 25 percent threshold typically seek to comply with the "Operating Company" exception, under which the fund would qualify as either a "Venture Capital Operating Company" or a "Real Estate Operating Company" (depending on its investment strategy). However, complying with either exemption could add significant cost and administrative burden.

Singapore Comparison

There is no Singapore equivalent to ERISA's special treatment for public pension funds participating in private funds.

FOIA

Certain government investors that are subject to the Freedom of Information Act of 1966 (FOIA) and similar U.S. state and local government rules may be required to publicly disclose confidential information about the fund. Similarly, certain non-U.S. governmental entities are subject to comparable rules in their jurisdictions. These rules are typically referred to as "FOIA laws" in the funds industry. To navigate these complexities, a fund manager typically will obtain representations from each investor to determine whether any FOIA laws apply. If so, the parties may agree to withhold certain information from these investors or disclose information to these investors in a particular format to mitigate the risks of retention and public disclosure of such information.

Singapore Comparison

There is currently no freedom of information legislation in force in Singapore. However, many of the Southeast Asia region's leading investors are subject to FOIA-like or similar requirements that Singapore managers should be mindful of when considering the ability to preserve confidentiality of fund matters.

CFIUS and Outbound Investments

The U.S. Committee on Foreign Investment in the United States (CFIUS) has the authority to review transactions for potential risks to U.S. national security, with most such transactions being voluntarily and jointly submitted for review by the parties before closing. In 2020, the Foreign Investment Risk Review Modernization Act of 2018 expanded the scope of CFIUS review to include certain nonpassive investments in U.S. businesses that deal with critical technology, critical infrastructure, and sensitive personal data, as well as certain real estate transactions that are in proximity to sensitive U.S. governmental facilities and mandating that certain of these transactions must be disclosed to CFIUS in advance.

As a general matter, an investment in a U.S. business by a fund where (1) its general partner is not a foreign person (and is not controlled by one), and (2) its non-U.S. investors do not have any control rights (excluding normal investor and investor advisory board rights) over the general partner or board rights and access to nonpublic material information about the investment, would typically be outside CFIUS's jurisdiction, even if the fund is domiciled outside the United States.

Additionally, the U.S. Department of the Treasury is finalizing an outbound investment regime that will prohibit or require notification of certain investments by U.S. investors into technologies of particular concern to the United States when these involve countries of concern, currently defined as China, including Hong Kong and Macau, with potential broad application to investments in third countries where these may involve a U.S. investor.

Singapore Comparison

In Singapore, the recently passed Significant Investments Review Act 2024 has given the Ministry of Trade and Industry

(MTI) authority to designate entities deemed critical to national security and to regulate significant investments by foreign and domestic investors in these entities. Although Singapore already had certain sector-specific controls on ownership in telecommunications, banking, utilities, and other industries, this new legislation allows MTI to regulate acquisitions of businesses and assets not previously covered by investment laws and regulations.

Sanctions (OFAC)

The U.S. Treasury's Office of Foreign Assets Control (OFAC) is responsible for administering and enforcing economic and trade sanctions based on U.S. foreign policy and national security goals. All U.S. persons must comply with sanctions imposed by OFAC, including the prohibition against engaging in or facilitating transactions with parties on OFAC's List of Specially Designated Nationals and Blocked Persons (SDNs) or any entity in which one or more SDNs have a 50 percent or greater interest. Non-U.S. persons are also subject to U.S. sanctions if they engage in activities that have a U.S. nexus, including transactions involving U.S. goods, services, or financial systems. Certain OFAC programs, such as those in effect against Iran, North Korea, Russia, and cyber and proliferation activities, also include "secondary sanctions" whereby OFAC can sanction non-U.S. persons even where there is no U.S. nexus to the transaction.

Singapore Comparison

Singapore has a dual approach sanctions regime:

- As a member state of the United Nations, Singapore implements UN sanctions through its United Nations Act 2001, which applies to nonfinancial institutions and individuals, and, through regulations issued by the MAS under the Monetary Authority of Singapore Act 1970, which apply to financial institutions.
- On an autonomous basis, Singapore also applies targeted financial sanctions against designated individuals and entities under its Terrorism (Suppression of Financing) Act 2002. Funds structured as VCCs in Singapore, akin to the protected cell companies sometimes used in U.S.

fund structures, are also required to comply with targeted financial sanctions issued under the Variable Capital Companies Act 2018.

Volcker Rule

The Volcker Rule is a regulation established under section 13 of the Bank Holding Company Act of 1956 (the BHCA). It generally prohibits banking entities (such as U.S. banks and non-U.S. banks with U.S. operations) from engaging in proprietary trading and sponsoring or investing in certain types of private investment funds. Accordingly, banks affiliated with investment funds are limited in their ability to invest in or manage covered funds. However, subsequent U.S. regulatory adjustments have eased some restrictions and added additional exemptions, making it easier for banks, particularly non-U.S. banks, to invest in PE, PERE, and VC funds.

BHC Investors

In addition to the restrictions under the Volcker Rule, bank holding companies (BHCs), and their affiliates are subject to activity restrictions under the BHCA. A BHC is generally prohibited from acquiring or controlling more than five percent of any class of "voting securities" or acquiring assets of a nonbanking company that is not engaged in permissible activities for a BHC. A BHC that has elected to be treated as a financial holding company may take advantage of additional investment authorities, such as merchant banking powers. Accordingly, a fund that may admit BHC investors should include relevant language in the fund's governing documents providing that BHC investors will hold only a noncontrolling position or nonvoting equity interests in the fund as needed to avoid application of the BHCA.

Singapore Comparison

Singapore has no direct equivalent to the Volcker Rule or BHCA in terms of regulating how deposit-taking banks participate in and otherwise interact with private funds. Instead, to safeguard financial stability and regulating the capital adequacy of banking institutions, Singapore has, like the EU member countries, gone down the alternative route of fully implementing the Basel III requirements.

Conclusion

A fund manager should carefully consider the foregoing issues when offering PE, PERE, or VC fund interests to U.S. investors, and keep in mind the similarities, and more critically, the differences to the Singapore regulations and typical practices relating to fund offerings. It is important to address these issues to attract U.S. investors while complying with the U.S. and Singapore regimes. As indicated by our brief overview above, the U.S. issues in particular can be complex and nuanced, especially to the uninitiated. However, with the support of experienced practitioners, these issues can be managed in a cost-efficient manner.

Note

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Mexico's Federal Executive Publishes the Secondary Legislation on Energy Matters

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In this article, the authors review a new decree essentially establishing a new framework for the energy sector in Mexico.

Mexican President Claudia Sheinbaum has signed and published in the Federal Official Gazette (Diario Oficial de la Federación or DOF), the "Decree issuing the Law of the State Public Enterprise, Federal Electricity Commission; the Law of the State Public Enterprise, Petróleos Mexicanos; the Electricity Sector Law; the Hydrocarbons Sector Law; the Energy Planning and Transition Law; the Biofuels Law; the Geothermal Law and the Law of the National Energy Commission; it also amends various provisions of the Law on the Mexican Petroleum Fund for Stabilization and Development and amends, adds and repeals various provisions of the Organic Law of the Federal Public Administration," essentially establishing a new framework for the energy sector in Mexico.

It is important to note that the decree came into force on March 19, 2025. In addition, on the same day, a decree that reforms, adds, and repeals various provisions of the Hydrocarbons Revenue Law, was published in the DOF, but in a separate act.

These reforms aim to establish new regulations for the electricity, hydrocarbons, and renewable energy sectors, to modernize and strengthen the country's energy industry. It will be interesting to closely follow the reaction of investors and energy industry participants in the country as a result of these reforms, which substantially alter the national energy sector.

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Main Points

From a general analysis of the new legal framework published, it is important to highlight the following main points:

- The Mexican State assumes strategic control over the energy sector.
- The Ministry of Energy (Secretaría de Energía) is granted most of the powers and prerogatives for planning, regulation, and supervision of the energy sector, which were previously assigned to the regulatory bodies that have now been dissolved.
- The National Energy Commission (Comisión Nacional de Energía or CNE) replaces, in its administrative role, the functions of the now-defunct Energy Regulatory Commission (Comisión Reguladora de Energía or CRE).
- The CNE will be composed of a general director, a technical committee, and administrative units to handle the procedures under its responsibility.
- The Federal Electricity Commission (Comisión Federal de Electricidad or CFE) will dominate the total annual electricity generation injected into the National Electricity System, with at least 54 percent of its share.
- PEMEX (Petróleos Mexicanos) will continue to have preference in project assignments involving the exploration and extraction of hydrocarbons in the country.
- The planning of the electricity sector will be binding, ensuring the State's preference in sector activities, aiming to promote electricity generation and supply at the lowest possible price.
- In the electricity sector, joint development projects between private investors and the State will be carried out under the "Mixed Development Scheme," which still needs further definition.
- For the hydrocarbons sector, a new system for assigning fields and reserves is established, along with the implementation of new mixed contracts.

Laws Repealed

It is important to mention that the aforementioned decree repealed the Federal Electricity Commission Law, the Petróleos Mexicanos Law, the Power Industry Law, the Hydrocarbons Law, the Energy Transition Law, the Bioenergy Promotion and Development Law, the Geothermal Energy Law, and the Coordinated Regulatory Bodies in Energy Matters Law.

Key Dates

Regarding the information available at the time of the publication of the secondary legislation, please note the following key dates:

- *Appointment of the Director General of the CNE*. The Federal Executive, within 30 calendar days following the implementation, must directly appoint the person to head the CNE as general director without requiring ratification by the Senate. The maximum date for this appointment was April 18, 2025.
- *Suspension of Deadlines for the CRE and National Hydrocarbons Commission (CNH)*. To ensure legal certainty regarding the transfer and continuity of actions, requests, matters, procedures, administrative proceedings, or any acts in progress or subject to deadline calculations at the CRE and the CNH, which fall under the jurisdiction of the Ministry of Energy or the CNE, a suspension of deadlines is declared for a period of 90 calendar days, starting from the commencement of the law. That is, restarting terms from June 17, 2025.
- *Issuance of the Regulation of the Hydrocarbons Sector Law*. The Federal Executive will issue the regulation of this law within 180 calendar days following its implementation. The maximum date for this issuance will be September 15, 2025.
- *Issuance of the Regulation of the Energy Planning and Transition Law*. The Federal Executive must issue the regulation of this law within 180 calendar days following its entry into force. The maximum date for this issuance will be September 15, 2025.

- *Issuance of the Regulation of the Biofuels Law*. The Federal Executive must issue the regulation of this law within 180 days following its commencement. The maximum date for this issuance will be September 15, 2025.
- *Issuance of the Regulation of the Geothermal Law*. The Federal Executive must issue the regulation of this law within 180 business days, starting from the implementation.

Note

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